versius®

Versius Surgical System

User Manual (Version 15.0)

Read before use

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REF 70000 **Versius Surgical System User Manual**

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This user manual provides the Instructions for Use for the Versius Surgical System version 1.1.

Rx only

How to use this user manual

Content of chapters

Chapter 1 contains product information, specifications and general warnings for the Versius Surgical System.

Chapter 2, 'System overview', is a guide to the entire system, giving the names and functions of the different parts.

Chapters 4 and 5 describe the head-up display (HUD) and the arm modes, which are used throughout surgery.

Chapters 6 to 23 contain operating information and 'how to' guidance for specific tasks during set-up, surgery and post-operative tasks.

For reprocessing instructions for the instruments, refer to the Reprocessing Instructions (REF 70100).

- If an alarm occurs, see chapter 20
- If conversion to manual surgery is required, see chapter 21

Reference material

The appendices provide quick references for cables, HUD icons, system symbols and troubleshooting.

For definitions of terms, refer to the glossary at the end of this user manual.

To locate information in this user manual, there is a table of contents at the start and an index at the end.

The arm modes map is on the inside back cover and a start-up checklist is on the outside back cover of this user manual.

Warning, precaution and information symbols in this user manual

Warnings, precautions and information points can be found throughout this user manual. General warnings and precautions are found in chapter 1 and any specific warnings, precautions and additional reference information about the information in each chapter can be found at the start of each chapter. For safe use of the Versius Surgical System, users should follow instructions highlighted by warning and precaution symbols as well as reading the important reference information, highlighted by the information symbol.

⚠ This symbol indicates a warning. Warnings in this user manual indicate situations that could result in injury to the patient or user

⚠ This symbol indicates a precaution. Precautions in this user manual indicate situations that could result in minor injury to the patient or user, or damage to the Versius Surgical System

ℹ This symbol indicates an information point. Information points in this user manual indicate important reference information

The version of this user manual

This user manual is version 15.0.

Table of Contents

Chapter 1

Introduction

1.1 General information

1.1.1 Contact information

Contact CMR Surgical customer services for ordering, reporting complaints or adverse events and for general information on our products.

CMR Surgical Limited, 1 Evolution Business Park,
Milton Road, Cambridge CB24 9NG, UK

Tel: +44 (0) 1223 750 975

For technical support:

If your system requires technical support or service, please call our technical support line:

Tel: +44 (0) 1223 750 975

Email: customer.service@cmrsurgical.com

CMR Surgical Limited, 1 Evolution Business Park,
Milton Road, Cambridge CB24 9NG, UK
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1.1.2 Compliance and classifications

The Versius Surgical System is in conformance with the essential requirements and provisions of the Medical Device Directive 93/42/EEC and the following standards:

- BS EN 60601-1 General requirements
- BS EN 60601-1-2 EMC requirements and tests
- BS EN 60601-1-6 Usability
- BS EN 60601-1-8 Alarms
- BS EN 60601-2-2 HF Surgical Equipment
- BS EN 60601-2-18 Endoscopic Equipment

1.2 Technical description

1.2.1 Equipment description

The Versius Surgical System is a robotic system used to perform minimal access surgery. The Versius Surgical System comprises a surgeon console, a visualisation bedside unit (an arm mounted on a cart) and an endoscopic camera, one or more instrument bedside units (each an arm mounted on a cart) and surgical instruments, and associated cables and drapes.

Versius Bedside Units are draped and used next to the operating table within the sterile field, and the surgeon console is used in the same operating theatre outside the sterile field.

System component	Reference number (REF)
Versius Surgical System	V-1000
Versius Instrument Bedside Unit	V-SS-2000
Versius Visualisation Bedside Unit	V-SS-3000
Versius Surgeon Console	V-SS-1000

Use these reference (REF) numbers to order Versius components from CMR Surgical. The REF numbers can also be found in labelling on the component or its packaging.

See the Instruments and Accessories Manual (REF 70050) for order codes and details on the instruments and accessories used in conjunction with the Versius Surgical System.

1.2.2 Physical dimensions

	Surgeon console	Bedside unit
Height (mm)	1325 – 2085	1425
Width (mm)	840	380
Depth (mm)	1040	380
Mass (kg)	Approximately 180	Approximately 100
Safe working load (kg)	**25** per hand controller (Downward load)	**25** per handle (Two handles may be used simultaneously, load may be either up or down)

	Packaged surgeon console	Packaged bedside unit*
Height (mm)	1630	1720
Width (mm)	930	590
Depth (mm)	1210	500
Mass (kg)	308	158
Ground clearance (mm)	45	45

*Bedside unit in sleep mode with brake activated for transportation

1.2.3 Environmental specifications

	Temperature (°C)	Humidity (%)	Pressure (hPa)
Operating conditions	15 to 27	30 to 75% non-condensing	700 to 1060
Storage conditions	−5 to 55	10 to 90% non-condensing	500 to 1060
Transport conditions	−20 to 55	10 to 90% non-condensing	500 to 1060

1.2.4 Electrical specifications

The Versius Surgical System has the following mode of operation, type of protection against electric shock and degree of ingress protection:

- **Mode of operation:** Continuous
- **Type of protection against electric shock:** Class I
- **IP rating:** No ingress protection

To isolate the system from mains power, switch the surgeon console power switch to the 'off' position (or switch off at the hospital mains socket).

The console and bedside unit height adjust mechanisms must not be operated for longer than 60 seconds continuously. The maximum on/off duty cycle is 15%.

Classification of applied parts:	
	Type BF for instruments, endoscope and camera
	Type B for visualisation and instrument bedside units (applied part by Risk Management only)

1.2.5 Power requirements

Versius is powered by a single connection to the mains power from the surgeon console:

100-240V, 50-60Hz, 20-10A

Surgeon console fuse	
Fuse type:	High Breaking Capacity, Time Lag
Rating (220-240V supply):	10A, 250V
Rating (100-120V supply):	20A, 250V

1.2.6 Network connection and IT requirements

⚠ Identify risks of connecting to the hospital IT network, as connecting may affect other equipment connected to the network and may result in previously unidentified risks to patients, users or third parties. The hospital using Versius should identify, analyse, evaluate and control these risks

⚠ Re-evaluate risks if the network configuration is updated or upgraded, or other equipment is connected or disconnected from the hospital IT network

Network connection and information flow

Versius is designed to be able to upload data relating to surgeries to CMR Surgical servers, for use in analysing and improving Versius, and analysing and improving minimal access surgical techniques. This data is uploaded using a wired Ethernet connection to the Internet. Versius will function normally if there is no connection to the Internet, but data will not be uploaded.

Versius does not download data, and cannot be upgraded or altered using the connection to the hospital network.

IT requirements and network configuration

Versius does not have customer configurable network connections. To connect Versius to the Internet contact CMR Surgical Customer Service to arrange a service visit.

Upload of data relating to surgeries requires a wired RJ45 Ethernet 100BASE-TX / 1000BASE-T network connection. The following network infrastructure requirements should be met:

- DHCP or static IP configuration
- https (TCP port 443) outbound access to the Internet (used to upload data to the CMR Surgical Cloud)
- ntp (UDP port 123) access to the Internet (used to set data timestamp correctly)

The Versius Surgical System requires an average upload bandwidth of up to 2 Mbit/s.

The Versius Surgical System is compatible with many proxy servers.

1.3 Professional instructions for use

1.3.1 Essential prescribing information

- **Device name:** Versius Surgical System
- **Rx only:** Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner)
- **Equipment version:** Versius v1.1

1.3.2 Indications for use

The Versius® Surgical System is a robotically-assisted surgical device that is intended to assist in the accurate control of its surgical endoscopic instruments including rigid endoscopes, blunt and sharp

endoscopic dissectors, scissors, forceps/pick-ups, needle holders, endoscopic retractors, electrosurgery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery and suturing during general, urologic, gynaecological and thoracic minimal access surgical procedures. The system is indicated for adult use only and is intended to be used by trained physicians in an operating theatre environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

1.3.3 Representative uses

The Versius Surgical System has been successfully used in the following procedures, among others:

Procedures	
Gynaecology	**General**
Salpingo-Oophorectomy Endometriosis Resection Radical Hysterectomy Hysterectomy	Cholecystectomy Inguinal Hernia Hernia repair Gastrectomy
Colorectal	**Urology**
Left & Right Hemicolectomy (Low) Anterior Resection	Nephrectomy Pyeloplasty Prostatectomy

⚠ Clinical data for the representative uses was based on evaluation of the device as a surgical tool that assists in the accurate control and performance of coordinated surgical tasks in the form of specific surgical procedures. Therefore, safety and effectiveness considerations were limited to validating the indications for use and do not imply that any outcomes related to surgeon training, skill or proficiency were considered. Outcomes related to any specific treatment for underlying disease or patient condition were not evaluated (i.e. local recurrence, disease-free survival, overall survival)

1.3.4 Training

⚠ Healthcare professionals must complete the Introduction to Versius Training Course provided by CMR Surgical, or for sterile nurses the Sterile Nurse Training Course provided by CMR Surgical, before using the Versius Surgical System.

The Versius Surgical System must only be operated by surgeons already trained and competent in minimal access surgery and who have developed adequate robotic skills to perform the tasks associated with the surgical procedure. Training provided by CMR Surgical does not replace the medical training and experience necessary to perform minimal access surgery

Before using the system, users should complete basic system training, which includes online and practical training. There are 13 online modules and the time to complete the entire online training is estimated as 8–10 hours. The minimum time for practical training for the surgeon and surgical team is as follows:

Introduction to Versius Training Course		
Session	Time	
	Surgeon	Bedside team
System Use: System Setup & Post-Operative Task Training	12hrs 20mins	12hrs 50mins
Surgical Time – Wet Lab and Dry Lab	9hrs	8hrs 45mins
Team Building	1hr 20mins	1hr 20mins

Where a Versius Surgical System is already in use at a hospital and at least one surgical team in the hospital have been trained in the full training course, additional sterile nurses can be trained in a shorter training course. The online element of this sterile nurse training is estimated as 15 hours.

The minimum time for practical training in the sterile nurse course is as follows:

Sterile Nurse Training Course	
Session	**Time**
Team building exercises and troubleshooting	1 hour 10 minutes
System use (set-up and post-operative tasks)	3 hours 40 minutes
Surgical time dry-lab (hands on)	3 hours

1.4 General warnings, precautions and contraindications

Read the Versius Instruments and Accessories Manual (REF 70050). All instructions, warnings and precautions in both this Versius Surgical System User Manual and the Versius Instruments and Accessories Manual must be followed for safe use of the system

Do not replace any part of the Versius Surgical System (including the mains power cable) with equipment that is not an approved Versius part

Check compatibility of all equipment connected to Versius or used with Versius inside the patient cavity according to information in the instructions for use for the equipment

⚠ When using other energised instruments or medical electrical equipment at the same time as Versius instruments or a Versius endoscope, all applied parts must be type BF or type CF, and patient leakage currents may be additive

⚠ Check the outer surfaces of the instruments and endoscope for any unintended rough surfaces, sharp edges or protrusions which may cause harm. **Do not** use instruments or endoscopes found to have mentioned abnormalities

⚠ Inspect the Versius Surgical System for damage before each use. **Do not** use the Versius Surgical System if damage is found

⚠ Check that the image on the console screen is in the correct orientation and the movements of the instruments are as expected

⚠ **Do not** touch the Versius Surgeon Console and the patient at the same time due to the risk of leakage currents flowing through the patient

⚠ **Do not** touch the metal pins inside the end of a bedside unit cable and the patient at the same time due to the risk of leakage currents flowing through the patient

⚠ **Do not** use a Versius Instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ **Do not** use any Versius part (including the instruments and the electrosurgery cables) except as part of the Versius Surgical System, connected as described in this user manual and the Instrument and Accessories Manual

1.4.1 Endoscopic procedure

⚠ Versius uses a 10 mm endoscope which has only been validated for use with an 11 mm Applied Medical balloon port

⚠ Versius uses wristed instruments which have been validated for use with 5 mm Applied Medical balloon ports. Inappropriate port size could lead to an incorrect fulcrum being detected during port-training

1.4.2 High frequency electrosurgery

Only surgeons having adequate training and experience with endoscopic electrosurgery should perform endoscopic procedures involving electrosurgery. The instructions, warnings and cautions provided with the Electrosurgery Unit (ESU) must be followed or else serious injury or surgical complications may occur to the patient.

⚠ The Versius Instrument Bedside Unit Monopolar Interface is designed for a maximum peak voltage of 3000V. **Do not** use settings on the ESU that exceed a 3000V peak

⚠ The Versius Instrument Bedside Unit Bipolar Interface is designed for a maximum peak voltage of 500V. **Do not** use settings on the ESU that exceed a 500V peak

⚠ **Always** refer to the Instrument and Accessories Manual (REF 70050) for specific maximum peak voltage limits which relate to specific instruments. **These limits may be less than those specified above**

⚠ **Do not** attempt to use the electrosurgery buttons on the hand controllers with ESUs that are not compatible with the Versius Surgical System. Consult with your CMR Surgical representative regarding compatible models

⚠ Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating theatre personnel

⚠ Inspect instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high-voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or user

⚠ Visual inspection alone may not be sufficient to ensure that the insulation is intact

⚠ **Do not** activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment

⚠ **Never** detach an electrosurgery instrument or clean its tip without first disconnecting the instrument electrosurgery cable as this may compromise patient and user safety

⚠ Electrosurgery may produce interference that adversely affects other electronic equipment in the operating theatre

⚠ **Do not** use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged

⚠ Ensure that the surgeon can hear the audio feedback from the electrosurgery generator when they are sitting or standing at the surgeon console

⚠ Follow all instructions, cautions and warnings provided with the electrosurgery unit, to avoid serious injury to the patient

⚠ Take care when cleaning the instrument tip as it may be still hot enough to cause burns even after the RF current has been deactivated

⚠ Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks and effective smoke evacuation equipment should be used in both open and laparoscopic procedures

⚠ **Do not** use in the presence of flammable anaesthetics or oxidising gases (such as nitrous oxide [N_2O] and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur

⚠ **Do not** place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire

⚠ **Do not** over-insufflate the patient prior to electrosurgery as this increases the risk of gas embolism

⚠ Keep all electrosurgery instruments in the field of view when activating electrosurgery and beware that capacitive coupling can produce heating of an inactive electrosurgery instrument

⚠ Place the monopolar instrument cables and bipolar instrument cables where they do not come into contact with the patient, with other cables or metal parts. Failure to do so could lead to transfer of monopolar energy by capacitive coupling and may cause burns to the patient

⚠ When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns

⚠ Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g. blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient

⚠ **Do not** use with hybrid trocar systems, i.e. a combination of metal and plastic, when using monopolar active components. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems

⚠ Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections

⚠ **Do not** allow an active electrosurgery instrument to make contact with the endoscope or another instrument, to avoid accidental burns to the patient

⚠ The Versius Surgical System was validated for activation of electrosurgery by hand controllers. **Avoid** using foot activation with Versius as the system has not been tested for this type of use and it may compromise patient and user safety

⚠ To avoid inadvertent thermal damage to surrounding tissue and other hazards, observe the following:

- Ensure that the dispersive electrode is securely affixed to the patient, placed as close as possible to the operating field, and properly connected to the ESU
- Always use the lowest output setting that achieves the desired surgical effect while staying within the maximum peak voltage. Maximum power levels to stay below this limit are listed in a table in the Instruments and Accessories Manual (REF 70050)
- Do not deliberately or unintentionally use one instrument to energise other endoscopic instruments. Energising other endoscopic instruments may cause tissue damage inside or outside the field of view. This damage could occur at points near the tip or at the port site of the energised instrument
- For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage
- Keep patient from coming in contact with grounded metal parts
- Place any monitoring electrodes as far as possible from the surgical electrodes or the dispersive electrode when high frequency (HF) surgical equipment and physiological monitoring equipment are used simultaneously on the same patient
- Do not use flammable anaesthetics or oxidising gases such as nitrous oxide and oxygen
- Use only non-flammable agents for cleaning and disinfecting. If flammable agents are used for cleaning or disinfecting or as solvents, they must be allowed to evaporate before application of HF energy

⚠ **Do not** use electrosurgery equipment unless properly trained in the specific procedure being undertaken. Follow all instructions, warnings, and precautions provided with the ESU

⚠ The intensity should be set as low as is necessary to achieve the desired effect

⚠ Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. **Do not** activate the instrument while cleaning. Injury to operating theatre personnel may result

1.4.3 Light source specifications and warnings

The Versius Surgical System was validated using a Wolf Endolight LED 2.2 light source. The following light sources are compatible with the system:

Brand	Model
Stryker	L9000
Stryker	L10 AIM
Stryker	L11
Stryker	Precision
Olympus	CLV-190
Olympus	CLV-S200-IR
Storz	TL-300
Storz	TL400
Storz	D-light P
B-Braun	OP950

Only use a compatible light source with Versius Surgical System. An adapter is required when using the Olympus light sources. See the Versius Instrument and Accessories Manual (REF 70050) for ordering information.

⚠ Follow all instructions, cautions and warnings provided with the light source, light cable and endoscope to avoid accidental tissue coagulation, unsafe high temperatures or ignition

⚠ **Do not** let the light cable rest on patient skin. Inadvertent contact with the patient may result in burns

⚠ **Do not** allow the end of the light cable to touch or point towards the patient or user when changing the endoscope as it may result in burns

⚠ Take care when removing the light cable from the light source as the end of the light cable may be hot

1.4.4 Installation and service

⚠ **No modification** of the Versius Surgical System is allowed

The Versius Surgical System requires no routine adjustments to maintain operation and must be serviced only by CMR Surgical or by an appointed agent. Unauthorised repairs or attempts to dismantle will invalidate the warranty.

1.4.5 Transportation and storage

⚠ **Do not** move the Versius Surgical System over rough surfaces or expose the Versius Surgical System to rain

⚠ **Always** deactivate the bedside unit brake before moving the bedside unit. Attempting to move the bedside unit without deactivating the brake could make the bedside unit unstable and lead it to topple over causing injury

⚠ Store and transport the system in the specified environmental conditions. Incorrect storage and transportation could lead to damage to the system

⚠ When moving a bedside unit over a threshold, pull the bedside unit using two hands. Attempting to push a bedside unit over a threshold could cause the bedside unit to become unstable and topple over

⚠ **Do not** move the Versius Surgical System if not trained to do so

1.4.6 Instrument and endoscope isolation

⚠ **Only** use a light source complying with IEC 60601-1 requirements and ensuring protection of the endoscope, for example by having an isolated light guide output socket, as otherwise the endoscope may not have type F applied part status

1.4.7 Accessory equipment interconnection

⚠ Accessory equipment connected to the Versius Surgical System (auxiliary screen and ESU) must be certified to IEC 60601-1

1.4.8 Viewing 3D images

⚠ Prolonged use of the 3D display can lead to side-effects such as headache, eye strain, nausea

1.4.9 Radiation

⚠ **Do not** use the Versius Surgical System near an X-ray source

1.4.10 Reprocessing

⚠ **Do not** attempt to re-sterilise or re-use the drapes. The drapes are intended for single use only

⚠ Versius instruments have a restricted number of uses. All instruments are supplied non-sterile, and must be cleaned and sterilised before each use

⚠ The Versius endoscopes and light cable are supplied non-sterile, and must be cleaned and sterilised before every use, following instructions provided with the endoscope and light cable

⚠ Versius monopolar instrument cables and bipolar instrument cables are supplied non-sterile, and must be cleaned and sterilised before every use, following instructions provided with the cables

⚠ Follow the Reprocessing Instructions (REF 70100) for the surgical instruments to reduce the risk of cross-infection

⚠ **Do not** attempt to sterilise any part of the Versius Surgical System apart from the endoscope, instruments and sterilisable cables. Any attempt to do so is likely to damage or destroy the device

The use life of the Versius Instruments is typically determined by factors such as wear and damage due to use and the nature of handling between uses. Inspect instruments for damage and test their functionality before use.

Drapes are supplied sterile, and are for single use only. The drapes are sterilised using ethylene oxide.

See the Reprocessing Instructions (REF 70100) for methods for sterilising instruments. Refer to the instructions provided with the cables and endoscope for reprocessing instructions.

1.4.11 Electrical safety

⚠ **Do not** position the surgeon console so that it is difficult to reach the wall socket or the switch to power off the system

⚠ To avoid the risk of electric shock, the Versius Surgical System must only be connected to an external power supply with protective earth

1.4.12 Thermal safety

The surface of the Versius Arm may reach up to 55 °C during use.

⚠ **Avoid** direct contact between the Versius Bedside Units and the patient's skin. This applies to draped and non-draped bedside units

1.4.13 Versius Arm movement

Figure 1.1 shows the areas where it is safe to hold or push the arm.

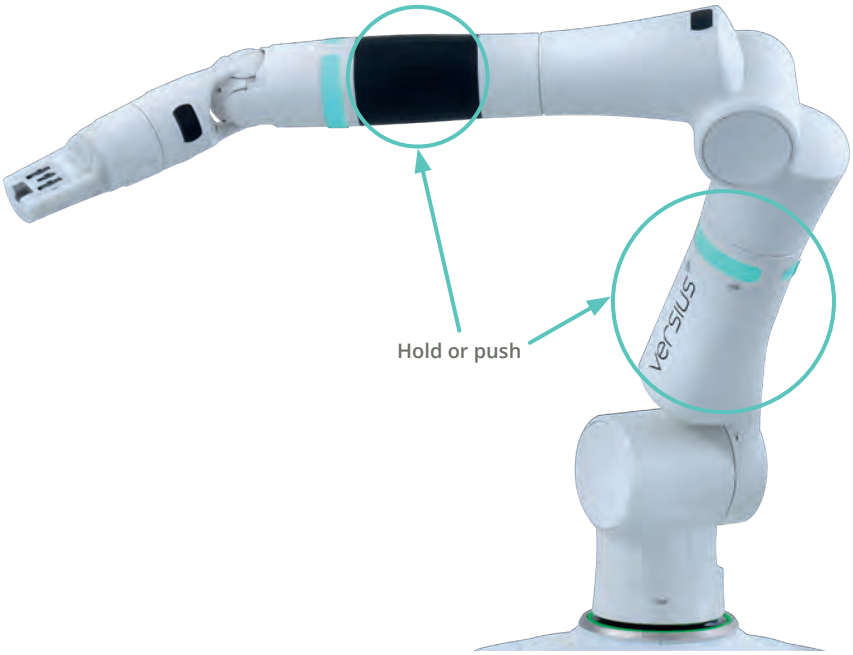


Figure 1.1 *Areas to hold or push the Versius arm*

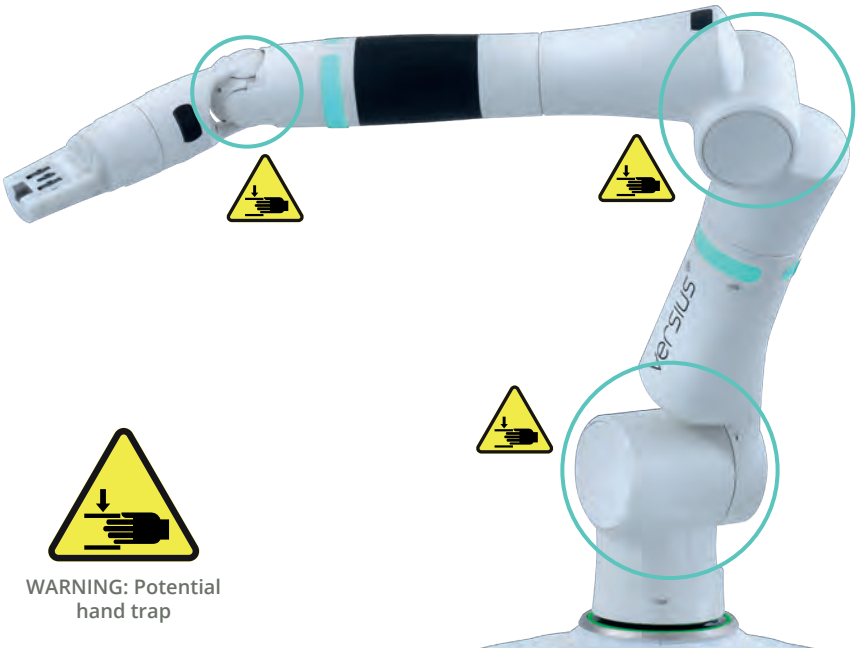


Figure 1.2 Hand traps on the Versius Arm

Figure 1.2 shows areas where the Versius Arm should not be touched when the arm is moving. There is a risk of hand traps if the arm is touched on a joint when the arm is moving.

⚠ **Do not** hold the arm directly on a joint due to the risk of hand traps in moving joints

1.4.14 Versius Bedside Unit movement

Figure 1.3 shows areas at the base of the bedside unit to avoid touching during brake activation and deactivation.

Bedside unit brake deactivated

Bedside unit brake activated

Figure 1.3 Areas to avoid touching during brake activation and deactivation

Figure 1.4 shows two symbols located on the bedside unit:

- **Symbol 1** indicates that the bedside unit column must not be pushed when the arm height is raised. This symbol can only be seen when the arm height is raised
- **Symbol 2** indicates that the arm must not be pushed

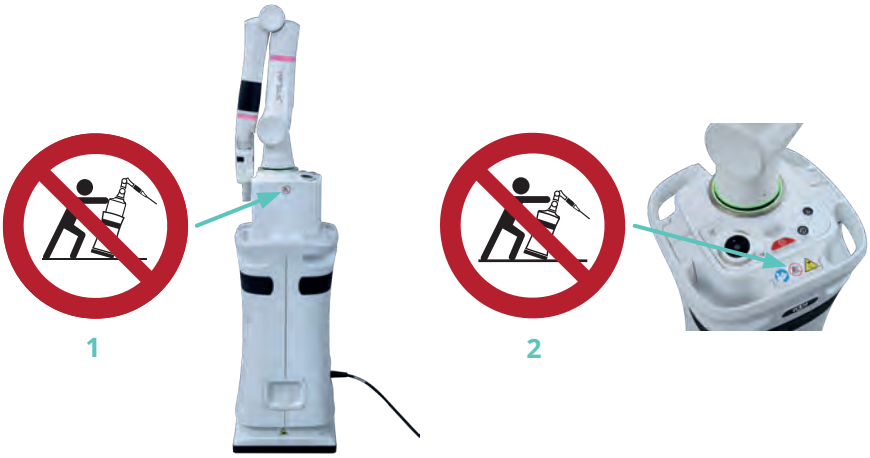


Figure 1.4 Symbols indicating areas of the bedside unit that must not be pushed

1.4.15 Misuse and abnormal stresses

For continued safety the Versius Surgical System must not be maltreated or used outside of its specified operational or storage conditions.

The Versius Surgical System contains protection against the effects of electrostatic discharge, but it is not protected against the currents produced by external heart defibrillators.

⚠ To avoid the risk of permanent damage, the Versius Surgical System must be disconnected and removed before defibrillation

Whenever it is likely that this protection has been impaired, the system must be made inoperative and secured against any unintended operation. The protection is likely to be impaired if, for example:

- There is visible damage
- Cables are twisted or strained
- The system fails to perform as intended
- There has been prolonged storage under unfavourable conditions
- There have been severe transport stresses
- The system has been in contact with a patient during defibrillation

1.4.16 Contraindications

Any and all relative and absolute contraindications to endoscopic surgical technique applicable to the use of conventional endoscopic surgical instruments apply to the use of the Versius Surgical System. General, non-procedure specific contraindications to endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy**.**

Do not use the Versius Surgical System for procedures involving the heart, circulatory system or central nervous system.

1.5 Technical essential performance

The Versius Surgical System only moves the instruments and endoscope under continuous control of a surgeon, or of an operator at the bedside.

When a Versius Arm is port-trained, the attached instrument or endoscope pivots around a fulcrum so that the instrument or endoscope shaft always points through the port.

The surgeon display either shows an accurate and real-time image from the endoscope, or is blank.

1.6 Electromagnetic compatibility (EMC)

Guidelines and manufacturer's declaration – Electromagnetic emissions

The Versius Surgical System is intended for use in the electromagnetic environment specified below. The user must ensure that the product is used in such an environment.

Emissions test	Frequency range	Compliance	Electromagnetic Environmental - Guidelines
Radiated Emissions CISPR 11	30 – 1000 MHz	Group 1	Versius uses RF energy only for its internal function. The RF emission level is extremely low and it is not likely to cause any interference in nearby electronic equipment.
Conducted Emissions CISPR 11	0.15 – 30 MHz	Class A	Versius is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions to IEC 61000-3-2		Class A	
In conformity with IEC 61000-3-3 "Emission of voltage fluctuations / flicker"			

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The Versius Surgical System is intended for use in the electromagnetic environment specified below. The user must ensure that the product is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance**	**Electromagnetic environmental guidelines**
Electrostatic discharge to IEC 61000-4-2	± 2, 4, 6, 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	Yes	Floors should be wood, concrete or ceramic tile. With floors made of synthetic material, the relative humidity of the ambient air must be at least 30%.
Electrical fast transience, bursts to IEC 61000-4-4	± 2 kV 5/50 ns, 5 kHz rep.	Yes	Main/line power quality should be that of a typical commercial or hospital environment.
Surge voltage to IEC 61000-4-5	± 0.5, 1 kV line to line voltage ± 0.5, 1, 2 kV line to earth voltage 1.2/50 µs	Yes	Main/line power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and supply voltage variations to IEC 61000-4-11	Voltage dip for 0.5 cycles >95% U_T Voltage dip for 5 cycles 60% U_T Voltage dip for 25 cycles 30% U_T Voltage dip for 5 sec >95% U_T	Yes	Main/line power quality should be that of a typical commercial or hospital environment. If the user of Versius requires continued operation during power main/line interruptions it is recommended that Versius be powered from an uninterruptible power supply or battery.
Note: U_T is the main/line voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	30 A/m	Yes	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.

Conducted RF immunity to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} for ISM frequencies 80% AM at 1 kHz	Yes	Portable and mobile RF communications equipment should be used no closer to any part of Versius, including cables, than the recommended separation distance d (metres) calculated from the equation in Table 1.6 applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Between 150 kHz and 80 MHz the field strength should be below 3 V/m. Interference may occur in the vicinity of devices with the following symbol: 
Radiated RF immunity to IEC 61000-4-3	Four faces 3V/m or 10V/m 80% AM @1 kHz 80 MHz to 2.5 GHz Spot frequencies 385 – 5785 MHz Four faces		

Table 1.5 *Guidelines and manufacturer's declaration – Electromagnetic immunity*

Recommended separation distances between portable and mobile RF communications equipment and Versius

The Versius Surgical System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Versius as recommended below.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 Mhz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 1.2 √ P	d = 1.2 √ P	d = 2.3 √ P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

d = recommended separation distance in metres (m)

P = maximum power of the transmitter in Watts (W)

Remarks: At 80 MHz and 800 MHz the higher frequency range applies. These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from structures, objects and people.

Table 1.6 *Recommended separation distances between portable and mobile RF communications equipment and Versius*

⚠ Changes or modifications to this equipment not expressly approved by CMR Surgical could void the user's authority to operate the equipment

1.7 Alarms information

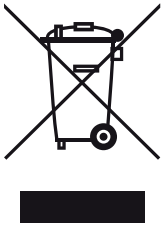
The Versius Surgical System is provided with high-priority and medium-priority alarms, with visual and audio signals. If a high-priority alarm and a medium-priority alarm are both present on a bedside unit, only the high-priority alarm is signalled.

Alarm	System component sounding alarm	Sound pressure level (dBa) at a distance of 1 m
High-priority	Bedside unit	69–79
Medium-priority	Bedside unit	69–78
Medium-priority	Surgeon console	71–88

1.8 Disposal information

Dispose of instruments, endoscopes and drapes in clinical waste and other parts according to local regulations for disposal of electrical equipment.

In Europe, compliance shall be made to follow the Waste Electrical and Electronic Equipment Directive (2012/19/EU).



1.8.1 Battery disposal

Each bedside unit contains four batteries (one lithium polymer and three lithium metal oxide batteries) which are not user-serviceable and must be disposed of according to local regulations.

⚠ **Do not** remove the batteries contained in the bedside units. Only CMR Surgical or its appointed accredited partners can remove the bedside unit batteries

Chapter 2

System overview

Warnings and precautions

⚠ Store the system in the specified environmental conditions. Storing the system inappropriately could lead to damage to the system

⚠ Inspect the bedside units for damage and **do not** use if any damage is found

2.1 Versius Surgical System components

The Versius Surgical System (Figure 2.1) consists of a surgeon console, one visualisation bedside unit and up to three instrument bedside units. See the Instrument and Accessories Manual (REF 70050) for information on the Versius Instruments and accessories.

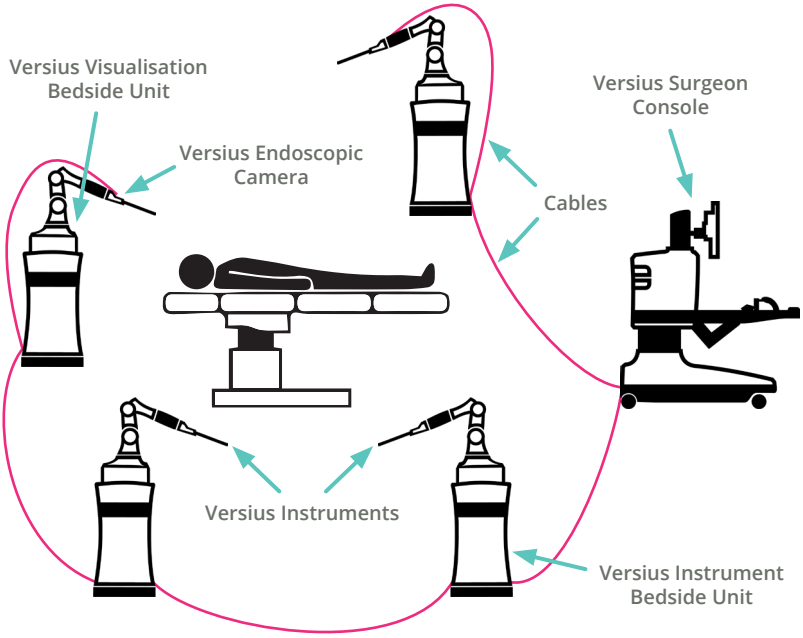


Figure 2.1 The Versius Surgical System components

2.2 Versius Surgeon Console

The surgeon console (Figure 2.2) is the main interface for the surgeon using the system. It also acts as a power hub to support the connected bedside units.

The surgeon sits or stands at the surgeon console outside the sterile field, using hand controllers to manipulate the instruments and endoscopic camera.

See chapter 13 for instructions on setting up the surgeon console and chapter 18 for instructions on using the surgeon console.

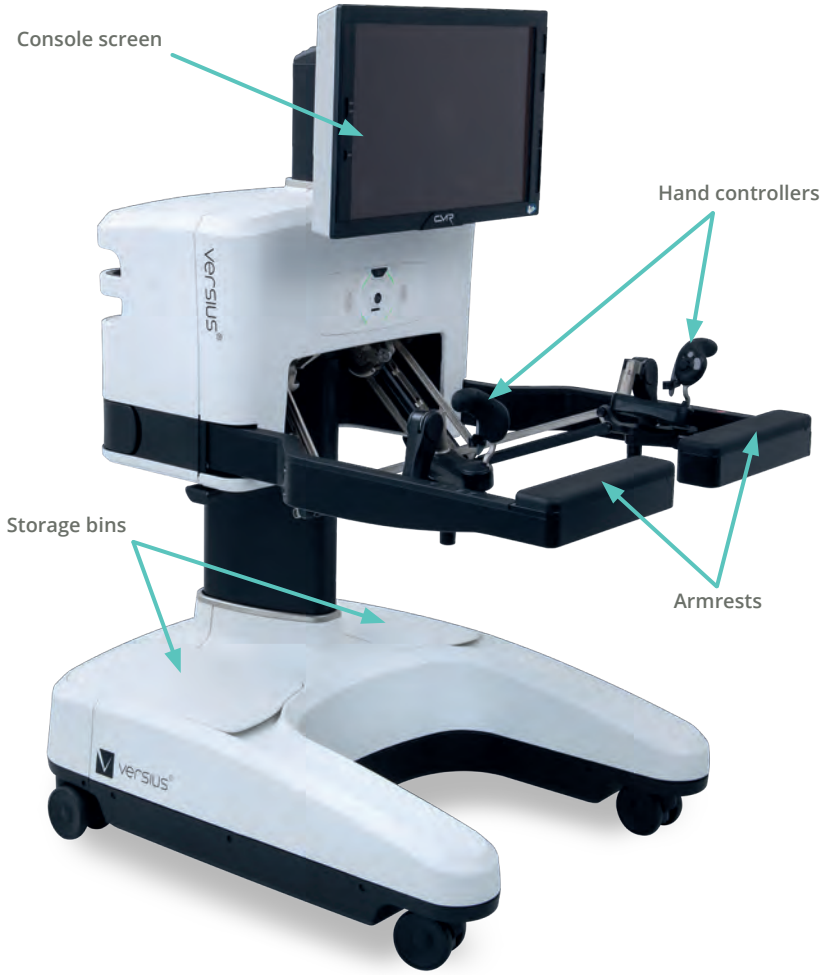


Figure 2.2 *The surgeon console*

2.2.1 Console screen

The surgeon wears circular polarising 3D glasses and views the surgical site on the console screen (Figure 2.6). The console screen displays the 3D endoscopic camera video feed, with the head-up display (HUD) overlaid. The video feed shown on the console screen can be changed from 3D to 2D.

An auxiliary screen (not supplied with the Versius Surgical System) can be connected to the surgeon console to show a 2D replica of the console screen for the bedside team to view. Both the console screen and the auxiliary screen show the endoscopic camera video feed with the HUD overlaid. The system is also compatible with integrated operating theatre systems.

2.2.2 Hand controllers

In surgical mode, the surgeon holds one hand controller (Figure 2.3) in each hand and manoeuvres them to control the instruments and endoscope.

See chapter 5 for more information on arm modes.

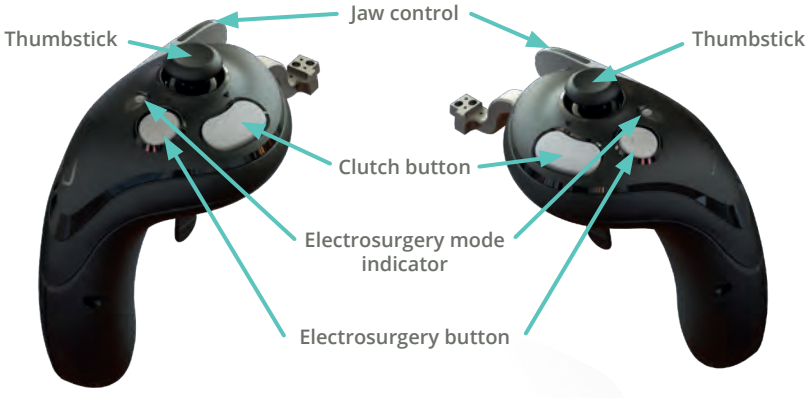


Figure 2.3 The hand controllers

The system detects when the hand controllers are held.

The hand controllers should be docked to the left and right of the surgeon console when they are not in use.

See chapter 18 for instructions on how to use the hand controllers.

2.2.3 Ergonomic adjustments

The surgeon console is adjustable, allowing the surgeon to either sit or stand in an ergonomic position.

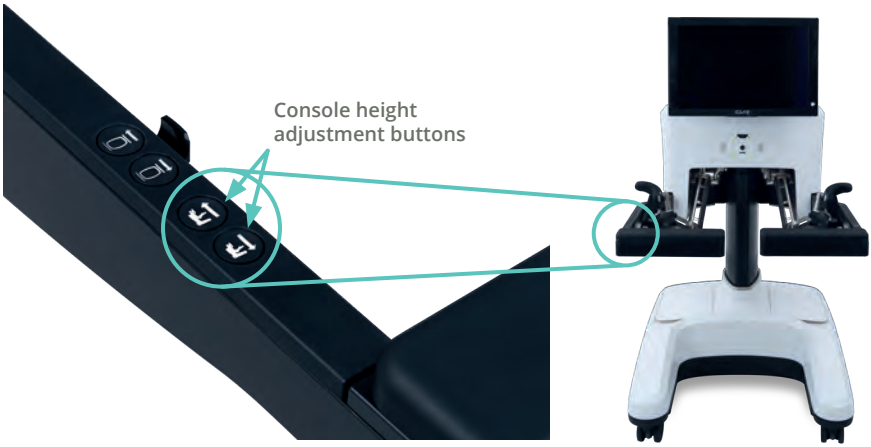


Figure 2.4 Surgeon console height adjustment buttons

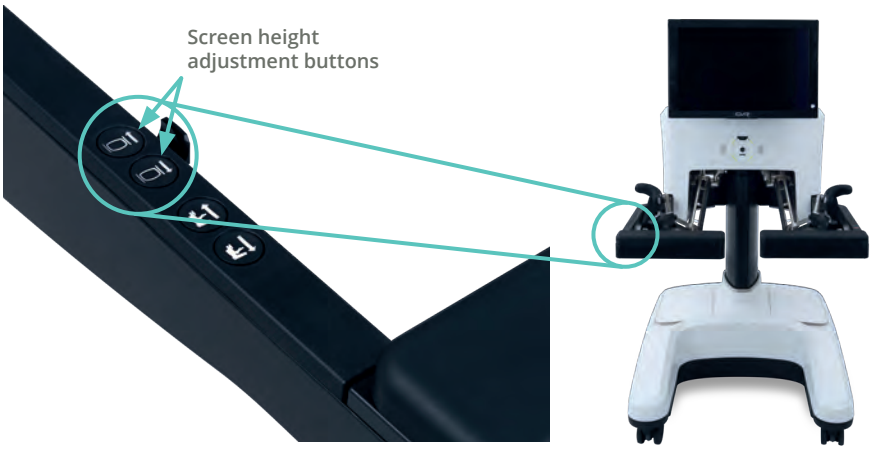


Figure 2.5 *Console screen height adjustment buttons*

Figure 2.6 *Sitting and standing at the surgeon console*

See section 13.1 for instructions on adjusting the surgeon console height and section 13.2 for instructions on adjusting the console screen height.

2.2.4 Surgeon console brake

The surgeon console brake secures the surgeon console in position. When stationary, the surgeon console is braked. To release the surgeon console brake, squeeze the handles on the back of the surgeon console (Figure 2.7). The surgeon console can now be moved. To brake the surgeon console, release the levers on the inside of the handles.

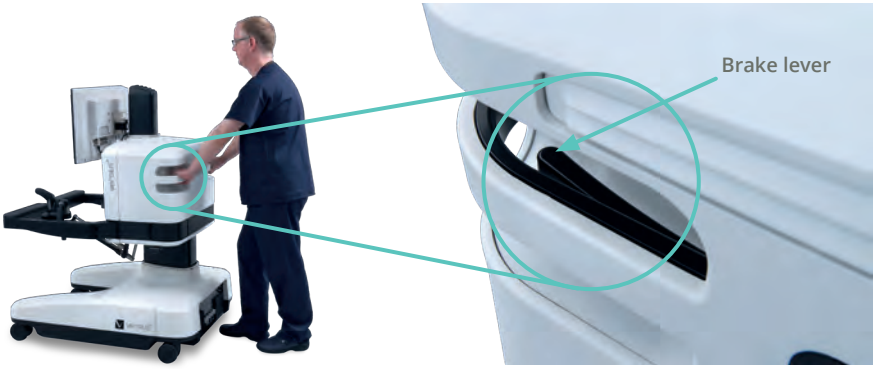


Figure 2.7 *Surgeon console brake levers*

2.2.5 Video recording

The endoscopic camera feed can be recorded and saved on an SD card. The SD card slot (Figure 2.8) is found below the screen.

See section 13.10 for instructions on how to record the video.

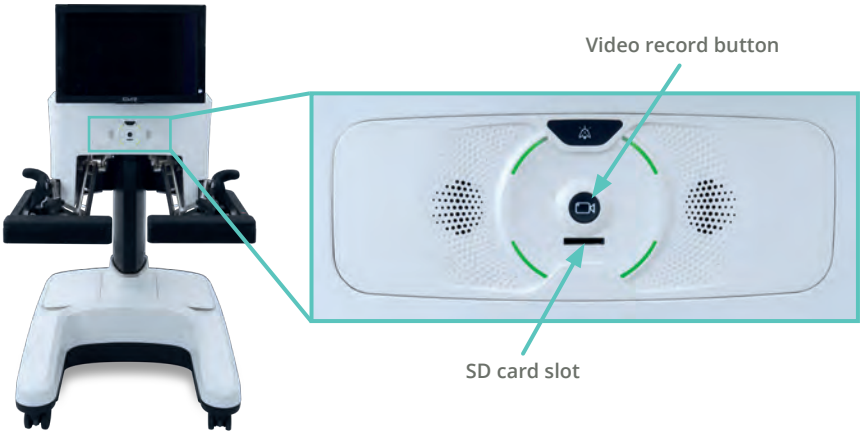


Figure 2.8 Video recording features on the surgeon console

2.2.6 Surgeon console status halo

The status halo on the surgeon console indicates the status of the system. Under normal operation the status halo is green in colour. In the event of a system alarm, the surgeon console status halo (Figure 2.9) will change colour to yellow and an alarm will sound. The alarm mute button is located below the console screen (Figure 2.9).

See chapter 20 for more information about alarms.

