SENSEI®

Instructions for Use

Model:

LP05-01 (Tethered Probe)

LP06-01 (Control Unit)

PROFESSIONAL USE ONLY

Further information available at: www.lightpointmedical.com

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CE 1282

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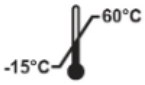
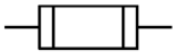
1. DEFINITIONS

This section defines key terms and symbols used in the Instructions for Use (IFU).

Key Terms/Symbol	Definition
Applied Part	The part of a piece of medical equipment that, in normal use, necessarily comes into physical contact with the patient to enable the medical electrical equipment or system to perform its function.
Autoclave	A strong heated container used for sterilisation and other processes using high pressures and temperatures.
Caution	Specific information provided to the user to prevent the misuse of the device which may cause it to malfunction or produce erroneous readings.
Cobalt-57 sealed radiation source	Specific radiation source required in order to conduct the SENSEI® probe check prior to clinical use.
Alive Signal	This is a test mechanism that checks the signal chain during routine use. The result is an audible / visible confidence signal that the system is functioning normally.
Control Unit	Control Unit enabling the use of the Tethered Probe.
Count Rate	The number of valid scintillation events in a predefined time period.
cps	Counts per second.
EMC	Electromagnetic Compatibility.
FWHM	Full Width at Half Maximum.
HCP	Healthcare Professional.
IFU	Instructions for Use.
IP	Ingress Protection.
Probe check	A procedure performed prior to the clinical use of SENSEI® to check the device using a Cobalt-57 sealed source.
SENSEI® System	Laparoscopic tethered gamma probe system (Tethered Probe + Control Unit).
Tethered Probe	Laparoscopic tethered gamma probe.
VAC	Voltage Alternating Current.
Warning	Specific information provided to the user to advise of situations where the misuse or unlabelled use of the device could present a hazard and therefore potentially harm, to the user or patient and/or could result in irreparable damage to the device or property.

2. SYMBOLS

Symbol	Definition	Symbol	Definition
	**Manufacturer** Lightpoint Medical Ltd. Misbourne Works, Waterside, Chesham, HP5 1PE United Kingdom		**Waste from Electrical and Electronic Equipment** The product should not be discarded as unsorted waste
	**Date of Manufacture** YYYY-MM-DD		**Temperature limits for the Tethered Probe and Control Unit** See operational and storage and transport for limits
	**Authorised Representative** Lightpoint Medical B.V. Joop Geesinkweg 901-999 Amsterdam-Duivendrecht 1114 AB, Netherlands		**Humidity limits for the Tethered Probe and Control Unit** See operational and storage and transport for limits
	**Use By** YYYY-MM-DD		**Keep away from sunlight**
	**Serial Number**		**Protect from heat and radioactive sources**
	**Model** LP05-01 (Tethered Probe) LP06-01 (Control Unit)		**Keep dry**
	**Quantity of item(s)**		**Refer to instruction manual/booklet**
	**Do not re-use** The medical device is intended for one use or for use on a single patient during a single procedure		**Consult electronic instructions for use**
	**Caution**		**Type BF**

STERILE EO	**Sterilized using ethylene oxide**		**Video Output** (DVI-D Connection to additional display)
	**Protective earth (ground)**	**IP68** **IP21**	**IP Rating** IP68 (Tethered Probe) IP21 (Control Unit)
	**Fuse Rating**		**Equipotential ground bond point**
	**Do not use if package is damaged**		**Fragile, handle with care**
CE 1282	**CE Mark**		

3. INTENDED USE

SENSEI® is an intra-operative laparoscopic tethered gamma probe system, intended to be used to detect and quantify gamma radiation emitted by a radiopharmaceutical. The system is comprised of a Tethered Probe, connected to a mains powered Control Unit.

3.1. INDICATIONS FOR USE

SENSEI® is indicated for use during sentinel lymph node biopsy in adult patients diagnosed with prostate, endometrial or cervical cancer.

The system can be used during robotic or manual laparoscopic surgery, as well as during open procedures. The system is intended to be used by trained healthcare professionals (HCPs) to support them in the detection of sentinel lymph nodes during sentinel lymph node biopsy procedures.

SENSEI® is not:

- Indicated for tumour localisation or for diagnosing the spread of cancer.
- Intended for use with radionuclides other than Technetium-99m (^{99m}Tc).
- Intended for any other diagnostic purposes.
- Intended for tumour margin delineation.
- To produce an image [planar or cross sectional] of the distribution of radiopharmaceuticals.
- To come into contact with the central circulatory system or central nervous system.

4.PERFORMANCE CHARACTERISTICS

4.1. PERFORMANCE SPECIFICATIONS

Parameter	Value
Maximum cps	99,999 cps
Sensitivity	1200 cps / MBq at 20 mm 680 cps / MBq at 30 mm
Angular resolution	43 degrees FWHM
Lateral resolution	29 mm FWHM at 30 mm
Background rejection	>99.9 %

4.2. OPERATING CONDITIONS

Tethered Probe:

Conditions	Range
Temperature	10-40 °C
Humidity	10 %-100 % RH (non-condensing)
Pressure	600-1200 hPa

Control Unit:

Conditions	Range
Temperature	10-50 °C
Humidity	10 %-100 % RH (non-condensing)
Pressure	600-1200 hPa

5. DEVICE DESCRIPTION

The Tethered Probe has been designed to be connected to a mains powered Control Unit. It is also possible to connect the Control Unit to an additional display (e.g., the da Vinci® Surgical System, manufactured by Intuitive Surgical, Inc.).

The Tethered Probe is supplied sterile (using ethylene oxide) and is intended for single use. The Tethered Probe can be connected to a Control Unit, which will be non-sterile and is designed to be reusable. The Control Unit does not come into contact with the patient and will be used outside of the sterile field.

Before using the SENSEI® System for the first time please read through the Instructions for Use and watch the training video available at www.senseisurgical.com.

5.1. TETHERED PROBE

The Tethered Probe allows a user to make a remote measurement in an area where an accumulation of a Technetium-99m (^{99m}Tc)[1] labelled radiopharmaceutical will emit gamma radiation. The signal from the Tethered Probe is translated into an audible signal and a visual representation of this is also displayed on the Control Unit.

The Tethered Probe incorporates a scintillator to convert gamma photons into optical photons for detection using a semiconductor-based device that converts the photons into electrical pulses. The Tethered Probe is sensitive to gamma rays emitted by a ^{99m}Tc source, which have had no interactions before reaching the detector (so called 'unscattered' gamma rays). It is also sensitive to scattered and non-target ^{99m}Tc background gamma radiation, so it is collimated and shielded to provide directional guidance and to limit the detection field of view in order to help isolate sentinel lymph nodes. The sensor and associated electronics are enclosed in the Tethered Probe head, which is packaged and sealed to ensure biocompatibility.

The Tethered Probe is 12 mm in diameter to allow it to be inserted into a patient via a suitable trocar. The Tethered Probe is fitted with a primary grip feature to enable it to be grasped and manipulated by a laparoscopic grasper, be that robotic or manual. The Tethered Probe is also fitted with secondary grip features (side pockets) that may be used to reorient the Tethered Probe. For open surgery a suitable grasper (e.g., Allis Tissue or Overholt forceps) can be used. The Tethered Probe has a 3 m tether cable and connector to attach it to the Control Unit.

THE TETHERED PROBE IS STERILE AND SHOULD ONLY BE OPENED IN A STERILE ENVIRONMENT

[1] ^{99m}Tc is a radionuclide that emits 140.5 keV photons and has a half-life of 6 hours. ^{99m}Tc photons are able to penetrate through several centimetres of tissue, with a Half-Value Layer of 4.6 cm of tissue.

The gamma ray detector and associated electronics are enclosed in the Tethered Probe head, which is packaged to:

- shield the sensor from visible radiation while minimising attenuation and scattering in the field of view, and to
- ensure biocompatibility of the Tethered Probe.