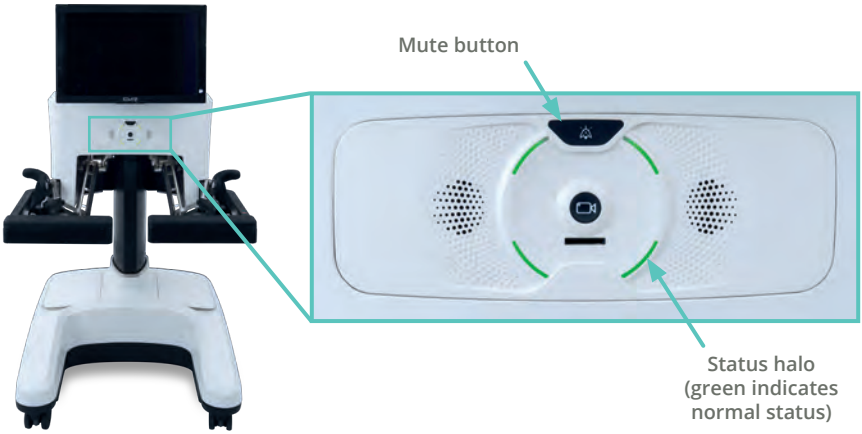


Figure 2.9 *Surgeon console status halo and alarm mute button*

2.2.7 Stop and resume buttons on the surgeon console

Stop and resume buttons are located on the right armrest of the surgeon console (Figure 2.10). The stop button stops the surgeon console and any connected bedside unit. The resume button is used for resuming the system operation. The stop and resume buttons on both the surgeon console and bedside unit (Figure 2.22) perform the same function.

See chapter 9 for more information on stopping and resuming the system.

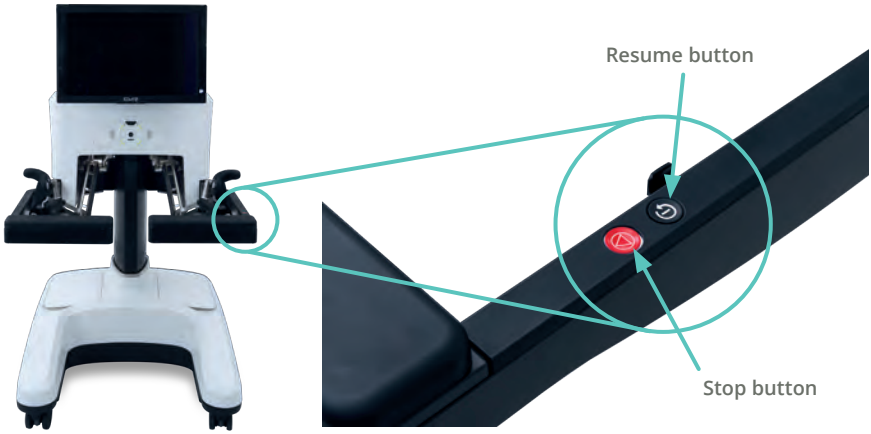


Figure 2.10 *Surgeon console stop and resume buttons*

2.3 Versius Instrument and Visualisation Bedside Units

A bedside unit consists of a Versius Cart and a Versius Arm (Figure 2.11). A Versius Instrument is attached to the arm on an instrument bedside unit. The Versius Endoscopic Camera is attached to the arm on a visualisation bedside unit.

In surgical mode, the arms move under control of the surgeon. In other modes, the sterile bedside team members can move the arms during surgery. See chapter 5 for more information on arm modes.

⚠ Inspect the bedside units for damage and **do not** use if any damage is found.

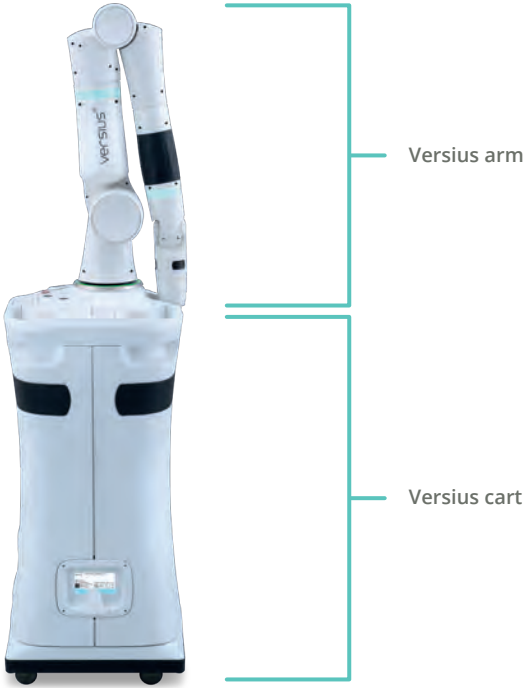


Figure 2.11 *The arm and cart labelled on the Versius Bedside Unit*

This section covers key bedside unit features:

- Versius Arm
- Versius Cart
- Arm colour identifier
- Elbow and V-Wrist buttons
- Bedside unit brake
- Arm height adjustment buttons
- Low battery indicator
- Orientation buttons
- Bedside unit status halo
- Bedside unit stop and resume buttons
- Bedside unit sleep button

2.3.1 Versius Arm

There are several joints in the Versius Arm. Three key joints allow the Versius Arm to mimic a human arm: base, elbow and V-Wrist (Figure 2.12). An instrument or an endoscopic camera is attached to the arm's distal end. The arm is mounted on a Versius Cart.

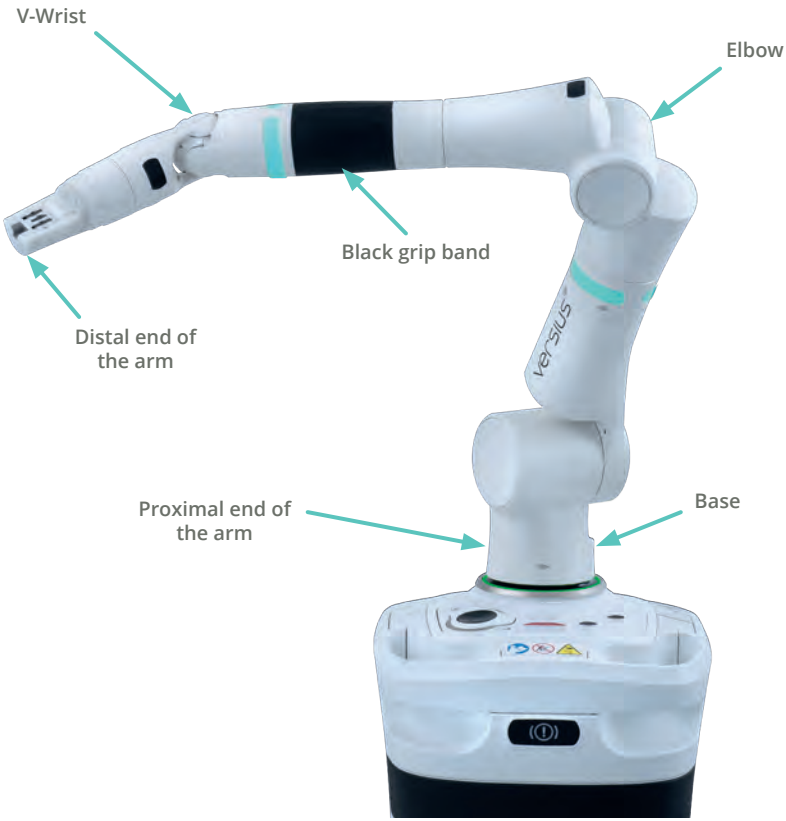


Figure 2.12 *Versius Arm*

2.3.2 Versius Cart

The Versius Cart (Figure 2.13) is the mobile unit on which the arm is mounted. There is a cart control panel on the top of the cart and a cart connection panel on the lower part of the back of the cart.

Figure 2.13 *Versius Cart*

See chapter 12 for instructions on how to use the cart control panel.

2.3.3 Arm colour identifier

There are two illuminated coloured bands on every arm. One band is above the V-Wrist joint and the other between the elbow and base joints (Figure 2.14). The colour of the illuminated bands cannot be changed and is used to identify the arm.

The colour of the arm colour identifier matches the background colour of the HUD icons related to the arm, its bedside unit and instrument (Figure 2.14).

This colour is not indicative of arm mode or bedside unit status. The colour is purely an aid for communication when referring to a particular arm, and for matching an arm with the relevant icons on the HUD

Only the elbow band is illuminated, and not the wrist band, when a bedside unit is on battery power

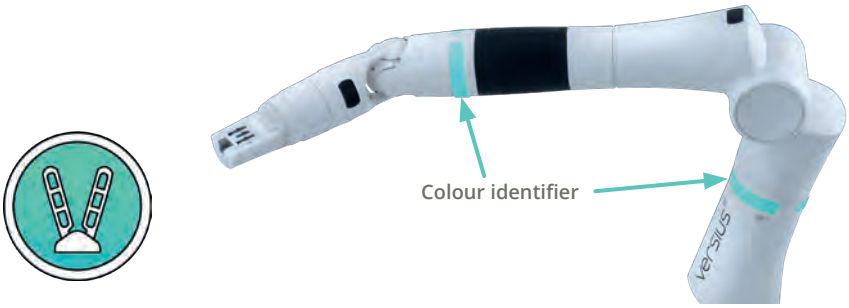


Figure 2.14 *The arm colour identifiers and the matching HUD icon background*

See chapter 4 for more information about the icons and appendix D for a list of icons.

2.3.4 Elbow and V-Wrist buttons

The elbow and V-Wrist buttons (Figure 2.15) are located on each arm and are used to access a sequence of different arm modes during set-up, surgery and post-operative tasks. Each arm has one elbow button and three V-Wrist buttons.

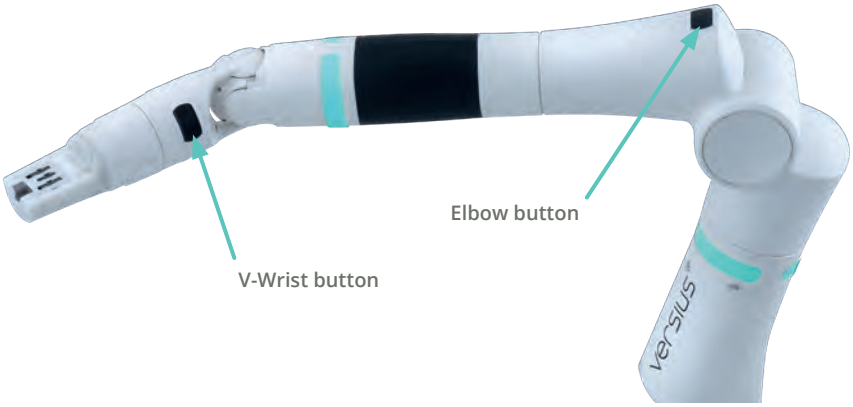


Figure 2.15 *V-Wrist and elbow buttons*

See chapter 5 for the description of arm modes.

2.3.5 Bedside unit brake button

The brake button (Figure 2.16) is located on the back of the bedside unit, below the cart control panel. Pressing and holding the brake button lowers the base of the bedside unit and lifts the wheels off the floor, so that the bedside unit cannot be moved.

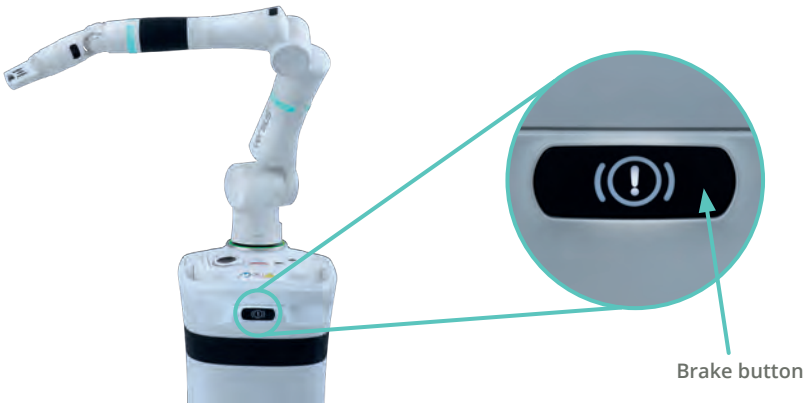


Figure 2.16 *Brake button on the bedside unit*

See section 12.2 for instructions on how to operate the brake.

2.3.6 Arm height adjustment buttons

The bedside unit column can be raised and lowered to position the arm for optimal access to the surgical area, using the height adjustment buttons on the cart control panel (Figure 2.17).

Figure 2.17 *Height adjustment buttons on the bedside unit*

2.3.7 Low battery indicator

Each bedside unit has its own battery power supply which will support the arm if power from the surgeon console is lost. A low battery indicator (Figure 2.18) illuminates if the battery charge is low.

Figure 2.18 *Location of low battery indicator on the bedside unit*

See section 12.4 for more information on the bedside unit battery.

2.3.8 Orientation buttons

A bedside unit can be positioned in any suitable location around the operating table. To ensure the hand controllers move the instruments in the correct direction, it is necessary to set the orientation of the bedside unit before surgery. This is done using one of the four direction arrows on the orientation pad (Figure 2.19).

Figure 2.19 *Orientation pad on the bedside unit*

See section 12.3 for instructions on setting the orientation.

2.3.9 Bedside unit status halo

The status halo on the bedside unit indicates the status of that bedside unit. Under normal operation the status halo is green in colour. In the event of an arm alarm on that bedside unit, the bedside unit status halo (Figure 2.20) will change colour to yellow or red and an alarm will sound. The alarm mute button is located on the cart control panel (Figure 2.21). See chapter 20 for more information about alarms.

Figure 2.20 *Status halo on the bedside unit*

Figure 2.21 *Mute button on the bedside unit*

2.3.10 Stop and resume buttons on the bedside unit

Stop and resume buttons are located on the cart control panel (Figure 2.22). The stop button stops the surgeon console and any connected bedside units. The resume button is used for resuming

the system operation. The stop and resume buttons on both the bedside unit and surgeon console (Figure 2.10) perform the same function.

Figure 2.22 Stop and resume buttons on the bedside unit

See chapter 9 for more information on stopping and resuming the system.

2.3.11 Bedside unit sleep button

The sleep button is located on the cart control panel (Figure 2.23). The button is used to wake up the arm and to put the arm into sleep mode.

Figure 2.23 *Sleep button on the bedside unit*

2.4 Versius Instruments

See Figure 2.24 for an example Versius Instrument. Refer to the Instrument and Accessories Manual (REF 70050) for detailed information and instructions for use on each instrument.

Figure 2.24 *A Versius Fenestrated Grasper and its corresponding HUD icon*

The instruments are attached to the distal end of an instrument arm after the arm drape has been fitted. Each instrument has a corresponding HUD icon.

Each instrument type has the same attachment head and a shaft of 6.8 mm diameter (Figure 2.25). The attachment head has latches for attaching the instrument to the arm, and fins, which mechanically drive the instrument during surgery. All Versius Instruments have three fins, except for the Monopolar Hook, which only has two.

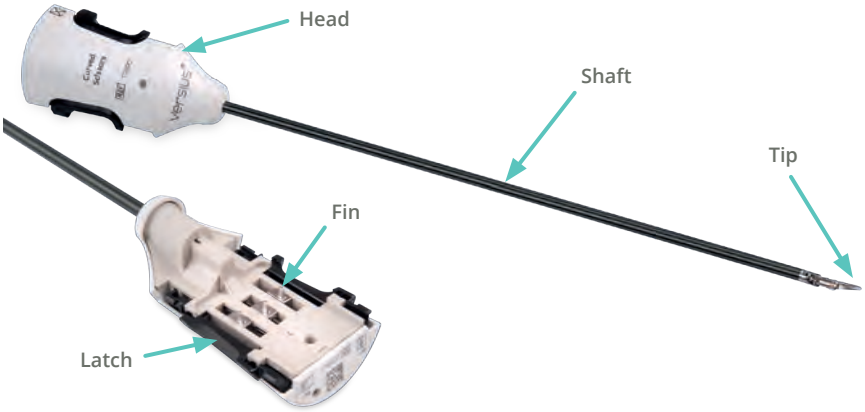


Figure 2.25 Versius Instrument

⚠ Versius Instruments are supplied non-sterile. Instruments must be cleaned, disinfected and sterilised before first use and after each use. Refer to the Reprocessing Instructions (REF 70100) and instructions for use on each instrument

2.5 Versius Endoscopic Camera

The Versius Endoscopic Camera (Figure 2.26) consists of a Versius Camera Head and a Versius Endoscope. The endoscopic camera provides an 81.1° field of view.

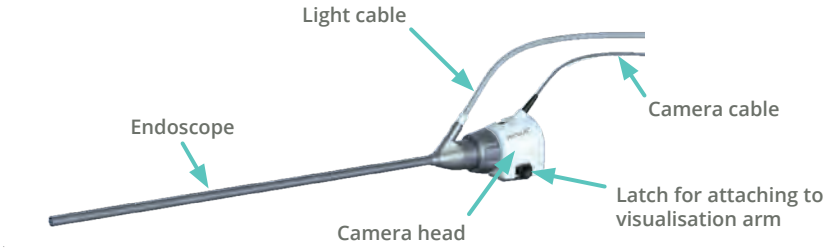


Figure 2.26 *Endoscopic camera*

The draped endoscopic camera is attached to the draped visualisation bedside unit. See chapter 11 for draping instructions and chapter 14 for instructions for attaching and detaching the endoscopic camera from the visualisation arm.

2.5.1 Versius Camera Head

The Versius Camera Head provides a 3D high definition image. A camera cable is permanently fixed to the camera head (Figure 2.27) and plugs into the visualisation bedside unit connection panel. The camera head is non-sterile and should not be sterilised.

Figure 2.27 *Versius Camera Head*

2.5.2 Versius Endoscopes

The Versius Surgical System uses Versius Endoscopes. The endoscopes have a 10 mm diameter shaft and a 300 mm working length. There are two types of endoscope (Figure 2.28): angled (30°) and straight (0°). The angled endoscope can be attached 30° up or 30° down. For instructions on changing the endoscope angle, see section 11.4.

Figure 2.28 *Endoscopes: angled or straight*

The endoscopes are supplied non-sterile and must be sterilised before the first use and after each use. Refer to the instructions provided with the endoscopes for detailed information about using the endoscope and for reprocessing instructions.

Versius Endoscope information

The Versius Endoscopes are manufactured by Richard Wolf GmbH and distributed by CMR Surgical.

Richard Wolf GmbH
75438 Knittlingen
Pforzheimerstr. 32
GERMANY
Telephone: +49 70 43 35-0
Telefax: +49 70 43 35-4300

2.6 Versius Drapes

Drape information

The Versius Drapes are made by P3 Medical and are distributed by CMR Surgical for use with the Versius Surgical System.

P3 Medical Limited
1 Newbridge Close
Bristol BS4 4AX
www.p3-medical.com

There are three types of Versius Drapes custom fitted to a part of the system:

- Instrument bedside unit drape (standard and long)
- Visualisation bedside unit drape (standard and long)
- Camera head drape

The draped Versius Instrument Bedside Unit can be seen in Figure 2.29. The surgeon console does not need to be draped as it is positioned outside the sterile field within the operating theatre.

Figure 2.29 *Draped instrument bedside unit*

Drapes are single-use and are provided sterile in individual peel packs. See chapter 11 for instructions for draping the system.

2.6.1 Bedside unit drape

The bedside unit drape is a drape that consists of two separate drapes (the arm drape and cart drape) that overlap. The elasticated collar secures the cart drape in place around the arm base. The drape cap is a piece of rigid plastic that fits onto the distal end of the arm and acts as the point of attachment for an instrument or endoscopic camera. The instrument bedside unit drape and the visualisation bedside unit drape are identical except for the drape caps, which have different fittings for the instruments and the endoscopic camera (Figure 2.30). See section 11.2 for instructions for draping the bedside unit.

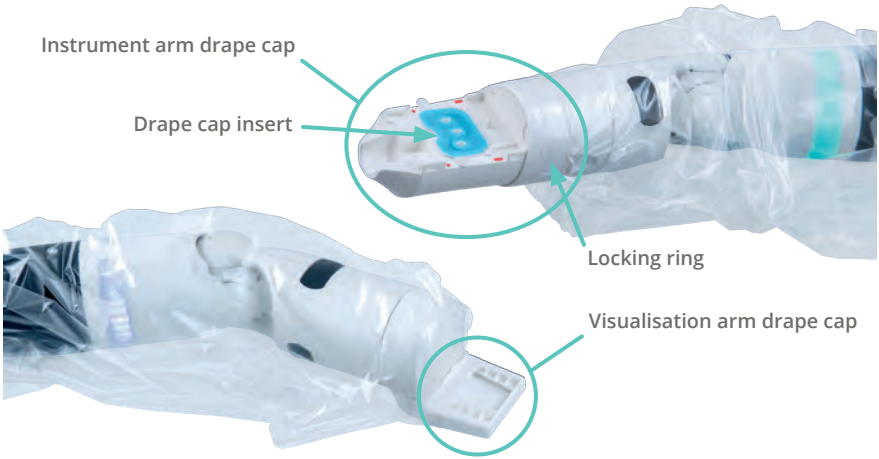


Figure 2.30 *The instrument arm and visualisation arm drape caps*

2.6.2 Camera head drape

The camera head drape (Figure 2.31) is a single-piece drape with an integral elasticated neck. The elasticated neck fits around the endoscope, and the endoscope is connected to the camera head inside the camera head drape.

Figure 2.31 *The camera head drape*

2.7 Versius Cables

Cables are used to connect the components of the Versius Surgical System together. See chapter 7 for instructions on connecting the system and appendix F for images of each cable. Refer to the Instrument and Accessories Manual (REF 70050) for information on electrosurgery cables.

Chapter 3

Operating theatre configuration

Warnings and precautions

⚠ Position the surgeon console away from the operating table, outside the sterile field to reduce the risk of contamination and prevent fluid from the surgery entering the surgeon console

⚠ **Do not** use the system near an X-ray source

⚠ To reduce the risk of trip hazards, consider the operating theatre layout and the routing of cables within the operating theatre. A trip in the operating theatre could lead to injury and unintended motion of instruments inside the patient

⚠ Position the auxiliary screen so it is clearly visible to all bedside team members at all times, enabling the team to quickly see the status of the system (particularly in the event of alarm conditions)

⚠ **Do not** use a wheeled chair at the surgeon console as the chair could be knocked and move unexpectedly, which could cause motion of the instruments inside the patient cavity and damage the anatomy

⚠ Ensure that the surgeon can hear the audio feedback from the electrosurgery generator when they are sitting or standing at the surgeon console

⚠ Set up the Versius Surgical System in a configuration that does not interfere with other essential surgical equipment. Interference with other essential equipment in the operating theatre could result in damage to the equipment and compromise patient safety

⚠ **Do not** connect more than three bedside units to one another in the daisy chain configuration

⚠ **Do not** reposition the operating table, patient or bedside units while instruments are inside the patient cavity. Moving the operating table could cause instruments to move unexpectedly inside the patient cavity and cause damage to the anatomy

⚠ **Avoid** direct contact between the Versius Bedside Units and the patient's skin. This applies to draped and non-draped bedside units

The Versius Surgical System can be connected in three configurations (Figure 3.1):

- **The spider**: all bedside units are connected directly to the surgeon console
- **The daisy chain:** the bedside units are connected to one another, with only one bedside unit connected to the surgeon console
- **The hybrid:** some bedside units are connected to each other and some to the surgeon console

Connect cables after the final positions of the auxiliary screen, the surgeon console and the bedside units have been decided. See Figure 3.2 for an example layout of the operating theatre.

After selecting a connection configuration, refer to chapter 7 for information on how to connect the system.

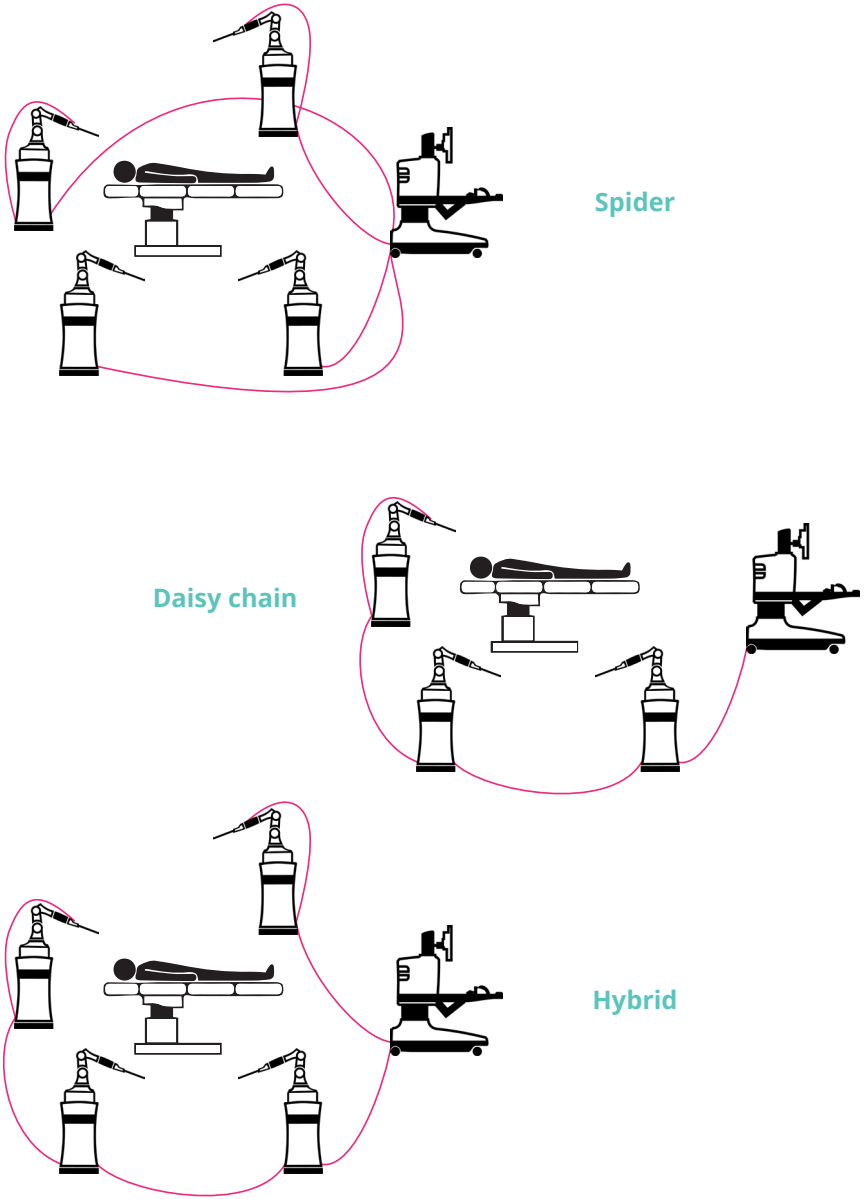


Figure 3.1 *The system cabling configurations*

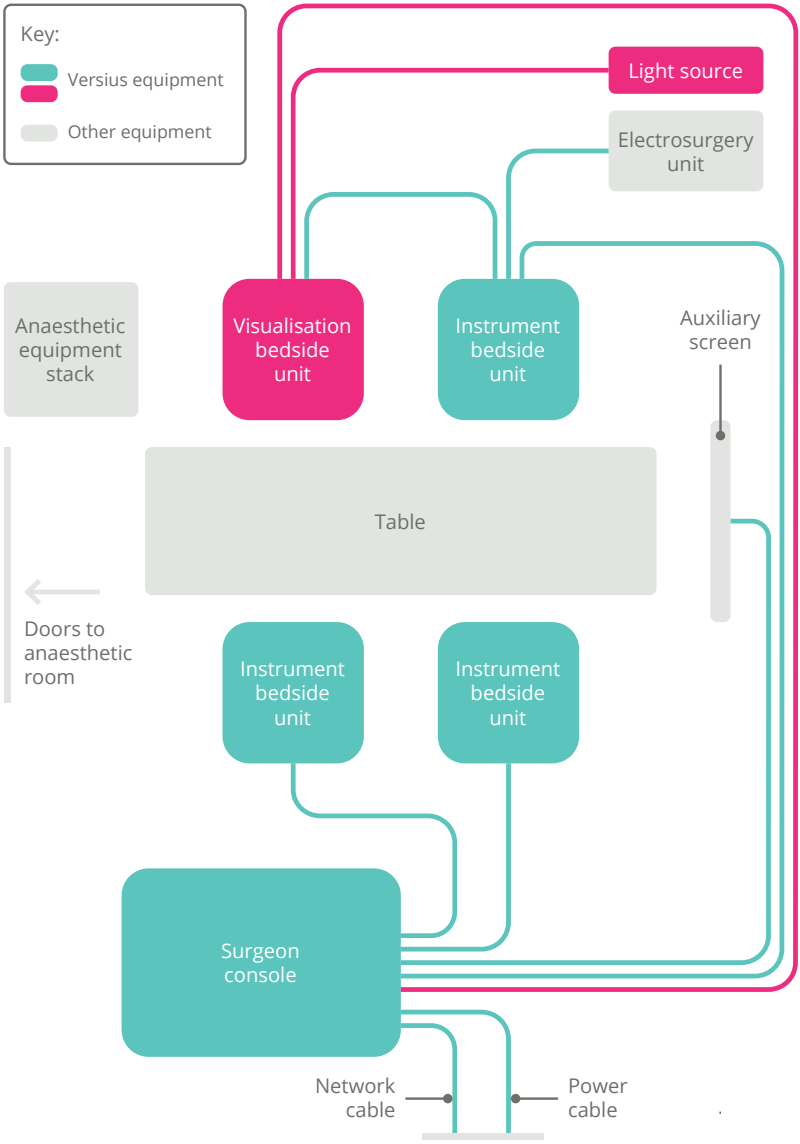


Figure 3.2 *Example layout of the Versius Surgical System with four bedside units*

3.1 Auxiliary screen positioning

The bedside team relies on the auxiliary screen to see the system status and the progress of the surgery. The auxiliary screen should be positioned so that the bedside team can see it at all times.

The auxiliary screen cable connects the auxiliary screen to the surgeon console. When possible, use a short auxiliary screen cable. When possible, the cable should run along a wall.

The auxiliary screen is not supplied as part of the Versius Surgical System.

3.2 Surgeon console positioning

The surgeon console is designed to promote communication between the surgeon and the rest of the surgical team. The position of the surgeon console should be chosen to make both visual and verbal communication as easy as possible.

The surgeon console is not sterile and should be placed away from the operating table, outside of the sterile field.

Cables connect the surgeon console to the hospital power supply, the hospital network, the auxiliary screen and at least one bedside unit. When possible, use a short video feed cable between the surgeon console and the visualisation bedside unit. When possible, the cables should run along a wall.

See Figure 3.2 for an example of the surgeon console position in the operating theatre.

3.3 Bedside unit positioning around the operating table

The positions of the bedside units around the operating table should be chosen with the surgical procedure in mind and should consider the region the arms need to reach. The bedside units should always be placed parallel to the operating table (in line with the operating table), with the brake button on the side of the cart furthest from the operating table (Figure 3.3).

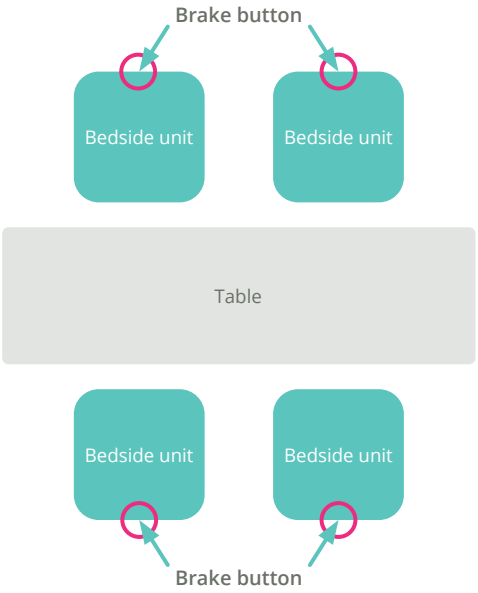


Figure 3.3 Bedside units parallel to the operating table

⚠ Versius is only validated for use with one visualisation bedside unit and up to three instrument bedside units in a procedure

When deciding on the position of the bedside units, consider the location of other equipment required for surgery:

- The light source, for connection to the visualisation bedside unit
- The electrosurgery unit, for connection to any instrument bedside units that may carry electrosurgery instruments

The bedside units can be placed close to each other, with the arms positioned so the V-Wrists are not likely to clash. The V-Wrist of each arm needs space to move. Position the bedside unit so that:

- The V-Wrist is not too close to other arms
- The V-Wrist will not clash with the base
- The arm does not need to extend any joints fully

Move any bedside units not in use away from the operating table to ensure appropriate access to the patient.

Chapter 4

The head-up display (HUD)

The head-up display (HUD) appears on both the console screen and the auxiliary screen, as an overlay of the endoscope video feed (Figure 4.1). The surgeon navigates the HUD with the thumbsticks and clutch buttons, which are located on the hand controllers (see section 2.2.2). The bedside team can see the HUD on the auxiliary screen.

Icons are used on the HUD to communicate system information and status to the surgical team. The icons cannot be hidden as the information they communicate is important.

This chapter introduces the icons used on the HUD and details how they are arranged and when they appear. For a list of icons, see appendix D.

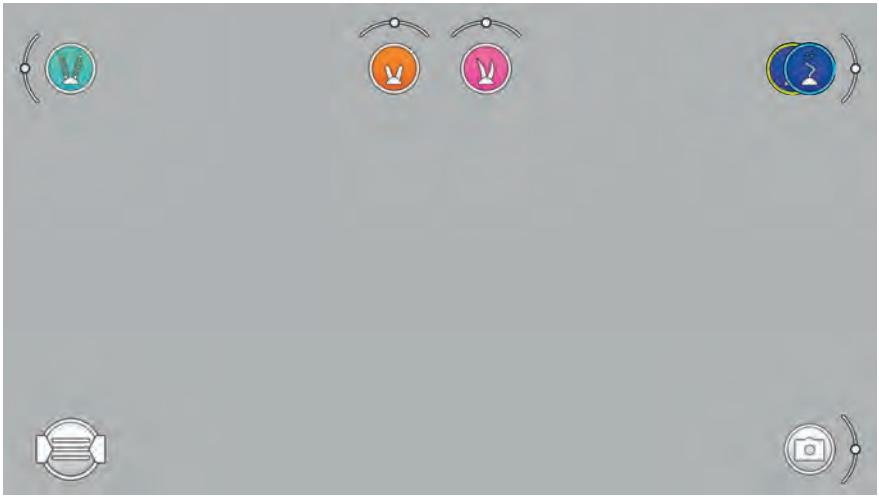


Figure 4.1 *The head-up display*

4.1 System and bedside unit icons

System icons relate to the entire system and are visible as soon as the surgeon console is powered on. Bedside unit icons each relate to one bedside unit, and only appear on the HUD when the bedside unit is connected to the surgeon console (see chapter 7 on system connections). The colour of the icon identifies whether the icon refers to the system or a particular bedside unit.

4.2 Icon colours

The background colour of an icon identifies the part of the system the icon relates to.

4.2.1 System icons

Icons associated with the entire system have a grey background (Figure 4.2). System icons are described in sections 4.5 to 4.11.

Figure 4.2 Grey icon background, used for the system icons

4.2.2 Bedside unit icons

Icons associated with a bedside unit have the same background colour as the arm colour identifier on the arm they relate to.

The visualisation bedside unit always has a white arm colour identifier and the related icons always have a white background (Figure 4.3). The icons relating to the endoscopic camera are shown in section 4.11.

Figure 4.3 *White icon background, used for the visualisation bedside unit icons*

Up to three instrument bedside units can be connected to the surgeon console and the Versius Surgical System uses different colours to identify them. There are six possible arm colour identifiers for the instrument bedside units, each with a corresponding icon background colour on the HUD (Figure 4.4). Instrument icons are described in section 4.12.

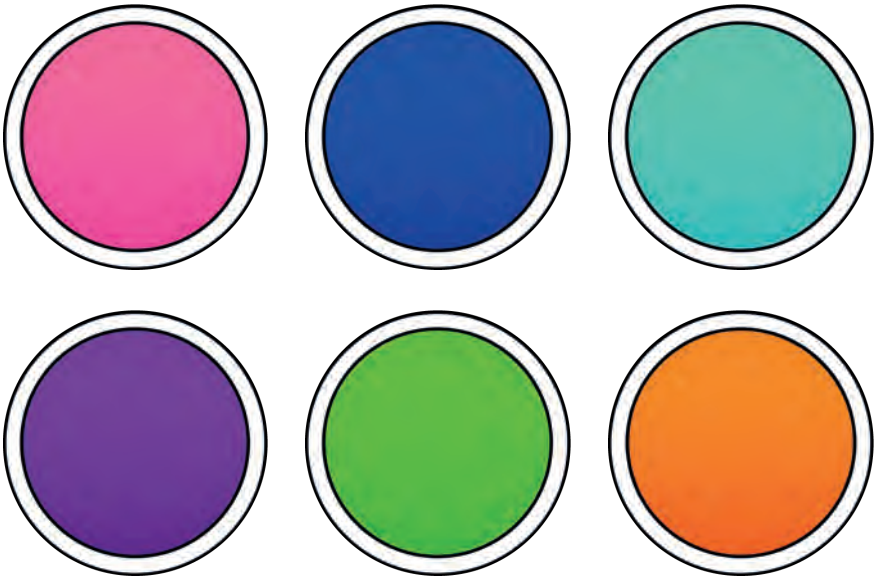


Figure 4.4 *Coloured icon backgrounds used for the instrument bedside unit icons*

4.2.3 Electrosurgery icons

Icons relating to the electrosurgery instruments have an extra feature to set them apart from the non-electrosurgery instruments and to allow the surgeon to change between the coagulation (COAG) and cut (CUT) modes.

The icon border of electrosurgery instrument icons is coloured blue for COAG and yellow for CUT mode. An additional, flashing icon indicates that electrosurgery is active on this instrument (Figure 4.5).

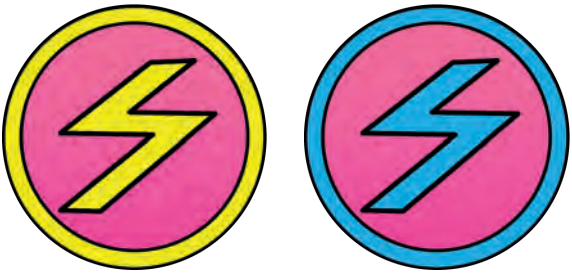


Figure 4.5 *An icon indicating active electrosurgery, in CUT and COAG modes, for a pink arm*

4.3 Icon groups

Each bedside unit connected to the system has an icon group on the HUD, where all the icons relating to that bedside unit appear (Figure 4.6). A large icon indicates the instrument attached to an arm, while smaller icons inform the surgical team of bedside unit status, arm mode and any alarms related to the arm.

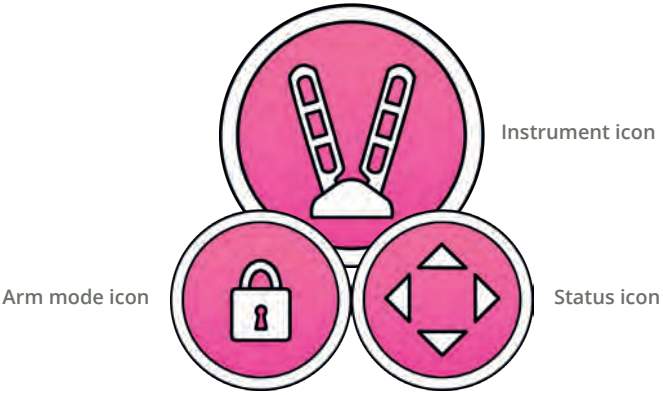


Figure 4.6 *An icon group related to a pink arm*

4.4 Icon locations on the HUD

Icons are organised on the HUD into various locations (Figure 4.7). System icons and console alarm icons appear at the bottom of the screen. The auto white balance icon appears in the middle of the screen.

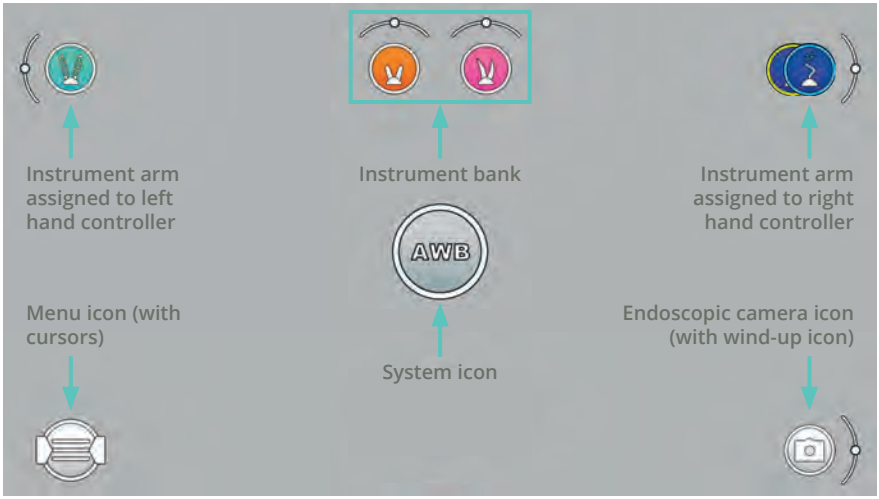


Figure 4.7 *HUD with marked icon locations*

The endoscopic camera icon appears in the bottom right-hand corner of the HUD (Figure 4.7).

When an instrument bedside unit is connected to the system, the icon group corresponding to the bedside unit appears at the top of the HUD in the instrument bank (Figure 4.8).

Figure 4.8 *Pink icon group in the instrument bank*

Once the surgeon assigns an instrument to the left or right hand controller, the icon group related to that instrument moves to the left- or right-hand side of the HUD (Figure 4.9).

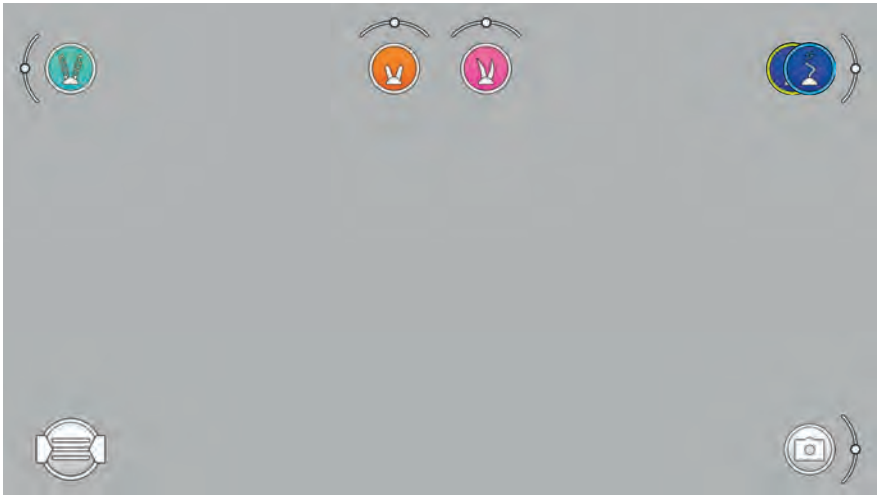


Figure 4.9 *Instrument icons on the left and right of the HUD*

Both the left- and right-hand sides of the HUD contain instrument icons most recently assigned to the corresponding hand controller. The surgeon can reassign an instrument from left to right hand controller and vice versa. The instrument icon will move to the appropriate location on the HUD.

4.5 Auto white balance icon

The endoscopic camera needs to be white balanced. For instructions on how to white balance the endoscopic camera, see section 13.9. An icon (Figure 4.10) in the middle of the HUD informs the surgical team that the endoscopic camera requires white balancing.

Figure 4.10 *Auto white balance icon*

4.6 Start-up icon

The start-up icon (Figure 4.11) appears when the bedside units and surgeon console are powering on. The background colour of the bedside unit start-up icon corresponds to the arm colour identifier. The surgeon console start-up icon is always grey.

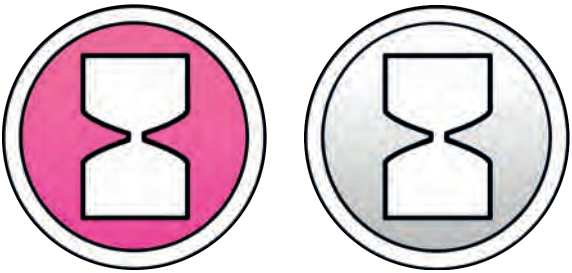


Figure 4.11 *Bedside unit start-up icon and surgeon console start-up icon*

4.7 No-hand-detected icons

Hand detection is one of the system's safety features. An instrument can be engaged with a hand controller only if the hand controller detects a hand holding it. If one or both hand controllers cannot detect a hand, one or both no-hand-detected icons (Figure 4.12) appear at the bottom of the HUD.

Figure 4.12 *No-hand-detected icons*

When a hand is holding a hand controller, the icon disappears from the HUD.

4.8 Stop icon

Stop buttons are located on the surgeon console and each bedside unit (see chapter 9). Pressing the stop button on the surgeon console or any connected bedside unit results in locking of all arms. A stop icon (Figure 4.13) appears at the bottom of the HUD when a stop button is pressed.

Figure 4.13 *Stop icon*

The stop icon disappears from the HUD when a resume button is pressed on the surgeon console or any of the connected bedside units.

4.9 HUD cursors

There are two HUD cursors (Figure 4.14), one for each hand controller. HUD cursors are used to facilitate the navigation.

Figure 4.14 *HUD cursors*

4.10 HUD menu icon

The surgeon can access settings and options (see section 13.8) by selecting the menu icon (Figure 4.15), displayed in the bottom left-hand corner of the HUD.

Figure 4.15 HUD menu icon

4.11 Endoscopic camera icons

An icon (Figure 4.16) in the bottom right-hand corner of the HUD appears when the visualisation bedside unit is connected to the system and the endoscopic camera is attached to the visualisation arm.

Figure 4.16 Endoscopic camera icon

When the visualisation bedside unit is connected to the system and the endoscopic camera is not attached to the visualisation arm, a manual endoscopic camera icon (Figure 4.17) appears in the bottom right-hand corner of the HUD.

Figure 4.17 Manual endoscopic camera icon

4.12 Instrument icons

Each instrument has a unique icon. See Figure 4.18 for some examples of instrument icons.

Figure 4.18 Instrument icons that represent Versius Instruments for a pink arm

The instrument icon is the main, largest icon of the icon group (Figure 4.6).

4.13 No-instrument icon

A no-instrument icon (Figure 4.19) appears on the HUD when a bedside unit with no instrument attached is connected to the surgeon console.