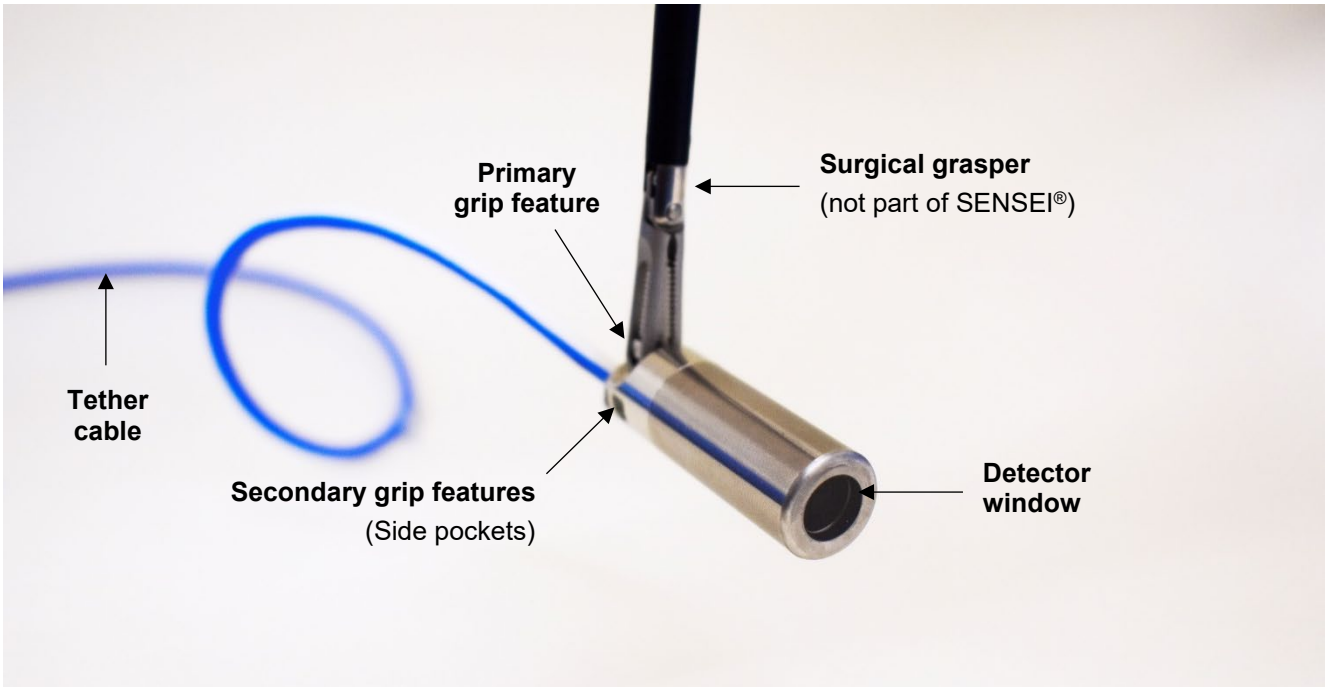


Figure 1 – SENSEI® Tethered Probe

5.1.1. SPECIFICATIONS

Tethered Probe specifications:

Length of Tethered Probe	42 mm
Diameter of Tethered Probe	12 mm
Length of tether cable	3 m
Diameter of tether cable	3.2 mm
Weight of Tethered Probe	107 g
IP rating	IP68

5.2. CONTROL UNIT

The Control Unit uses digital technology to collect and analyse the signals from the Tethered Probe and to report the level of gamma radiation. The presentation includes both audible and visual outputs, which vary in response to the level of radiation. The visual display includes a count rate together with a graphical representation of the level.

It is important to note that the SENSEI® System does not display an image of the inside of the body or an image of the distribution of the radiopharmaceutical.

It is possible to use the SENSEI® System in a standalone mode. Alternatively, it can be used with a laparoscopic or robotic-assisted surgical device (e.g., the da Vinci® Surgical System, manufactured by Intuitive Surgical, Inc.), where it can provide a remote visual representation of the audio output via a DVI connection.