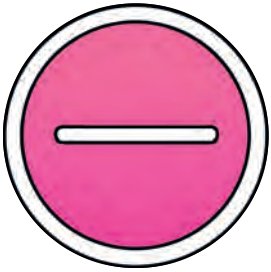


Figure 4.19 *No-instrument icon, for a pink arm*

4.14 Instrument out-of-life icon

If an instrument has reached the end of its life and needs to be discarded, the following icon (Figure 4.20) appears in the related icon group.

Figure 4.20 *Instrument out-of-life icon*

4.15 Instrument not recognised icon

If an instrument attached to an arm is not recognised by the system the following icon (Figure 4.21) appears instead of the instrument icon.

Figure 4.21 *Instrument not recognised icon*

4.16 Wind-up icon

The wind-up icon is next to the instrument icon and gives an indication of the amount of rotation the end of the arm has undergone. The ball moves up and down the arc as the distal end of the arm rotates away from a neutral position. Once the ball reaches the end of the arc, the end of the arm cannot rotate any further (Figure 4.22).

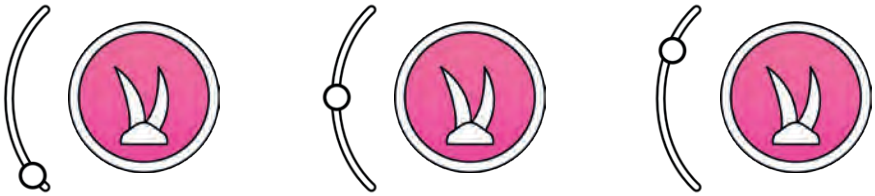


Figure 4.22 *Curved scissors icons for a pink arm, and the corresponding wind-up icons, indicating three different degrees of rotation*

To automatically unwind the end of the arm and straighten and close the instrument jaws, press down on the thumbstick on the hand controller engaged with that arm.

4.17 Arm mode icons

A Versius Arm has seven modes, used in surgery, set-up and post-operative tasks. Each mode, apart from surgical mode, is shown by an arm mode icon (Figure 4.23) next to the instrument icon. In surgical mode the arm mode icon disappears.

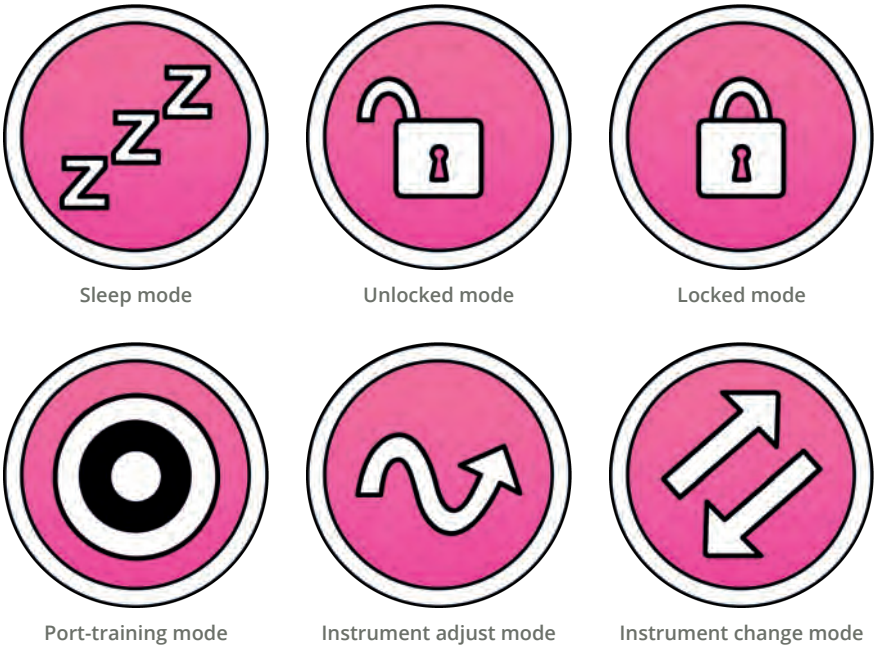


Figure 4.23 *Arm mode icons for a pink arm*

The arm modes are described in chapter 5.

4.18 Arm clash icon

A Versius arm detects an arm clash if it is pushed too hard, by a user pushing or by the arm colliding with an object. If an arm clash occurs, an arm clash icon (Figure 4.24) appears in the icon group of the affected bedside unit.

Figure 4.24 *Arm clash icon for a pink arm*

If the arm clash is on the visualisation bedside unit, both hand controllers disengage from any engaged arms and surgery cannot continue until the arm clash has been resolved.

To resolve the arm clash:

- If the clash was from manual pushing, let go of the arm
- If the clash was from a collision, manually move the arm away from the object

In some cases, an arm clash can lead to a medium-priority arm alarm. If a medium-priority arm alarm occurs, see section 20.4 for information on how to respond to the alarm.

4.19 Bedside unit status icons

Bedside unit status icons for an instrument bedside unit appear next to the corresponding instrument icon in an icon group (Figure 4.6). Bedside unit status icons for the visualisation bedside unit appear next to the endoscopic camera icon.

4.19.1 Bedside unit brake icon

If the bedside unit brake is not activated, the following icon (Figure 4.25) is shown in the related icon group.

Figure 4.25 Bedside unit brake icon

The icon disappears when the bedside unit brake is activated.

4.19.2 Bedside unit orientation icon

If the bedside unit orientation is not set, the following icon (Figure 4.26) is shown in the related icon group.

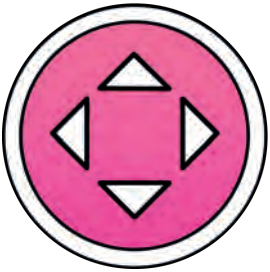


Figure 4.26 *Bedside unit orientation icon*

The icon disappears when the bedside unit orientation is set.

4.19.3 Bedside unit battery charging icon

When a bedside unit battery is charging, an animated icon (Figure 4.27) appears in the related icon group.

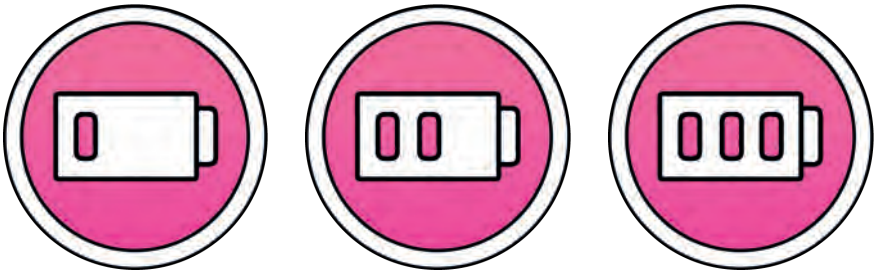


Figure 4.27 *Bedside unit battery charging icon (animated sequence)*

If a surgeon attempts to engage the bedside unit while it is charging, a flashing 'battery charging' icon (Figure 4.28) appears in the related icon group. This icon indicates to the surgeon why the arm cannot be engaged.

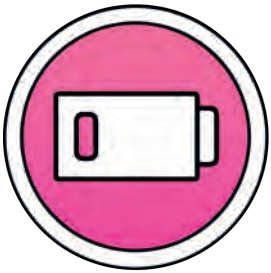


Figure 4.28 *Bedside unit battery charging icon (flashing)*

4.20 Alarm icons

The system indicates alarms to the surgical team with sounds, status halo lights and HUD icons. Arm alarm icons only appear on the HUD if the affected bedside unit is plugged in and the system network connections are still working.

The alarms are either medium-priority or high-priority. Alarm icons are listed below. For how to deal with alarms, see chapter 20.

4.20.1 Bedside unit service required icon

If a bedside unit is beyond its recommended service interval, a medium-priority arm alarm is triggered. The following icon (Figure 4.29) flashes in the related icon group.

Figure 4.29 *Service required icon*

4.20.2 Medium-priority arm alarm icon

If a medium-priority arm alarm occurs, the icon in Figure 4.30 flashes in the related icon group.

Figure 4.30 *Medium-priority arm alarm icon*

4.20.3 High-priority arm alarm icon

If a high-priority arm alarm occurs, the following flashing icon (Figure 4.31) appears in the related icon group.

Figure 4.31 *High-priority arm alarm icon*

4.20.4 Console alarm icons

If the system is left powered on for too long, a restart required alarm occurs. The icon in Figure 4.32 flashes on the HUD. Power off the system at least once every 24 hours to prevent this alarm from occuring.

Figure 4.32 *Restart required icon*

If the system is beyond its recommended service interval, a service required alarm is triggered. The icon in Figure 4.33 flashes on the HUD.

Figure 4.33 *Service required icon*

If a general console alarm occurs, the following icon (Figure 4.34) flashes on the HUD.

Figure 4.34 *Console alarm icon*

4.20.5 Alarm sound muted icon

When a console alarm sound has been muted, the following icon appears in the centre of the HUD (Figure 4.35).

Figure 4.35 *Console alarm sound muted icon*

Chapter 5

Arm modes

Warnings and precautions

⚠ **Do not** hold the arm directly on a joint due to the risk of hand traps in moving joints

⚠ **Do not** put an arm into unlocked mode while the instrument attached to the arm is inside the patient

⚠ **Do not** leave the arm in unlocked mode or instrument adjust mode by the operating table

⚠ **Always** take care when moving the instruments in the patient cavity in instrument adjust mode as the arm can be moved freely

⚠ In instrument adjust mode the previous position will **not** be remembered and the arm will **not** prevent movement deeper into the patient cavity

⚠ **Do not** attempt to put the arm into sleep mode with the drape cap attached and the arm height lowered, as this may cause damage to the drape cap and lead to contamination. The arm will not go into sleep mode while still draped and persisting to try to put the arm to sleep will not work and may result in damage to the bedside unit casework

⚠ **Do not** touch an arm while waking it from sleep mode. The arm will perform checks on its sensors which may fail if it is touched

⚠ **Do not** hold the port during port-training

⚠ **Do not** hold the distal end of the arm while port-training

This chapter describes the arm modes and how to use them during set-up, surgery and post-operative tasks.

The mode for each arm is set individually using the sleep, elbow and V-Wrist buttons. Each arm mode has an associated HUD icon, which appears in the icon group of a bedside unit (Figure 5.1). The arm modes are the same for an instrument arm and a visualisation arm.

The arm mode map (Figure 5.2) shows the sequence in which the arm modes can be accessed. Each coloured arrow represents a button press on a Versius Arm. Follow the arrows, press the relevant buttons and complete any necessary tasks to navigate to the arm mode required.

Look at the head-up display (HUD) to see the current arm modes

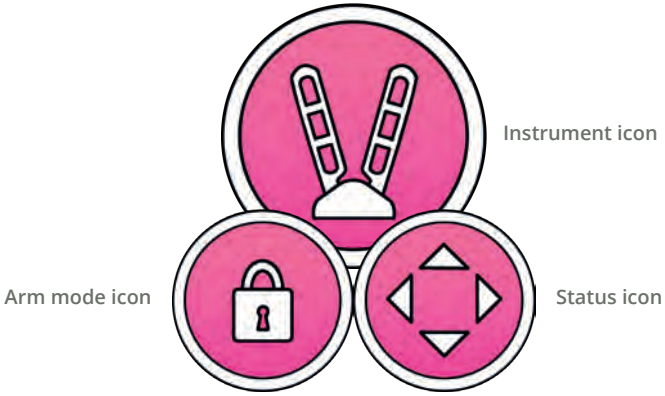


Figure 5.1 *Icon group example for a pink arm*

Arm mode map

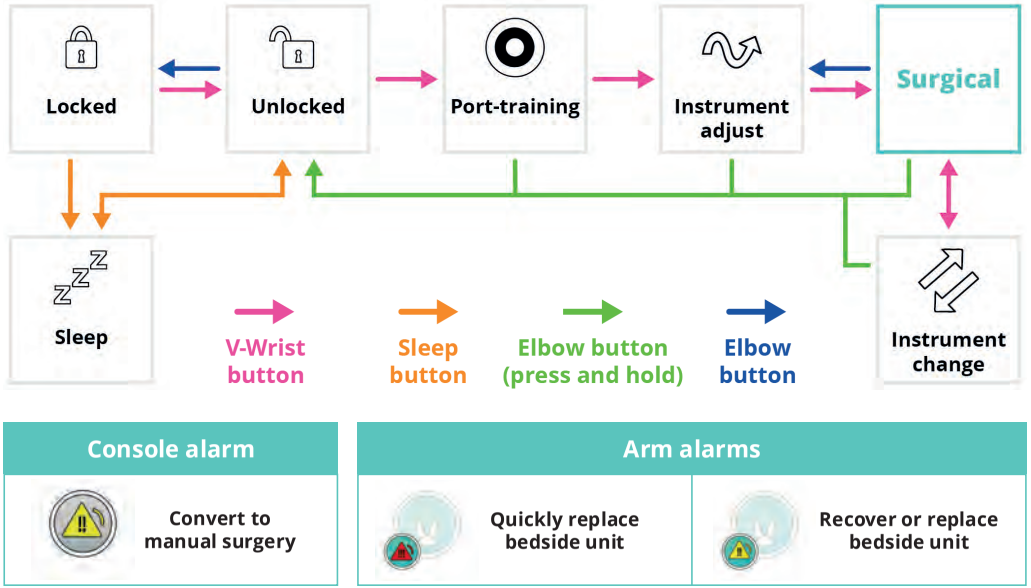


Figure 5.2 Versius arm mode map

5.1 Sleep mode

In sleep mode, the arm is locked in a compact position and cannot be moved (Figure 5.4). Sleep mode is used for transport and storage.

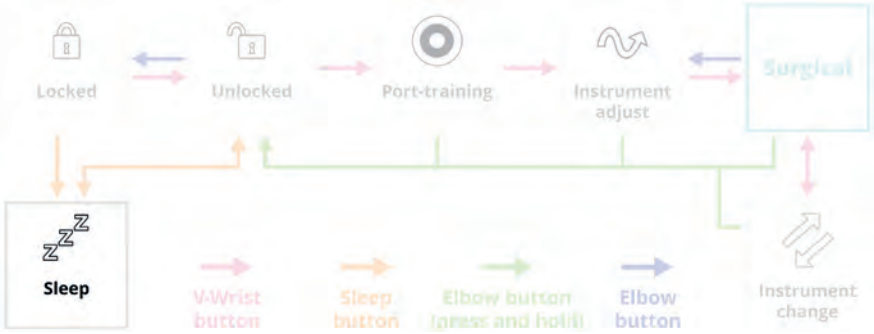


Figure 5.3 *Sleep mode in the arm mode map*

Figure 5.4 *Bedside unit in sleep mode*

The sleep mode icon appears in the bedside unit icon group on the HUD when an arm is in sleep mode and connected to the surgeon console. The sleep mode icon is animated while the arm is being woken or being put into sleep mode.

5.1.1 To wake up an arm

⚠ **Do not** touch an arm while waking it from sleep mode. The arm will perform checks on its sensors which may fail if it is touched

- Press and hold the sleep button (Figure 5.5), without touching the arm, until the bedside unit makes the 'yes' sound

The arm unfolds itself from sleep mode while the sleep button is pressed.

If the arm is woken before the bedside unit has been connected to the surgeon console, it will use battery power.

5.1.2 To put an arm to sleep

- Press and hold the sleep button (Figure 5.5) until the arm has folded into the sleep position and the sleep mode icon is static.

The arm folds itself into the sleep position while the button is pressed (see section 8.4 on setting arms to sleep).

Figure 5.5 Bedside unit sleep button

An arm will not go to sleep if there is an instrument attached to the arm.

⚠ **Do not** touch the arm while it is either unfolding from sleep mode or folding into sleep mode

⚠ Watch the area around the arm while the arm is folding itself into sleep mode

To stop folding of the arm:

- Release the press on the sleep button

This will stop the arm moving and lock it in position.

To resume the folding of the arm:

- Press and hold the sleep button until the arm has folded into the sleep position and the sleep mode icon on the HUD is static

5.2 Unlocked mode

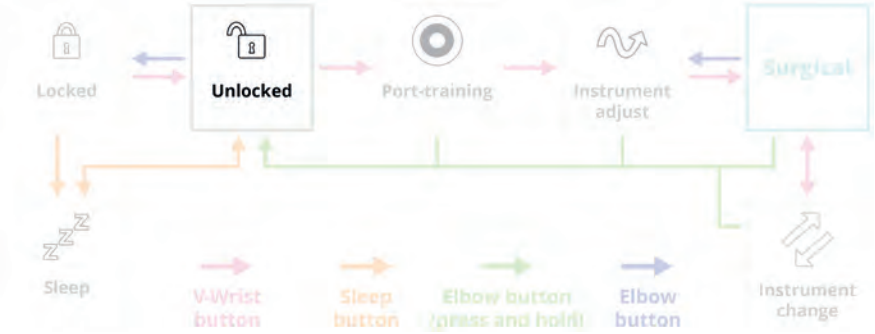


Figure 5.6 Unlocked mode in the arm mode map

When an arm is woken from sleep mode, it enters unlocked mode. In unlocked mode the arm can be moved manually. The arm holds its position when not being moved.

Unlocked mode is used when the bedside team needs to freely move and position the arm, for example during positioning for draping and positioining the arm into an arc before port-training.

⚠ **Do not** leave the arm in unlocked mode or instrument adjust mode by the operating table

⚠ **Do not** hold the arm directly on a joint due to the risk of hand traps in moving joints

The unlocked mode icon appears in the bedside unit icon group on the HUD when an arm is in unlocked mode and connected to the surgeon console.

There are three possible routes into unlocked mode (see the arm mode map in Figure 5.2).

To put an arm into unlocked mode:

- From any arm mode: press and hold the elbow button
- From locked mode: press the V-Wrist button
- From sleep mode: press and hold the sleep button

⚠ **Do not** put an arm into unlocked mode while an instrument or endoscope attached to the arm is inside the patient cavity

If an arm with an attached instrument or endoscope inside the patient cavity must be put into unlocked mode, first detach the instrument or endoscope from the arm and manually remove it from the patient cavity.

5.3 Locked mode

In locked mode, the arm cannot be moved from its position, with an exception for rotating the distal end (see Figure 5.7). The distal end of the arm can be rotated, for example to see the drape cap insert. The arm will not make any other movements. Locked mode is used when the arm needs to stay in position if force is intentionally or unintentionally applied to the arm, for example when attaching an instrument to the arm before port-training.

Put the arm into locked mode if it will be left unattended.

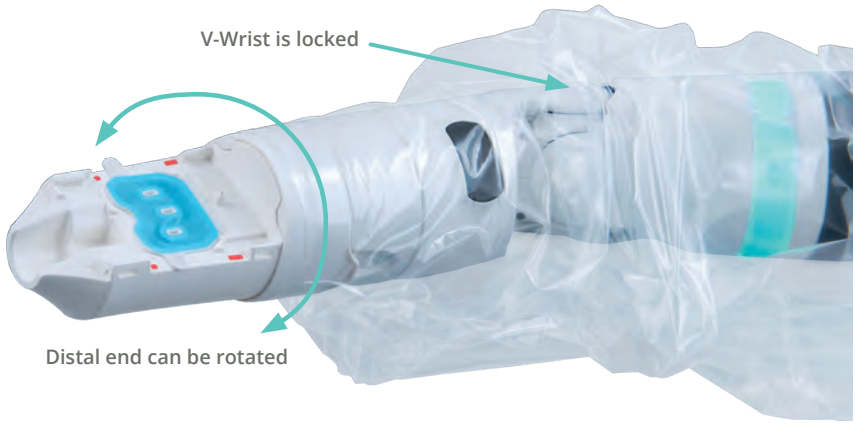


Figure 5.7 *Rotating the distal end of the arm in locked mode*

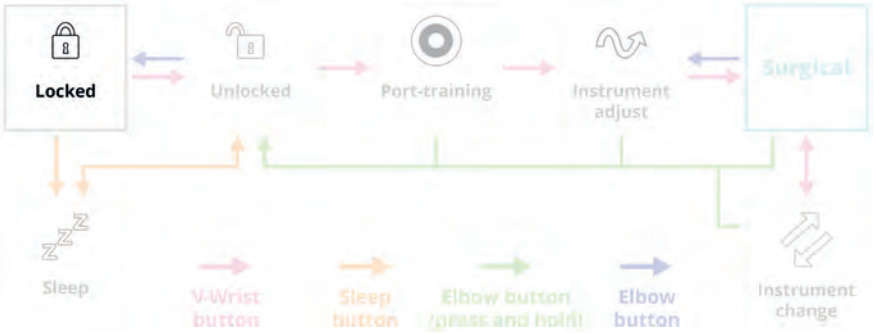


Figure 5.8 Locked mode in the arm mode map

The locked mode icon appears in the bedside unit icon group on the HUD when an arm is in locked mode and connected to the surgeon console.

5.3.1 To put an arm into locked mode

- Press the elbow button from unlocked mode

5.4 Port-training mode

The Versius instruments and endoscope pivot around the fulcrum, a set point inside the port. This minimises stress at the port site when the instruments and endoscope are moving inside the patient.

In port-training mode, the system learns where the fulcrum should be. See chapter 17 for detailed information about port-training.

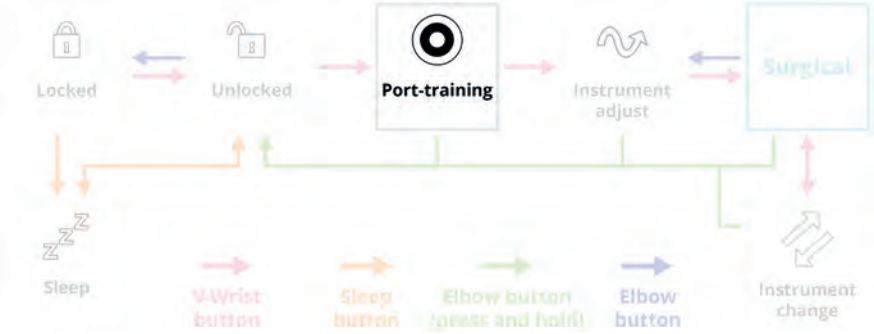


Figure 5.9 *Port-training mode in the arm mode map*

Port-training is performed once the bedside unit is set up, at the point an endoscope or an instrument is inserted into the port but is not yet inside the patient cavity.

The animated port-training icon appears in the bedside unit icon group on the HUD when an arm is in port-training mode.

5.4.1 To port-train an arm

1. From unlocked mode, press the V-Wrist button
2. Hold the black grip band
3. Move the arm in a circle until the port-training icon on the HUD is static and the bedside unit makes the port-training success sound

⚠ **Do not** hold the port during port-training

⚠ **Do not** hold the distal end of the arm while port-training

The system remembers the fulcrum location in instrument adjust mode, surgical mode and instrument change mode. Port-training needs to be repeated if:

- A port-trained arm is put into unlocked mode
- The bedside unit orientation is changed
- The arm height is changed
- The bedside unit brake is deactivated

Only insert an endoscope or an instrument into the patient cavity after successful port-training of the arm that the endoscope or instrument is attached to.

5.5 Instrument adjust mode

Instrument adjust mode is used to advance the instruments and the endoscope inside the patient cavity under vision after port-training is complete.

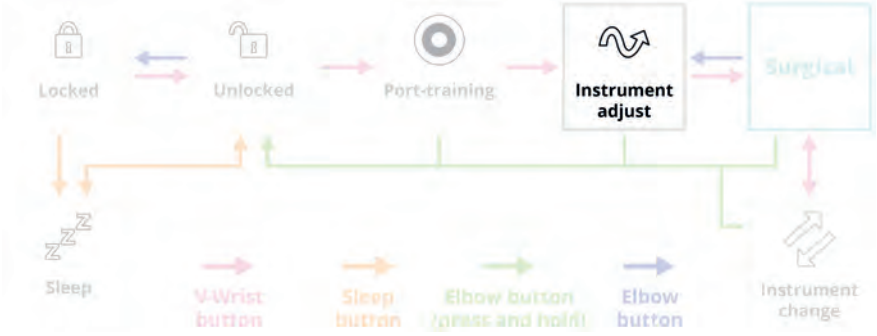


Figure 5.10 *Instrument adjust mode in the arm mode map*

The arm can be manually moved with complete freedom of movement while respecting the fulcrum position.

The instrument adjust mode icon appears in the bedside unit icon group on the HUD when an arm is in instrument adjust mode.

5.5.1 To put an arm into instrument adjust mode

- Press the V-Wrist button after successful port-training

When an arm is in instrument adjust mode, the other instrument arms used in the procedure must not be moved.

⚠ **Do not** leave the arm in instrument adjust or unlocked mode next to the operating table

⚠ Take care when moving an instrument in the patient cavity in instrument adjust mode as the arm can be moved freely

5.6 Surgical mode

In surgical mode the surgeon manipulates the endoscopic camera and the instruments using the hand controllers on the surgeon console. The system respects the fulcrums to minimise the pressure on the ports.

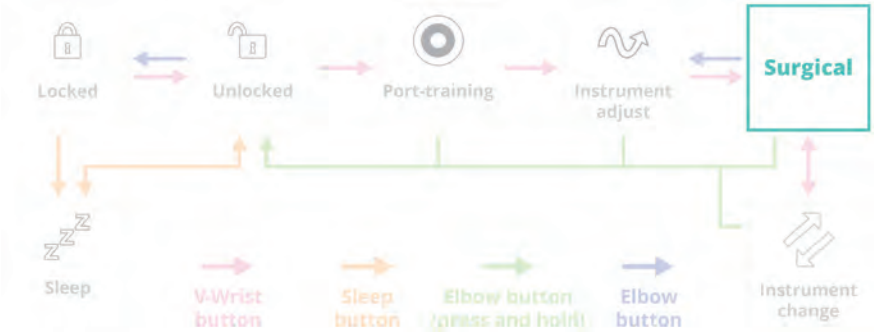


Figure 5.11 *Surgical mode in the arm mode map*

⚠ **Do not** hold the arm directly on a joint due to the risk of hand traps in moving joints

⚠ **Do not** attempt to adjust the position of the V-Wrist when an arm is in surgical mode

ⓘ There is no HUD icon for surgical mode

In surgical mode, watch the arms for potential clashes. The bedside team can move the elbow to improve access to the patient and to prevent arms from clashing. Adjusting the elbow position does not affect the instrument or endoscope position.

5.6.1 To put an arm into surgical mode

- Press the V-Wrist button when the arm is in instrument adjust or instrument change mode

ⓘ The instrument tip must be deep enough into the patient cavity (**5 cm**) before the arm will enter surgical mode. If the bedside unit makes a 'no' sound instead of entering surgical mode, carefully advance the instrument further into the patient cavity and then press the V-Wrist button again

5.7 Instrument change mode

Instrument change mode is used to change an instrument, clean the endoscope or withdraw an instrument or endoscope at the end of the surgery.

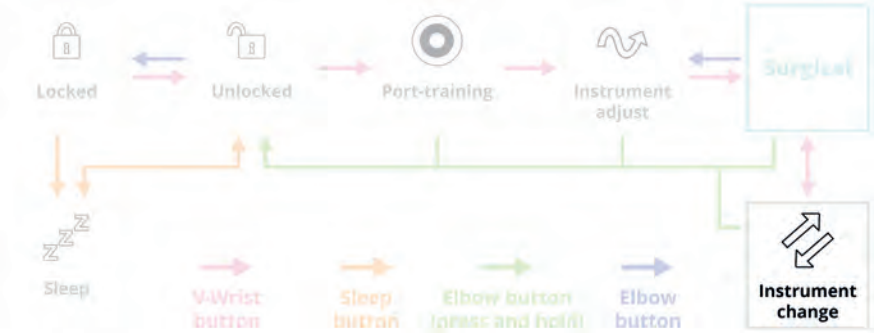


Figure 5.12 Instrument change mode in the arm mode map

The instrument change mode icon appears in the bedside unit icon group on the HUD when an arm is in instrument change mode.

In instrument change mode the instrument or endoscope can be removed from the port and reinserted by the bedside team. The arm respects the fulcrum and the arm's motion is restrained by the system, so that the arm and instrument or endoscope can only be moved in a straight line along the axis of the instrument.

In instrument change mode, the system remembers the instrument position upon entering instrument change mode and prevents movement deeper into the patient cavity

5.7.1 To put an arm into instrument change mode

- From surgical mode, press the V-Wrist button

5.7.2 Inserting an instrument or endoscope back into the patient

Once the instrument or endoscope has been changed, or the endoscope is clean, the instrument or endoscope can be reinserted into the port. Always move the instruments inside the patient cavity under vision. While the instrument is outside of the patient, look directly at the instrument. When the instrument tip is inside the port, look at the instrument on the auxiliary screen.

When inserting the instrument or endoscope back into the port, the arm remembers its previous location inside the patient cavity. The arm prevents deeper movement into the patient cavity than the original position.

Pressing the V-Wrist button on an arm in instrument change mode returns the arm to surgical mode.

5.7.3 Using instrument adjust instead of instrument change

In some positions when the arm is near the limit of its reach, instrument change mode cannot be used.

In this case:

- Use instrument adjust mode to withdraw and reinsert the instrument or endoscope

⚠ In instrument adjust mode the previous position will **not** be remembered and the arm will **not** prevent movement deeper into the patient cavity

Although the arm will respect the fulcrum in the port, arm movement in instrument adjust mode is not as constrained as in instrument change mode. As the arm can be moved along several different axes it is recommended that care is taken to move the arm in as straight a line as possible.

Chapter 6

Moving the system

Warnings and precautions

⚠ **Do not** hold the arm directly on a joint due to the risk of hand traps in moving joints

⚠ **Always** lower the surgeon console screen and armrests to their lowest settings before moving the surgeon console, to reduce the risk of damage while the surgeon console is being transported

⚠ **Always** use both hands to engage the levers on both handles when moving the surgeon console. Attempting to move the surgeon console with only one lever engaged could cause unexpected movement of the surgeon console

⚠ **Always** deactivate the bedside unit brake before moving the bedside unit. Attempting to move the bedside unit without unbraking could make the bedside unit unstable and lead it to topple over causing injury

⚠ **Do not** take any part of the system outside a building in the rain due to the risk of water entering the system and causing damage

⚠ **Do not** move the system over unpaved or rough surfaces due to the risk of damage during transportation

⚠ Use at least two handles to manoeuvre a bedside unit. Using only one handle could cause the user to lose control of the bedside unit, which could lead to damage to the bedside unit and/or injury to users

⚠ When moving a bedside unit over a threshold, pull the bedside unit using two hands. Attempting to push a bedside unit over a threshold could cause the bedside unit to become unstable and topple over

⚠ **Do not** disconnect a bedside unit from the surgeon console when the attached instrument or endoscope is inside a port

⚠ **Always** dock the hand controllers when the hand controllers are not in use. Leaving the hand controllers undocked could lead to significant damage to the hand controllers as without power the hand controllers are no longer supported in space and will drop to the floor. Using damaged hand controllers in a surgical procedure could lead to injury to the patient or user. Take care that the hand controllers remained docked during transport and when in storage

⚠ Put the arm into sleep mode using the sleep button before transporting or putting the bedside unit into storage. If the arm is not folded into sleep mode, there is an increased risk of damage to the arm which could lead to a malfunction during surgery and injury to the patient or user

⚠ **Always** lower the arm height to its lowest setting before transportation to reduce the risk of damage to the arm. Damage to the bedside unit or arm could lead to a malfunction during surgery resulting in injury to the patient or user

⚠ **Do not** force the arm beyond its range of movement as users applying excessive forces to the arms increase the risk of damage to the system and injury to the patient and/or user

This chapter describes how to move the system between rooms and within an operating theatre. The surgeon console and each bedside unit are moved individually.

6.1 Moving the surgeon console

Before moving the surgeon console to storage or to another operating theatre:

1. Dock the hand controllers (Figure 6.1)
2. Lower the armrests and console screen to the lowest height settings
3. Disconnect all cables from the surgeon console
4. Push the armrests back into the surgeon console
5. Ensure there is visibility and a clear path to where the surgeon console will be moved

Figure 6.1 Docked hand controllers on the surgeon console

To move the surgeon console:

1. Release the surgeon console brakes by squeezing the handles on the back of the surgeon console
2. Hold both handles on the back of the surgeon console
3. Push the surgeon console to move it (Figure 6.2)

Figure 6.2 *Wheeling the surgeon console*

When the surgeon console is in place in the operating theatre, adjust the surgeon console and console screen to a height that allows the surgeon to sit or stand in an ergonomic position. For how to adjust the surgeon console, see chapter 13.

⚠ **Always** use both hands to engage the levers on both handles when moving the surgeon console. Attempting to move the surgeon console with only one lever engaged could cause unexpected movement of the surgeon console

6.2 Moving the bedside units

⚠ When moving a bedside unit over a threshold, pull the bedside unit using two hands. Attempting to push a bedside unit over a threshold could cause the bedside unit to become unstable and topple over

Before moving a bedside unit to storage or to another operating theatre:

1. Set the arm to its lowest height setting
2. Put the arm into sleep mode
3. Disconnect all cables from the bedside unit
4. Ensure there is visibility and a clear path to where the bedside unit will be moved to

In sleep mode, the arm is locked in a folded position. This reduces the risk of damage during transport and storage. For how to put an arm into sleep mode, see section 5.1.2.

Before moving a bedside unit within an operating theatre:

- Put the arm into locked mode, to prevent any unexpected arm movement that could result in injury or damage
- Ensure there is a clear path to where the bedside unit will be moved to. Other bedside units can be disconnected temporarily if cables are in the way

If a bedside unit in surgical mode is disconnected from the surgeon console the bedside unit will make a ‘no’ sound. The arm will lock but the rest of the system will continue to function normally.

Before moving a bedside unit away from the operating table, check that:

- The instrument is not inside the patient
- The arm position allows the bedside unit to be moved away from the operating table without making contact with the patient

To move a bedside unit:

1. Deactivate the brake
2. Hold two handles (Figure 6.3)
3. If the ground is flat and level, push the bedside unit to move it. If the bedside unit is to be moved over a threshold, pull the bedside unit using two hands.

Figure 6.3 *Pushing the bedside unit using two handles*

6.3 Bedside unit brake

Each bedside unit has a brake for safety during storage, set-up and surgery. When the brake is activated the bedside unit is stable and cannot be moved from its position. When the brake is deactivated, the bedside unit can be wheeled freely.

6.3.1 Using the bedside unit brake

Each bedside unit has a brake button that activates and deactivates the brake on that bedside unit. The bedside unit brake can be activated and deactivated whether or not it is connected to the surgeon console. Activating and deactivating the brake is the same for both the instrument and visualisation bedside units.

In certain arm modes it is not possible to deactivate the bedside unit brake for safety reasons:

- Port-training mode
- Instrument adjust
- Surgical mode
- Instrument change

> After the arm has been port-trained, the bedside unit brake cannot be deactivated unless the instrument or endoscope is fully retracted out of the port or detached from the arm

If the bedside unit is connected to the surgeon console, a brake icon appears on the HUD when the brake is deactivated.

It is recommended that the brake is activated whenever a bedside unit is left unattended.

6.3.2 To activate the bedside unit brake

1. Ensure the area under the bedside unit is clear
2. **Press and hold** the brake button

If the bedside unit is connected to the surgeon console:

- Hold the brake button until the brake icon disappears from the HUD

If the bedside unit is not connected to the surgeon console:

- Hold the brake button until the base of the bedside unit reaches the floor

If the brake button is released before the brake is fully activated, the bottom of the bedside unit will rise again. This is a safety feature designed to prevent injuries to the surgical team. Avoid touching the bottom of the bedside unit when activating or deactivating the brake to avoid hand trap injuries.

Figure 6.4 Brake activated on the bedside unit

6.3.3 To deactivate the bedside unit brake

- Press the brake button once

No power is required to release the brake. When bringing a bedside unit from storage, press the brake button once and wheel the bedside unit into the operating theatre.

Figure 6.5 Brake deactivated on the bedside unit

6.4 Moving the arms

⚠ **Do not** touch the joints when the arms are being moved to avoid hand trap injuries

See Figure 1.1 in Chapter 1 for safe places to hold and push the arm.

Arms only move when they are continuously controlled, either by the surgeon using the hand controllers or by the surgical team pushing manually. Push the arms in a careful and controlled way. If the arm is pushed too hard it will detect an arm clash (see section 6.4.2) and this may lead to a medium-priority arm alarm (see section 20.4).

How freely an arm can be moved depends on the arm mode. For detailed information on how the arm moves in different modes see chapter 5.

To manually move an arm:

1. Put the arm into a mode that allows manual movement
2. Hold the arm in a safe place
3. Push or pull the arm to move it into position

Figure 6.6 *Moving an arm*

6.4.1 The range of motion

Each joint in an arm has a set range of motion. If an arm reaches a position where one or more joints are at the end of their range, it will be impossible to move the arm in some directions.

If the arm will not move in one direction, move it in the opposite direction and change the positions of the joints, then try again.

Figure 6.7 *Arm range of motion*

6.4.2 Arm clash

A Versius arm detects an arm clash if it is pushed too hard, by a user pushing or by the arm colliding with an object. If an arm clash occurs, the bedside unit makes a 'no' sound and this icon appears in the icon group of the affected bedside unit(s):

The ‘no’ sound will play repeatedly until the arm clash is resolved. If the arm clash is on the visualisation bedside unit, both hand controllers disengage from any engaged arms and surgery cannot continue until the arm clash has been resolved.

To resolve the arm clash:

- If the clash was from manual pushing, let go of the arm
- If the clash was from a collision, manually move the arm away from the object

In some cases, an arm clash can lead to a medium-priority arm alarm. If a medium-priority arm alarm occurs, see section 20.4 for information on how to respond to the alarm.

Chapter 7

System connections

Warnings and precautions

⚠ Check for any visible damage to the arm before connecting the bedside unit to power

⚠ Follow all manufacturer's instructions for the ESU and check settings before starting electrosurgery

⚠ Tether the cables to the arm before moving the bedside unit to avoid interference with other equipment or accidentally tethering the cable to a different drape

⚠ Ensure that the surgeon can hear the audio feedback from the electrosurgery generator when they are sitting or standing at the surgeon console

⚠ **Do not** run any Versius Cables underneath the operating table

⚠ **Do not** unplug a bedside unit when the surgeon is using or relying on the availability of the arm

⚠ **Do not** move the bedside unit over the video feed cable as this may damage the cable to the extent that it will be unusable

ℹ It is advisable to tether the light cable to the visualisation arm drape

ℹ It is **not** advised to connect bedside units in a 'daisy chain' cabling scheme if those bedside units would need to be pulled away from the operating table in opposing directions

ℹ It is advisable to have spare cables available to replace cables if they are damaged

This chapter describes how to connect the parts of the Versius Surgical System using Versius Cables. It also describes how to connect the necessary parts external to the Versius Surgical System.

For a list of all cables necessary to connect the Versius Surgical System see appendix F.

There are three possible system cabling configurations for the system: the 'spider', the 'daisy chain' and the 'hybrid' (see Figure 3.1 and see chapter 3 for more information on system cabling configurations).

7.1 Connecting the surgeon console

7.1.1 Surgeon console connection panel

Located on the base of the surgeon console at the rear, the connection panel (Figure 7.1) is where all the cables are connected to the surgeon console.

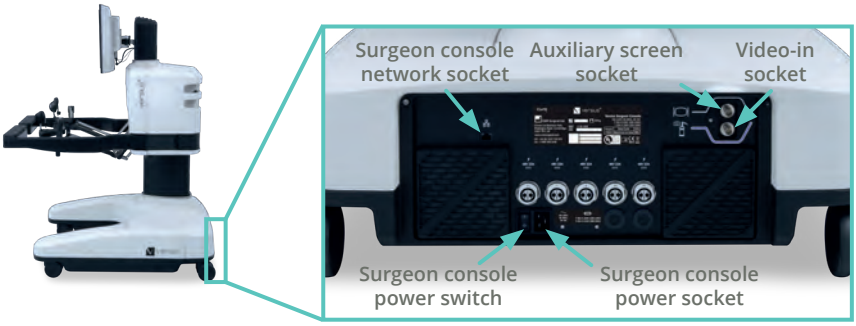


Figure 7.1 *The surgeon console connection panel*

The cables connected to the surgeon console are:

- Surgeon console power cable (non-sterile)
- Network cable (non-sterile)
- Auxiliary screen cable (non-sterile)
- Video feed cable (non-sterile)
- Bedside unit cable(s) (non-sterile)

7.1.2 Connecting the surgeon console power cable

The surgeon console power cable (Figure 7.2) connects the surgeon console to the mains power.

Figure 7.2 *Surgeon console power cable*

Connect the surgeon console power cable to:

1. The socket on the surgeon console connection panel (Figure 7.1)
2. The hospital mains power (supported by emergency power supply)

The surgeon console can then be powered on by switching the surgeon console power switch to the ‘on’ position.

For more information on switching the system on, see chapter 8.

7.1.3 Connecting a network cable

A network cable (Figure 7.3) connects the surgeon console to the hospital network. For information on connecting the Versius Surgical System to the hospital network see section 1.2.6.

Figure 7.3 *An example network cable*

Connect a network cable to:

1. The network socket on the surgeon console connection panel (Figure 7.1)
2. A network connection (RJ45 Ethernet 100BASE-TX/1000BASE-T) with Internet access

7.1.4 Connecting the auxiliary screen cable

An auxiliary screen does not come as part of the Versius Surgical System. An existing operating theatre auxiliary screen may be used. The system is also compatible with integrated operating theatre set-ups.

The auxiliary screen cable (Figure 7.4) connects the surgeon console to an auxiliary screen. The cable is available in two lengths: short (5 metres) and long (10 metres). The cable has a standard SDI connection, which is compatible with most existing operating theatre auxiliary screens and integrated operating theatre set-ups.

Figure 7.4 *Auxiliary screen cable*

To connect the surgeon console to the auxiliary screen:

1. Insert an auxiliary screen cable connector into the auxiliary screen socket on the surgeon console connection panel (Figure 7.5)
2. Rotate clockwise to lock in position
3. Insert the other cable connector into an SDI input socket on the auxiliary screen
4. Rotate clockwise to lock in position

Figure 7.5 *Auxiliary screen cable plugged into the surgeon console*

7.2 Connecting a bedside unit to the system

7.2.1 Bedside unit power-in and power-out sockets

The sockets on a bedside unit are all found in the cart connection panel (Figure 7.6) located at the back, below the brake button.

The power-in and power-out sockets available on a cart connection panel are used to connect a bedside unit to either the surgeon console or another bedside unit, based on the system configuration (cabling scheme) chosen: ‘spider’, ‘daisy chain’ or ‘hybrid’ (see chapter 3 for more information on system configurations).

Visualisation cart connection panel

Instrument cart connection panel

Figure 7.6 *Cart connection panels*

7.2.2 Bedside unit cable

The bedside unit cable (Figure 7.7) connects a bedside unit to the surgeon console or to another bedside unit. The cable is available in two lengths: short (5 metres) and long (10 metres).

Figure 7.7 *Bedside unit cable*

7.2.3 Connecting a bedside unit to the surgeon console

To connect the bedside unit to the surgeon console:

1. Align the alignment marker on the bedside unit cable connector with the alignment marker on the power-in socket on the cart connection panel (Figure 7.8)
2. Push the cable connector into the power-in socket until the cable connector's locking ring rotates into place. An audible click will confirm that the bedside unit cable is correctly connected
3. Align the alignment marker on the other cable connector with the alignment marker on a power-out socket on the surgeon console connection panel (Figure 7.8). Any of the five power-out sockets on the surgeon console may be used
4. Push the cable connector into the power-out socket until the cable connector's locking ring rotates into place. An audible click will confirm that the bedside unit cable is correctly connected
5. Look at the auxiliary screen – there should be a coloured icon group corresponding to the arm colour identifier in the instrument bank on the HUD

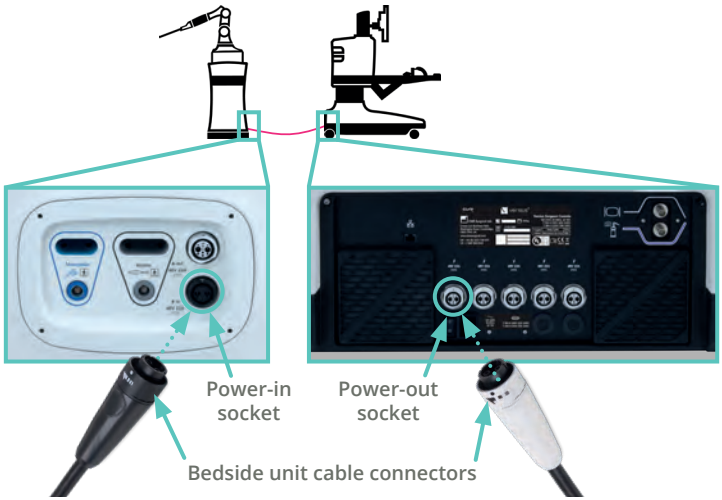


Figure 7.8 Connecting a bedside unit to the surgeon console

7.2.4 Connecting a bedside unit to another bedside unit

To connect a bedside unit to another bedside unit:

1. Align the alignment marker on the bedside unit cable connector with the alignment marker on the power-in socket on the cart connection panel (Figure 7.9)
2. Push the cable connector into the power-in socket until the cable connector's locking ring rotates into place. An audible click will confirm that the bedside unit cable is correctly connected
3. Align the alignment marker on the other cable connector with the alignment marker on the power-out socket on the other cart connection panel (Figure 7.9)
4. Push the cable connector into the power-out socket until the cable connector's locking ring rotates into place. An audible click will confirm that the bedside unit cable is correctly connected

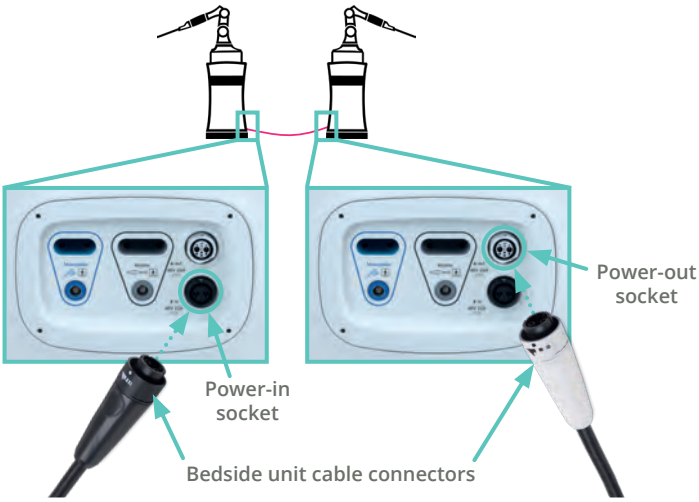


Figure 7.9 Connecting a bedside unit to another bedside unit

⚠ **Do not** unplug a bedside unit when the surgeon is using or relying on availability of the arm

To disconnect either connector of the bedside unit cable, rotate the locking ring counter-clockwise and pull the cable out of the socket.

7.2.5 Securing bedside unit power cables

Cables connected to the bedside unit can be secured in place using the clip at the bottom of a bedside unit (Figure 7.10).

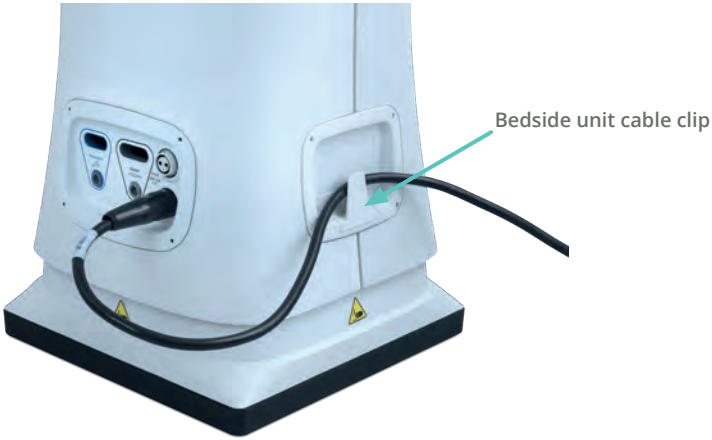


Figure 7.10 *Bedside unit cable clip*

7.2.6 Visualisation cart connection panel

The sockets on a visualisation bedside unit are all found in the cart connection panel (Figure 7.11) located at the back, below the brake button.

The cables connected to the visualisation bedside unit are:

- Bedside unit cable(s) (non-sterile)
- Video feed cable (non-sterile)
- Camera cable (non-sterile)

Figure 7.11 shows where to connect each cable on a visualisation bedside unit.

Figure 7.11 *Visualisation cart connection panel*

7.2.7 Connecting the video feed cable

The video feed cable connects the visualisation bedside unit and the surgeon console (Figure 7.12). The cable is available in two lengths: short (5 metres) and long (10 metres).

Figure 7.12 *Video feed cable*

To connect the video feed cable:

1. Insert a connector (either end of the cable) into the video-in socket on the surgeon console connection panel (Figure 7.1)
2. Rotate clockwise to lock in position
3. Insert the other connector into the video-out socket on the visualisation cart connection panel (Figure 7.13)
4. Rotate clockwise to lock in position

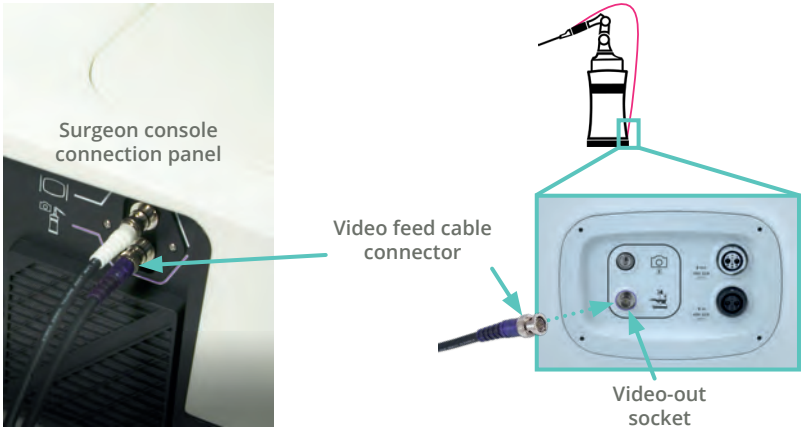


Figure 7.13 Connecting the video feed cable

⚠ **Do not** move the bedside units, surgeon console or other equipment over cables as this may damage the cables to the extent that they will be unusable

It is advisable to have a spare video feed cable available to use as a replacement

7.2.8 Connecting the endoscopic camera

The endoscopic camera (Figure 7.14) is draped and attached to the distal end of the visualisation bedside unit's arm.

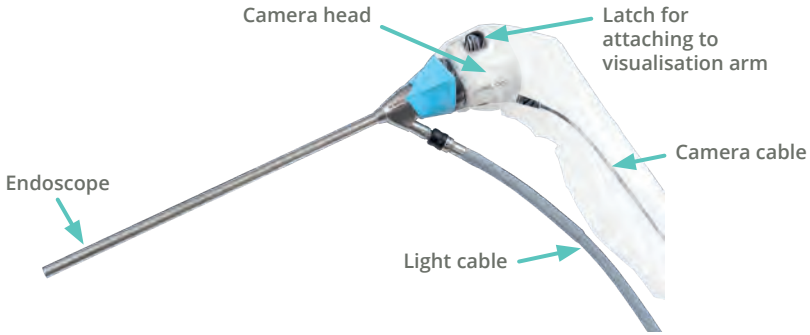


Figure 7.14 The draped endoscopic camera

Two cables are connected to the endoscopic camera:

- Camera cable (non-sterile)
- Light cable (sterile)

7.2.9 Connecting the camera head to the visualisation bedside unit

The camera cable connects the camera head to the visualisation bedside unit. It is permanently attached to the camera head (Figure 7.15).

Before connecting the camera head to the visualisation bedside unit, drape the endoscopic camera. For how to drape the camera head, see section 11.3.

Figure 7.15 The camera cable attached to the camera head

To connect the camera cable to the visualisation cart connection panel (Figure 7.16):

1. Insert the cable connector into the camera cable socket
2. Rotate clockwise to lock in place

The camera cable is not sterile and runs inside the camera head drape.

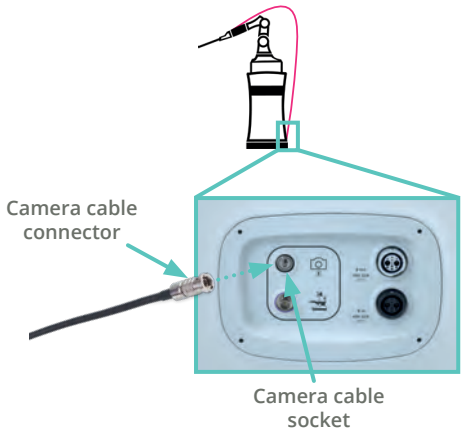


Figure 7.16 Connecting the camera head to the visualisation bedside unit

7.2.10 Connecting the endoscopic camera to a light source

⚠ Follow all instructions, cautions and warnings provided with the light source, light cable and endoscope to avoid accidental tissue coagulation, unsafe high temperatures or ignition

⚠ **Do not** let the light cable rest on patient skin. Inadvertent contact with the patient may result in burns

⚠ **Do not** allow the end of the light cable to touch or point towards the patient or user when changing the endoscope as it may result in burns

⚠ Take care when removing the light cable from the light source as the end of the light cable may be hot

The light cable (Figure 7.17) connects the endoscope to the light source. See section 1.4.3 for a list of compatible light sources.

Figure 7.17 *Light cable*

Connect the light cable to:

1. The endoscope (Figure 7.18)
2. The light source (Figure 7.18)

The light cable is not supplied sterile and must be sterilised before first use and after each use. The light cable should be connected to the endoscope after the camera head is draped.

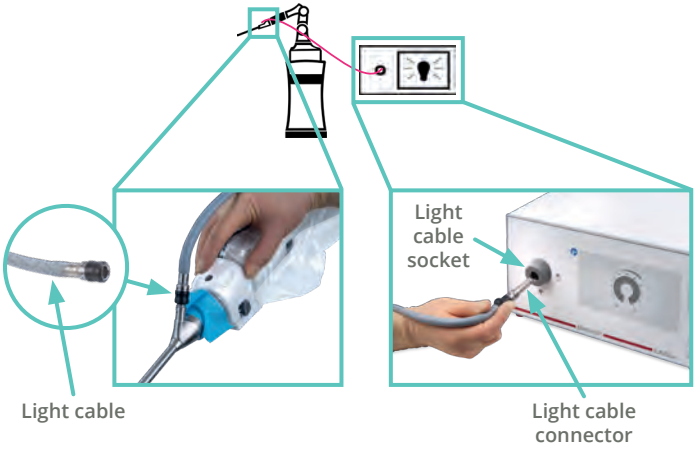


Figure 7.18 *Connecting the endoscopic camera to a light source*

After the cable is connected to the endoscope and the endoscopic camera is attached to the visualisation arm, the light cable should be tethered to the visualisation arm drape. Tethering the light cable is important as it balances the forces on the arm during surgery and helps to prevent the cable becoming snagged or entangled during use.

For how to tether the light cable see section 14.1.

It is recommended to have a spare light cable available, due to the fragility of the cable and possibility of damage

7.3 Connections for electrosurgery

See the Versius Instrument and Accessories Manual (REF 70050) for instructions on connecting electrosurgery cables and for the correct electrosurgery unit settings for each compatible ESU.

See the Electrosurgery Instrument Cables Instructions for Use (REF 72000) for safety information and reprocessing instructions specific to the electrosurgery instrument cables.

⚠ Follow all instructions, cautions and warnings provided with the ESU to avoid serious injury to the patient

⚠ Inspect instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high-voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator

⚠ The Versius Instrument Bedside Unit Monopolar Interface is designed for use with a maximum peak voltage of 3000V. **Do not** use settings on the ESU that exceed a 3000V peak

⚠ The Versius Instrument Bedside Unit Bipolar Interface is designed for use with a maximum peak voltage of 500V. **Do not** use settings on the ESU that exceed a 500V peak

⚠ **Always** refer to the Instrument and Accessories Manual (REF 70050) for specific maximum peak voltage limits which relate to specific instruments. **These limits may be less than those specified above**

⚠ Keep all electrosurgery instruments in the field of view when activating electrosurgery and beware that capacitive coupling can produce heating of an inactive electrosurgery instrument

⚠ Place the monopolar instrument cables and bipolar instrument cables where they do not come into contact with the patient, with other cables or metal parts. Failure to do so could lead to transfer of monopolar energy by capacitive coupling and may cause burns to the patient

Chapter 8

Powering on and powering off

Warnings and precautions

⚠ **Do not** attempt to put the arm into sleep mode with the drape cap attached and the arm height lowered, as this may cause damage to the drape cap and lead to contamination. The arm will not go into sleep mode while still draped and persisting to try to put the arm to sleep will not work and may result in damage to the bedside unit casework

⚠ **Do not** touch an arm while waking it from sleep mode. The arm will perform checks on its sensors which may fail if it is touched

⚠ Dock the hand controllers when the hand controllers are not in use. Leaving the hand controllers undocked could lead to significant damage to the hand controllers as without power the hand controllers are no longer supported in space and will drop to the floor. Using damaged hand controllers in a surgical procedure could lead to injury to the patient or user. Take care that the hand controllers remained docked during transport and when in storage

Before connecting and powering on any component of the Versius Surgical System, consider the layout of the operating theatre (see chapter 3).

8.1 Powering on the surgeon console

The surgeon console powers the system. The surgeon console does not have a battery and must be connected to the mains power supply (supported by the hospital emergency power supply).

8.1.1 To power on the surgeon console

1. Connect the surgeon console power cable to the console connection panel (Figure 8.1). An audible click indicates when the cable is correctly connected

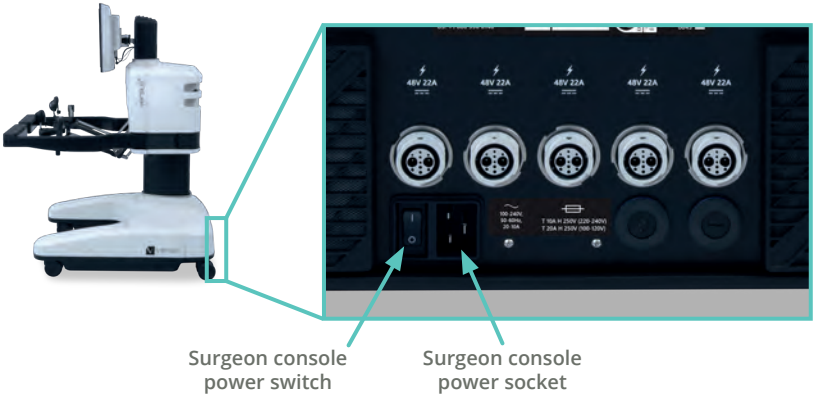


Figure 8.1 *The power switch and socket on the surgeon console connection panel*

2. Connect the plug on the surgeon console power cable to a power socket that is supported by the hospital emergency power supply and switch it on at the power socket
3. Press the power switch on the surgeon console connection panel to the 'on' position (Figure 8.1)

While powering on:

4. The surgeon console screen initially shows a blue screen, or the endoscope video feed if the endoscopic camera is already connected.

It is recommended that the hand controllers are not held while the surgeon console is powering on. The surgeon console is performing checks on its sensors which may fail if the hand controllers are touched.

5. The surgeon console performs an internal safety check and makes the flourish sound when this is complete
6. This is followed by the appearance of the Versius splash screen (Figure 8.2)
7. Finally, when the surgeon console is ready to use, the HUD appears (see chapter 4)

Figure 8.2 *The Versius splash screen displayed on the surgeon console screen*

The surgeon console status halo (see section 2.2.6) and the status halo of each of the connected bedside units show green lights when the system is powered on and no alarm is detected.

8.2 Powering on the bedside units

The bedside units are powered by the surgeon console. The bedside units are connected via a cable to the surgeon console either directly or indirectly (see chapter 3 on operating theatre configuration). Each bedside unit has its own battery which supports the arm temporarily if the bedside unit is not connected to the surgeon console.

The bedside unit is powered off if the arm is in the sleep position and unplugged from the surgeon console. As soon as the bedside unit is connected to a powered on surgeon console, the bedside unit has power. The start-up icon in Figure 8.3 appears in the icon group on the HUD.

If the bedside unit is not connected to the surgeon console, the bedside unit is powered on by pressing and holding the sleep button until it unfolds from the sleep position and enters unlocked mode.

To power on the bedside unit:

1. Connect the bedside unit cable from the power-out socket on the surgeon console, or on another bedside unit, to the power-in socket on the bedside unit connection panel
2. The start-up icon appears in the icon group of the connected bedside unit (Figure 8.3)
3. The bedside unit icon group appears on the HUD in the instrument bank (Figure 4.8)

Figure 8.3 *Bedside unit start-up icon*

8.3 Waking up an arm

⚠ **Do not** touch an arm while waking it from sleep mode. The arm will perform checks on its sensors which may fail if it is touched

When an arm is woken, it moves from sleep mode to unlocked mode.

8.3.1 To wake up an arm

1. Press and hold the sleep button (Figure 8.4), without touching the arm, until the bedside unit makes the 'yes' sound

Figure 8.4 *Sleep button on the bedside unit control panel*

If the bedside unit is connected to the surgeon console, the animated sleep icon on the HUD changes to an unlocked mode icon when the arm has successfully woken up.

If the sleep button is released before the arm completes its checks, the arm does not unlock and must be fully folded again by pressing and holding the sleep button. After fully folding, wake the arm from sleep, making sure the press on the sleep button is held until the bedside unit makes the 'yes' sound.

8.4 Putting an arm into sleep mode

The arm can be put into sleep mode from locked or unlocked modes. When an arm is put into sleep mode, it moves itself into a folded position.

8.4.1 To put the arm into sleep mode

1. Remove any attached instrument or endoscopic camera
2. Remove the bedside unit drape
3. Press and hold the sleep button (Figure 8.4), without touching the arm, until the bedside unit makes the 'yes' sound

While the sleep button is pressed and the arm is folding, an animated sleep mode icon is shown on the HUD. When the arm has successfully folded, the arm is in sleep mode, the bedside unit makes the 'yes' sound and the sleep mode icon stops animating.

8.5 Powering off the bedside units

Once the arm is in sleep mode, the bedside unit can be powered off.

8.5.1 To power off the bedside unit

1. Put the arm into sleep mode
2. Disconnect the bedside unit cable from the connection panel on the surgeon console and from the connection panel on the bedside unit

Bedside units must be in sleep mode before they can be powered off.

8.6 Powering off the surgeon console

The surgeon console must be powered off every 24 hours. This is commonly done following post-operative disconnecting and cleaning.

8.6.1 To power off the surgeon console

1. Put all arms to sleep
2. Check that the hand controllers on the surgeon console are docked (Figure 8.5)
3. Press the power switch on the surgeon console connection panel to the 'off' position (Figure 8.1)

In the event of a system restart required alarm (see chapter 20 on alarms), follow steps 1 to 3.

Figure 8.5 Docked hand controllers on the surgeon console

⚠ Dock the hand controllers when the hand controllers are not in use. Leaving the hand controllers undocked could lead to significant damage to the hand controllers as without power the hand controllers are no longer supported in space and will drop to the floor. Using damaged hand controllers in a surgical procedure could lead to injury to the patient or user. Take care that the hand controllers remained docked during transport and when in storage

Chapter 9

Stopping and resuming the system

Warnings and precautions

⚠ The stop button only stops movement on bedside units connected to the surgeon console. Pressing a stop button on a bedside unit not connected to the surgeon console only stops that bedside unit. In the event that the entire system requires stopping, press the stop button on a connected bedside unit or the surgeon console

⚠ When a bedside unit is first connected to the system, the bedside unit has to fully start up before the stop button is functional

The Versius Surgical System can be stopped at any point during surgery.

9.1 Stopping the system

A stop button is located on each cart control panel (Figure 9.1). A stop button is also located on the right armrest of the surgeon console (Figure 9.1).

Figure 9.1 Stop buttons on the surgeon console and bedside units

9.1.1 To stop the system

- Press a stop button on the surgeon console or any connected bedside unit

Pressing any stop button stops all connected bedside units and the surgeon console. The arms on connected bedside units lock in position and do not respond to the hand controllers on the surgeon console.

When a stop button is pressed, the stop icon appears at the bottom of the HUD (Figure 9.2).

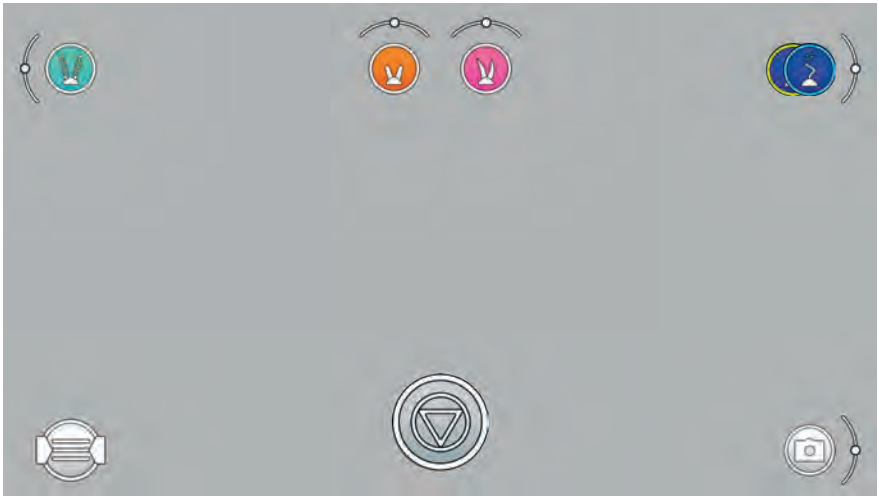


Figure 9.2 *Stop icon on the HUD*

If a bedside unit is not connected to the surgeon console, it will not be stopped if a stop button is pressed on another bedside unit or on the surgeon console. Pressing the stop button on a disconnected bedside unit only stops that bedside unit.

9.2 Resuming the system

A resume button is located on each bedside unit, on the cart control panel (Figure 9.3). A resume button is also located on the right armrest of the surgeon console (Figure 9.3).

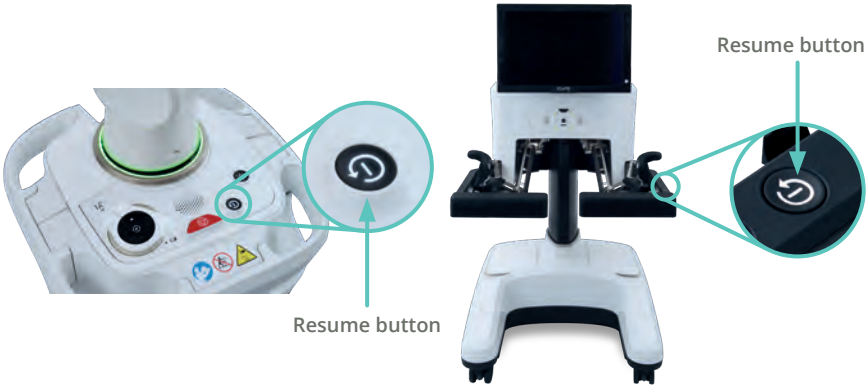


Figure 9.3 Resume buttons on the surgeon console and bedside units

9.2.1 To resume the system

- Press a resume button on the surgeon console or any connected bedside unit

Pressing the resume button returns all arms on connected bedside units to the mode they were in before stop was pressed. Remember that different arms may be in different modes.

When a resume button is pressed, the stop icon disappears from the HUD.

Any bedside unit that is not connected to the surgeon console will be unaffected if a resume button is pressed on another bedside unit or on the surgeon console. Pressing the resume button on a disconnected bedside unit only affects that bedside unit.

Chapter 10

Bedside unit battery

Warnings and precautions

⚠ **Immediately** connect a bedside unit with a flashing low battery indicator to the powered-on surgeon console. If the bedside unit battery becomes too low, a high-priority alarm is triggered and the arm is at risk of drooping and causing injury to a user and/or patient

⚠ **Do not** unplug a bedside unit when it is low on battery as that would trigger a high-priority arm alarm

Bedside units connected to the surgeon console are powered via the surgeon console. Each bedside unit has its own battery which provides power to the arm if the bedside unit is not connected to the surgeon console or if power from the surgeon console is lost. The surgeon console does not have a battery and relies on being connected to the mains power.

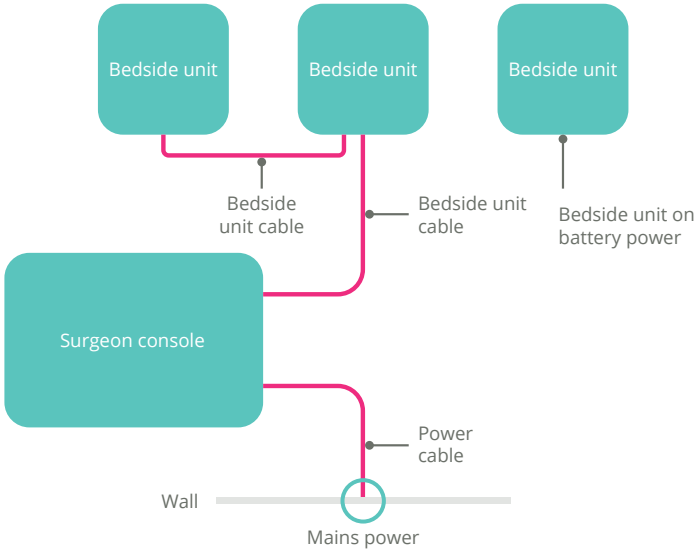


Figure 10.1 *Different power connections for the Versius Surgical System*

This chapter explains:

- Bedside unit use on battery power
- Charging the bedside unit battery
- Low battery

10.1 Bedside unit low battery indicator

An indicator on the cart control panel informs the user of the battery status of a bedside unit (see Figure 10.3 to Figure 10.5). See Table 10.2 for information on the low battery indicator behaviour.

Battery status	Low battery indicator
Charged	Not lit
Charging	Not lit
Low	Flashing yellow
Very low	Flashing red

Table 10.2 *Low battery indicator behaviour*

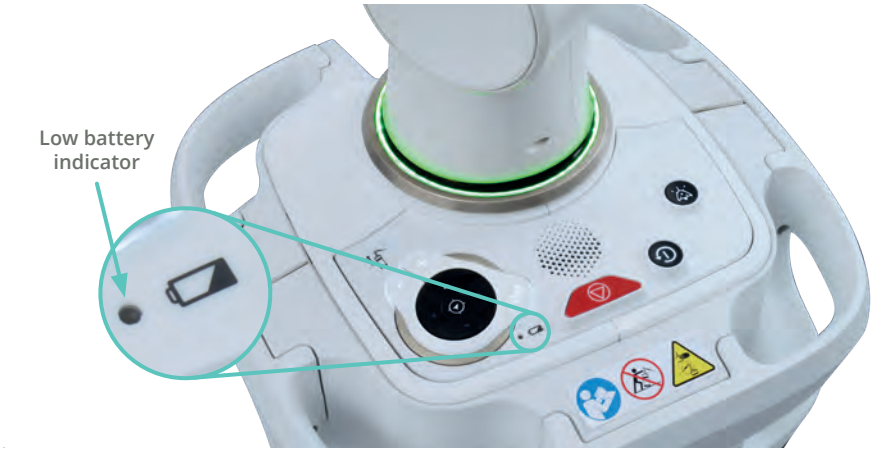


Figure 10.3 *Green status halo and low battery indicator not lit: bedside unit battery is charged or charging*

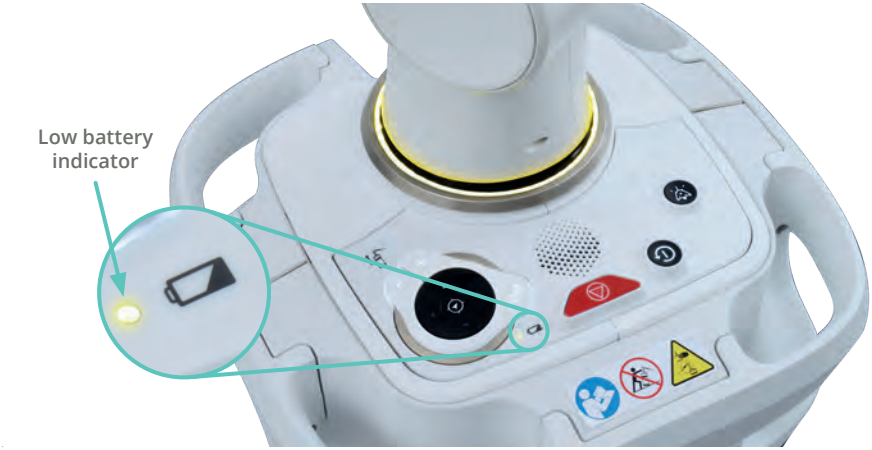


Figure 10.4 *Yellow status halo and low battery indicator flashing yellow: bedside unit battery is low*

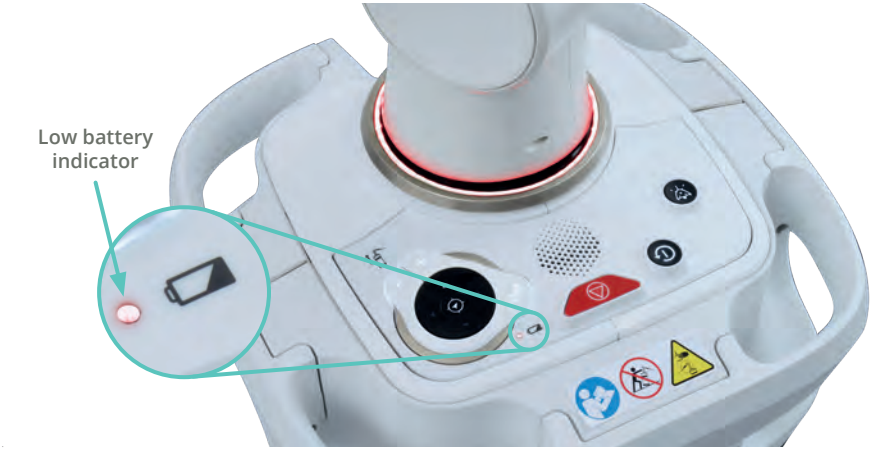


Figure 10.5 *Red status halo and low battery indicator flashing red: bedside unit battery is very low*

10.2 Bedside unit use on battery power

The battery will support the arm for at least 20 minutes. When the bedside units are supported on battery power, there are restrictions on what the bedside unit can do.

10.2.1 Available modes and tasks on battery power

- Navigate between locked, unlocked and sleep mode using the elbow and wrist buttons
- Move the arm manually in unlocked mode
- Activate and deactivate the brake using the brake button
- Move the bedside unit around the hospital and in the operating theatre (no battery required to wheel the bedside unit)
- Setting the orientation

10.2.2 Unavailable modes and tasks on battery power

- Port-training, instrument adjust mode, surgical mode, instrument change mode
- Adjusting arm height

If the bedside unit is disconnected from the surgeon console while in port-training, instrument adjust, surgical or instrument change mode, the arm locks in position. The bedside unit makes a 'no' sound.

If the bedside unit is reconnected, the arm returns to the mode it was in before disconnection. If it is in surgical mode, it is disengaged and the surgeon must engage the arm before continuing to control the instrument. It is not recommended that a bedside unit is disconnected during surgery when a surgeon is relying on the use of that particular bedside unit arm.

Only the elbow band is illuminated, and not the wrist band, when a bedside unit is on battery power

10.3 Charging the bedside unit battery

The bedside unit battery charges when the bedside unit is connected to the surgeon console (providing the surgeon console is connected to the mains power and powered on).

To charge the bedside unit battery:

1. Connect the surgeon console to mains power
2. Turn on the surgeon console
3. Connect the bedside unit to the surgeon console

When the battery is charging, the low battery indicator on the cart control panel will not be lit (Figure 10.3) and the animated battery charging icon appears on the HUD (Figure 10.6). The arm cannot be port-trained and the surgeon cannot engage the arm. If the surgeon tries to engage with the arm on the charging bedside unit, a battery with one bar blinks in the icon group.

When the bedside unit has enough charge to fully support the weight of the arm in an emergency, the animated icon disappears from the HUD and the surgeon may engage the arm.

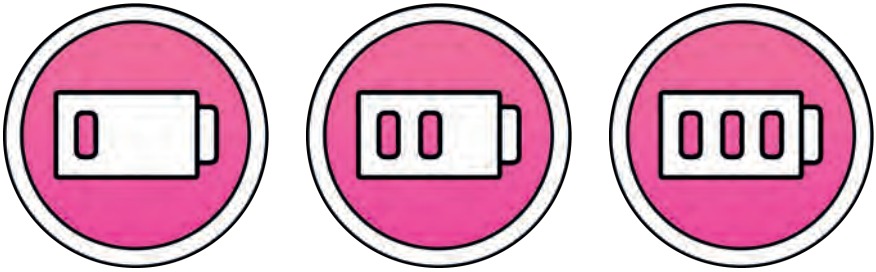


Figure 10.6 *Animated battery charging icon*

10.4 Low bedside unit battery

If a bedside unit battery is low and is not charging, a medium-priority arm alarm occurs and the low battery indicator on the cart control panel flashes yellow (Figure 10.4).

If a bedside unit battery is very low and is not charging, a high-priority arm alarm occurs, the low battery indicator on the cart control panel flashes red (Figure 10.5) and the arm should be supported immediately.

For more information on alarm conditions, see chapter 20.

Chapter 11

Draping

Warnings and precautions

⚠ **Do not** use a drape if its packaging is torn, damaged or open, or if it has passed its expiry date, as it may be contaminated. Dispose of the affected drape

⚠ **Do not** re-use the Versius Drapes. The drapes are single-use only, as indicated by this symbol which appears on the drape packaging:  Dispose of the drapes at the end of each surgical procedure

⚠ **Always** open and handle the drapes using aseptic technique. If aseptic technique is not used when handling the drapes, the drapes could become contaminated and lead to the patient contracting an infection

⚠ Move draped bedside units away from undraped bedside units, to reduce the risk of transferring contaminants from non-sterile to sterile zones

⚠ **Do not** place ports (apart from the endoscope port) without using an endoscopic camera

⚠ **Always** maintain an overlap between the arm and cart drape. If there is a gap between the drapes which exposes the bedside unit, sterility is broken and the patient may be at risk of contracting an infection

⚠ **Always** pose arms for draping away from sterile equipment to reduce the risk of contamination of the sterile field

⚠ The camera head is **not** sterile

⚠ Take care to ensure that aseptic technique is used when draping the camera head

⚠ Take care not to damage the drape cap insert when securing the drape cap insert in place and attaching and detaching instruments. The material of the drape cap insert is fragile and if torn, it will no longer provide a sterile barrier. Dispose of the used drape cap insert and attach a new replacement drape cap insert, supplied separately

⚠ Ensure that the instrument arm drape cap/visualisation arm drape cap is securely attached to the arm. When securely fitted, the drape cap wings are slotted in place over the ridges on the distal end of the arm, accompanied by an audible 'click'. If the drape cap is not securely fitted, the instrument or endoscopic camera could become detached from the arm during surgery and cause injury to the patient

⚠ Ensure the elasticated collar of the bedside unit drape is in the drape groove on the bedside unit to maintain sterility. If the collar is not securely in place in the drape groove, movement of the arm could rotate the lower portion of the bedside unit drape during surgery which may result in a sterility break

⚠ Always ensure that both the drape cap insert and instrument are fully attached to the instrument arm. If either the drape cap insert or instrument are not fully attached, it may lead to damage to the drape cap insert and a break in sterility

⚠ Activate the bedside unit brake before draping the bedside units. If the brake is not activated, the bedside unit is not as stable and could topple if excessive force is applied to the arm during draping

Versius Surgical System drapes create a sterile barrier between the system and the patient. Drapes are provided sterile in individual peel packs.

Drape information

The Versius Drapes are made by P3 Medical and are distributed by CMR Surgical for use with the Versius Surgical System.

P3 Medical Limited
1 Newbridge Close
Bristol BS4 4AX
www.p3-medical.com

11.1 Before draping the system

- Move the bedside units and their arms to a convenient position away from sterile equipment
- Choose standard or long bedside unit drapes depending on the required arm height and operating table position

11.2 Draping the bedside unit

Instrument bedside unit drapes and visualisation bedside unit drapes are identical except for their attached drape caps, which are designed to fit either an instrument or the endoscopic camera (Figure 11.1).

The instrument arm drape cap consists of the drape cap, the locking ring and the drape cap insert, while the visualisation arm drape cap consists of a single piece.

Replacement drape cap inserts are supplied separately

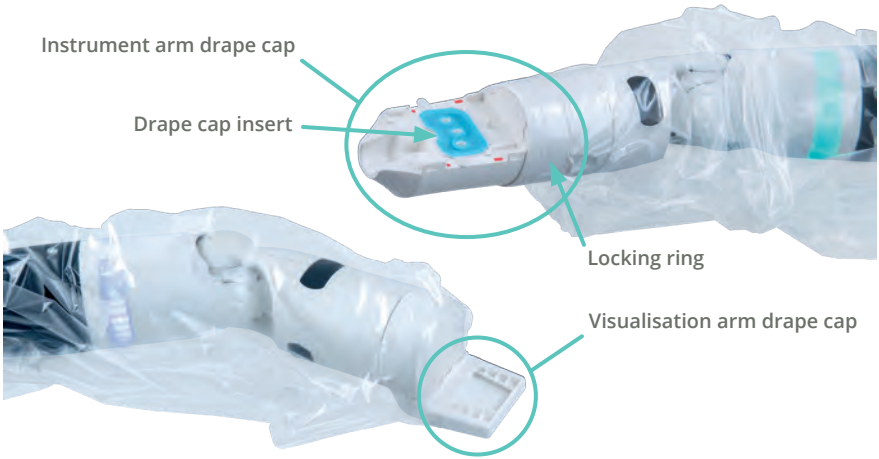


Figure 11.1 *Drape caps for the instrument arm and visualisation arm*

The bedside unit drape consists of two separate drapes (one piece for the arm and one piece for the cart) that are connected using coloured tape and are packaged so there is an overlap between the two. This overlap must be maintained throughout set-up and surgery to maintain the sterile barrier. Follow the draping method in the steps on the following pages to ensure the overlap is not broken.

The method for draping the visualisation bedside unit and instrument bedside units is identical apart from the attachment of the drape caps.

Choose the correct type of drape for either an instrument bedside unit or a visualisation bedside unit.

Non-sterile tasks

1. Open the bedside unit drape packaging	

Sterile tasks

2. Remove the bedside unit drape from its packaging	
3. Using the indicative stickers as a guide, place hands inside the folded drape	
4. Move hands through to the end of the folded drape, beyond the elasticated collar	

5. Stretch the elasticated collar to reveal the indicative stickers	
6. Insert the arm into the central drape opening	
7. Feed the drape onto the arm – not beyond the elbow – and remove hands from drape	
8. Move the locking ring on the drape cap to expose the red marks on drape cap wings	
9. Push drape cap onto arm until wings are secure on arm features	

10. Push the locking ring on the drape cap towards the proximal end of the arm until the red marks are hidden

11. Place a finger across the drape cap insert and push the drape cap insert downwards so the red marks are hidden on the drape cap

12. Remove the red tape from the drape cap insert

If, for any reason, the **drape cap insert** becomes detached from the drape cap, sterility is compromised. Dispose of the used drape cap insert and attach a new replacement drape cap insert, supplied separately

13. Reinsert hands into drape and feed the drape along the arm until it is beyond the elbow joint

14. Remove the yellow tape to release the cart section of the drape	

Non-sterile tasks

15. Pull the folded edge of the drape down towards the cart	
16. While the sterile person does steps 17 and 18, continue to unfold the drape over the cart until completely unfolded	

Sterile tasks

17. Ease the elasticated collar over the base joint	
18. Fit the elasticated collar into the drape groove on the top of the cart	
19. Secure the drape in place using the drape tethers near the V-Wrist and elbow, leaving enough loose drape material for the arm to move freely	
20. Remove the two pieces of green tape from the drape	

The standard bedside unit drape does not extend to the base of the cart

11.2.1 Instrument attachment

Once the instrument arm is draped, any of the Versius Instruments can be attached to the drape cap (see chapter 15). If the drape cap insert is perforated or damaged, re-drape the bedside unit.

Before attaching the endoscopic camera to the visualisation arm, the camera head drape must be applied (see section 11.3).

11.3 Draping the camera head

The camera head and the camera cable are non-sterile. The endoscope must be sterilised before first use and after each use. The camera head and the proximal end of the endoscope must be fitted together inside the camera head drape.

Choose the endoscope angle

Before the camera head drape is applied, choose the endoscope required for the procedure (30° up, 0° straight, or 30° down).

To drape the camera head:

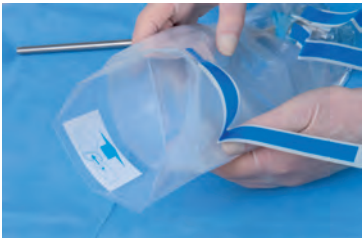
1. Locate the camera head, the sterile endoscope and the camera head drape

Non-sterile tasks

2. Open the camera head drape packaging	

Sterile tasks

3. Remove the camera head drape from its packaging	
4. Place camera head drape on a sterile trolley	
5. Stretch the elasticated neck of the camera head drape	

6. Put the proximal end of endoscope through the stretched elasticated neck. The elasticated neck should fit tightly around the proximal end of the endoscope, so that it forms a seal around the endoscope	
7. Pull the elasticated neck as far onto the endoscope as possible, leaving the light cable connector exposed	
8. Open the folded end of the camera head drape	

Non-sterile tasks

9. Insert the camera head into the opening in the camera head drape	

10. Hold the camera cable above the camera head drape to lower the camera head through the drape	

Sterile tasks

11. Use hands to feed the camera head towards the elasticated neck of the drape	
12. Align the camera head and the endoscope	

13. Push the camera head and the endoscope together (there should be an audible click to indicate that they have been successfully connected). Take care not to trap excess drape material between the endoscope and the camera head. See section 11.4 for more detailed instructions on connecting the camera head and endoscope	

Non-sterile tasks

14. Pinch the edge of the folded drape in one hand	
15. Hold the camera cable in the other hand	

Sterile tasks

16. Pull the draped camera cable until the camera head drape is fully deployed	

11.3.1 Securing the camera head drape

There are three strips of tape on the camera head drape that secure the drape in place.

Sterile tasks

1. Use one strip of tape to secure the elasticated neck to the proximal end of the endoscope	
2. Use one strip of tape to gather excess drape near the light cable connection to prevent obstruction of the endoscopic camera attachment to the arm	

Non-sterile tasks

3. Use one strip of tape to tightly clinch the drape around the camera cable to prevent the drape riding up the cable	

11.3.2 Attaching the endoscopic camera

Once the visualisation arm and camera head drapes are fitted together, attach the endoscopic camera to the visualisation arm drape cap (see chapter 14).

11.4 Connecting the camera head and endoscope

The endoscope has features on the proximal end indicating where it slots into the camera head (Figure 11.2).

Figure 11.2 *Endoscope and camera head connection features*

Before starting to drape, familiarisation with the slots on the camera head may ease fitting the endoscope and camera head together inside the camera head drape.

11.4.1 Endoscope angle

To achieve a 30° down or 30° up endoscope, rotate the endoscope 180° so the tip is at the required orientation (Figure 11.3).

Figure 11.3 *Orientation for 30° down (left) or 30° up (right) endoscope tip*

- When the light cable connector is orientated upwards, the endoscope is angled 30° down
- When the light cable connector is orientated downwards, the endoscope is angled 30° up

Choose the correct endoscope angle on the HUD before the start of surgery (see section 13.8.5).

Chapter 12

Bedside unit set-up

Warnings and precautions

⚠ Look underneath the bedside unit before activating the brake to check there is nothing underneath. If the bedside unit is braked on an obstruction, the bedside unit is at risk of tipping over and causing an injury. If a user's hand or foot is underneath the bedside unit, this could lead to injury to this user when the brake is activated

⚠ **Always** deactivate the bedside unit brake before moving the bedside unit. Attempting to move the bedside unit without deactivating the brake could make the bedside unit unstable and lead it to topple over causing injury

⚠ **Always** position the bedside unit parallel to the operating table. When the bedside unit is placed correctly, the brake button is on the side of the cart farthest from the operating table. If the bedside units are not parallel to the operating table, the instruments will move in unexpected directions which could lead to patient injury

⚠ **Always** set bedside unit orientation during bedside unit set-up and check that the bedside unit orientations are set correctly (selected arrow buttons on all bedside units should point in the same direction)

⚠ **Do not** choose any part of the patient or operating table as the orientation reference direction. Instead, use a fixed point in the room as the reference

⚠ **Avoid** direct contact between the Versius Bedside Units and the patient's skin. This applies to draped and non-draped bedside units

⚠ Be aware of the patient and other Versius Arms when raising or lowering the arm height to avoid collisions

⚠ **Do not** unplug a bedside unit when it is low on battery as that would trigger a high-priority arm alarm

This chapter explains how to set up a bedside unit for surgery once it is connected to the surgeon console and draped. The process for setting up a bedside unit is identical for instrument and visualisation bedside units. At the end of this chapter, the arm will be ready to be port-trained.

12.1 Positioning for bedside unit set-up

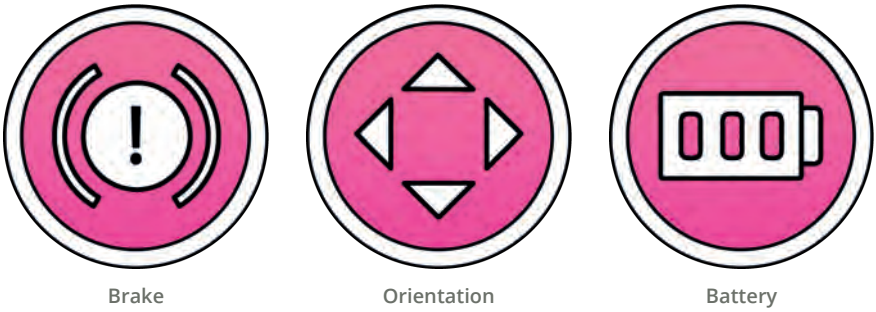


Figure 12.1 Bedside unit status icons for brake, orientation and battery

The bedside unit status HUD icons show which set-up tasks need to be done (Figure 12.1). These status icons appear in the icon groups for the visualisation and instrument bedside units.

Once a bedside unit is draped and ready to be brought to the operating table:

1. Deactivate the brake
2. Position the bedside unit parallel to the operating table with the brake button on the side of the cart farthest from the operating table

12.2 Bedside unit set-up: brake activation

The brake must be activated before the bedside unit orientation can be set.

The bedside unit brake icon on the HUD indicates that the bedside unit brake is not activated (Figure 12.2).

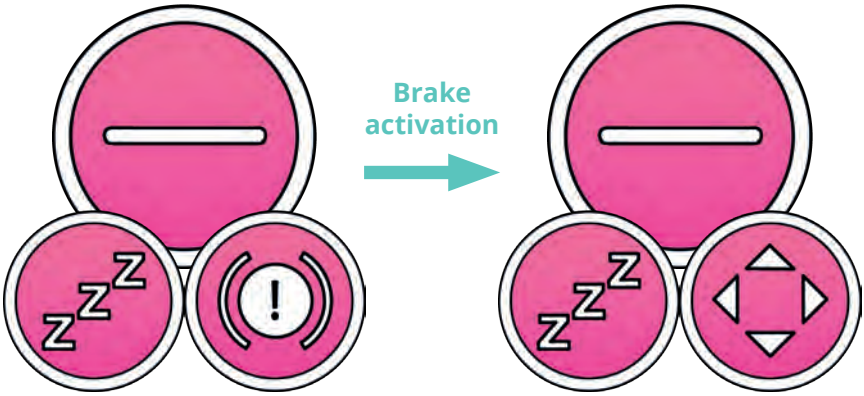


Figure 12.2 *Activation of brake button shown on the HUD*

To activate the brake:

1. Ensure the area under the bedside unit is clear
2. Press and hold the brake button (Figure 12.3)
3. Release the press on the button when the brake icon disappears from the HUD

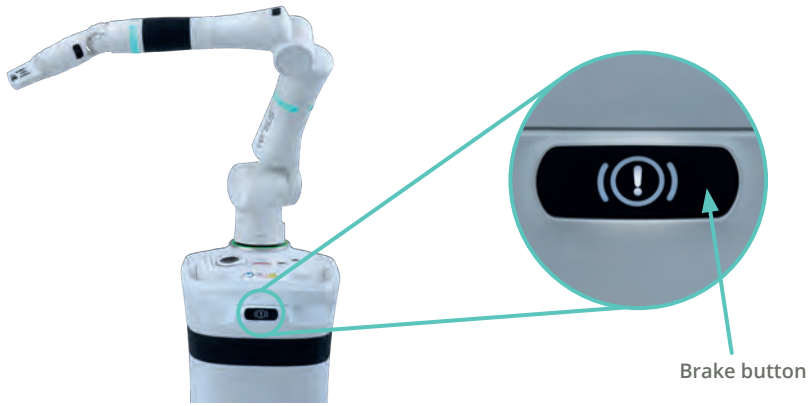


Figure 12.3 *Brake button on the bedside unit*

12.3 Bedside unit set-up: setting the orientation

The system needs to know the orientation of each bedside unit to ensure that the instruments and endoscopic camera move in the correct directions.

The orientation is set after the bedside unit is draped and positioned next to the operating table and the brake is activated. Setting the orientation is the same for the instrument and visualisation bedside units.

The bedside unit orientation icon on the HUD indicates that orientation of the bedside unit needs to be set.

12.3.1 Choosing an orientation reference direction

To ensure that the orientations of all bedside units are set correctly, choose a reference direction such as the '12 o'clock' direction.

⚠ **Do not** choose any part of the patient or operating table as the orientation reference direction. Instead, use a fixed point in the room as the reference

In Figure 12.4, the same direction arrow has been chosen on each bedside unit.

Figure 12.4 Orientation reference direction

12.3.2 Setting the bedside unit orientation

The orientation is set using one of the four arrow buttons on the orientation pad (Figure 12.5):

- Press the arrow button which is pointing in the chosen orientation reference direction
- Ensure the same orientation direction is selected for all connected bedside units

Figure 12.5 Orientation pad location on the bedside unit control panel

When the orientation is set the bedside unit makes a 'yes' sound and the bedside unit orientation icon disappears from the HUD. Only the selected arrow button remain illuminated. In Figure 12.5 only one arrow button is illuminated as this is the orientation that has been selected on this bedside unit.

- If the selection is incorrect, it can be overridden by pressing a different arrow button on the orientation pad

If the bedside unit brake is deactivated at any time, the orientation must be reset

Port-training needs to be repeated if bedside unit orientation is reset during surgery

12.4 Bedside unit set-up: checking battery status

If the bedside unit battery is very low and is not charging, a high-priority arm alarm occurs (see section 20.5) and the low battery indicator on the cart control panel flashes red (see section 10.4).

If the bedside unit battery is low the arm cannot be port-trained. See section 10.2.2 for other unavailable modes and tasks on battery power

- If the bedside unit battery is low, as indicated by the low battery indicator, connect the bedside unit to the surgeon console

The animated battery charging icon appears on the HUD. This indicates that the battery is charging but that the charge is currently too low for the arm to be used for surgery.

While the battery is charging, the bedside unit can be draped and moved into position, the brake can be activated and its orientation can be set.

- Wait for the battery charging icon to disappear from the HUD before attaching an endoscopic camera or instrument to the arm

12.5 Adjusting the arm height

Adjusting the arm height is an optional set-up task. If a higher or lower arm position is required to improve reach during surgery, raise or lower the bedside unit column:

- Press the up (+) or down (–) arm height adjustment button on the bedside unit control panel as required (Figure 12.6)

The arm height cannot be changed when the instrument attached to that arm is inside the patient cavity. If the arm height buttons are pressed when the instrument attached to that arm is in the patient cavity the bedside unit plays a 'no' sound.

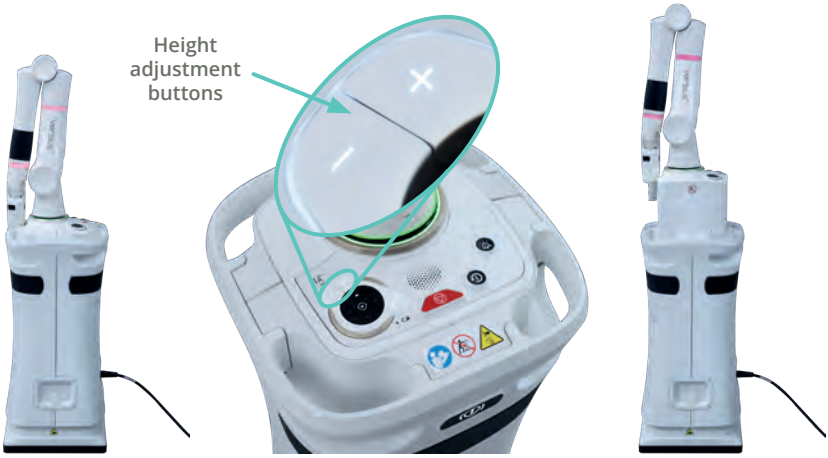


Figure 12.6 *Arm height adjustment buttons*

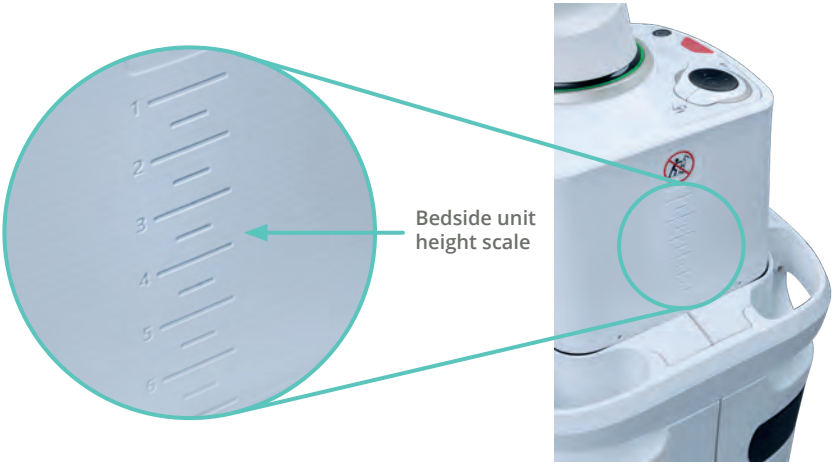


Figure 12.7 Height scale on bedside unit column

Do not push the bedside unit column when the arm height is raised. There is a symbol located on the column as a reminder (see Figure 12.8).

Figure 12.8 Do not push on the bedside unit column when the arm height is raised

12.6 Repositioning the bedside unit if required

If the bedside unit position needs to be adjusted after set-up:

1. Deactivate the brake
2. Move the bedside unit to the correct position (e.g. change arm height or physically move the location of the bedside unit)
3. Activate the brake
4. Set the orientation

Chapter 13

Surgeon console set-up

Warnings and precautions

⚠ **Do not** touch the surgeon console while a surgeon is using the hand controllers due to the risk of hand traps

⚠ **Do not** use a wheeled chair at the surgeon console as the chair could be knocked and move unexpectedly, which could cause motion of the instruments inside the patient cavity and damage the anatomy

⚠ Select the endoscope angle during surgeon console set-up

⚠ Select the correct language using the HUD menu during surgeon console set-up

⚠ Select the hand scaling settings as part of surgeon console set-up

⚠ Ensure the armrests on the surgeon console are completely extended before surgery starts. When properly set up, the armrests lock in position and should not move. If the armrests are not set up properly, they could slide mid-procedure, causing the surgeon's arms to move and resulting in unintended instrument motion inside the patient cavity

⚠ Use an ergonomic position when working at the surgeon console and use a suitable chair (non-wheeled). If the incorrect position and chair are used, there is an increased risk of unintended motion of the instruments which may cause damage to the patient anatomy

⚠ Auto white balance the endoscopic camera to produce a clear, realistic video feed on the console screen and auxiliary screen. Ensure the correct method for auto white balancing is used. If the video feed is not clear, the surgeon has poor vision inside the patient cavity which may lead to damage to the patient anatomy

This chapter explains how to set up the Versius Surgeon Console, including the settings accessed from the HUD menu. For details of how to control the endoscopic camera and instruments from the surgeon console, see chapter 18.

During surgery, the console screen should be positioned optimally for the surgeon. If the surgical team require more than one auxiliary screen, the console screen may be extended to further screens or used with an integrated operating theatre system.

Once the surgeon console is powered on and in position outside the sterile field, several surgeon console settings can be adjusted.

Adjusting the surgeon console settings enables the surgeon to achieve a comfortable, ergonomic position. The surgeon console is fully adjustable, allowing the surgeon to either sit or stand in an ergonomic position (Figure 13.1). In the most ergonomic position the surgeon has a straight back and feet flat on the floor.

If a comfortable ergonomic position cannot be achieved by adjusting the settings on the surgeon console, the surgeon uses the system at their own risk.

It is recommended that the surgeon console height is adjusted before the console screen height.

13.1 Adjusting the surgeon console height

There is one button to increase the height of the surgeon console and one button to reduce the height of the surgeon console.

Figure 13.1 *Sitting and standing at the surgeon console*

There is a numbered scale on the back of the surgeon console (Figure 13.2). The scale ranges from 1 to 10.5.

When the surgeon has found a comfortable, ergonomic position, the number on this height scale can be noted so the surgeon console can be set to the same height more quickly for future surgeries by the same surgeon.

13.1.1 To adjust the surgeon console height

- To increase the height of the surgeon console, press and hold the 'up' arrow button on the left armrest (Figure 13.3)
- To stop, release the button
- To reduce the height of the surgeon console, press and hold the 'down' arrow button on the left armrest (Figure 13.3)
- To stop, release the button

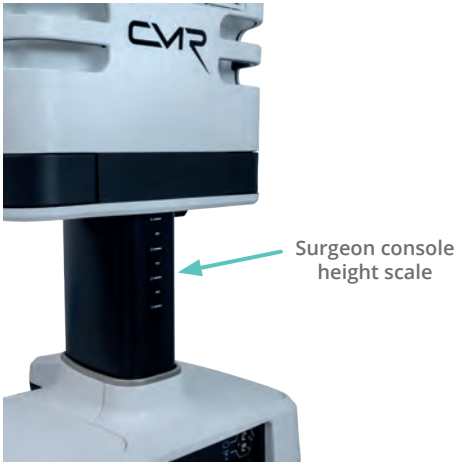


Figure 13.2 *Height scale on surgeon console*

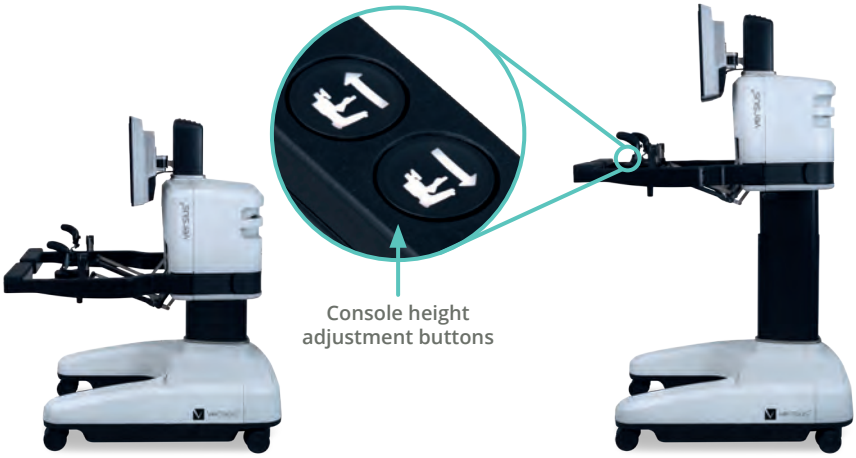


Figure 13.3 *Surgeon console height adjustment buttons*

13.2 Adjusting the console screen height

To ensure optimal 3D vision, the surgeon's eyes must be aligned with the centre of the console screen. To position the console screen appropriately, use the console screen height adjustment buttons.

There is one button for raising the screen and one button for lowering the screen. The two buttons are located next to each other (Figure 13.4).

There is a numbered scale on the column that the screen moves up and down. The scale ranges from 1 to 7 (Figure 13.5).

When the surgeon has found a comfortable, ergonomic position, the number on this screen height scale can be noted so the console screen can be set to the same height more quickly for future surgeries by the same surgeon.

13.2.1 To adjust the console screen height

- To increase the console screen height, press and hold the 'up' arrow of the screen height adjust buttons on the left armrest (Figure 13.4)
- To stop, release the button
- To reduce the console screen height, press and hold the 'down' arrow of the screen height adjust buttons on the left armrest (Figure 13.4)
- To stop, release the button

Figure 13.4 *Surgeon console screen height adjustment buttons*

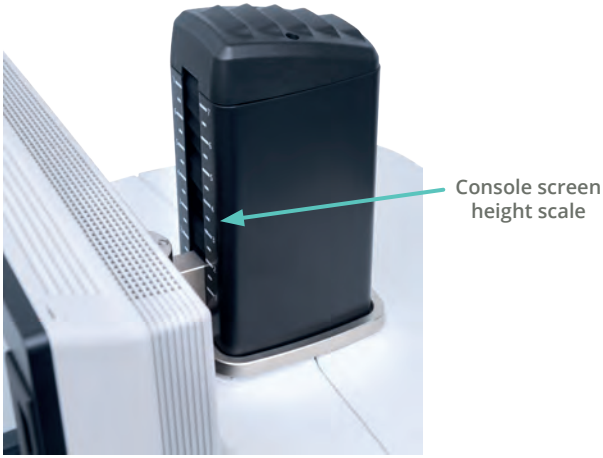


Figure 13.5 *Height scale on surgeon console screen*

13.3 Changing the console screen display mode

The video captured by the endoscopic camera may be displayed in either 2D or 3D.

13.3.1 To set the console screen 2D or 3D display mode

1. Press the control button located below the power indicator on the right-hand side of the screen (Figure 13.6)

The menu buttons will now be illuminated (Figure 13.7)

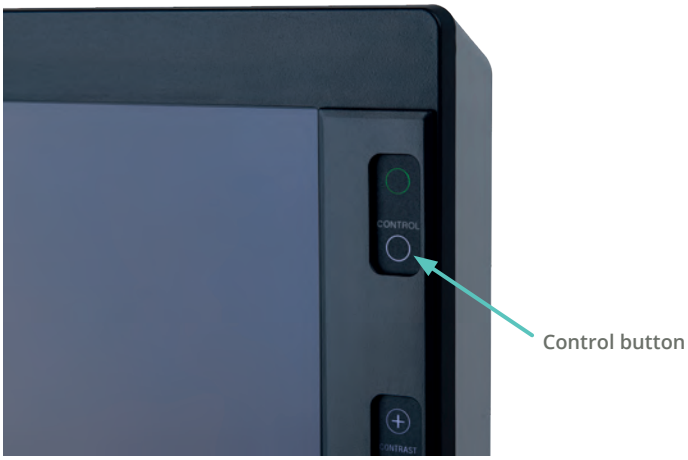


Figure 13.6 *Control button on the console screen*

2. To access 3D, press the A-1 button on the left of the screen (Figure 13.7)
3. To access 2D, press the A-2 button on the left of the screen (Figure 13.7)

Figure 13.7 *3D and 2D menu buttons on the console screen*

Wear circular polarising 3D glasses if the console screen is in 3D view. In 2D view the 3D glasses are not required. When the glasses are not required, store the glasses somewhere safe. Keep the 3D glasses clean to ensure a high-quality view of the endoscope feed.

⚠ Prolonged use of the 3D display can lead to side-effects for some users such as headache, eye strain, nausea

13.4 Setting up the armrests

The surgeon console has left and right armrests (Figure 13.8). The armrests are set individually into position.

The surgeon console armrests can be set to two positions: one compact position for storage and transportation; and one extended position for surgery (Figure 13.8).

Figure 13.8 *The two armrest set-up positions*

13.4.1 To set up the armrest for surgery

1. Push in the latch on the side of the surgeon console (Figure 13.9)
2. Slide the latch until the armrest is fully extended and locks in position
3. Release the latch

If the latch is released before the armrest locks in position, the armrest will glide freely backwards and forwards. Make sure both armrests are locked in the extended position before the surgeon uses the surgeon console.

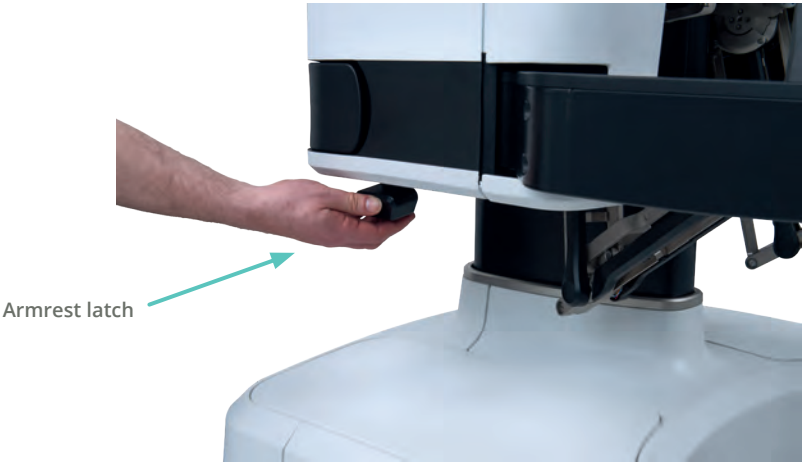


Figure 13.9 *Armrest latch*

13.5 Docking the hand controllers

Each hand controller has its own docking station and should be slotted into the docking station while not in use (Figure 13.10). This reduces the risk of damage to the hand controllers and increases the ease with which the surgeon console is transported.

Figure 13.10 *Hand controllers docked on the surgeon console*

It is important to dock the hand controllers before the surgeon console is powered off. The surgeon console powers the 'floating' hand controllers. When powered off, the surgeon console does not support the hand controllers and the hand controllers will fall under their own weight if not docked.

The docking stations are hinged and during surgery they can be positioned out of the area that the hand controllers move through.

13.5.1 To dock a hand controller

- Slot the hand controller into the docking station (Figure 13.10)

13.6 Adjusting the jaw control band

The surgeon puts their index finger through the band on the jaw control (Figure 13.11). The band holds the index finger in place when the hand controllers are used. The size of the band can be adjusted depending on the surgeon's preference. There are several size settings on the band (Figure 13.12).

Figure 13.11 *The jaw control band holds the index finger in place*

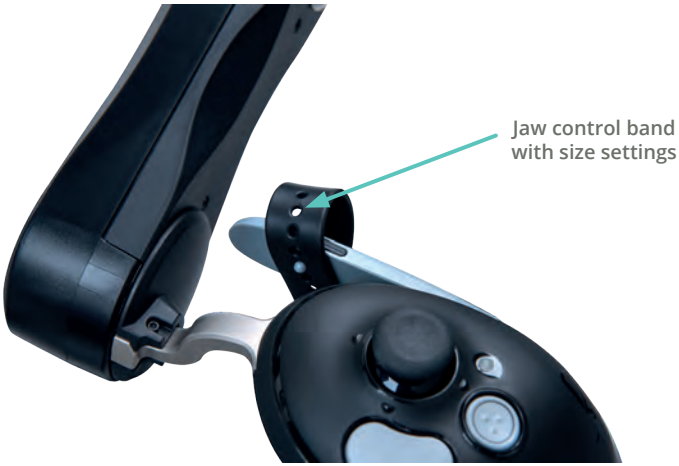


Figure 13.12 *Size settings on the jaw control band*

13.6.1 To adjust the size of the jaw control band

1. Release the band from the peg holding it in place
2. Put the peg through the new size setting on the band

It is recommended that the jaw control band is not adjusted so tightly that it impedes release of hand controller when required

13.7 Navigating the HUD menu

The HUD has left and right cursors (Figure 13.13).

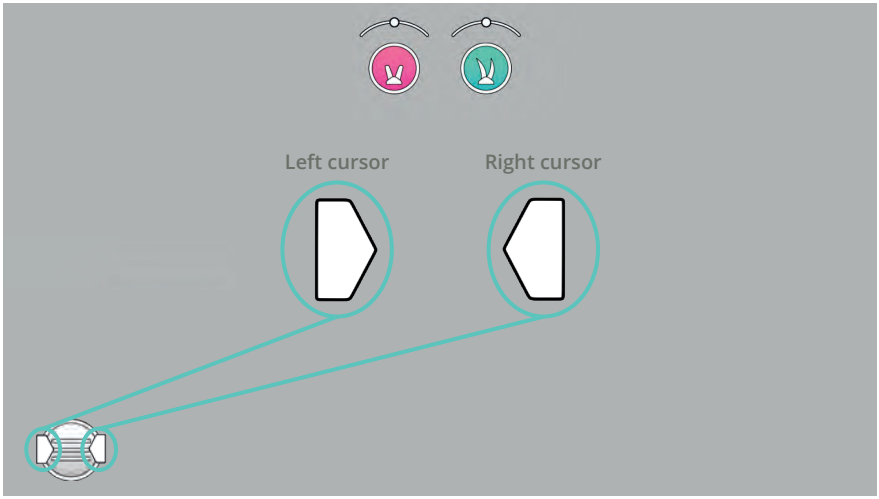


Figure 13.13 Left and right cursors on the HUD

- Use the thumbstick on the left hand controller to move the left cursor
- Use the thumbstick on the right hand controller to move the right cursor

To access the HUD menu options:

1. Move one of the cursors to the HUD menu icon
2. Press the clutch button to open the menu
3. Use the thumbstick on the same hand controller to navigate the menu
4. Press the clutch button to select a menu option

13.8 Menu option overview

The HUD menu (Figure 13.14) provides access to additional functions and surgeon console settings, as detailed in the following menu options. All options in the menu are navigated to using the thumbstick and selected by pressing the clutch button.

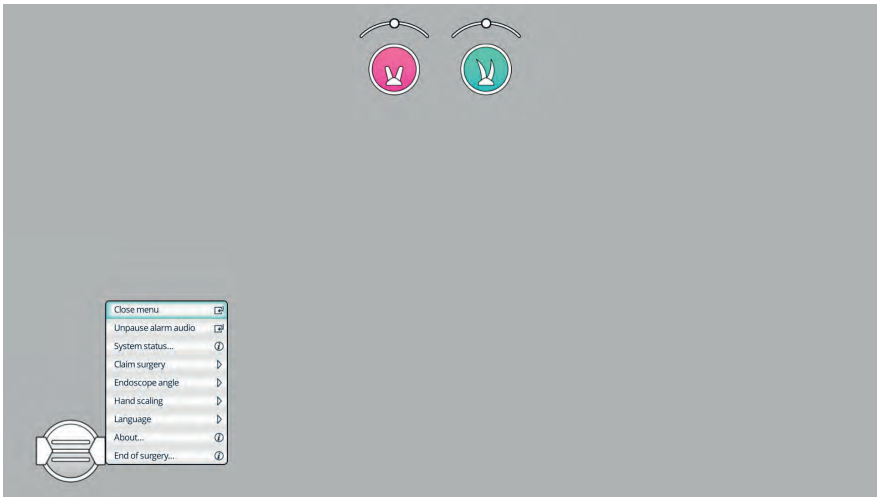


Figure 13.14 The HUD menu

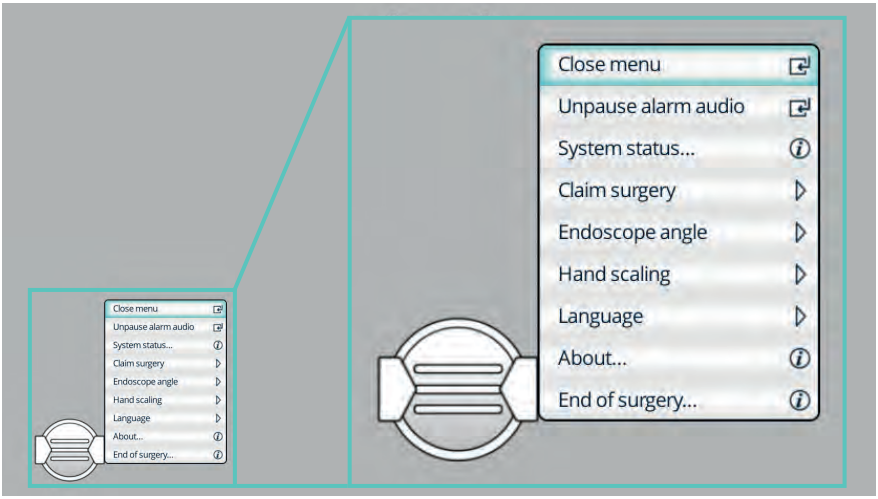


Figure 13.15 *The HUD menu*

During surgery, disengage from any engaged arms before attempting to move the cursors to the HUD menu. Once the menu is closed, the hand controllers can be re-engaged with the arms.

13.8.1 Menu option: Close menu

To close the list of menu options:

1. Navigate using the thumbstick to the 'Close menu' option (Figure 13.16)
2. Press the clutch button to close the menu

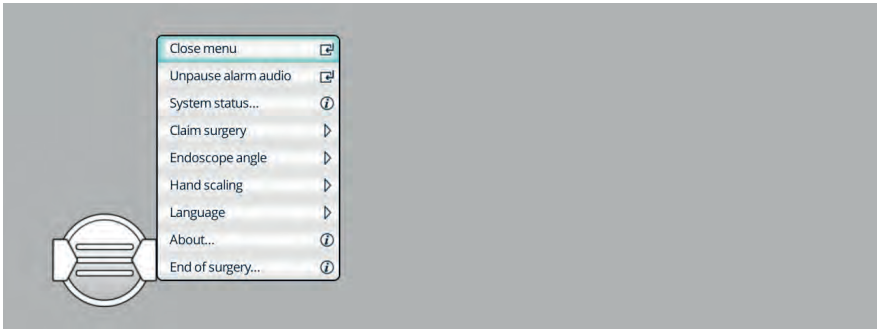


Figure 13.16 'Close menu' selected on the HUD menu

13.8.2 Menu option: Unpause alarm audio

An active alarm sound can be muted for two minutes by pressing the mute button on the surgeon console or bedside unit which is sounding the alarm, and re-enabled by pressing the mute button again. For a system alarm a muted alarm sound can also be re-enabled by navigating to the 'Unpause alarm audio' option on the HUD menu:

1. Navigate to the 'Unpause alarm audio' option (Figure 13.17)
2. Press the clutch button to re-enable the alarm sound

Figure 13.17 'Unpause alarm audio' selected on the HUD menu

13.8.3 Menu option: System status...

At any point during surgery the status of the system can be obtained from the menu, including a list of instruments used in a procedure, their serial numbers and the number of uses remaining for each instrument. To access the status of the system:

1. Navigate to the 'System status...' option (Figure 13.18)
2. Press the clutch button to access the status of system

The system tracks the number of uses per instrument as there is a safety limit on the number of uses.

Discard any instruments that have reached their maximum number of uses.

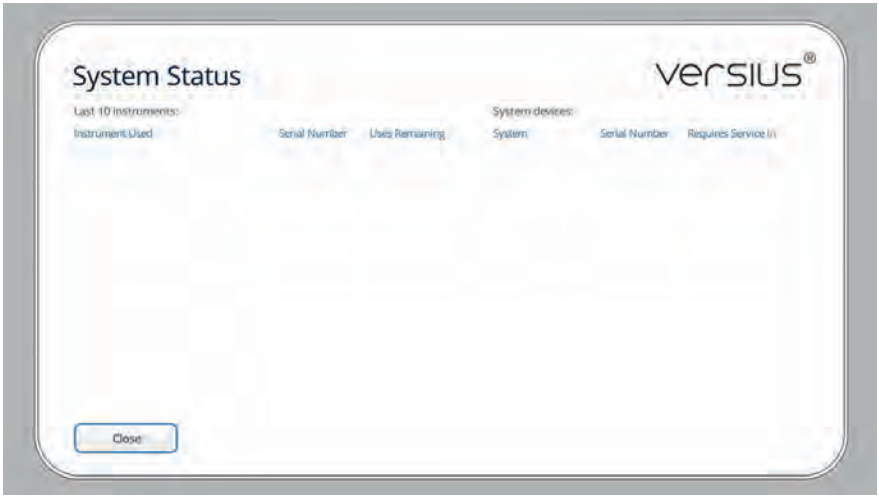


Figure 13.18 'System status...' selected on the HUD menu

13.8.4 Menu option: Claim surgery

Versius enables a surgeon to 'claim' a surgical procedure with the MyVersius app in order to review the Versius Surgical System data from that particular surgical procedure.

To claim surgery:

1. Sign in to the MyVersius app on a mobile device
2. Navigate to the 'Claim surgery' option in the HUD menu (Figure 13.19)
3. Select 'Claim surgery' using the clutch button
4. Scan the QR code using the mobile device

This can be done at any point during the procedure.

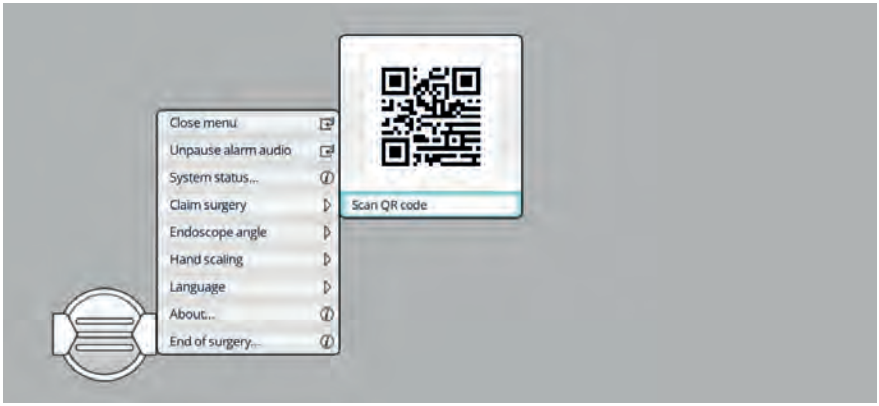


Figure 13.19 'Claim surgery' selected on the HUD menu

13.8.5 Menu option: Endoscope angle

Before the start of surgery, specify the type of endoscope attached to the camera head (30° up, 0° straight, or 30° down). To specify the endoscope angle:

1. Navigate to the 'Endoscope angle' option (Figure 13.20)
2. Press the clutch button to access the three endoscope angle options
3. Navigate to and select the correct endoscope angle option

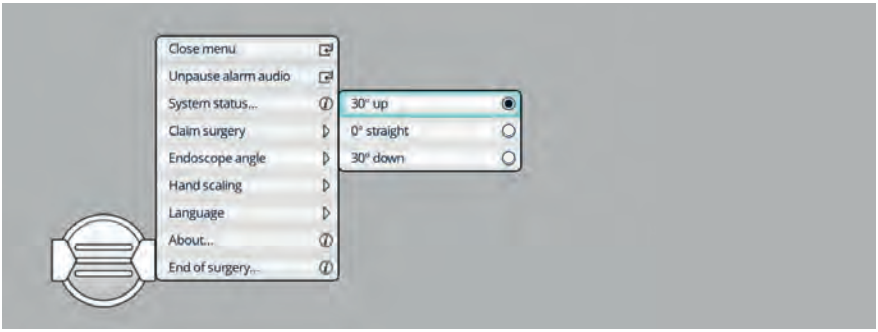


Figure 13.20 'Endoscope angle' selected on the HUD menu

13.8.6 Menu option: Hand scaling

Choose the scaling between movement of the hand controllers and movement of the instrument tip using the 'Hand scaling' option on the HUD menu. There are three hand scaling settings to choose from:

- Slow – instrument motion is slow (for fine movements and greater dexterity)
- Medium – instrument motion is medium
- Fast – instrument motion is fast (for gross movements and less dexterity)

To choose a hand scaling option:

1. Navigate to the 'Hand scaling' option (Figure 13.21)
2. Press the clutch button to access the three hand scaling options
3. Navigate to and select the chosen hand scaling option

Test how the instruments respond to movement of the hand controllers by making fine movements inside the cavity, away from anatomy. Adjust the hand scaling settings if the instruments are not responding as required. Hand scaling settings can be changed at any time.

The hand scaling does not affect movement of the endoscope

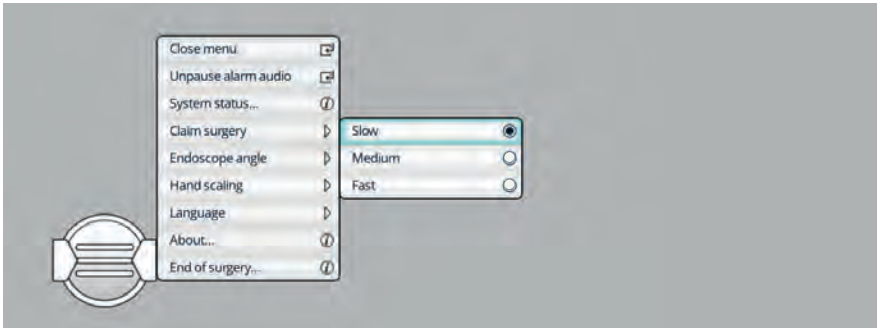


Figure 13.21 *'Hand scaling' selected on the HUD menu*

13.8.7 Menu option: Language

The Versius Surgical System can show the HUD in several languages. To choose the language option:

1. Navigate to the 'Language' option (Figure 13.22)
2. Press the clutch button to access the language options
3. Navigate to and select the chosen language option

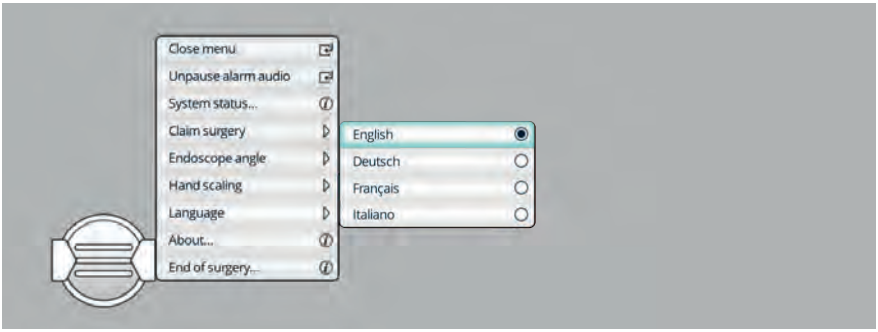


Figure 13.22 *'Language' selected on the HUD menu*

13.8.8 Menu option: About...

The 'About...' option (Figure 13.23) provides serial numbers and time remaining until next service for the surgeon console and its connected bedside units.

This option also provides information on the software version installed on the surgeon console.

Figure 13.23 *'About...' selected on the HUD menu*

13.8.9 Menu option: End of surgery...

After the surgeon finishes the procedure and the Versius Instruments are no longer required, tell Versius that the surgery has ended:

1. Navigate to the 'End of surgery...' option (Figure 13.24)
2. Select 'End of surgery' by pressing the clutch button. A dialog box appears on the HUD (Figure 13.25) asking for confirmation that the surgeon would like to end surgery
3. Navigate to OK and press the clutch button to select OK. When OK is selected, the dialog box in Figure 13.26 appears stating which instruments were used in the procedure. This dialog box also gives the surgeon another opportunity to claim the surgery by providing a QR code (Figure 13.26)
4. If the surgery has not already been claimed, scan the QR code
5. Select 'Finish' by pressing the clutch button

When ‘Finish’ is selected, data collection for the current surgery stops and the system is ready to start data collection for the next surgery. If ‘Finish’ is selected while video recording is in progress, recording will stop, with the video file saved to the SD card.

Figure 13.24 *End of surgery on the HUD menu*

Figure 13.25 *End of surgery selection*

When ‘End of surgery’ is selected on the HUD, it overlays the endoscope view. If the endoscope is still required for manual use, select cancel to exit the ‘End of surgery’ dialog box and restore the endoscope view.

Figure 13.26 *'End of surgery...' selected on the HUD menu*

When the 'End of surgery...' option is selected on the HUD menu, the remaining number of uses per instrument can be seen.

Discard any instruments that have reached their maximum number of uses.

13.9 Auto white balancing the endoscopic camera

For the surgeon console screen to show a true-colour video from the endoscopic camera, the following are required:

- The surgeon console must be connected to the visualisation bedside unit via the video feed cable
- The visualisation bedside unit must be connected to the endoscopic camera via the camera cable
- The endoscope must be connected to the light source
- The light source must be turned on and the intensity adjusted as required
- The endoscopic camera must be auto white balanced

Auto white balance is required to produce a clear, realistic video feed on the console screen and the auxiliary display. The endoscopic camera can be auto white balanced only after the video feed cable, camera cable and light cable are connected, and the light source intensity is set (see chapter 7).

The auto white balance icon (Figure 13.27) appears on the HUD when the endoscopic camera requires auto white balancing.

Figure 13.27 *The auto white balance icon*

13.9.1 To auto white balance the endoscopic camera

1. Point the distal end of the endoscope at a white object (e.g. a clean white swab) from a distance of approximately 1 cm, or wrap the distal end of the endoscope in white gauze (Figure 13.28)
2. Press the auto white balance button on the camera head (Figure 13.28)

Figure 13.28 Auto white balancing the endoscopic camera

When auto white balance has been successful, the auto white balance icon disappears from the HUD.

13.10 Recording video

The system allows 2D video from the 3D endoscopic camera to be recorded and saved on an SD card during a procedure. The SD card slot is found below the screen (Figure 13.29). Video cannot be recorded unless an SD card is inserted into the surgeon console. A standard, full sized SD card is required. Class 4 or above is technically required and Class 10 or above is recommended.

13.10.1 To record video

To record video:

1. Insert SD card into the slot on the surgeon console
2. Press the video record button (Figure 13.29) to start recording
3. Press the video record button again to stop recording

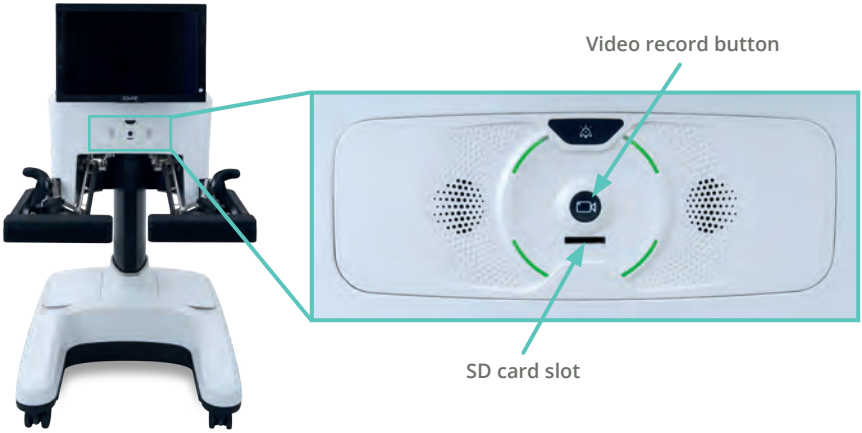


Figure 13.29 Video record button and SD card slot on the surgeon console

The video record button lights up when recording is in progress and the light goes out when the recording is stopped. Recording stops when the video record button is pressed or when the 'End of surgery' HUD menu option is selected (and confirmed by pressing 'Finish').

The video record button may flash for up to four seconds while the system checks the SD card and then lights up when recording starts. If the video record button continues to flash after four seconds, video cannot be recorded to the SD card. See section A.1.8 for troubleshooting of video recording.

13.11 Assigning an instrument arm to a hand controller

Instrument arms may be assigned to either the left hand controller or the right hand controller, based on the preference of the surgeon as to which instrument they like to control with which hand. The instrument arm cannot be engaged for surgery until it is assigned to one of the hand controllers.

13.11.1 To assign an instrument arm to a hand controller

1. Using the thumbstick (Figure 2.3), move the right or left cursor to the instrument icon in the instrument bank corresponding to the arm to be assigned (Figure 13.30)
2. Press the clutch button (Figure 2.3) on the left or right hand controller to assign the instrument arm to that hand controller

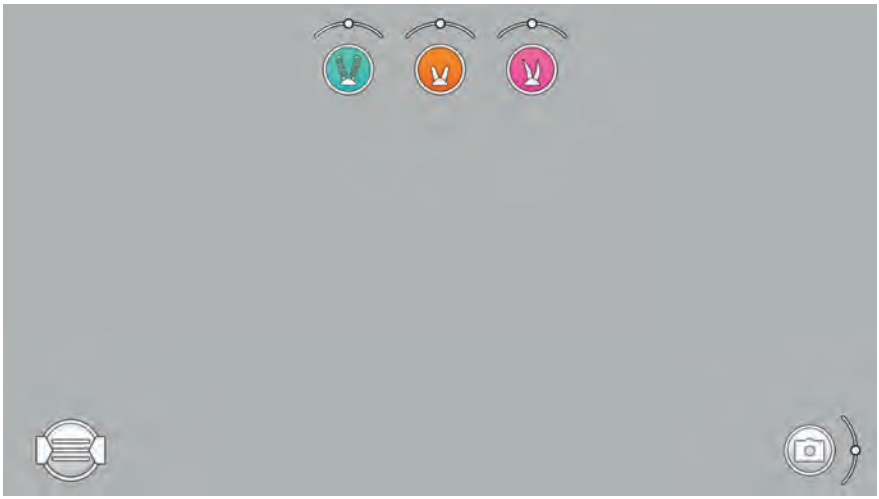


Figure 13.30 *HUD with instrument bank*

The instrument icon group moves from the instrument bank to either the right-hand or left-hand side of the HUD (Figure 13.31). The instrument arm is not under surgeon control, but is available to be engaged with the hand controller corresponding to the side of the HUD where the instrument icon is located.

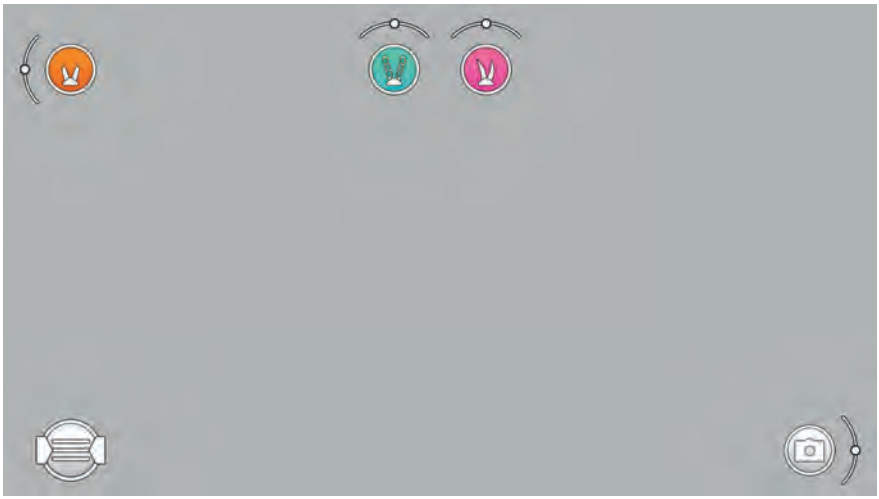


Figure 13.31 *HUD with instrument assigned to the left hand controller*

Instrument arms can be reassigned at any time during surgery using the clutch button on the opposite hand controller. When an arm is reassigned, the instrument icon moves from one side of the HUD to the other.

See chapter 18 for instructions on advancing to surgical mode and controlling the instruments inside the patient cavity.

Chapter 14

Attaching and detaching the endoscopic camera

Warnings and precautions

⚠ **Always** ensure all steps in section 14.2 are followed when attaching the endoscopic camera so that the camera head is properly attached to the arm. Failure to attach the endoscopic camera properly may lead to harm to the patient

⚠ **Always** ensure that aseptic technique is used when attaching the endoscopic camera to the arm

This chapter explains how to attach and detach the endoscopic camera, as required during set-up, surgery and post-operative cleaning.

14.1 Before attaching the endoscopic camera

Before attaching the endoscopic camera to the visualisation arm, ensure that:

- The visualisation bedside unit has been draped and the drape cap is fitted securely in place
- The camera head drape has been fitted
- The camera head has been connected to the endoscope inside the camera head drape

The endoscopic camera can be used manually to assist port placement before attaching to the visualisation arm

14.2 Attaching the endoscopic camera

⚠ **Always** ensure all steps in section 14.2 are followed when attaching the endoscopic camera so that the camera head is properly attached to the arm. Failure to attach the endoscopic camera properly may lead to harm to the patient

⚠ **Always** ensure that aseptic technique is used when attaching the endoscopic camera to the arm

Once the visualisation bedside unit and camera head have been draped and the drape cap is fitted securely in place, the endoscopic camera can be attached to the drape cap.

To attach the endoscopic camera:

1. Put the arm into locked mode
2. Hold the latches on the sides of the camera head at the proximal end of the endoscopic camera and align the camera head with the drape cap (Figure 14.1)

Figure 14.1 *Camera head aligned with drape cap before attachment*

3. Squeeze the latches and push the camera head down onto the visualisation arm drape cap. Take care that an excessive amount of drape material is not trapped between the camera head and the drape cap
4. Use one hand to support the arm near the camera head attachment point and grip the distal end of the endoscope with the other hand. Notice that there is a gap between the back of the camera and the arm (Figure 14.2)

Figure 14.2 *Support the arm near the camera head and grip the end of the endoscope; gap between the camera head and the arm is open*

5. Lift the end of the endoscope until the gap between the back of the camera and the arm closes (Figure 14.3)

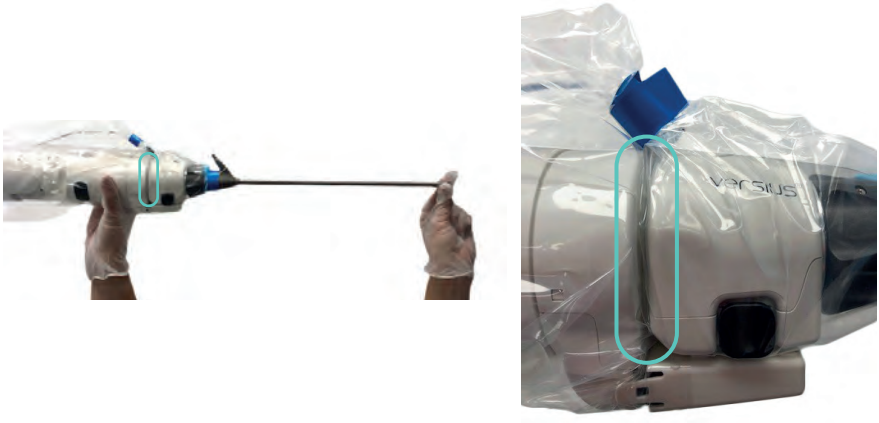


Figure 14.3 *Gap between the camera head and the arm is closed*

6. Let go of the endoscope so that it returns to its natural position
7. Repeat steps 4 to 6
8. Once the light cable has been connected to the endoscope, secure the light cable and the camera cable to the visualisation arm using the two drape tethers on the visualisation arm drape (Figure 14.4)

Figure 14.4 *Securing the light cable and the camera cable with drape tethers*

Check that the correct endoscope angle has been selected on the HUD menu.

If the endoscope becomes detached from the camera head, replace the endoscope with a new, sterile endoscope and fit a new camera head drape

If the endoscopic camera becomes detached from the visualisation arm, the hand controllers disengage immediately

While the endoscopic camera is attached to the visualisation arm, the arm cannot be put to sleep

The endoscopic camera icon appears on the HUD when the endoscopic camera is correctly attached to the visualisation arm.

The auto white balance icon appears on the HUD when the endoscopic camera requires auto white balancing.

14.3 Detaching the endoscopic camera

The method for detaching the endoscopic camera is the same mid-procedure or post-procedure.

To detach the endoscopic camera:

- Squeeze the latches on the sides of the camera head at the proximal end of the endoscopic camera and lift the camera head away from the drape cap

Chapter 15

Attaching and detaching the instruments

Warnings and precautions

⚠ Versius Instruments must be sterilised before first use and after each use to reduce the risk of a patient contracting an infection

⚠ **Do not** touch the metal parts at the distal end of the instrument arm that are exposed when the drape cap insert is not fitted, except when outside the sterile field, to avoid the risk of electrical harm to the patient

⚠ **Do not** attach an instrument to an instrument arm without a drape cap insert fitted securely in place

⚠ Always ensure that both the drape cap insert and instrument are fully attached to the instrument arm. If either the drape cap insert or instrument are not fully attached, it may lead to damage to the drape cap insert and a break in sterility

⚠ **Do not** use an instrument if the instrument has been dropped as it may be damaged. Dispose of the instrument

⚠ Using the hand controllers, move the instruments in free space inside the patient cavity to test that the instruments are assigned to each hand controller, as intended, and are functioning correctly. **Do not** use an instrument that is not functioning correctly

⚠ **Do not** handle the instruments by the instrument tip due to the risk of sharps injury and burns. Hold the instruments at the proximal end (the end that attaches to the drape cap)

⚠ Have manual minimal access surgical instruments available for use

This chapter explains how to attach and detach the instruments, as required during set-up, surgery and post-operative cleaning.

15.1 Before attaching an instrument

Before attaching an instrument to an instrument arm, ensure that:

- The instrument is sterile (instruments must be cleaned and sterilised before their first use and after each use). Refer to the Reprocessing instructions (REF 70100)
- There is a spare instrument of each type available for use
- The instrument bedside unit has been draped
- The drape cap and drape cap insert are fitted securely in place

Refer to the Instrument and Accessories Manual (REF 70050) for information and instructions relating to specific instruments.

15.2 Attaching an instrument

Any of the Versius Instruments can be attached to the instrument arm drape cap.

To attach an instrument:

1. Put the arm into locked mode
2. Hold the latches on the sides of the attachment head at the proximal end of the instrument and align the instrument with the drape cap (Figure 15.1)

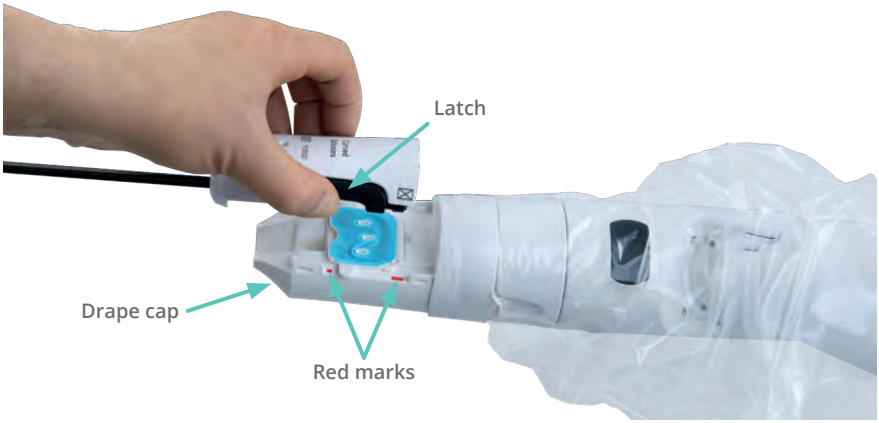


Figure 15.1 *Instrument aligned with drape cap before attachment*

3. Squeeze the latches and push the instrument down onto the drape cap
4. Release the latches when the instrument is in place
5. The instrument is securely attached when the red marks on the drape cap are obscured (Figure 15.2)

Figure 15.2 *Red marks on drape cap are obscured when instrument is securely attached*

When the instrument is attached, the no-instrument icon on the HUD changes to the corresponding instrument icon.

15.3 Instrument not recognised

Each Versius Instrument is recognised by the system when the instrument is attached to a connected bedside unit. In the unlikely event that the system does not recognise the instrument attached to the arm, this icon (Figure 15.3) appears on the HUD in the affected bedside unit icon group:

Figure 15.3 Instrument not recognised icon

The instrument is not functional and the arm of the affected bedside unit cannot be port-trained or engaged by a hand controller. The other bedside units and the surgeon console continue to function as normal.

In the event of an instrument not being recognised:

1. Replace the affected instrument with a valid Versius instrument and continue with surgery
2. Send the affected instrument to sterile services
3. Contact CMR Surgical technical support to arrange return of the affected instrument

15.4 Instrument out of life

Each Versius Instrument has a safe number of uses. Once the instrument has reached the recommended maximum number of uses, the following icon (Figure 15.4) appears on the HUD in the affected bedside unit icon group:

Figure 15.4 *Instrument out-of-life icon*

The arm of the affected bedside unit cannot be port-trained or engaged by a hand controller. The other bedside units and the surgeon console continue to function as normal.

In the event that an instrument is out of life:

1. Replace the affected instrument with a valid Versius instrument and continue with surgery
2. Send the affected instrument to sterile services
3. Dispose of the instrument if the instrument has reached the end of its life

While an instrument is attached to an arm, the arm cannot be put into sleep mode

15.5 Detaching an instrument

The method for detaching an instrument is the same mid-procedure or post-procedure. If it is necessary to detach the instrument while the instrument tip is inside the patient cavity, precautions must be taken.

Before detaching an instrument from an instrument arm, the surgeon must straighten the instrument wrist and close the instrument jaws. Do this by pressing down on the thumbstick on the hand controller engaged with that instrument. The instrument wrist will straight and the jaws will close automatically.

To detach an instrument:

1. Squeeze the latches on the sides of the attachment head at the proximal end of the instrument
2. Lift the instrument away from the drape cap
3. The instrument icon changes on the HUD to a no-instrument icon (Figure 15.5)

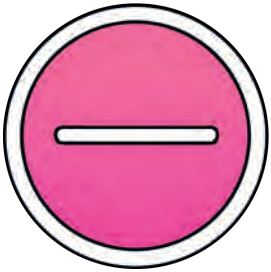


Figure 15.5 No-instrument icon

Chapter 16

Inserting an endoscope or instrument into the port

Warnings and precautions

⚠ Take care when advancing instruments into the patient cavity and always advance instruments under vision

⚠ **Always** watch the instrument on the video feed when moving an instrument inside the patient

⚠ **Do not** move any instrument if the auxiliary screen is not functioning correctly

⚠ **Do not** advance the instrument into the cavity if the arm is not port-trained

⚠ **Always** port-train the arm before inserting the endoscopic camera or instrument into the patient cavity. If the arm is not port-trained the endoscope or instrument may apply stress at the port site causing injury to the patient

⚠ Take care when advancing instruments into the cavity in instrument adjust mode. The arm only prevents deeper movement into the patient cavity in instrument change mode. There is no end stop when advancing an instrument in any other mode

⚠ Close and straighten the instrument jaws before retracting the instrument from the port

⚠ Instrument change mode cannot be used in some positions when the arm is near the limit of its reach. Use instrument adjust mode to withdraw and reinsert the instrument. This must be done with care and under vision of the instrument tip

This chapter describes how to insert the endoscope or instrument into the port. Do this in unlocked mode before port-training an arm, and in instrument change mode each time an instrument is removed and a new instrument is inserted, or the endoscope is removed and reinserted.

16.1 Before inserting the endoscope or instrument

- The patient must be insufflated
- The port must be inserted and ready for use
- The bedside unit must be in position by the patient
- The bedside unit brake must be activated and the orientation must be set
- The arm must be in either unlocked mode (before port-training) or instrument change mode (during a procedure)
- The instrument or endoscope must be correctly attached to the arm

ⓘ The endoscope may be inserted manually or when attached to the visualisation arm

16.2 Inserting the endoscope into the port

⚠ Versius uses a 10 mm endoscope which has only been validated for use with an 11 mm Applied Medical balloon port

The endoscope must be inserted into the port and cavity before the instruments, as any movement by the instruments in the cavity must be done under vision.

To insert the endoscope manually

1. Use a compatible port for the 10 mm endoscope
2. Put the visualisation arm into unlocked mode
3. Hold the camera head with one hand and the port with the other
4. Looking directly at the endoscope, insert the endoscope into the port
5. Looking at the auxiliary screen, advance the endoscope into the patient cavity

To insert the endoscope using the arm

1. Use a compatible port for the 10 mm endoscope
2. Put the visualisation arm into unlocked mode
3. Hold the visualisation arm at the black grip band with one hand and the port with the other
4. Looking directly at the endoscope, guide the arm to insert the endoscope into the port
5. Looking at the auxiliary screen, guide the arm to advance the endoscope to the distal end of the port

If the visualisation arm is not port-trained, do not advance the endoscope beyond the distal end of the port. Press the V-Wrist button to enter port-training mode (Figure 16.1).

If the visualisation arm is in instrument adjust or instrument change mode, advance the endoscope into the cavity while watching the video feed, then press the V-Wrist button to return to surgical mode (see Figure 16.2).

Figure 16.1 *Transition between unlocked mode and port-training on the arm mode map*

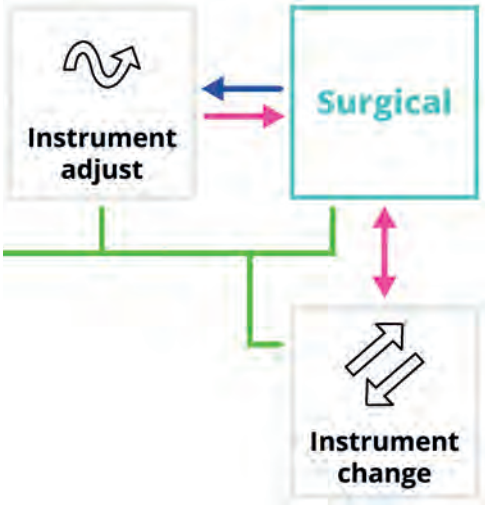


Figure 16.2 *Transition between instrument change, instrument adjust and surgical mode on the arm mode map*

Figure 16.3 *Key to button presses on the arm mode map*

16.3 Inserting the instrument into the port

⚠ Versius uses wristed instruments which have been validated for use with 5 mm Applied Medical balloon ports. Inappropriate port size could lead to an incorrect fulcrum being detected during port-training

To insert the instrument

1. Use a compatible port for the instrument
2. Put the instrument arm into unlocked mode
3. Hold the instrument arm with one hand and the port with the other
4. Looking directly at the instrument, guide the arm to insert the instrument into the port (Figure 16.4)
5. Looking at the auxiliary screen, guide the arm to advance the instrument to the distal end of the port

Figure 16.4 *Instrument entering the port*

If the instrument arm is not port-trained, do not advance the instrument beyond the distal end of the port. Press the V-Wrist button to enter port-training mode (Figure 16.1).

If the arm is in instrument adjust or instrument change mode, advance the instrument into the cavity while watching the video feed then press the V-Wrist button to return to surgical mode (Figure 16.2).

Chapter 17

Port-training

Warnings and precautions

⚠ **Do not** advance the endoscope or an instrument into the cavity before the arm has been port-trained

⚠ **Do not** place ports (apart from the endoscope port) without using an endoscopic camera

⚠ Check that port-training was successful on an arm before advancing the attached instrument into the patient cavity. The bedside unit makes a 'port-training success' sound and the port-training icon on the HUD is static when port-training is successful

⚠ If an instrument is bent during surgery, it is likely that an incorrect fulcrum was identified during port-training. Discard the instrument and repeat port-training with a new instrument

⚠ **Do not** hold the port during port-training

⚠ **Always** hold the arm at the black grip band during port-training. If the arm is held in a different location during port-training, an incorrect fulcrum could be detected by the system. This may lead to a damaged instrument or cause excessive stress at the port site and patient injury

⚠ Ensure that the instrument and endoscope are port-trained to an appropriate depth to avoid unnecessary stress at the port site

This chapter describes how to port-train a visualisation or instrument arm. Port-training informs the system where inside the port the fulcrum is located. The system will then pivot the endoscope and instruments around this fulcrum to minimise stress on the port site. Both instrument and visualisation arms require port-training.

Each arm must be port-trained following bedside unit set-up. Port-training must be repeated if the bedside unit brake is deactivated, the bedside unit orientation is changed, the arm height is adjusted or the patient is repositioned.

17.1 Before port-training

Before port-training an arm:

- The patient must be insufflated
- The port must be inserted and ready for use
- The bedside unit must be draped, the brake activated, the orientation set and at the correct height for surgery
- An endoscopic camera or instrument must be attached to the arm
- The arm must be in unlocked mode
- The auxiliary screen must be visible before, during and after port-training
- The endoscope or instrument must be positioned inside the port, with the instrument wrist at the distal end of the port
- The patient must be in the final position for surgery

⚠ **Do not** advance instruments into the patient cavity before an arm has been port-trained

⚠ **Do not** place ports (apart from the endoscope port) without using an endoscopic camera

Figure 17.1 *Draped arm with instrument inside the port*

Figure 17.2 *Instrument inside port at correct location for port-training*

17.2 Port-training an arm

⚠ **Do not** hold the port during port-training

17.2.1 To port-train an arm

1. Once the endoscope or instrument is in position inside the port (Figure 17.2), press the V-Wrist button to enter port-training mode. The bedside unit makes a 'yes' sound and an animated port-training icon appears on the HUD
2. Hold the arm at the black grip band just above the V-Wrist joint and move the V-Wrist in a circular arc in a clockwise direction (Figure 17.3)
3. Move the V-Wrist back in an anticlockwise direction, retracing the circular arc
4. Repeat steps 2 and 3 until one of the following happens: the bedside unit makes the port-training success sound and the port-training icon stops animating; **or** the bedside unit makes a 'no' sound and the locked mode icon appears

If port-training fails, press the V-Wrist button to enter unlocked mode and then repeat steps 1 to 4.

ⓘ If port-training sets an incorrect fulcrum location, an endoscope or instrument may be bent. If this happens, repeat steps 1 to 4 with a new endoscope or instrument

Figure 17.3 *Instrument inside the port with an arrow to indicate circular arc trajectory*

In some positions, the arm cannot be successfully port-trained. Try moving the arm to a different position if an arm will not port-train

All arm joints should be bent for port-training, the base should not be vertical and the wrist should not be perpendicular to the base.

Figure 17.4 shows an optimal arm position for port-training and Figure 17.5 shows an arm position where port-training may not work.

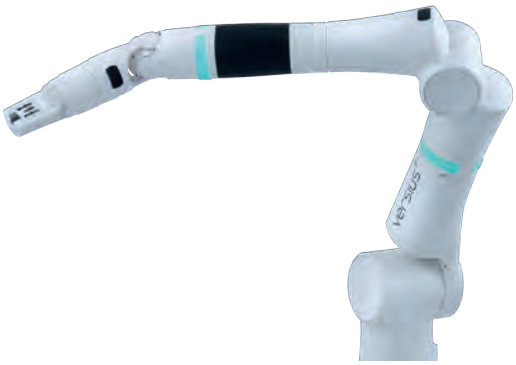


Figure 17.4 *An optimal arm position for port-training*

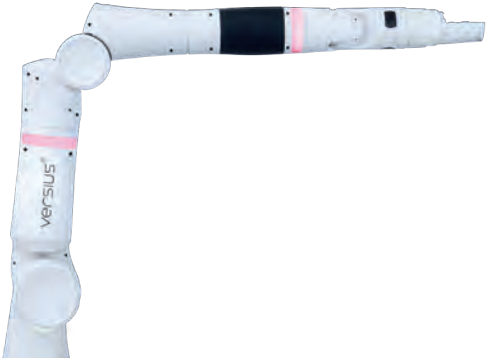


Figure 17.5 *An arm position where port-training may not work*

17.3 After port-training

Once the arm is port-trained, the arm locks. To allow the surgeon to take control:

1. Press the V-Wrist button to enter instrument adjust mode
2. Advance the instrument or endoscope carefully into the patient cavity under vision

Once the instrument or endoscope is inside the patient cavity and positioned appropriately for the surgeon to take control:

3. Press the V-Wrist button again to enter surgical mode

> The instrument tip must be deep enough into the patient cavity (**5 cm**) before the arm will enter surgical mode. If the bedside unit makes a 'no' sound instead of entering surgical mode, carefully advance the instrument further into the patient cavity and then press the V-Wrist button again

Chapter 18

Controlling the instruments and endoscopic camera

Warnings and precautions

⚠ **Always** move instruments under vision. The surgeon should watch the console screen and the bedside team should watch auxiliary screens

⚠ **Do not** hold the arm directly on a joint due to the risk of hand traps in moving joints

⚠ **Do not** rest hands while holding the hand controllers, or dock the hand controllers, with the instruments actively engaged, as hand movements will move the instruments, which may damage the patient anatomy

⚠ Check the bedside unit orientation is correct if the instruments are responding in a different way than expected

⚠ Check the endoscope angle setting if the endoscope does not pan and zoom as expected

⚠ Using the hand controllers, move the instruments in free space inside the patient cavity to test that the instruments are assigned to each hand controller, as intended, and are functioning correctly. **Do not** use an instrument that is not functioning correctly

⚠ Test the hand scaling settings before making gross movements towards the patient anatomy

⚠ Take care when using the buttons on the hand controllers. Always check the correct button is pressed. Accidentally pressing the electrosurgery button could cause injury to the patient

⚠ After engaging with an electrosurgery instrument, move the instrument in free space in the patient cavity within the field of view to confirm the intended instrument for electrosurgery is engaged

⚠ **Always** refer to arms by the arm colour identifier and the instrument type to avoid confusion, for example: “pink arm, fenestrated grasper”

⚠ Watch the arms during surgery and move the elbow if necessary to prevent arm clashes that could cause instrument movement inside the patient

⚠ **Do not** touch the surgeon console while a surgeon is using the hand controllers due to the risk of hand traps

⚠ **Do not** move any instruments in the patient cavity while one or more of the arms is in instrument adjust mode, as instrument arms could collide and knock the arm in instrument adjust mode

⚠ **Do not** put the arm into unlocked mode with the instrument or endoscopic camera inside the cavity

⚠ **Do not** leave arms in unlocked mode or instrument adjust mode at the bedside, as if the arm is knocked it could cause unintended instrument motion inside the patient cavity

⚠ Check the arm modes of all arms continually using the auxiliary screen or the console screen. If the surgical team are not aware of the arm modes, an arm may move or not move as expected causing injury to the patient or users

⚠ If an instrument is damaged during surgery, check that no part of the instrument has been left inside the patient cavity. A foreign body left inside the patient cavity could lead to harm to the patient

⚠ **Always** have multiple Versius Instruments available during a procedure

⚠ **Always** have manual minimal access surgical instruments available

This chapter describes how the surgeon controls the Versius Instruments and Versius Endoscopic Camera, using the hand controllers (Figure 18.1) on the Versius Surgeon Console in surgical mode.

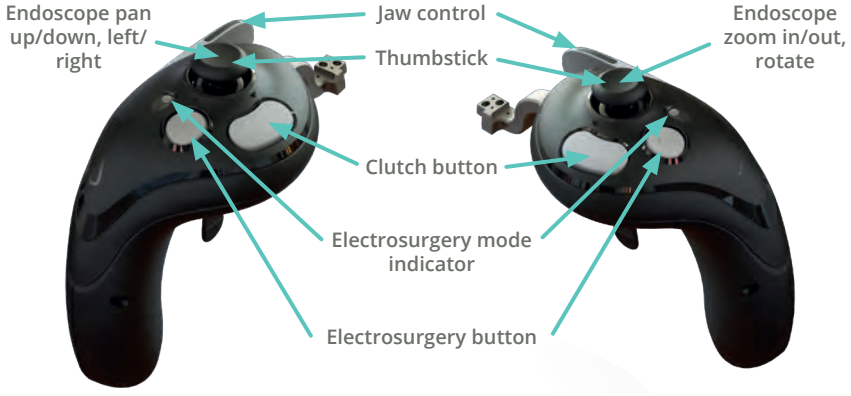


Figure 18.1 *Hand controllers with marked buttons and levers*

The surgeon can only move the instruments and endoscope or navigate the HUD when a hand controller detects the surgeon's hand is in correct contact. If a hand controller is moved while no hand is detected, the endoscope or instrument will not move inside the patient. Use the hand controllers with clean, dry hands

18.1 Putting an arm into surgical mode

Once an arm has been port-trained and the endoscope or instrument has been advanced into the patient cavity in instrument adjust mode, press the V-Wrist button to enter surgical mode (Figure 5.2).

18.2 Engaging an arm

The surgeon can only engage an arm when the arm is in surgical mode (see chapter 5).

For an instrument arm:

- The arm must assigned to the left or right hand controller
- The visualisation arm must be in surgical mode

To engage an instrument arm

1. Hold the hand controller with a relaxed grip
2. Move the cursor to the instrument icon of the arm to be engaged
3. Press and release the clutch button (Figure 18.2)
4. The instrument icon increases in size

This process is the same for both the left and right hand controllers.

Figure 18.2 Engaging an instrument arm with the hand controller

When an instrument arm is engaged, the surgeon uses the hand controller to control the instrument. Each hand controller can be used to control one instrument at a time.

The surgeon can engage a different instrument arm at any time during surgery. To engage a different instrument arm:

1. Press the clutch button to disengage the current arm
2. Move the cursor to the instrument icon of the new arm
3. Press and release the clutch button

18.3 Moving the instruments using hand controllers

An instrument can only be moved using a hand controller when the arm it is attached to is in surgical mode and engaged.

To move an instrument using a hand controller

- Move a hand controller that is engaged to an instrument arm

The distance that the instrument moves depends on the hand scaling setting. The hand scaling settings can be changed in the HUD menu (see section 13.8.6).

The hand scaling does not affect movement of the endoscope

It is important to be familiar with how the instruments move with the current hand scaling setting before making gross movements. Test how the instruments respond to moving the hand controllers by making fine movements inside the cavity, away from anatomy.

18.3.1 Instrument jaw control

To close the instrument jaws:

1. Place an index finger through the loop on the jaw control (Figure 18.3) on the hand controller
2. Push the index finger against the jaw control to close the jaws of the instrument (Figure 18.4)

To open the instrument jaws:

- Release the jaw control

This returns the jaw control to its rest position and the instrument jaws open.

Figure 18.3 *Hand controller with jaw control in neutral position*

To keep the instrument jaws closed:

1. Squeeze the jaw control with the index finger to close the jaws
2. Press the clutch to disengage the instrument before releasing the index finger

Once disengaged, the hand controller is free to move without opening the instrument jaws or moving the instrument.

Figure 18.4 Hand controller with jaw control pushed in

To re-open the instrument jaws:

- Re-engage the instrument by pressing the clutch button

The instrument jaws will not open until the index finger has resumed its previous position of squeezing the jaw control.

Then when the jaw control is released the instrument jaws will open.

18.3.2 Instrument straighten

This function straightens and closes the instrument and unwinds rotation of the V-Wrist. It can be used at any point in surgical mode.

Straightening an instrument is helpful when the instrument needs to be advanced or withdrawn within the cavity or removed from the port.

Instrument straighten is also used when the instrument wrist has reached its maximum range of rotation and cannot be rotated any further. The wind-up icon indicates the level of rotation of the instrument wrist.

To straighten the instrument:

1. Press and hold the thumbstick (use the thumbstick like a button)

This straightens the instrument, unwinds the V-Wrist and closes the instrument jaws (Figure 18.5).

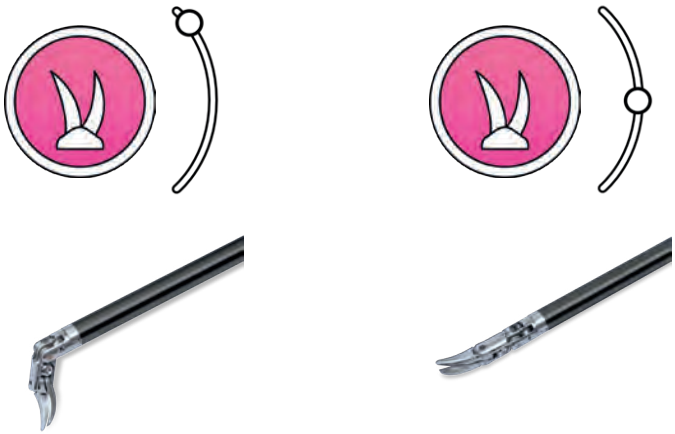


Figure 18.5 *Instrument straighten function*

18.4 Disengaging an instrument arm

To disengage an instrument arm

- Press and release the clutch button

To re-engage an instrument arm, follow the steps in section 18.2.

To briefly disengage an arm to adjust hand controller position without moving the instrument, press and hold the clutch button

18.5 Arm range of motion

Each joint in the arm has a set range of motion. If an arm reaches a position where one or more joints are at the end of their range, it will be impossible to move it in certain directions.

If an instrument will not move in one particular direction, move it in the opposite direction and manually change the pose of the arm, then try again.

18.5.1 Repositioning the bedside unit

It may be necessary to reposition a bedside unit during surgery. To reposition a bedside unit:

1. Remove the instrument or endoscope from the cavity
2. Deactivate the bedside unit brake
3. Move the bedside unit to a new position
4. Activate the bedside unit brake
5. Change the arm height if required
6. Reset the bedside unit orientation
7. Port-train the arm (see chapter 17)

Do not put the arm into unlocked mode with the instrument or endoscopic camera inside the cavity

18.6 Electrosurgery

The electrosurgery instrument icons on the HUD have a coloured ring to indicate cut (yellow) or coagulation (blue) mode.

Additionally, there are two icons associated with an electrosurgery instrument icon. One indicates cut (yellow) and the other coagulation (blue) mode (Figure 18.6). They are used to change electrosurgery mode.

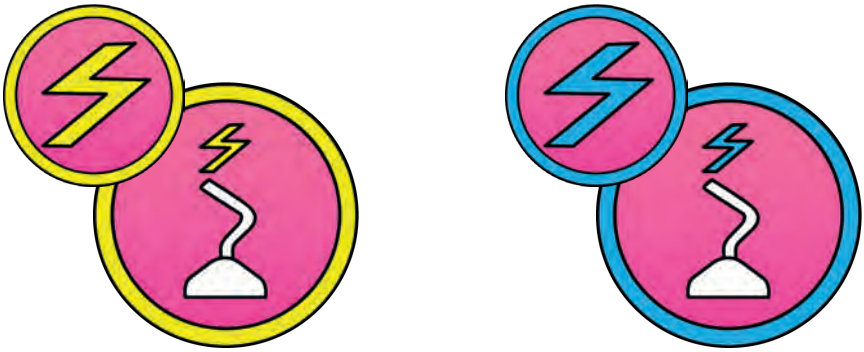


Figure 18.6 *Electrosurgery instrument icon with cut and coagulation mode icons visible (as shown on HUD)*

The bipolar instruments only have coag as an electrosurgery mode option (blue icon border)

18.6.1 Selecting electrosurgery mode

To select cut or coagulation mode:

1. Move a HUD cursor to the electrosurgery instrument icon
2. Move the cursor to the cut or coagulation mode icon
3. Press and release the clutch button
4. The electrosurgery mode is now selected and the arm is engaged simultaneously

18.6.2 Activating electrosurgery

To activate electrosurgery:

- Press and hold the electrosurgery button (Figure 18.7)

The electrosurgery mode indicator LED colour indicates the mode to which the instrument is set: yellow for cut and blue for coagulation. The electrosurgery active icon adjacent to the instrument icon flashes. The electrosurgery unit provides a sound feedback.

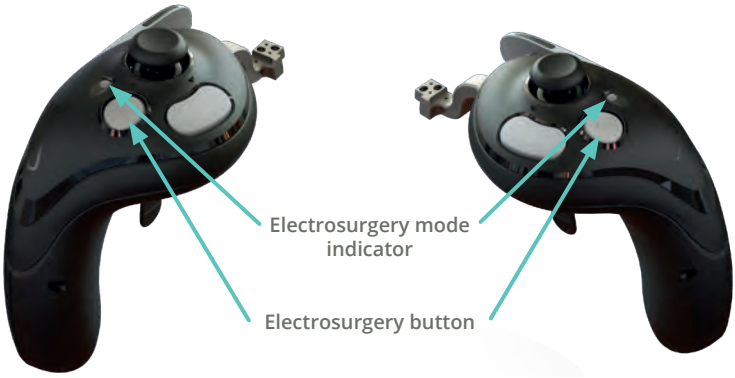


Figure 18.7 *Hand controllers with electrosurgery button and electrosurgery mode indicator*

It is recommended that the volume of the sound feedback from the electrosurgery unit is not decreased. The volume is sufficiently loud if all members of the surgical team can hear the sound.

18.6.3 Deactivating electrosurgery

To deactivate electrosurgery:

- Release the electrosurgery button

18.6.4 Changing electrosurgery mode

To change the electrosurgery mode:

1. Press and release the clutch button to disengage
2. Move the cursor to the required electrosurgery mode icon
3. Press and release the clutch button

The electrosurgery mode is now selected and the arm engaged simultaneously.

18.7 Controlling the endoscopic camera

When the endoscopic camera is attached to the visualisation arm the endoscopic camera icon appears on the HUD.

The endoscopic camera can be controlled with a thumbstick on a hand controller if:

- The endoscopic camera is attached to the visualisation arm
- The visualisation arm is in surgical mode
- The hand controller is engaged to an arm (instrument or visualisation)

Figure 18.8 shows how the thumbsticks control the endoscopic camera.

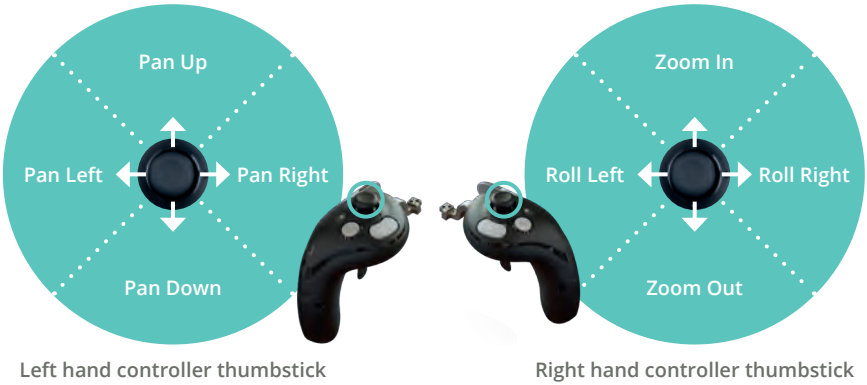


Figure 18.8 *Endoscopic camera control with the hand controller thumbsticks*

On the left hand controller, use the thumbstick to pan the endoscope:

- Move the thumbstick forward to pan up
- Move the thumbstick back to pan down
- Move the thumbstick left to pan left
- Move the thumbstick right to pan right

On the right hand controller, use the thumbstick to control the zoom and rotation of the endoscope:

- Move the thumbstick forward to zoom in
- Move the thumbstick back to zoom out
- Move the thumbstick left to roll left
- Move the thumbstick right to roll right

Zooming in using the thumbstick advances the endoscopic camera into the cavity

18.7.1 Controlling the endoscopic camera manually

The endoscopic camera may be used manually. When the endoscopic camera is not attached to the visualisation arm, the manual endoscope icon appears on the HUD.

Handle the endoscopic camera with care as it is fragile.

To use the endoscopic camera manually:

1. Detach the endoscopic camera from the visualisation arm (see chapter 14)
2. Move the endoscopic camera manually

18.7.2 Changing the endoscope angle

If the endoscope angle needs to be changed from 0° to 30° up or down:

1. Detach the endoscope from the camera head
2. Remove and dispose of the camera head drape
3. Locate the new sterile endoscope and a new sterile camera head drape
4. Drape the endoscopic camera using the new camera head drape
5. Select the new endoscope angle on the HUD menu
6. Attach the endoscopic camera to the visualisation arm and continue surgery

If a 30° endoscope needs to be changed to either up or down:

1. Detach the endoscope from the camera head
2. Rotate the endoscope 180° and reattach to the camera head
3. Select the new endoscope angle on the HUD menu
4. Attach the endoscopic camera to the visualisation arm and continue with surgery

See section 11.4.1 for more information on achieving the desired the endoscope angle.

18.8 Accessing the HUD menu during surgery

If the HUD menu needs to be accessed during surgery:

1. Disengage from the visualisation or instrument arm first. Do this by pressing the clutch button on the hand controller enaged with that arm
2. Now when the thumbstick is moved, it just moves the HUD cursors and not the endoscopic camera
3. Move the cursor to the HUD menu icon by moving the thumbstick
4. Press the clutch button on that hand controller to select the HUD menu

18.9 Resting hands during surgery

⚠ **Do not** rest hands while holding the hand controllers, or dock the hand controllers, with the instruments actively engaged, as hand movements will move the instruments, which may damage the patient anatomy

The surgeon should have a relaxed grip on the hand controllers to prevent fatigue. The grip on the hand controllers can be released to allow the surgeon to rest.

To rest a hand during surgery:

1. If an arm is engaged to the hand controller, press the clutch button to disengage
2. Release the grip on the hand controller

The relevant no-hand-detected icon will appear on the HUD (Figure 18.9).

Figure 18.9 No-hand-detected icons

Chapter 19

Removing an endoscope or instrument from the port

Warnings and precautions

⚠ **Always** watch the instrument on the video feed when moving an instrument inside the patient

⚠ **Do not** move instruments inside the cavity if the auxiliary screen is not functioning correctly

⚠ Move the instrument clear of tissue and close and straighten the instrument jaw before retracting the instrument from the port

⚠ Check the instrument is clear of tissue before retracting the instrument from the port

⚠ Move the instruments in as straight a line as possible when in instrument adjust mode as the arm can be moved along several different axes. Instrument adjust does not remember the point at which the mode was entered so the system will not prevent the arm from advancing deeper into the patient cavity. The arm will respect the fulcrum so stress on the port is minimised

⚠ The arm only prevents deeper movement into the patient cavity in instrument change mode. There is no end stop when advancing an instrument in any other mode. Take care when advancing instruments into the cavity in instrument adjust mode

⚠ Fully remove the instrument from the port before changing the instrument

This chapter describes how to remove the endoscope or instrument from the port. If a fault with the Versius Surgical System prevents removal using the arm modes, see section 21.3 on moving instruments manually.

It is recommended that the surgical team refer to the instruments by the type of instrument or by the arm colour identifier of the arm the instrument is attached to.

Before removing the instrument from the port:

- Check that the instrument is clear of tissue
- Close the instrument jaws
- Straighten the instrument wrist

19.1 Removing the endoscope or instrument from the port

To remove the endoscope or instrument from the port:

1. Put the arm into instrument change mode (the instrument change mode icon appears on the HUD)
2. Hold the arm with one hand and the port with the other
3. Pull on the arm to remove the endoscope or instrument from the port (Figure 19.1). For safety, the endoscope or instrument is constrained to move only along its axis

If the distal end of the instrument appears damaged, make sure no foreign bodies are left in the patient cavity

If the position of the arm prevents removal of the endoscope or instrument in instrument change mode, use instrument adjust mode.

Figure 19.1 Instrument being removed from the port

19.2 Using instrument adjust instead of instrument change mode

⚠ **Do not** reinsert an endoscope or instrument too deep into the cavity and take care to move the arm in as straight a line as possible

In some positions when the arm is near the limit of its reach, instrument change mode cannot be used. In this case instrument adjust mode can be used to remove the instrument or endoscope from the port.

In instrument adjust mode the previous position will **not** be remembered and the arm will **not** prevent movement deeper into the cavity. The arm will respect the fulcrum, but movement will **not** be constrained to a straight line.

To remove an instrument or endoscope in instrument adjust mode:

1. Put the arm into instrument adjust mode (the instrument adjust mode icon appears on the HUD)
2. Hold the arm with one hand and the port with the other
3. With care and with the instrument tip under vision, pull on the arm to remove the instrument or endoscope from the port

Chapter 20

Alarms

Warnings and precautions

⚠ **Immediately** support the arm at the black grip band in the event of a high-priority arm alarm, as the arm may begin to droop, risking harm to the patient

⚠ If an arm alarm occurs, while supporting the arm if it is a high-priority alarm, remove the instrument from the patient, move the bedside unit away from the operating table and unplug from the surgeon console

⚠ **Always** maintain the sterility of the drape. If the draped bedside unit is removed from the sterile field to recover from an alarm the drape could become contaminated. If necessary, remove the bedside unit drape and re-drape before returning the bedside unit to the sterile field

⚠ **Do not** attempt to put the arm into sleep mode with the drape cap attached and the arm height below 1 on the bedside unit height scale, as this may cause damage to the drape cap and lead to contamination

⚠ **Do not** mute an alarm sound without taking further action to deal with the cause of the alarm

This chapter describes what happens and what action should be taken in the event of an alarm from the Versius Surgical System.

20.1 Alarms overview

The Versius Surgical System can have console alarms and arm alarms. A console alarm comes from the surgeon console and affects use of the entire system. An arm alarm comes from only one bedside unit, and if it is an instrument bedside unit then other instrument bedside units can still be used. An alarm on the visualisation bedside unit alarm affects the use of the entire system.

The surgeon console and bedside units use both audible and visual signals to indicate two levels of alarm:

- **Medium-priority alarms**

There are medium-priority alarms for the arms and for the console. If a medium-priority alarm occurs there is no immediate danger to the patient.

- **High-priority alarms**

High-priority alarms only occur on arms. The patient could be in immediate danger in the case of a high-priority alarm. Support the arm immediately to prevent the patient coming to harm.

Some alarms relate to low battery and can be cleared by recharging. The thresholds for alarms relating to low battery are:

- **Medium-priority alarms:** approximately 5 minutes of battery charge left, depending on what the arm is doing
- **High-priority alarms:** approximately 30 seconds of battery charge left, depending on what the arm is doing

If there is a medium-priority arm alarm the bedside unit may be recovered or replaced. A bedside unit is recovered if putting it to sleep and waking it up again clears the alarm. When the alarm is cleared, the bedside unit can be used again for surgery. If the alarm cannot be cleared the bedside unit may be replaced by a functional bedside unit.

Console alarms indicating restart required can be cleared by restarting the system. Other console alarms cannot be cleared.

20.2 Muting an alarm sound

The alarm sounds can be silenced temporarily using mute buttons on the surgeon console and the bedside units (Figure 20.2). Pressing a mute button will silence the alarm sound for two minutes. After two minutes, the sound will resume automatically.

⚠ **Do not** mute an alarm sound without taking further action to deal with the cause of the alarm

A repeating 'no' sound is not an alarm sound and cannot be silenced. A repeating 'no' sound may indicate an arm clash, see section 6.4.2 for how to resolve an arm clash.

20.2.1 Muting the alarm sound on the surgeon console

To mute a system alarm sound, press the mute button on the surgeon console (Figure 20.2).

When a console alarm sound has been muted, the following alarm muted icon appears in the centre of the HUD:

To re-enable a console alarm sound, press the mute button again on the surgeon console **or** navigate to the HUD menu and select alarm unpause (Figure 20.1).

Figure 20.1 shows the HUD menu with the unpause alarm option selected.

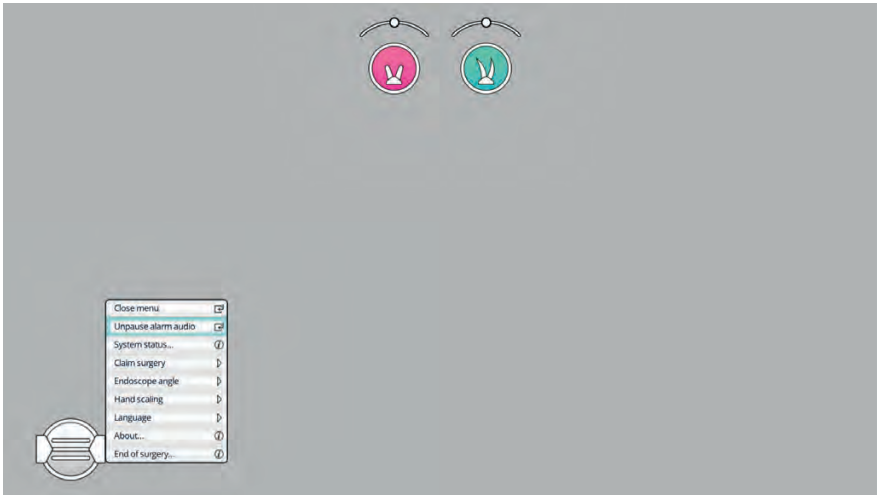


Figure 20.1 *Unpause alarm option on the HUD menu*

20.2.2 Muting the alarm sound on a bedside unit

To mute an arm alarm sound, press the mute button on the cart control panel (Figure 20.2).

When an arm alarm sound has been paused, the mute button flashes. To re-enable an arm alarm sound, press the mute button again on the cart control panel (Figure 20.2).

Figure 20.2 indicates the location of the mute buttons on the surgeon console and on the bedside units.

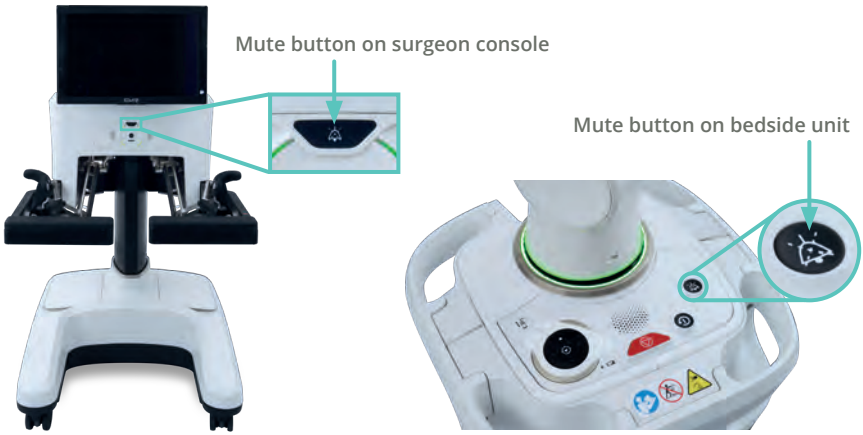


Figure 20.2 Mute buttons on the surgeon console and bedside units

20.3 Console alarm

If a console alarm occurs, the following signals occur:

- Flashing yellow light on the status halo on the surgeon console
- Alarm sound from the surgeon console
- Flashing icon in the centre of the HUD

Figure 20.3 *Status halo on the surgeon console indicating a console alarm*

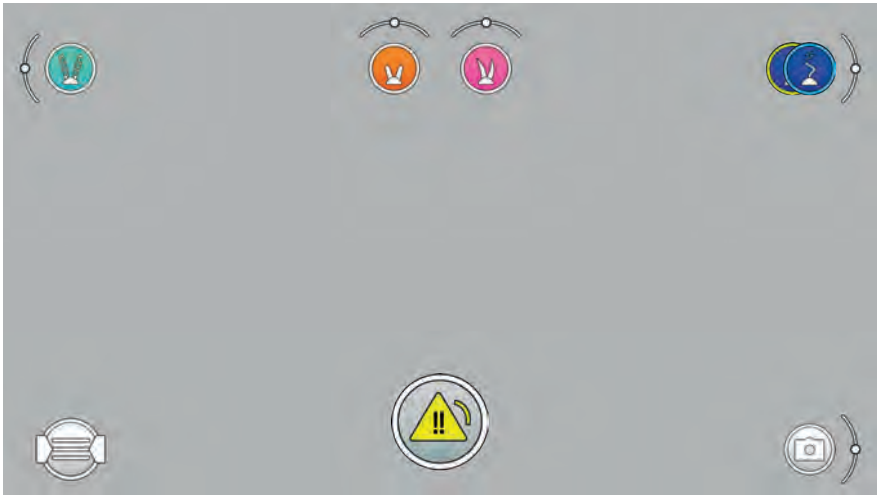


Figure 20.4 *Console alarm icon in the centre of the HUD*

20.3.1 Impact of a console alarm

The console can no longer be used for surgery and all bedside units connected to the console will disengage.

1. Convert to manual surgery (see chapter 21)
2. Prioritise moving any bedside units away from the operating table that have any low battery indicators active
3. Contact CMR technical support to resolve the issue

20.3.2 Surgeon console service-required

If the recommended service interval has been exceeded, a console alarm occurs. This icon flashes in the centre of the HUD:

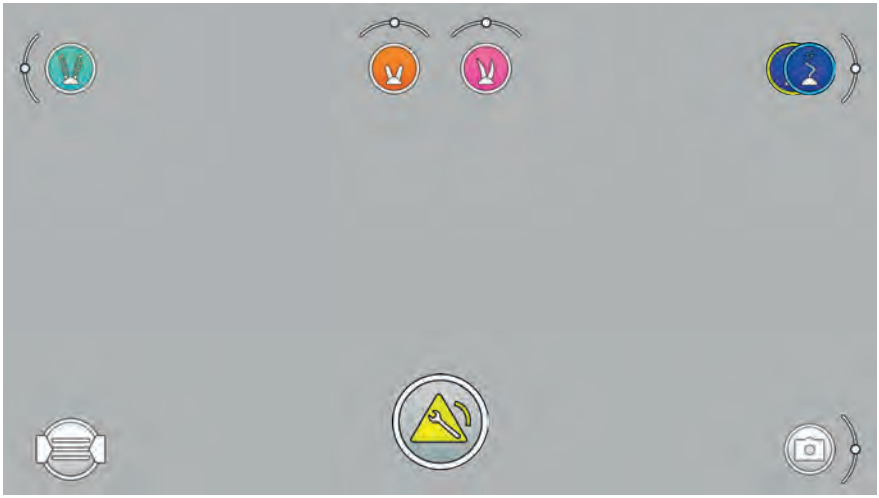


Figure 20.5 *Service required icon in the centre of the HUD*

Contact CMR Surgical technical support to arrange a service. A loan surgeon console will be provided for use while the current surgeon console is serviced.

20.3.3 System restart required

Power off the system at least once every 24 hours. If the system is left powered on for too long, a console alarm occurs. This icon flashes in the centre of the HUD (Figure 20.6).

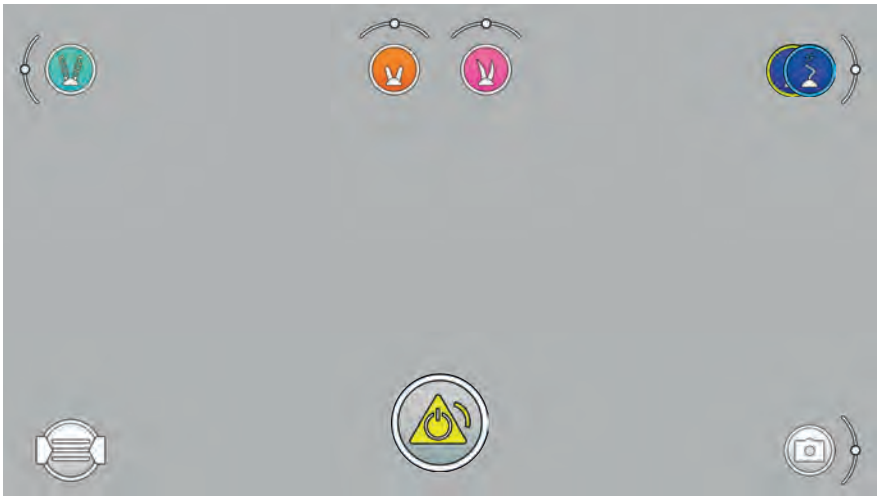


Figure 20.6 *Restart required icon in the centre of the HUD*

1. Put all arms to sleep
2. Power off the surgeon console
3. Power on the surgeon console

20.4 Medium-priority arm alarm

If a medium-priority arm alarm occurs, the following signals occur:

- Flashing yellow light on the status halo on the affected bedside unit (Figure 20.7)
- Alarm sound from the bedside unit
- Flashing icon below the affected instrument icon on the HUD (Figure 20.7)

Figure 20.7 *Status halo on the bedside unit indicating an arm alarm*

There are three types of medium-priority arm alarm:

1. The bedside unit battery is low and the bedside unit is not powered by the surgeon console (Figure 20.8)

Figure 20.8 Low battery indicator

2. Service required on the bedside unit. This icon flashes on the HUD in an icon group (Figure 20.9)

Figure 20.9 Service required icon in icon group

3. The bedside unit detects any other medium-priority arm alarm condition. This icon flashes on the HUD in an icon group (Figure 20.10)

Figure 20.10 *Medium-priority arm alarm icon in icon group*

20.4.1 Impact of a medium-priority arm alarm

The arm on the affected bedside unit will lock. Any hand controller engaged to the arm will automatically disengage. The surgeon console and all other connected bedside units will remain operational.

If the visualisation bedside unit has an alarm, both hand controllers disengage with any engaged arm. It will not be possible to engage with any arm. Surgery cannot continue until the visualisation bedside unit is recovered or a replacement visualisation bedside unit is connected.

20.4.2 Recovering a bedside unit with a medium-priority arm alarm

⚠ **Always** maintain the sterility of the drape. If the draped bedside unit is removed from the sterile field to recover from an alarm the drape could become contaminated. If necessary, remove the bedside unit drape and re-drape before returning the bedside unit to the sterile field

⚠ **Do not** attempt to put the arm into sleep mode with the drape cap attached and the arm height below 1 on the bedside unit height scale, as this may cause damage to the drape cap and lead to contamination

If a bedside unit has an alarm relating to low battery, clear the alarm by recharging the battery.

- Connect the bedside unit to the surgeon console
- If the low battery indicator remains lit when the bedside unit is connected, try a different bedside unit cable

If the bedside unit requires servicing, contact CMR Surgical technical support.

If the bedside unit has any other medium-priority alarm, attempt to recover the bedside unit:

1. Remove the instrument or endoscope. If the instrument or endoscope is inside the patient cavity, follow the instructions in chapter 21 to remove it manually
2. Deactivate the bedside unit brake and move the bedside unit away from the operating table
3. Remove the bedside unit drape, or ensure the arm height is high enough to allow space for the drape cap when the arm is folded (Figure 20.11)
4. Ensure the bedside unit is connected to the surgeon console
5. Press and hold the sleep button until the arm folds into the sleep position

If the arm will not fold into the sleep position after steps 1–4 have been followed, power off the arm without folding (see section 20.7).

6. Disconnect the bedside unit

The status halo will stop flashing and the alarm sound will stop. If they do not, power off the arm without folding (see section 20.7).

7. Reconnect the bedside unit
8. Press and hold the sleep button to wake up the arm

If the arm wakes up with no alarm, re-drape the bedside unit if necessary and the bedside unit can be used for surgery.

If the alarm restarts, repeat steps 4–8 above, or power off the arm without folding (see section 20.7).

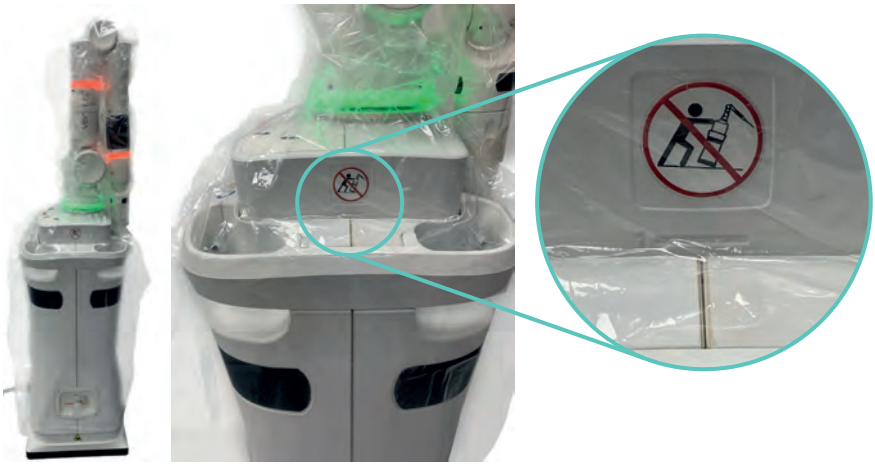


Figure 20.11 Minimum arm height for folding a draped arm

20.5 High-priority arm alarm

⚠ **Immediately** support the affected arm by holding the black grip band

A high-priority arm alarm occurs if:

- An arm loses power and is unable to use the battery in the bedside unit
- The bedside unit battery is very low
- The bedside unit detects any other high-priority arm alarm condition

The arm may begin to droop, putting the patient in immediate danger. A high-priority arm alarm can occur in either the instrument or visualisation bedside unit.

If a high-priority arm alarm occurs while the bedside unit is connected to the console, the following audible and visual signals occur:

- Flashing red light on status halo on the cart control panel of the affected bedside unit (Figure 20.13)
- Alarm sound from the bedside unit
- Flashing icon appears below the affected instrument icon (Figure 20.12)

Figure 20.12 *High-priority arm alarm icon in icon group*

Figure 20.13 *Status halo on the bedside unit indicating a high-priority alarm*

The high-priority arm alarm icon will not be visible if the bedside unit is not connected to the console and is running on battery.

Figure 20.14 *Low battery indicator*

A high-priority arm alarm cannot be cleared by the user.

20.5.1 Immediate response to a high-priority arm alarm

1. Support the arm at the black grip band and continue to do so through steps 2 to 5 (Figure 20.15)
2. Detach the instrument or endoscope from the arm
3. Remove the instrument or endoscope. If the instrument or endoscope is inside the patient cavity, follow the instructions in chapter 21 to remove it manually
4. Deactivate the bedside unit brake
5. Move the affected bedside unit away from the operating table into a space where it is safe if the arm droops
6. Disconnect the bedside unit
7. Connect a replacement bedside unit if necessary

Figure 20.15 *Supporting the arm (with both hands) at the black grip band*

20.6 Replacing a bedside unit after an alarm

If a bedside unit cannot be recovered, power it off for storage (see section 20.7). Connect and set up a functional bedside unit.

Check that all bedside units are now connected to the surgeon console, and are not in an incomplete daisy chain.

Contact CMR Surgical technical support to resolve the issue.

20.7 Powering off a bedside unit with an alarm

If a bedside unit has an alarm that cannot be cleared and the arm will not fold into the sleep position, power off the bedside unit without folding the arm:

- Remove any attached endoscopic camera or instrument
- Remove the bedside unit drape
- Disconnect the bedside unit
- Hold the sleep button for 30 seconds

Take care while the arm is powered off, as the arm may droop.

If the arm had a medium-priority alarm it may be possible to recover the bedside unit for surgical use after powering off without folding:

- Connect the bedside unit
- Press and hold the sleep button to wake up the arm
- Repeat steps 4–8 in section 20.4.2

Chapter 21

Converting to manual surgery

Warnings and precautions

⚠ Make small movements with the instrument when moving an instrument manually and be aware that the distal end of the instrument may move further than the proximal end

⚠ **Always** have manual minimal access surgical instruments available for every procedure

⚠ Take into account that the conversion to manual minimal access or open surgery may take more time due to the close proximity of the bedside units to the patient

When using the Versius Surgical System, it may be necessary to convert to manual surgery. This may be manual minimal access surgery or open surgery.

21.1 Using the endoscope during manual surgery

The Versius Endoscopic Camera can be used manually during manual surgery.

If a fault with the camera, surgeon console or cables prevents viewing the video feed from the Versius Endoscopic Camera, use another endoscope for visualisation of instruments while removing them from the patient.

The endoscope can be removed from its port and the same port can be used for inserting another endoscope.

21.2 Process for converting to manual surgery

The surgeon clears all instruments from tissue and straightens the instruments using the hand controllers. The surgeon can then leave the surgeon console to scrub for manual surgery, and the bedside team remove the instruments from the patient cavity, remove the endoscope if it is not being used, and move the bedside units away from the operating table.

For each bedside unit:

1. Put the arm into instrument change mode
2. Check that the instrument is clear of tissue (if a fault prevents the surgeon clearing instruments from tissue using the hand controllers, see section 21.3 on moving instruments manually)
3. Hold the black grip band with one hand and the port with the other
4. Guide the arm to remove the instrument or endoscope clear of the port
5. Detach the instrument or endoscopic camera from the arm
6. Deactivate the bedside unit brake
7. Move the bedside unit away from the operating table

In an emergency the bedside units can be moved away from the operating table with instruments or endoscope attached. Take care when moving around the operating theatre if an instrument or endoscope is still attached to a bedside unit.

21.3 Moving instruments manually

In the case of a fault with the system, the instruments may need to be detached from the arms and removed from the patient manually.

If the instrument is grasping tissue the jaws must be opened before moving it.

To open the instrument jaws manually:

1. Carefully detach the instrument from the arm
2. Find the three metal fins on the side of the instrument that was attached to the arm
3. Push in the distal direction on the outside two fins (Figure 21.1)
4. Check the grasp on the tissue is released
5. Remove the instrument from the port, while holding onto the port with one hand. The instrument jaws will close as the instrument is pulled through the port

Figure 21.1 *Push in the distal direction on the outside two fins*

Chapter 22

Post-operative: disconnecting and cleaning

Warnings and precautions

⚠ **Do not** attempt to put the arm into sleep mode with the drape cap attached and the arm height lowered, as this may cause damage to the drape cap and lead to contamination. The arm will not go into sleep mode while still draped and persisting to try to put the arm to sleep will not work and may result in damage to the bedside unit casework

⚠ **Do not** use excess fluid that may get inside the casework, as fluid can cause internal damage to the system

⚠ Send all instruments, the endoscope, the monopolar instrument cable, the bipolar instrument cable and the light cable for reprocessing after surgery

⚠ **Always** clean and disinfect bedside units away from the sterile field, to avoid cross-contamination

⚠ **Do not** clean or disinfect the connection panels on the bedside units until the bedside units have been disconnected from the surgeon console and electrosurgery unit due to the risk of injury to the user if electrosurgery is active

⚠ Wipe clean all surfaces of the bedside unit during post-operative disconnecting and cleaning to avoid cross-contamination

⚠ Take care when reprocessing the Versius Surgical System and its accessories. Follow local guidelines and hospital procedures to reprocess the Versius Surgical System and its accessories

⚠ **Always** inspect Versius instruments after use and discard any damaged instrument

⚠ Check instrument life after surgery and discard any instruments that are out of life

⚠ Avoid using unnecessary force to rub the protection plate surface/ monitor surface with a stained cloth. The protection plate surface/ monitor surface may be scratched

This chapter describes how to disconnect, clean and disinfect the Versius Surgical System after surgery. This chapter also covers how to make the system ready for the next surgery or for being placed into storage.

ℹ Keep the auxiliary screen connected and powered on until all the arms are in sleep mode. This allows the surgical team to see the bedside unit status icons during post-operative tasks. The console screen can also be rotated to provide an additional screen for the surgical team

ℹ Use universal sanitising wipes in accordance with manufacturer's instructions

22.1 Selecting end of surgery on the HUD

When the procedure has finished and the Versius instruments are no longer required, tell the system that the surgery has ended:

1. Disengage both hand controllers from the instrument arms
2. Navigate to the menu icon on the HUD
3. Select the menu by pressing the clutch button
4. Navigate to the 'End of surgery...' option
5. Press the clutch button to select 'End of surgery' and follow the prompts on the console screen
6. If the surgery has not already been claimed, scan the QR code

See section 13.8.9 for more details.

If the End of surgery HUD menu option is selected (and confirmed by pressing 'Finish') while video recording is in progress, recording will stop, with the video file saved to the SD card.

When 'End of surgery' is selected on the HUD, it overlays the endoscope view. If the endoscope is still required for manual use, select cancel to exit the 'End of surgery' dialog box and restore the endoscope view.

22.2 Checking number of instrument uses remaining

Versius instruments have a restricted number of uses. When 'End of surgery' is selected and confirmed, a dialog box appears stating the instruments used and the number of uses remaining.

- Dispose of any instruments that have reached their maximum number of uses, following the hospital procedure for disposal of biologically contaminated sharps

This information can also be viewed by selecting 'System status' on the HUD menu (see section 13.8.3).

22.3 Detaching the instruments

Once the instruments have been removed from the ports, the instruments can be detached from the arms.

1. Squeeze the latches on either side of the attachment head
2. Lift the instrument away from the arm

22.4 Instrument point-of-use preparation

Once the instruments have been detached from the arms, they require reprocessing. The instruments must be reprocessed after each use. The first step of instrument reprocessing is the point-of-use preparation. The aim of the point-of-use preparation is to keep the instrument moist to facilitate reprocessing.

⚠ **Do not** soak the instrument in salt solution as the salt solution could cause damage to the instrument

Begin instrument point-of-use preparation immediately after surgery. See the Reprocessing Instructions (REF 70100) for point-of-use preparation instructions.

Send the instruments to the reprocessing area immediately after surgery

22.5 Detaching the endoscopic camera

Once the endoscope has been removed from the port, the endoscopic camera can be detached from the visualisation arm.

1. Squeeze the latches on the sides of the camera head
2. Lift the endoscopic camera away from the drape cap

22.6 Removing and disposing of the drapes

Move the instrument bedside units and the visualisation bedside unit away from the operating table to improve access for drape removal and to prevent contamination of the sterile field (see section 6.2 for instructions on moving bedside units).

22.6.1 Removing the bedside unit drapes

1. Remove the drape cap insert by pulling 'up' on either of the two insert tabs
2. Pull the locking ring towards the distal end of the arm, exposing the red marks on the drape cap wings
3. Unclip the drape cap wings from the arm and pull the drape cap distally, freeing it from the arm
4. Roll the cart drape together with the lower part of the arm drape up to the base of the arm, and check that both drapes are rolled up
5. Continue to roll the cart and arm drapes along the length of the arm until they are completely removed

22.6.2 Removing the camera head drape

1. Remove all tapes on the camera head drape
2. Detach the endoscope from the camera head inside the camera head drape by rotating the ring on the camera head
3. Remove the proximal end of the endoscope from the elasticated neck
4. Remove the camera head and camera cable from the drape
5. Send the endoscope for reprocessing

22.6.3 Disposing of drapes

- Dispose of all used drapes following the hospital procedure for processing biologically contaminated materials
- Do not re-use the Versius Drapes

⚠ **Do not** re-use the Versius Drapes. The drapes are single-use only, as indicated by this symbol which appears on the drape packaging: Dispose of the drapes at the end of each surgical procedure.

22.7 Reprocessing the endoscopic camera

The endoscopic camera must be detached from the endoscope and reprocessed after each use. Send the endoscope for reprocessing (refer to the instructions provided with the endoscope).

Use universal sanitising wipes such as CaviWipes™ to wipe the camera head and camera cable. Components should be allowed to dry before use. Refer to the universal sanitising wipe manufacturer's safety guidelines.

To clean the camera head and camera cable:

- Wipe the camera head and camera cable thoroughly with universal sanitising wipes for one minute and thirty seconds (1 minute and 30 seconds)
- Pay close attention to any seams, crevices and recessed surfaces
- Additional cleaning may be required until the camera head and camera cable is visibly clean
- Dispose of the used wipes after cleaning before beginning disinfection

To disinfect the camera head and camera cable:

- Wet the camera head and camera cable thoroughly with fresh universal sanitising wipes
- Continue to wipe the camera head and camera cable so that they remain visibly wet per the universal sanitising wipe manufacturer's recommended dwell time to ensure that the bioburden is reduced
- Pay close attention to any joints, seams, crevices and recessed surfaces

Store the camera head and camera cable appropriately

22.8 Reprocessing the system

The system should be cleaned and disinfected, away from the sterile field, in line with the hospital's procedures. Use universal sanitising wipes such as CaviWipes™ to wipe the surgeon console and bedside units. Components should be allowed to dry before use. Refer to the universal sanitising wipe manufacturer's safety guidelines.

⚠ **Always** clean and disinfect bedside units away from the sterile field, to avoid cross-contamination

⚠ **Do not** clean or disinfect the connection panels on the bedside units until the bedside units have been disconnected from the surgeon console and electrosurgery unit

22.8.1 Cleaning and disinfecting the bedside units

Before cleaning and disinfecting the bedside units, ensure that:

- Drapes have been removed
- The bedside unit brake has been activated to expose the lower part of the base of the cart

After each surgical procedure, reprocess the distal end of the arm and the area at the base of the cart that was not covered by the drape (Figure 22.1).

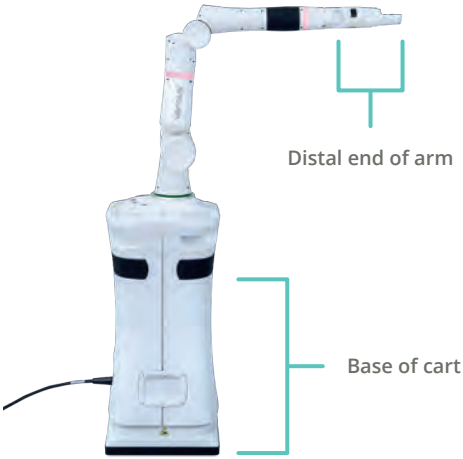


Figure 22.1 *Areas of the bedside unit to be reprocessed*

To clean the distal end of the arm and the cart base:

- Wipe all the areas thoroughly with universal sanitising wipes for a total of seventy seconds (70 seconds)
- Pay close attention to any joints, seams, crevices and recessed surfaces and move the arm joints through their full range of motion to expose all surfaces for cleaning
- Additional cleaning may be required until the areas are visibly clean
- Dispose of the used wipes after cleaning before beginning disinfection

To disinfect the distal end of the arm and the cart base:

- Wet the areas thoroughly with fresh universal sanitising wipes
- Continue to wipe the areas so that they remain visibly wet per the universal sanitising wipe manufacturer's recommended dwell time to ensure that the bioburden is reduced
- Pay close attention to any joints, seams, crevices and recessed surfaces

If an area of the bedside unit is visibly soiled, reprocess the soiled area.

To clean the soiled area:

- Wipe the area thoroughly with universal sanitising wipes for thirty seconds (30 seconds) per 4 sq ft (60 x 60 cm) of soiled area
- Pay close attention to any joints, seams, crevices and recessed surfaces and move the arm joints through their full range of motion to expose all surfaces for cleaning
- Additional cleaning may be required until the area is visibly clean
- Dispose of the used wipes after cleaning before beginning disinfection

To disinfect the soiled area:

- Wet the area thoroughly with fresh universal sanitising wipes
- Continue to wipe the area so that it remains visibly wet per the universal sanitising wipe manufacturer's recommended dwell time to ensure that the bioburden is reduced
- Pay close attention to any joints, seams, crevices and recessed surfaces

22.8.2 Cleaning and disinfecting the surgeon console

After each surgical procedure, reprocess all touchpoints where the operator comes into contact with the surgeon console, which include:

- Hand controllers
- Armrests (including inside the storage compartments)
- Armrest buttons
- Armrest latches
- Video recording panel (below the console screen)
- Buttons on the sides of the console screen

To clean the surgeon console touchpoints:

- Wipe all the areas thoroughly with universal sanitising wipes for a total of thirty-five seconds (35 seconds)
- Pay close attention to any seams, crevices and recessed surfaces
- Additional cleaning may be required until the areas are visibly clean
- Dispose of the used wipes after cleaning before beginning disinfection

To disinfect the surgeon console touchpoints:

- Wet the areas thoroughly with fresh universal sanitising wipes
- Continue to wipe the areas so that they remain visibly wet per the universal sanitising wipe manufacturer's recommended dwell time to ensure that the bioburden is reduced
- Pay close attention to any joints, seams, crevices and recessed surfaces

If an area of the surgeon console is visibly soiled, reprocess the soiled area.

To clean the soiled area:

- Wipe the area thoroughly with universal sanitising wipes for thirty seconds (30 seconds) per 4 sq ft (60 x 60 cm) of soiled area
- Pay close attention to any seams, crevices and recessed surfaces
- Additional cleaning may be required until the area is visibly clean
- Dispose of the used wipes after cleaning before beginning disinfection

To disinfect the soiled area:

- Wet the area thoroughly with fresh universal sanitising wipes
- Continue to wipe the area so that it remains visibly wet per the universal sanitising wipe manufacturer's recommended dwell time to ensure that the bioburden is reduced
- Pay close attention to any joints, seams, crevices and recessed surfaces

22.8.3 Cleaning the console screen

Before cleaning the console screen, disconnect the surgeon console from the mains power.

A material that withstands disinfection is used for the front protection plate of the medical use LCD monitor. The protection plate surface is specially treated to reduce light reflection. When solvents

such as benzene or thinner, or acid, alkaline or abrasive detergent, or chemical cleaning cloth are used for the protection plate surface/ monitor surface, the performance of the monitor may be impaired or the finish of the surface may be damaged.

Take care with respect to the following:

- Clean the protection plate surface/monitor surface with a 50 to 70 v/v% concentration of isopropyl alcohol or a 76.9 to 81.4 v/v% concentration of ethanol using a swab method. Wipe the protection plate surface gently (wipe using less than 1 N force).
- Stubborn stains may be removed with a soft cloth such as a cleaning cloth lightly dampened with mild detergent solution using a swab method and then clean using the above chemical solution. Never use solvents such as benzene or thinner, or acid, alkaline or abrasive detergent, or chemical cleaning cloth for cleaning or disinfection, as they will damage the protection plate surface/ monitor surface.

⚠ Avoid using unnecessary force to rub the protection plate surface/ monitor surface with a stained cloth. The protection plate surface/ monitor surface may be scratched

22.9 Disconnecting and reprocessing cables

22.9.1 Disconnecting the sterile cables

- Light cable
- Monopolar and bipolar instrument cables

22.9.2 Reprocessing the sterile cables

- Send the light cable for reprocessing (refer to the instructions provided with the light cable)
- Send the electrosurgery instrument cables for reprocessing (refer to the instructions provided with the cables [REF 72000])

22.9.3 Disconnecting the non-sterile cables

Before disconnecting the surgeon console power cable, check that the surgeon console has been properly powered-off

Disconnect the non-sterile cables:

- Surgeon console power cable
- Network cable
- Bedside unit cables
- Monopolar and bipolar bedside unit cables
- Video feed cable
- Auxiliary screen cable

22.9.4 Cleaning and disinfecting the non-sterile cables

Reprocess non-sterile cables in line with the hospital's procedures.

Use universal sanitising wipes such as CaviWipes™ to wipe the non-sterile cables. Components should be allowed to dry before use. Refer to the universal sanitising wipe manufacturer's safety guidelines.

If a non-sterile cable is visibly soiled, reprocess the cable.

To clean the non-sterile cables:

- Wipe long bedside unit cables thoroughly with universal sanitising wipes for two and a half minutes (2 minutes and 30 seconds)
- Wipe all other non-sterile cables thoroughly with universal sanitising wipes for one and a half minutes (1 minute and 30 seconds)
- Pay close attention to any seams, crevices and recessed surfaces
- Additional cleaning may be required until the cables are visibly clean
- Dispose of the used wipes after cleaning before beginning disinfection

To disinfect the non-sterile cables:

- Wet the cables thoroughly with fresh universal sanitising wipes
- Continue to wipe the cables so that they remain visibly wet per the universal sanitising wipe manufacturer's recommended dwell time to ensure that the bioburden is reduced
- Pay close attention to any joints, seams, crevices and recessed surfaces

22.10 Putting the arms to sleep

Once the bedside units have been cleaned and disinfected, the arms can be placed in sleep mode (Figure 22.2) ready for storage (see chapter 5 for more information on arm modes). The arm cannot be folded with an instrument or endoscopic camera attached.

- Press and hold the sleep button until the sleep mode icon is static

⚠ **Do not** attempt to put the arm into sleep mode with the drape cap attached and the arm height lowered, as this may cause damage to the drape cap and lead to contamination. The arm will not go into sleep mode while still draped and persisting to try to put the arm to sleep will not work and may result in damage to the bedside unit casework

Figure 22.2 An arm in sleep mode

22.11 Powering-off the surgeon console

Before disconnecting the power to the surgeon console:

- Check that all arms have been put to sleep
- Check that the hand controllers have been docked

The surgeon console needs to be stored in a compact position to reduce the risk of damage and for ease of movement.

1. Lower the surgeon console height to its lowest position
2. Lower the console screen to its lowest position
3. Use the levers to move the armrests to their storage position
4. Switch off the surgeon console using the switch on the connection panel
5. Unplug the surgeon console power cable
6. Store 3D glasses somewhere safe

22.12 Moving the system into storage

Before moving the system into storage, check that:

- The arms are in the folded sleep position
- The arms are at their lowest height
- The surgeon console is in its compact storage position
- The hand controllers are docked
- All bedside unit and surgeon console cables are disconnected
- The bedside units and surgeon console have been cleaned

See chapter 6 for information on safely moving the system.

22.12.1 Storing non-sterile cables

- Store bedside unit cables in the storage bins at the base of the surgeon console (Figure 22.4)
- Store the surgeon console power cable on the back of the surgeon console (Figure 22.3)

22.12.2 Storing the bedside units

1. Deactivate the brake
2. Hold two handles
3. If the ground is flat and level, push the bedside unit to move it into storage. If the bedside unit is to be moved over a threshold, pull the bedside unit using two hands
4. Activate the bedside unit brake

22.12.3 Storing the surgeon console

1. Check that the intended path of the surgeon console from the operating theatre into storage is clear
2. Squeeze the brake levers on the inside of the handles at the back of the surgeon console
3. Wheel the surgeon console into storage
4. Release the brake levers on the inside of the handles at the back of the surgeon console

Figure 22.3 *Surgeon console power cable stored on the back of the surgeon console*

Figure 22.4 *Bedside unit cables stored in the surgeon console storage bins*

Chapter 23

Installation, storage, maintenance and servicing

23.1 Installation

First time installation requires a CMR accredited agent to attach and connect the surgeon console screen.

Contact CMR Surgical on:

Tel: +44 (0) 1223 750 975

Follow the hospital procedure for connecting equipment to the hospital network.

Instruments are supplied non-sterile and must be cleaned and sterilised prior to use.

The endoscope is supplied non-sterile and must be cleaned and sterilised prior to first use and after each use.

23.2 Storage

Store the system in a powered-off state, in a room where the following conditions will be maintained:

- Temperature between –5°C and 55°C
- Humidity between 10% and 90% non-condensing
- Air pressure between 500hPa and 1060hPa

Store the bedside units in the sleep position and the arm heights at their lowest height settings. Lower the surgeon console height and the console screen to the lowest settings.

23.3 Maintenance

The system does not contain any user-serviceable parts and requires no routine adjustments by the user to maintain operation. Unauthorised repairs or dismantling will invalidate the warranty.

If a fault occurs in any instrument, endoscopic camera, bedside unit, or cable apart from the camera cable, the faulty part can be replaced by a functioning equivalent part.

If the surgeon console stops working and the relevant steps in the troubleshooting guide (appendix A) have been followed and the surgeon console is still not working, contact CMR Surgical on this phone number to arrange repair or replacement:

Tel: +44 (0) 1223 750 975

23.4 Servicing

The surgeon console and each bedside unit requires servicing every quarter. Use the HUD menu option 'About' to find out when the next service is due (see Figure 13.23).

To arrange a service, please contact technical support at CMR Surgical on:

Tel: +44 (0) 1223 750 975

The instruments and endoscopic camera do not require servicing. The instruments and endoscopic camera should be discarded at the end of their life.

The system (including the surgeon console, the instrument bedside units, the visualisation bedside unit and the instruments) can only be serviced by CMR Surgical.

⚠ **Do not** attempt to service any component of the Versius Surgical System

Chapter 24

Versius Trainer

Warnings and precautions

⚠ **Do not** leave the Versius Trainer, the Versius Trainer cable or the HDMI cable connected to, or attempt to connect these to, the Surgeon Console during a surgical procedure

Users can develop their skills on the Versius Surgeon Console using the Versius Trainer simulator. The following sections describe how the Versius Trainer can be connected to and disconnected from the console.

24.1 Changing from Surgical View to Versius Trainer

1. Connect the Versius Trainer to the surgeon console screen by pushing the HDMI cable into the HDMI sockets (Figure 24.1)

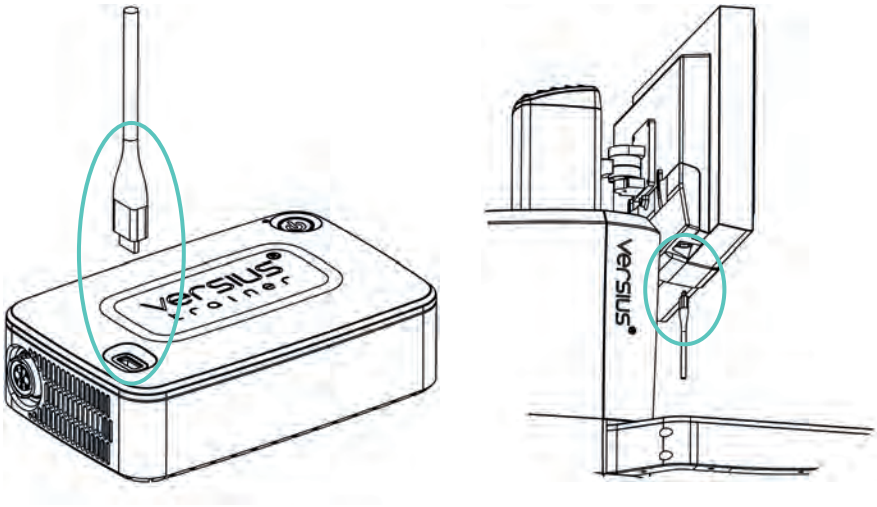


Figure 24.1 Connecting the Versius Trainer HDMI cable

2. Connect the power-in end of the Versius Trainer cable to the socket on the back of the Versius Trainer by aligning the alignment marker on the power-in end of the Versius Trainer cable to the socket on the back of the Versius Trainer. Push

the cable connector into the socket until the cable connector's locking ring rotates into place. An audible click confirms that the Versius Trainer cable is correctly connected (Figure 24.2 [A])

3. Connect the power-out end of the Versius Trainer cable to the surgeon console by aligning the marker on the end of the Versius Trainer cable with the alignment marker on any of the five power-out sockets on the surgeon console connection panel. The locking ring rotates into place and an audible click confirms that the Versius Trainer cable is correctly connected (Figure 24.2 [B])

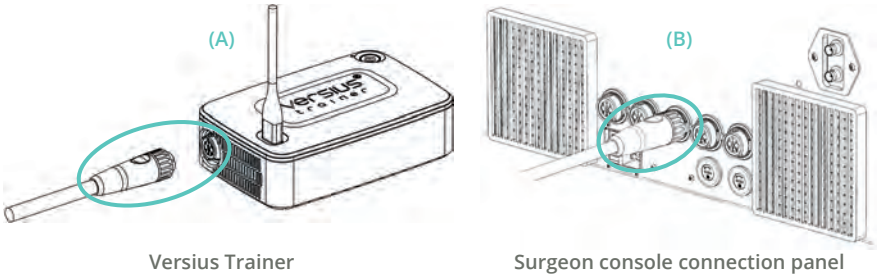


Figure 24.2 *Connecting the Versius Trainer cable*

4. Turn the power on the Versius Trainer by pressing the power button (Figure 24.3). The power indicator LED will change from a blue light to a white light

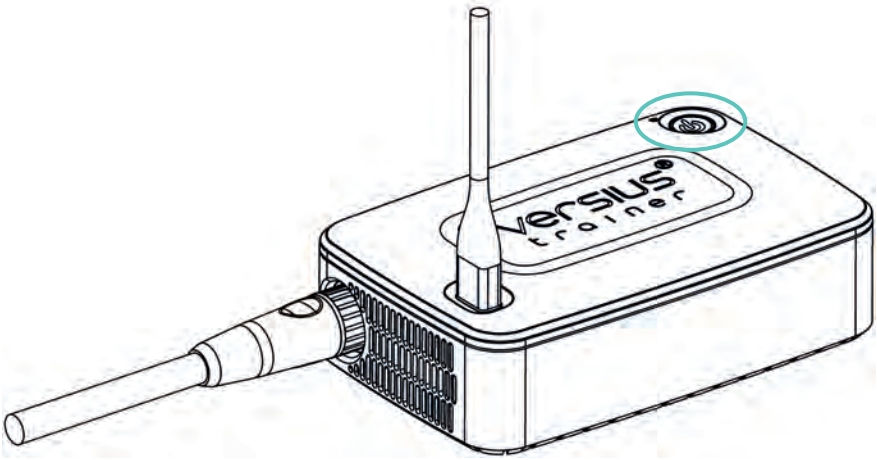


Figure 24.3 *Versius Trainer power button*

5. Change the console screen display mode from 3D or 2D to DVI. Do this by firstly pressing the control button located below the power indicator on the right-hand side of the screen to illuminate the menu buttons. Then press the DVI button on the left-hand side of the screen (Figure 24.4)

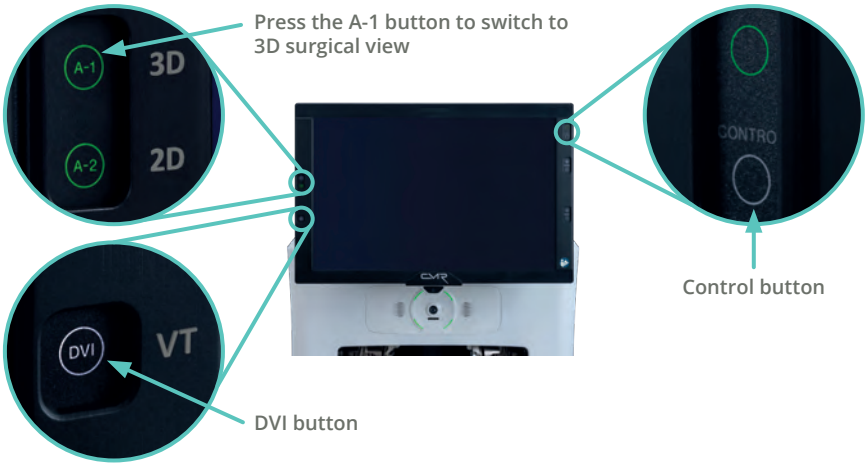


Figure 24.4 *Location of the control, DVI, A-1 and A-2 buttons on the surgeon console screen*

6. The Versius Trainer performs an internal safety check and makes a flourish sound when this is complete

7. When the Versius Trainer is ready to use, the Versius Trainer home screen appears

24.2 Changing from Versius Trainer to Surgical View

1. Power off the Versius Trainer by pressing the power button (Figure 24.3). The power indicator LED will change from a white light to a blue light

2. Disconnect the Versius Trainer from the surgeon console by removing the Versius Trainer cable from the surgeon console connection panel

3. Ensure the hand controllers are docked. Reboot the surgeon console by pressing the power switch on the surgeon console connection panel to the 'off' position followed by the 'on' position (Figure 24.5)

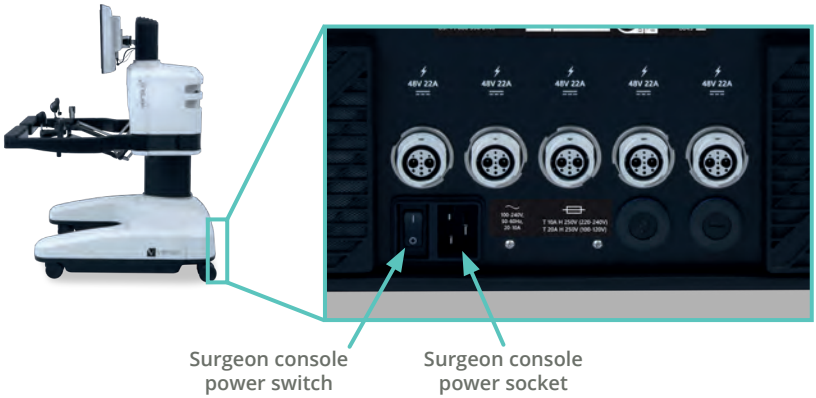


Figure 24.5 The power switch and socket on the surgeon console connection panel

4. Remove the HDMI cable from the console screen by pulling it out of the HDMI socket (Figure 24.1)
5. Change the console screen display mode from DVI to 3D or 2D by firstly pressing the control button located below the power indicator on the right-hand side of the screen to illuminate the menu buttons (Figure 24.4)
6. Next, press either the A-1 button on the left of the screen to access 3D or the A-2 button to access 2D (Figure 24.4)

Chapter 25

Warranty

Standard Warranty

The Versius® Surgical Robotic System is warranted for a minimum period of 1 year (12 months) to be free from manufacturing defects in materials and workmanship at the time of delivery. The liability of CMR Surgical under this warranty shall be solely limited (at its option) to repair or replace individual defective components or, to replace the entire product free of charge.

CMR Surgical endeavours to restore systems to working order as efficiently as possible and will determine the most appropriate remedial approach: either on-site at your facility or remotely at your nearest CMR Surgical Approved Service Centre. Warranty will include all transport costs for the delivery and return of parts, any loan system and, if applicable, the return and re-delivery of the customer's own system.

When a product is repaired under Warranty or otherwise, the Warranty on the repaired or replacement component shall be extended to 180 days after the return to the Customer, or the remainder of the original Warranty term shall apply, whichever is the greater.

Exclusions

CMR Surgical will be under no liability for any defect arising from misuse, negligence, wilful damage, fair wear and tear, failure to correctly follow the Instructions for Use, unauthorised or accidental alteration of software, unauthorised alteration or repair of hardware.

Charges may be raised for any faults which, at the discretion of CMR Surgical, fall outside the warranty cover. When charges are necessary, replacement parts will be charged at the manufacturer's list prices and labour will be charged at the prevailing hourly rate.

This warranty also specifically excludes products that have been purchased or acquired through public auctions, whether online or otherwise.

THIS WARRANTY SHALL BE IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTIABILITY OR FITNESS FOR A PURPOSE.

Terms of Warranty

Applicable to Standard Warranty.

Due Diligence

In the event of a fault or malfunction, appropriately trained hospital staff should first attempt to (a.) perform a check of the cable connections being plugged in and/or being switched-on, (b.) perform practical checks using the Troubleshooting Guide provided in the Instructions for Use. Finally, it is recommended that at an appropriate time between clinical procedures, (c.) the set-up procedures be repeated following the step-by-step illustrated sections of the Instructions for Use to identify possible reasons.

Technical Support

If the problem persists, the customer should contact their Sales Representative or our Technical Support Team through the contacts provided in the Instructions for Use. If the fault or malfunction cannot be rectified by telephone assistance and expert troubleshooting by our Technical Support Team, CMR Surgical will take further steps to restore system functionality. This may include on-site repair or the installation of a Free-Loan system and collection of the original system for off-site repair.

Returns & Repair Procedure

In the event that a return becomes necessary, the following points must be adhered to:

Before any goods can be exchanged/returned, it is the responsibility of the customer to:

- Obtain return merchandise authorisation from CMR Surgical
- Ensure the system is decontaminated prior to return
- Provide a signed Decontamination Certificate with the system
- Provide contact details of the appropriate person(s) on headed paper

Our technicians will carefully inspect the goods to identify the cause of the fault or malfunction and assess its validity as a Warranty Repair. A decision will be made whether to (a.) repair and return the original system or (b.) issue a free replacement system.

In the event that a Free-Loan is provided to the customer, the customer must accept full responsibility for the use and storage of the Free-Loan system, including but not limited to undertaking appropriate electrical safety checks.

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Appendix A

Troubleshooting guide

This troubleshooting guide provides solutions to common problems that might occur during surgery, set-up and post-operative tasks.

If these solutions do not solve the problem, contact CMR Surgical technical support on:

Tel: +44 (0) 1223 750 975

If an alarm indicator occurs (such as an icon in Figure A.1 or a yellow light on a status halo or audio signals), refer to chapter 20 on alarms.

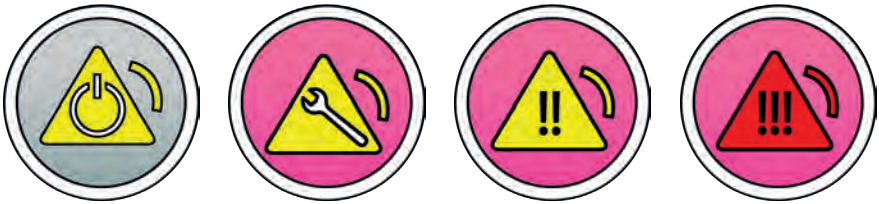


Figure A.1 Alarm icons

A.1 Surgeon console

A.1.1 The surgeon console screen has frozen during powering on

If the console screen freezes:

1. Power off the surgeon console using the switch on the surgeon console connection panel
2. Power on the surgeon console again

If the surgeon console still fails to turn on, contact CMR Surgical technical support

A.1.2 The surgeon console height or console screen height does not adjust

Check that:

- The surgeon console is powered on
- The surgeon console height and console screen height are not being adjusted at the same time
- The surgeon console or console screen has not reached its minimum or maximum height

A.1.3 There are no lights on the system

Check that:

- The surgeon console is connected to a mains power socket and the mains power socket is switched on (see section 7.1)
- The surgeon console is powered on (see section 8.1)

A.1.4 The console screen is not showing the endoscope feed

Check that:

- The console screen is switched on (see section 8.1)
- The console screen brightness is at a sufficient level
- The console screen is set to 2D or 3D mode and not a different input source (see section 13.3.1)
- The camera cable is connected to the visualisation bedside unit (see section 7.2.9)
- The camera cable is not damaged. If the camera cable is damaged, use an alternative camera head and call CMR Surgical Technical Support
- The video feed cable is connected to the surgeon console and to the visualisation bedside unit (see section 7.2.7)
- A short video feed cable is used if possible
- The video feed cable is not damaged. If the video feed cable is damaged, use a replacement cable
- The light source is on and set at sufficient brightness
- The light cable is connected to the light source and the endoscopic camera
- The light cable is not damaged
- The endoscope is properly attached to the camera head
- The console screen is not damaged. If the screen is damaged, call CMR Surgical Technical Support
- The camera head is not damaged. If the camera head is damaged, use an alternative camera head and call CMR Surgical Technical Support

A.1.5 The endoscope feed on the console screen is a strange colour

Check that:

- The auto white balance procedure has been done correctly. Repeat if necessary (see section 13.9)
- The console screen is brightness is at a sufficient level

A.1.6 The auxiliary screen is not showing the endoscope feed

Check that:

- The auxiliary screen is connected to the surgeon console (see section 7.1.4)
- A short auxiliary screen cable is used if possible
- The auxiliary screen is switched on and set to the correct input (consult the user manual of the auxiliary screen)
- The auxiliary screen is not damaged. If the screen is damaged, use an alternative screen
- The auxiliary screen cable is not damaged. If the auxiliary screen cable is damaged, use a replacement cable

A.1.7 The 3D display is uncomfortable to view

Check that:

- The surgeon is sitting central to the display
- The surgeon console is at the correct height (see section 13.1)
- The surgeon is using circular polarising 3D glasses
- The glasses are clean

If the 3D display is still uncomfortable to view, change the screen to 2D (see section 13.3.1).

A.1.8 Video recording will not start

Check that:

- The SD card is class 4 or above (class 4 or above is technically required, class 10 or above is recommended)
- The SD card has enough free space
- The write-protect lock switch on the left side of the SD card is moved up into the off position
- The SD card is in EXFAT format

Remove the SD card and follow steps 1–3 from section 13.10.1, with a new SD card if necessary.

A.2 Bedside unit

A.2.1 A bedside unit brake will not activate

Check that:

- The brake button is not released too early
- The space underneath the bedside unit is clear
- The floor underneath the bedside unit is level

If these checks do not solve the problem, connect to a powered on surgeon console. If the bedside unit is already connected to a powered on surgeon console, contact CMR Surgical technical support.

A.2.2 A bedside unit brake will not deactivate

Check that:

- The brake is activated (see section 12.2)
- The arm is in unlocked, locked or sleep mode
- The brake button is pressed hard enough
- The instrument or endoscope is fully retracted out of the port or detached from the arm

A.2.3 A bedside unit is unstable

Check that:

- The space underneath the bedside unit is clear
- The floor underneath the bedside unit is level

A.2.4 A bedside unit will not move

Check that:

- The brake is deactivated
- There is no obstacle in the way, such as a cable

A.2.5 A bedside unit is not powering on

See section A.3.1.

A.2.6 A bedside unit cable has become disconnected

- Connect the bedside unit cable to the correct socket in the cart connections panel, by pushing until you hear a click and the locking ring clicks into place

The bedside unit is supported by battery power when not connected to the surgeon console. An alarm occurs when the battery charge is low.

A.2.7 A bedside unit battery is low

If the bedside unit battery is low a medium-priority arm alarm occurs and the low battery indicator on the cart control panel flashes yellow (see section 10.4).

If the bedside unit battery is very low a high-priority arm alarm occurs, the low battery indicator on the cart control panel flashes red (see section 10.4) and the arm should be supported immediately.

- Connect the bedside unit to the surgeon console

A.2.8 A bedside unit cannot move over cables

If the cable is a bedside unit cable and the surgeon is not using an endoscopic camera or instrument attached to the bedside unit:

- Disconnect the cables and move the bedside unit

The bedside unit is supported by battery power when not connected to the surgeon console. An alarm occurs when the battery charge is low.

A.2.9 A bedside unit is repeating a sound that will not mute

See section A.3.10.

A.3 Arm

A.3.1 An arm is not waking up

Check that:

- The bedside unit is connected to the surgeon console (see section 7.2.3)
- The surgeon console is powered on
- Any daisy-chain of bedside units is complete
- The system is not stopped (if it is, press the resume button on the surgeon console)
- The sleep button is not released too early
- The arm is not the same colour as another arm already connected (see section 2.3.3)

A.3.2 An arm will not go to sleep

Check that:

- The arm is in either locked or unlocked mode
- There is no endoscopic camera or instrument attached
- The bedside unit drape has been removed (see section 22.6)
- The arm has not reached its maximum range of motion (see section A.3.9)
- The arm is not stopped (if it is, press the resume button on the cart control panel)
- The sleep button is not released too early

If the bedside unit has an alarm, see section 20.4.

A.3.3 An arm will not port-train

Check that:

- All the arm joints are bent and that the base is not vertical (see Figure 17.4)
- The wrist is not perpendicular to the base

In some positions, the arm cannot be successfully port-trained. Try moving the arm to a different position if an arm will not port-train

A.3.4 An arm height cannot be adjusted

Check that:

- The bedside unit is connected to the surgeon console
- The arm is in either unlocked or locked mode

A.3.5 An arm will not go into surgical mode

Check that:

- The arm is in either instrument adjust or instrument change mode
- The tip of the endoscope or instrument attached to the arm is inserted far enough into the patient cavity (approximately **5 cm**)

If the instrument is in either instrument adjust or instrument change and the instrument is far enough into the patient cavity and the arm still will not go into surgical mode:

1. Remove the instrument from the patient cavity
2. Long press the elbow button to enter unlocked mode
3. Repeat port-training

See also chapter 17 on port-training, which must be complete before entering instrument adjust or instrument change mode.

A.3.6 An arm will not move when manually pushed

Check that:

- The arm is not in locked mode
- The arm is not in sleep mode
- The arm is not in instrument change mode
- The arm is not stopped (if it is, press the resume button on the cart control panel)

For more information on arm modes, see chapter 5.

> In surgical mode, the arm can only be manually pushed from the elbow joint

If changing the arm mode does not solve the problem, the arm may have reached a limit of its movement. See section A.3.9.

A.3.7 An instrument arm does not move when controlled from the surgeon console

Check that:

- The visualisation arm is in surgical mode
- The hand controller has detected a hand
- The correct arm is engaged to the correct hand controller
- The system is not stopped (if it is, press a resume button)
- The arm has not detected an arm clash
- The visualisation arm has not detected an arm clash
- The arm height is appropriate for the movement that is required (see section 12.5 on arm height adjustment)
- The tip of the instrument attached to the arm is inserted far enough into the patient cavity (approximately **5 cm**)

If the above checks do not solve the problem, the arm may have reached a limit of its movement. See section A.3.9.

A.3.8 A visualisation arm does not move when controlled from the surgeon console

A hand controller can only move the endoscope if either an instrument arm or the visualisation arm is engaged to that hand controller.

Check that:

- The visualisation arm is in surgical mode
- The hand controller has detected a hand
- An instrument or visualisation arm is engaged to the correct hand controller
- The system is not stopped (if it is, press a resume button)
- The arm has not detected an arm clash
- The arm height is appropriate for the movement that is required (see section 12.5 on arm height adjustment)
- The tip of the endoscope is inserted far enough into the patient cavity (approximately **5 cm**)

If the above options do not solve the problem, the arm may have reached a limit of its range limit. See section A.3.9.

A.3.9 An arm stops after a short period of movement

If the bedside unit is also making a 'no' sound, see A.3.10. If the arm is stopping and the bedside unit is not making any sound, it is likely that the arm is reaching a limit of its movement.

To solve this problem:

- Move the arm in the opposite direction to the intended direction
- If this does not work, move the arm in any direction that is safe and will allow movement
- Move the arm to a position where the joints have more freedom of movement

Consider changing the arm height or the position of the bedside unit. The endoscope or instrument must be removed from the port before the arm height can be changed or the bedside unit brake deactivated.

A.3.10 An arm has limited movement and the bedside unit is making a repeated sound

The bedside unit repeats a 'no' sound if it has detected an arm clash (see section 6.4.2). If the bedside unit is connected to the surgeon console an arm clash icon will be shown on the HUD.

To resolve the arm clash:

- If the clash was from manual pushing, let go of the arm
- If the clash was from a collision, manually move the arm away from the object

If the above options do not solve the problem:

- Re port-train the affected arm

In some cases, the patient position can move slightly or insufflation can change or the bed position can change and place an increased pressure on the instrument which the arm reads as an arm clash. In this case, re port-train the arm to alleviate the pressure and ensure the correct fulcrum is being respected.

A.3.11 A drape cap will not detach from an arm

Check that:

- The drape cap insert has been removed

A.4 Instrument and endoscope

A.4.1 An instrument will not attach to the arm

Check that:

- The instrument is a valid Versius Instrument (see section 2.4 on Versius Instruments)
- The arm is an instrument arm and not a visualisation arm
- The arm is properly draped
- The instrument jaws are closed and the instrument is straight
- The tape from the drape cap insert has been removed

A.4.2 A camera head will not attach securely to the arm

Repeat steps 4 to 6 in section 14.2.

A.4.3 A HUD instrument icon is missing

Check that:

- The bedside unit is connected to the surgeon console
- Any daisy-chain of bedside units is complete
- The console screen is working (see section A.1.4)

If the instrument icon turns into a no-instrument icon on the HUD mid-surgery:

1. Remove the instrument from the patient cavity
2. Detach the instrument from the arm
3. Check that all electrosurgery cables are tethered securely to the correct arms as loosely tethered cables can cause interference with the HUD
4. Re-attach the instrument to the arm

If the instrument icon still does not appear, the instrument is faulty. Use an alternative instrument.

A.4.4 An instrument will not respond to the hand controller

See section A.3.7.

A.4.5 The endoscope will not respond to the hand controller

See section A.3.8.

A.4.6 The endoscope does not pan or zoom as expected

Check that:

- The correct endoscope angle has been selected (see section 13.8.5 on the HUD menu)
- All bedside unit orientations are set correctly

A.4.7 An endoscope or instrument cannot be fully removed from the port

Check that:

- The arm has not reached a limit of its movement
- The instrument jaws are closed
- The instrument wrist is straight

Use instrument adjust mode to manually move the arm to a position where it is possible to fully extract the endoscope or instrument from the port.

A.4.8 An instrument will not straighten in response to the hand controller

Check that:

- The hand controller has detected a hand
- The correct arm is engaged to the correct hand controller
- The system is not stopped (if it is, press a resume button)
- The tip of the instrument is inserted far enough into the patient cavity (approximately **5 cm**)

If the above options do not solve the problem, remove the instrument from the patient (see chapter 19), detach the instrument from the arm (see chapter 15) and try another instrument.

A.4.9 Instrument jaws will not respond to the hand controller

Check that:

- The hand controller has detected a hand
- The correct arm is engaged to the correct hand controller
- The system is not stopped (if it is, press a resume button)
- The tip of the instrument is inserted far enough into the patient cavity (approximately **5 cm**)
- The instrument jaws are not locked closed: push the jaw control with the index finger to its furthest position and then release the jaw control

If the above options do not solve the problem, remove the instrument from the patient (see chapter 19), detach the instrument from the arm (see chapter 15) and try another instrument.

A.4.10 An instrument is moving in an unexpected direction

Check that:

- The correct endoscope angle has been selected (see section 13.8.5 on the HUD menu)
- All bedside unit orientations have been set correctly

A.4.11 An instrument moves faster or slower than expected

Check that the hand scaling has been set appropriately (see section 13.8.6 on the HUD menu).

- If the instruments are moving faster than expected, reduce the hand scaling
- If the instruments are moving slower than expected, increase the hand scaling

A.4.12 An instrument is damaged or faulty

Do not use the instrument. Replace with an equivalent functioning instrument and contact CMR Surgical technical support.

A.5 Hand controllers

A.5.1 The thumbstick will not move the endoscope

See section A.3.8.

A.5.2 The clutch button will not engage an arm

Check that:

- The arm is in surgical mode
- The bedside unit is connected to the surgeon console
- The visualisation bedside unit is also connected to the surgeon console (if engaging an instrument arm)
- Any daisy-chain of bedside units is complete
- The bedside unit battery is not very low
- The system is not stopped (if it is, press a resume button)
- The visualisation arm has not detected an arm clash
- The endoscopic camera is attached to the visualisation arm
- The orientation is set on the visualisation bedside unit
- A valid Versius instrument is attached (if engaging an instrument arm)
- The tip of the endoscope or instrument attached to the arm is inserted far enough into the patient cavity (approximately **5 cm**)

A.5.3 The electrosurgery button does not activate electrosurgery

Check that:

- The hand controller has detected a hand
- The correct instrument arm is engaged to the correct hand controller
- An electrosurgery instrument is attached to the correct arm
- Electrosurgery cables connect the instrument to the bedside unit and the bedside unit to the electrosurgery unit (see the Versius Instrument and Accessories Manual [REF 70050])
- The electrosurgery unit is powered on
- The electrosurgery unit settings are appropriate
- The electrosurgery button is being held down
- The system is not stopped (if it is, press a resume button)

A.6 Reporting adverse events

Report any adverse events that occur using the Versius Surgical System to CMR Surgical.

Contact CMR Surgical Customer Services:

Tel: +44 (0) 1223 750 975

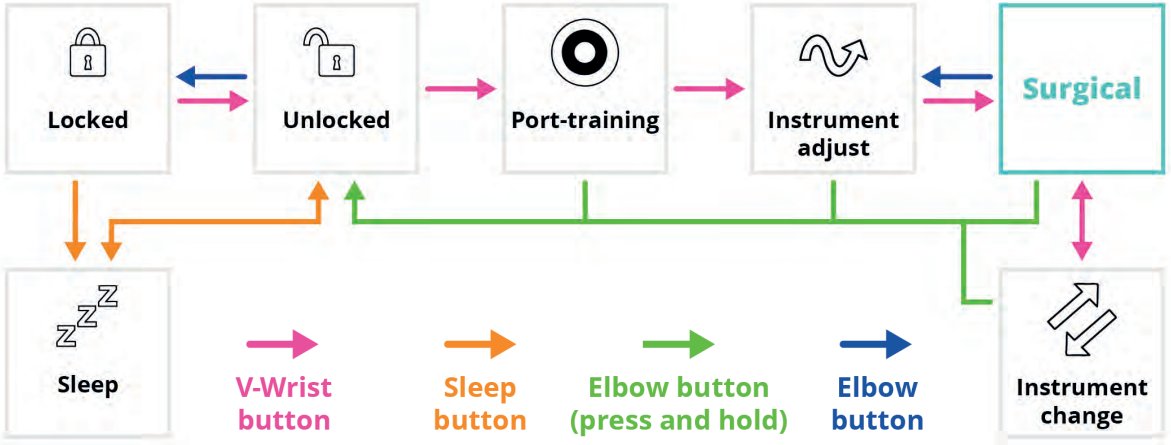
Appendix B

Arm mode map

Arm mode map

The arm mode map is a resource to help the bedside team navigate through the arm modes of the Versius Surgical System. Each coloured arrow represents a button press on a Versius Arm. Follow the arrows, press the relevant buttons and complete any necessary tasks to navigate to the arm mode required. See chapter 5 on arm modes for further information.

Arm mode map



Console alarm

Convert to manual surgery

Arm alarms

Quickly replace bedside unit

Recover or replace bedside unit

Appendix C

Start-up checklist

Start-up checklist

Use this start-up checklist to make quick checks that the Versius Surgical System is ready for surgery. The start-up checklist is also found on the back cover of this user manual and can be marked with non-permanent marker pen to ‘check off’ each task.

Start-up checklist

Before patient enters the operating theatre

- ☐ Have all bedside units been restarted within the last 24 hours?
- ☐ Has the surgeon console been restarted within the last 24 hours?
- ☐ Do all bedside units have adequate service life remaining?
- ☐ Does the surgeon console have adequate service life remaining?
- ☐ Are the bedside units adequately charged?
- ☐ Does the surgeon have a chair with a stable base available at the surgeon console?
- ☐ Have the arm rests on the surgeon console been fully extended and locked in position?
- ☐ Have the correct drape lengths been selected based on patient positioning and cart height?

Before surgery

- ☐ Is the orientation of all bedside units set in the same direction?
- ☐ Have the electrosurgery cables been connected and the appropriate ESU settings checked?
- ☐ Are the drape cap inserts correctly fitted on the distal end of instrument arms?
- ☐ Can all cables be easily moved in case of emergency?
- ☐ Is the auxiliary screen visible by every member of the team?
- ☐ Has the correct arm height been set before proceeding to port-training?
- ☐ Has the correct endoscope angle been selected on the HUD menu?
- ☐ Has the surgeon set the required hand scaling option?

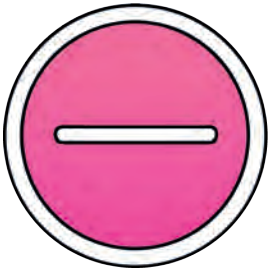
After surgery

- ☐ Has “End of surgery” been selected on the HUD menu?
- ☐ Has the bedside unit been braked to expose all surfaces of the cart for cleaning?
- ☐ Have instruments at the end of their life been disposed of appropriately?
- ☐ Have hand controllers been docked correctly ready for storage?
- ☐ Have all arms been put to sleep before moving to storage?
- ☐ Has the surgeon console height been lowered before moving to storage?

Appendix D

Icons

Instrument icons

No instrument	
Instrument example: Fenestrated grasper	
Electrosurgery instrument example: Bipolar Maryland grasper	

Endoscopic camera icons

Endoscopic camera	
Manual endoscopic camera	

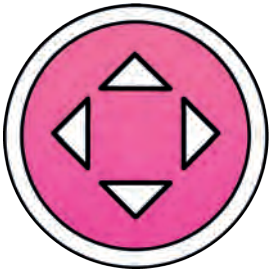
Arm mode icons

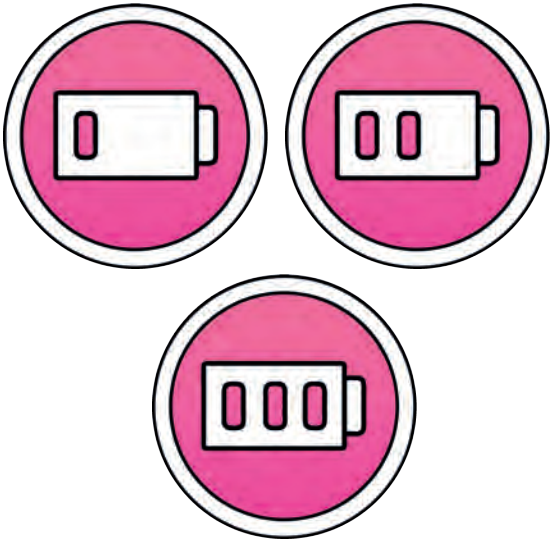
Sleep mode	

Unlocked mode	
Locked mode	
Port-training mode	
Instrument adjust mode	

Instrument change mode	

Bedside unit status icons

Bedside unit brake	
Bedside unit orientation	

Bedside unit battery charging	
Arm clash	
Wind-up	

Instrument out of life	
Instrument not recognised	
Start-up	

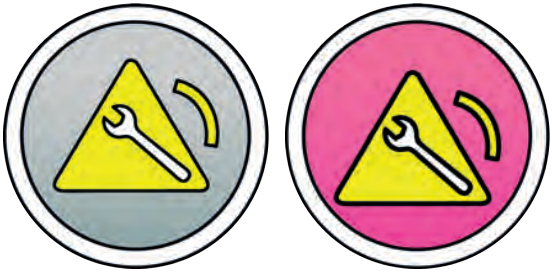
System icons

Auto white balance	

No hand detected	
Menu	
Stop	
Start-up	

HUD cursor	

Alarm icons

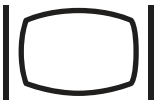
Restart required	
Surgeon console and bedside unit service required	
Console alarm	

Medium-priority arm alarm	
High-priority arm alarm	
Console alarm sound muted	

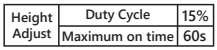
Appendix E

Symbols

Surgeon console: located on the connection panel

Symbol	Meaning	Location
	Hospital network socket	Surgeon console connection panel
 48V 22A	Bedside unit power requirements	Surgeon console connection panel
 100-240V, 50-60Hz, 20-10A	Surgeon console power requirements	Surgeon console connection panel
 T 10A H 250V (220-240V) T 20A H 250V (100-120V)	Fuse rating of the surgeon console	Surgeon console connection panel
	Auxiliary screen socket	Surgeon console connection panel
	Video-in socket	Surgeon console connection panel

	CMR Surgical logo	Surgeon console connection panel
	Versius Surgical System logo	Surgeon console connection panel
	The manufacturer	Surgeon console connection panel
	Date of manufacture	Surgeon console connection panel
REF	The manufacturer's catalogue number	Surgeon console connection panel
SN	The manufacturer's serial number	Surgeon console connection panel

	Height adjust mechanism: maximum on/off duty cycle (15%); maximum on time (60 seconds)	Surgeon console connection panel
	Mass including safe working load	Surgeon console connection panel
	UL Certification Mark	Surgeon console connection panel
	Consult the instructions for use	Surgeon console connection panel
	CE Mark	Surgeon console connection panel

	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005	Surgeon console connection panel

Surgeon console: located on the armrests

Symbol	Meaning	Location
	Console screen height adjustment button (up)	Surgeon console armrest
	Console screen height adjustment button (down)	Surgeon console armrest

	Surgeon console height adjustment button (up)	Surgeon console armrest
	Surgeon console height adjustment button (down)	Surgeon console armrest
	Stop button	Surgeon console armrest
	Resume button	Surgeon console armrest

Surgeon console: located on the console screen

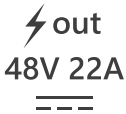
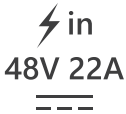
Symbol	Meaning	Location
	Read the user manual before operating the system	On console screen

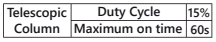
Surgeon console: located below the console screen

Symbol	Meaning	Location
	Alarm mute button	Below console screen
	Video record button	Below console screen

Visualisation bedside unit: located on the connection panel

Symbol	Meaning	Location
	Camera cable socket	Visualisation bedside unit connection panel
	Type BF Applied Part	Visualisation bedside unit connection panel

	Video-out socket	Visualisation bedside unit connection panel
	Power-out socket	Visualisation bedside unit connection panel
	Power-in socket	Visualisation bedside unit connection panel
	CMR Surgical logo	Visualisation bedside unit connection panel
	Versius Surgical System logo	Visualisation bedside unit connection panel
	The manufacturer	Visualisation bedside unit connection panel

	UL Certification Mark	Visualisation bedside unit connection panel
	Consult the instructions for use	Visualisation bedside unit connection panel
	CE Mark	Visualisation bedside unit connection panel
	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005	Visualisation bedside unit connection panel
	Height adjust mechanism: maximum on/off duty cycle (15%); maximum on time (60 seconds)	Visualisation bedside unit connection panel

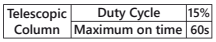
	Mass including safe working load	Visualisation bedside unit connection panel
	Date of manufacture	Visualisation bedside unit connection panel
	The manufacturer's catalogue number	Visualisation bedside unit connection panel
	The manufacturer's serial number	Visualisation bedside unit connection panel

Instrument bedside unit: located on the connection panel

Symbol	Meaning	Location
Monopolar 	Monopolar instrument cable socket + Monopolar bedside unit cable socket	Instrument bedside unit connection panel

Bipolar 	Bipolar instrument cable socket + Bipolar bedside unit cable socket	Instrument bedside unit connection panel
	Type BF Applied Part	Instrument bedside unit connection panel
out 48V 22A	Power-out socket	Instrument bedside unit connection panel
in 48V 22A	Power-in socket	Instrument bedside unit connection panel
CMR	CMR Surgical logo	Instrument bedside unit connection panel
versius®	Versius Surgical System logo	Instrument bedside unit connection panel

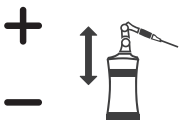
	The manufacturer	Instrument bedside unit connection panel
	UL Certification Mark	Instrument bedside unit connection panel
	Consult the instructions for use	Instrument bedside unit connection panel
	CE Mark	Instrument bedside unit connection panel
	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005	Instrument bedside unit connection panel

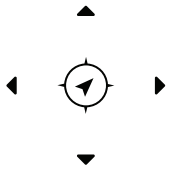
	Height adjust mechanism: maximum on/off duty cycle (15%); maximum on time (60 seconds)	Instrument bedside unit connection panel
	Mass including safe working load	Instrument bedside unit connection panel
	Date of manufacture	Instrument bedside unit connection panel
	The manufacturer's catalogue number	Instrument bedside unit connection panel
	The manufacturer's serial number	Instrument bedside unit connection panel

Bedside unit: located on the cart

Symbol	Meaning	Location
	Bedside unit brake button	Cart, below the control panel
	Warning: hand trap	Cart
	Do not push on the bedside unit column when the arm height is raised (see Figure 1.4 in Chapter 1)	Bedside unit column

Bedside unit: located on the control panel

Symbol	Meaning	Location
	Arm height adjustment buttons: up (+) and down (–)	Cart control panel

	Sleep button	Cart control panel
	Orientation buttons	Cart control panel
	Low battery indicator	Cart control panel
	Stop button	Cart control panel
	Resume button	Cart control panel
	Alarm mute button	Cart control panel

	Warning: hand trap	Cart control panel
	Do not push on the arm (see Figure 1.4 in Chapter 1)	Cart control panel
	Read the user manual before operating the system	Cart control panel

Cables

Symbol	Meaning	Location
REF	The manufacturer's catalogue number	Cable packaging
LOT	The manufacturer's batch code or lot number	Cable packaging

	Date of manufacture	Cable packaging
	The product needs to be protected from heat	Cable packaging
	Consult the instructions for use	Cable packaging
	The product needs to be protected from moisture	Cable packaging
	CE Mark	Cable packaging
	The manufacturer	Cable packaging

	Three items in package	Cable packaging
	CMR Surgical logo	Cable packaging
	Versius Surgical System logo	Cable packaging
	The product is supplied non-sterile	Cable packaging
	General caution	Cable packaging
	Warning: risk of burns	Cable packaging

	Warning: risk of interference with cardiac pacemaker	Cable packaging
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	Electrosurgery cable label

Other symbols and labels

Symbol	Meaning	Location
	Type B Applied Part	
	Do not reuse. Single-use only	Drape packaging
	Indicates the temperature limits to which the product can be safely exposed	Drape packaging

	Indicates the range of humidity to which the product can be safely exposed	Drape packaging
	Indicates a product that should not be used if the package has been damaged or opened	Drape packaging
	Product is latex-free	Drape packaging
	Product sterilised using ethylene oxide	Drape packaging
Rx ONLY	Prescription only	Drape packaging
	Indicates the date after which the product is not to be used	Drape packaging

EC REP	Authorised representative in the EU	User manual inside front cover

Appendix F

Cables

Surgeon console power cable	
Sterilise before use?	No
Connects:	Surgeon console connection panel
To:	Mains power socket

Network cable	
Sterilise before use?	No
Connects:	Surgeon console connection panel
To:	Hospital network socket

Auxiliary screen cable	
short and long cables available	
Sterilise before use?	No
Connects:	Auxiliary screen
To:	Surgeon console connection panel

Video feed cable	
short and long cables available	
Sterilise before use?	No
Connects:	Visualisation bedside unit
To:	Surgeon console connection panel

Bedside unit cable	
short and long cables available	
Sterilise before use?	No
Connects:	Bedside unit
To:	Surgeon console connection panel or another bedside unit

Camera cable	
Sterilise before use?	No (draped)
Connects:	Camera head
To:	Visualisation bedside unit

Light cable	
Sterilise before use?	Yes
Connects:	Endoscope
To:	Light source

Monopolar bedside unit cable	
Sterilise before use?	No
Connects:	Bedside unit
To:	Electrosurgery unit

Bipolar bedside unit cable	
Sterilise before use?	No
Connects:	Bedside unit
To:	Electrosurgery unit

Monopolar instrument cable	
Sterilise before use?	Yes
Connects:	Bedside unit
To:	Electrosurgery instrument

Bipolar instrument cable	
Sterilise before use?	Yes
Connects:	Bedside unit
To:	Electrosurgery instrument

Appendix G

Frequently used functions

Frequently used functions

Deactivate the brake on a cart
Activate the brake on a cart
Place hands into the bedside unit drape folds as indicated by the labels
Place a drape on a robotic arm
Unfurl the sleeve of a drape below the elbow (but before the arm base)
Drape the endoscope
Drape the camera head
Attach the endoscopic camera to the arm
Insert the endoscope into the port ready for port-training
Port-train the endoscope
Move the endoscope to the operative area in instrument adjust mode
Put a visualisation arm into surgical mode
Unpack the instrument bedside unit drape and expose the sterile drape to a sterile person
Place hands into the bedside unit drape folds as indicated by the labels
Fit the drape cap to the instrument/visualisation arm
Engage the locking ring on an instrument arm drape cap
Remove the red tape from a drape cap insert
Unfurl an instrument arm drape sleeve down an arm
Remove the yellow tape on the instrument arm drape

Pull down the cart drape to cover the cart either from inside or using the cuff
Locate the cart drape elastic at the top of the cart column
Tether a drape in place on an arm
Remove the green tape from the cart drape
Press the elbow button to lock an arm before moving to the operating table
Deactivate the cart brake for cart positioning
Activate the cart brake for cart positioning
Set and check relative cart orientation
Adjust the arm height for arm set-up
Tether an electrosurgery instrument cable down on an arm
Disengage an instrument
Attach a new instrument
Press the wrist button to unlock the arms
Insert an instrument into the port
Switch an arm to port-training mode by locating and pressing the wrist button
Port-train an arm by moving the V-Wrist in an arc back and forth
Advance an instrument into the cavity using the arm so that the instrument is visible to the surgeon
Engage an instrument
Actuate jaw control
Actuate an articulated instrument (instrument pitch, roll, yaw)
Select electrosurgery mode (CUT/COAG)

Actuate electrosurgery
Select an alternative instrument/arm
Disengage an instrument from the hand controllers
Surgeon clears the instrument jaws of anatomy
Surgeon straightens and closes the instrument jaws manually
Surgeon straightens and closes the instrument jaws using the thumbstick
Use one hand to retract an instrument by sliding along the virtual Z rail. Use the other hand to hold the port
Remove an instrument by squeezing together the latches on the instrument using one hand
Attach a new instrument
Slide a new instrument along the virtual Z rail until it is in view of the endoscope
Press the wrist button to return an arm from instrument change mode to surgical mode
User uses instrument adjust mode to retract an instrument
User moves to instrument adjust mode by pressing the elbow button
Use one hand to retract an instrument by sliding back through the port. Use the other hand to hold the port
User reinserts an instrument into the port and advances to the surgical site in instrument adjust mode under visualisation
Press the wrist button to return an arm from instrument adjust mode to surgical mode (system returns to surgical mode)
Long press the elbow button to move to fully compliant
Press the elbow button to lock the arm

Glossary of Terms

A	
Alarm icon	HUD icon showing an alarm state of an arm or the system
Alarm indicator	Audible or visual indicator of an alarm: a sound, an alarm icon or a colour change of the status halo on the surgeon console or a bedside unit
Arm	Robotic arm that is mounted on a cart to form a mobile bedside unit, and holds either an instrument (instrument arm) or endoscopic camera (visualisation arm)
Arm alarm	An alarm coming from one bedside unit. The affected arm will lock but the system will remain operational. An arm alarm may be a medium-priority or high-priority alarm
Arm clash	Event where the arm detects it is being pushed too hard, by a user pushing or by the arm colliding with an object
Arm colour identifier	Band of coloured LEDs used to identify the arm and match it to the corresponding HUD icons
Arm drape	Drape placed around an instrument arm (instrument arm drape) or visualisation arm (visualisation arm drape) to create a sterile barrier
Arm mode	Status of an arm that determines how users can move the arm. Different modes are used throughout set-up, surgery and post-operative tasks
Arm mode icon	HUD icon showing arm mode
Armrest	Part of the surgeon console where the surgeon places their arms. The armrests are retracted for storage and extended for surgery

Auto white balance button	Button on the camera head that auto white balances the endoscopic camera when pressed
Auxiliary screen	Screen connected to the surgeon console that shows a replica of the console screen for the surgical team to view (auxiliary screen not supplied with the Versius Surgical System)
Auxiliary screen cable	Cable that connects the surgeon console to the auxiliary screen
Auxiliary screen socket	Socket on the surgeon console connection panel for connecting the auxiliary screen cable
B	
Base	Arm joint located closest to where the arm joins the cart
Bedside unit	A robotic arm mounted on a cart, that holds either an instrument (instrument bedside unit) or endoscopic camera (visualisation bedside unit)
Bedside unit brake	Brake for securing the bedside unit in position and providing stability
Bedside unit brake button	Button on the bedside unit that activates and deactivates the bedside unit brake
Bedside unit cable	Cable that connects a bedside unit to either the surgeon console or another bedside unit
Bedside unit column	Section between the cart and the base of the arm that can move vertically to change the arm height
Bedside unit connection panel	Panel of sockets on the bedside unit for connecting the bedside unit cable and either electrosurgery cables (instrument bedside unit) or the camera cable and video feed cable (visualisation bedside unit)

Bedside unit drape	Consists of two separate drapes (See Arm drape and Cart drape) that are connected using coloured tape when packaged
Bedside unit orientation pad	Group of four buttons for setting the orientation of a bedside unit, located on the cart control panel
Bedside unit status icon	HUD icon indicating the bedside unit status
Bipolar bedside unit cable	Cable that connects an instrument bedside unit to an electrosurgery unit
Bipolar instrument cable	Cable that connects a bipolar instrument to an instrument bedside unit
C	
Camera cable	Cable that connects the camera head to the visualisation bedside unit
Camera head	Housing for the electronics in the endoscopic camera, providing mounting for the endoscope
Camera head drape	Drape placed around a camera head, a camera cable and the proximal end of the endoscope to create a sterile barrier
Capacitive coupling	When electric current is passed from an activated electrosurgery instrument to another material (for example tissue, another surgical instrument, cable or metal part) without the activated electrosurgery instrument directly touching the material
Cart	The lower part of a bedside unit that supports the arm

Cart control panel	Panel on the top of a cart containing a low battery indicator and buttons for arm height adjustment, orientation, sleep mode, alarm mute, stop and resume
Cart drape	Drape placed around a cart to create a sterile barrier
Clutch button	Button located on the hand controller, used to engage and disengage an arm and to make selections on the HUD
Console alarm	An alarm coming from the surgeon console, affecting use of the entire system. All console alarms are medium-priority alarms
Console screen	Screen on the surgeon console showing in 3D (or optionally 2D) the endoscope video feed overlaid by the HUD
D	
Disengaged arm	Arm that is not linked to a hand controller, so that the surgeon must select and engage it before controlling the instrument attached to it
Disposal	Removal of a system component out of circulation. For example when an instrument has been dropped, damaged or reached its maximum number of uses
Drape cap	A rigid plastic part of an arm drape, creating a sterile barrier between an arm and an instrument (instrument arm drape cap) or an arm and a camera head drape (visualisation arm drape cap)
Drape cap insert	An insert that fits into the drape cap to create a sterile barrier between the instrument fins and the instrument arm

Drape cap wings	Wings on the drape cap that slot over ridges on the distal end of the arm when attaching the drape cap to the arm
Drape groove	A ridge on the top of the cart that the elasticated collar on the drape fits into
E	
Elasticated collar	Elasticated section of the drape that fits into the drape groove
Elasticated neck	Stretchy section of material at the end of a camera head drape
Elbow	Arm joint between the V-Wrist and the base
Elbow button	Button on the elbow of an arm used to change arm mode
Electrosurgery button	Button on the hand controller used to activate electrosurgery
Electrosurgery cable	One of four types of electrosurgery cables, for connecting an electrosurgery instrument to the bedside unit (monopolar or bipolar instrument cable) and the bedside unit to the electrosurgery unit (monopolar or bipolar bedside unit cable)
Electrosurgery instrument	Surgical instrument compatible with a Versius Arm and equipped with a cable connection for electrosurgery
Electrosurgery mode indicator	Light on the hand controller that shows the mode of electrosurgery selected: blue for coagulation and yellow for cut
Electrosurgery socket	One of four sockets on the instrument bedside unit connection panel, for connecting an electrosurgery cable

Electrosurgery unit (ESU)	Generator of radio frequency current for electrosurgery (ESU not supplied with the Versius Surgical System)
Endoscope	Removable shaft of the endoscopic camera, containing optics for viewing a surgical site
Endoscopic camera	Camera for viewing a surgical site, consisting of a camera head and a connected endoscope
Engaged arm	Arm that is linked to a hand controller so that its endoscope or instrument can be controlled by the surgeon
Ergonomic position	Seated or standing position of the surgeon with a straight back, feet flat on the floor and eyes in line with the centre of the console screen
ESU	See electrosurgery unit
F	
Flourish	Sound that the surgeon console plays at power-on
Fulcrum	The point which instruments pivot around, as set during port-training. For example, the fulcrum is in the abdominal wall during general, urologic and gynaecological surgical procedures
H	
Hand controller	Controller on the surgeon console that is held by the surgeon and used to control the instruments and endoscopic camera, and to navigate the HUD
Hand scaling	Scaling factor between the distance the hand controller moves and the distance the instrument moves

Hand trap	Area on a Versius Bedside Unit where hands may get caught when the arm is in motion or the brake is deactivating
Head-up display (HUD)	Interactive display with icons and menu that overlays the endoscope video feed on the console screen and the auxiliary screen, and provides information about the status of the system
High-priority arm alarm	Alarm condition where the user must immediately support the affected arm, indicated by a red flashing icon on the HUD, red flashing status halo on the bedside unit and an alarm sound
HUD	See head-up display
HUD icon	Icon on the HUD providing visual feedback to users on the state of the system
I	
Icon group	Collection of icons relating to the same arm, with backgrounds coloured to match the arm colour identifier
Instrument	Versius instrument that is attached to an instrument arm for use during surgery
Instrument adjust mode	Arm mode where the user can freely move the arm manually and the arm will respect the fulcrum, used to adjust the position of an endoscope or instrument inside the patient
Instrument arm	Arm that can hold an instrument
Instrument arm drape	Drape placed around an instrument arm to create a sterile barrier, secured by an instrument arm drape cap

Instrument bank	The central top section of the HUD, where icons appear when an instrument bedside unit is first connected to the system
Instrument bedside unit	Bedside unit that can hold an instrument, consisting of an instrument arm mounted on a cart
Instrument change mode	Arm mode used for changing an instrument or cleaning an endoscope, where movement of the arm is restricted to retracting and advancing an instrument or endoscope along its axis. The system will not permit reinserting the instrument or endoscope further into the cavity than when instrument change mode was entered
Instrument icons	Icon indicating which instrument is attached to an instrument arm, with a background coloured to match the arm colour identifier
Instrument wrist	Part of an instrument that allows rotating for better access and control within the patient cavity
J	
Jaw control	Lever on the hand controller used to open and close the instrument jaws
Jaws	Parts of an instrument that can open and close
Joint	Motorised part of an arm. The three key joints are the base, elbow and V-Wrist
L	
Leakage current	Any unwanted electric current that may flow through a patient or user

Light cable	Cable that connects an endoscope to the light source
Light source	Unit that supplies light to the endoscopic camera
Locked mode	Arm mode where the arm is locked in position and cannot be moved except to rotate the distal end. The arm should be in locked mode when the bedside unit is moved around the operating theatre
Locking ring	Ring on the drape cap that is pushed towards the V-Wrist to secure the drape cap into place
Low battery indicator	Light on the cart control panel that lights when the battery is low or very low
M	
Medium-priority alarm	Alarm condition indicated by a flashing icon on the HUD, flashing yellow status halo and an alarm sound. There are two kinds of medium-priority alarms: Arm alarm: the affected arm will lock, but the system will remain operational Console alarm: the system will no longer be operational
Monopolar bedside unit cable	Cable that connects a bedside unit to an electrosurgery unit
Monopolar instrument cable	Cable that connects a monopolar instrument to a bedside unit
Mute button	Button below the surgeon console screen and on each cart control panel that when pressed silences an alarm sound temporarily (for two minutes). Pressing the button again re-enables the alarm sound

N	
'No' sound	Sound indicating an unexpected event, such as an arm clash, a bedside unit cable becoming disconnected during surgery or an attempt to enter port-training mode with the bedside unit brake deactivated
P	
Port-training mode	Arm mode where the system learns where the fulcrum should be. The arm must be port-trained before entering surgical mode
Port-training success sound	Sound played by the bedside unit when port-training is complete
Power-in socket	Socket on the bedside unit connection panel, for connecting a bedside unit cable
Power-out socket	Socket on the surgeon console and the bedside unit connection panels, for connecting a bedside unit cable
Power switch	Switch on the surgeon console connection panel for turning on or off the mains power to the system
R	
Reprocessing	Process of preparing an instrument or accessory for use. The process ensures the accessories are sterile before each use. Instruments and sterile cables must be reprocessed before first use and after each subsequent use

Reprocessing instructions	Separate set of instructions provided with the Versius Surgical System that instructs users on how to reprocess the instruments before first use and after each use (REF 70100). Refer to instructions provided with the sterile cables and endoscope for reprocessing instructions on these accessories
Resume button	Button used to continue surgery after the system has been stopped. It is located on the right armrest of the surgeon console and on the cart control panel. The arms will return to the state they were in when the system was stopped
S	
SD card slot	Slot for inserting an SD card to record the 2D video from the 3D endoscope video feed, located below the console screen
Sleep button	Button on the cart control panel that is held down to wake up an arm or to put it into sleep mode
Sleep mode	Arm mode where the arm is locked in its folded position and cannot be moved, used for storage and transport
Status halo	Ring of lights below the console screen and around the arm base. The light colour indicates either normal (green) or alarm states (yellow or red)
Stop button	Button used to stop the system. The button is located on the right armrest of the surgeon console and on all cart control panels

Surgeon console	Console used by the surgeon to control the instruments and endoscopic camera which also houses electronics and provides power to the bedside units
Surgeon console connection panel	Panel on the surgeon console for connecting cables for power, video feed and the hospital network
Surgeon console power cable	Cable that connects the surgeon console to hospital mains power
Surgeon console power socket	Black socket on the surgeon console connection panel for connecting the surgeon console power cable
Surgical mode	Arm mode where the surgeon can use the hand controllers to control the instrument (instrument arm) or endoscopic camera (visualisation arm)
System	See Versius Surgical System
System icon	Icon indicating the state of the system
T	
Thumbstick	Part of the hand controller used to move the endoscope and to navigate the HUD
Tip	End of the instrument or endoscope furthest from the part that attaches to the bedside unit or camera head
U	
Unlocked mode	Arm mode where the arm can be moved freely, used for manually positioning the arm

V	
Versius	See Versius Surgical System
Versius Surgical System	Connected system of bedside units, surgeon console, endoscopic camera, instruments, drapes and cables
Video feed cable	Cable that carries the endoscope video feed from the visualisation bedside unit to the surgeon console
Video-in socket	Socket on the surgeon console for connecting a video feed cable, carrying the endoscope video feed from the visualisation bedside unit
Video-out socket	Socket for output of the endoscope video feed, located on the visualisation bedside unit and on the surgeon console (from the visualisation bedside unit to the surgeon console and from the surgeon console to the auxiliary screen)
Video record button	Button below the console screen for starting and stopping the recording of 2D endoscope video feed onto an SD card
Visualisation arm	Arm that can hold an endoscopic camera
Visualisation arm drape	Drape placed around a visualisation arm to create a sterile barrier, secured by a visualisation arm drape cap
Visualisation bedside unit	Bedside unit that can hold an endoscopic camera, consisting of a visualisation arm mounted on a cart
V-Wrist	The proprietary joint near the distal end of a Versius Arm (closest to the drape cap attachment point)

V-Wrist button	Any of three identical buttons on the V-Wrist, used to change arm mode
W	
Warning	Indicates situations that could result in injury to the patient or user. For safe use of the Versius Surgical System, users should follow instructions highlighted by warning symbols. Warnings are located in chapter 1 and at the start of each subsequent chapter
Wind-up	Limit of rotation of the instrument wrist, where the instrument must be unwound before continuing
Y	
'Yes' sound	Sound indicating a change of arm mode

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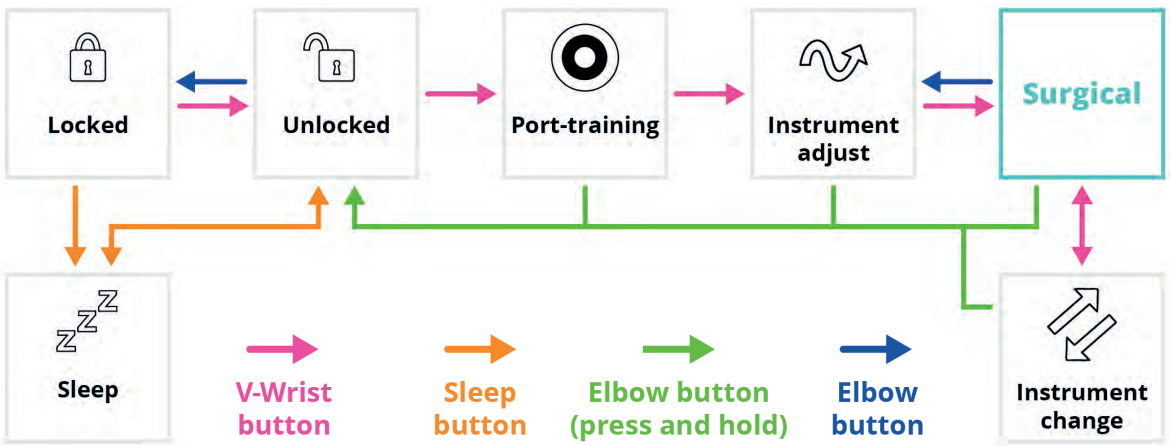
Arm mode map



Console alarm

Convert to manual surgery

Arm alarms

Quickly replace bedside unit

Recover or replace bedside unit

Start-up checklist

Before patient enters the operating theatre

- ☐ Have all bedside units been restarted within the last 24 hours?
- ☐ Has the surgeon console been restarted within the last 24 hours?
- ☐ Do all bedside units have adequate service life remaining?
- ☐ Does the surgeon console have adequate service life remaining?
- ☐ Are the bedside units adequately charged?
- ☐ Does the surgeon have a chair with a stable base available at the surgeon console?
- ☐ Have the arm rests on the surgeon console been fully extended and locked in position?
- ☐ Have the correct drape lengths been selected based on patient positioning and cart height?

Before surgery

- ☐ Is the orientation of all bedside units set in the same direction?
- ☐ Have the electrosurgery cables been connected and the appropriate ESU settings checked?
- ☐ Are the drape cap inserts correctly fitted on the distal end of instrument arms?
- ☐ Can all cables be easily moved in case of emergency?
- ☐ Is the auxiliary screen visible by every member of the team?
- ☐ Has the correct arm height been set before proceeding to port-training?
- ☐ Has the correct endoscope angle been selected on the HUD menu?
- ☐ Has the surgeon set the required hand scaling option?

After surgery

- ☐ Has “End of surgery” been selected on the HUD menu?
- ☐ Has the bedside unit been braked to expose all surfaces of the cart for cleaning?
- ☐ Have instruments at the end of their life been disposed of appropriately?
- ☐ Have hand controllers been docked correctly ready for storage?
- ☐ Have all arms been put to sleep before moving to storage?
- ☐ Has the surgeon console height been lowered before moving to storage?

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Technical support

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