Figure 2 – SENSEI® Control Unit

5.2.1 SPECIFICATIONS

Control Unit specifications:

Height (With the handle folded back on top of the Control Unit)	162 mm
Height (With the handle in the carry position)	228 mm
Width	315 mm
Depth	263 mm
Weight	4.2 kg
IP Rating	IP21

5.3. POWER SUPPLY/FUSE RATING

Three mains power cords are supplied with the SENSEI® Control Unit (UK plug, EU plug and US plug). The mains power supply provided for the Control Unit will conform to the following characteristics:

Power supply:

Input voltage:	100 – 250 VAC
Input current:	1.22 A at 100 VAC 0.6 A at 250 VAC
Input frequency:	50 – 60 Hz

Power cords:

United Kingdom	IEC C13 250 VAC / 10 A
Europe	IEC C13 250 VAC / 10 A
United States	IEC C13 125 VAC / 15 A

Fuses:

Rating	T 2A HBC / 250 VAC
Length	20 mm
Quantity	2 in line fuses

Electromagnetic compatibility (EMC)

Phenomenon	**Emission test levels** **Professional healthcare facility environment**
Emissions [2]	EN 55011*
Radiated and conducted RF emissions	*Classification: Group 1 and Class A
Conducted emissions	150 kHz – 500 kHz: QP 79 dBµV; AV 66 dBµV 500 kHz – 5 MHz: QP 73 dBµV; AV 60 dBµV 5 MHz – 30 MHz: QP 73 dBµV; AV 60 dBµV
Radiated emissions	30 MHz – 230 MHz: QP 52-45 dBµV/m at 3 m 230 MHz –1 GHz: QP 52 dBµV/m at 3 m 1 GHz – 3 GHz: AV 56 dBµV/m at 3 m and PV 76 dBµV/m at 3 m 3 GHz – 6 GHz: AV 60 dBµV/m at 3 m and PV 80 dBµV/m at 3 m

Phenomenon	**Standards**	**Immunity test levels** **Professional healthcare facility environment**
Electrostatic Discharge	EN 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air
Radiated Immunity	EN 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communication equipment	EN 61000-4-3	See Frequency range and level: RF wireless communication equipment table (below)

[2] Complies without any deviations from EN 60601-1-2 and normative references.

Phenomenon	Standards	Immunity test levels Professional healthcare facility environment
Electrical fast transients / bursts	EN 61000-4-4	±2 kV 100 kHz
Surge	EN 61000-4-5	±0.5 kV, ±1 kV and ±2 kV
Conducted disturbances induced by RF fields	EN 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Power frequency magnetic fields	EN 61000-4-8	30 A/m
Voltage dips	EN 61000-4-11	0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° for dips 0 % Vn 10 ms 0° for all other dips (0 % Vn 20 ms and 70 % Vn 500 ms)

Frequency range and level: RF wireless communication equipment		
Test frequency (MHz)	**Modulation**	**Immunity level (V/m)**
385	Pulse Modulation: 18 Hz	27
450	Pulse Modulation: 18 Hz	28
710 745 780	Pulse Modulation: 217 Hz	9
810 870 930	Pulse Modulation: 18 Hz	28
1720 1845 1970	Pulse Modulation: 217 Hz	28
2450	Pulse Modulation: 217 Hz	28
5240 5500 5785	Pulse Modulation: 217 Hz	9

6. CONTRAINDICATIONS ⚠

⚠ **SENSEI® should only be used with ^{99m}Tc labelled radiopharmaceuticals (or a Cobalt-57 sealed radiation source). Other types of radiopharmaceuticals injected into the patient are NOT approved for use with the device.**

⚠ **The device should not be used by anyone other than trained HCPs, nuclear medicine physicians or surgeons performing surgery in cancer patients.**

⚠ **SENSEI® should not be used other than as described in these Instructions for Use (IFU).**

7. SYSTEM WARNINGS, CAUTIONS AND NOTES

The section below should be read and understood before operating SENSEI®. This section provides operational warnings, cautions, and notes for the safe operation of SENSEI®.

7.1. WARNINGS ⚠

⚠ **DO NOT USE THE TETHERED PROBE IF THE PACKAGING IS DAMAGED OR BROKEN**

⚠ **DO NOT USE THE TETHERED PROBE IF IT IS NO LONGER STERILE**
(e.g., the Tethered Probe has been placed on a surface outside of the sterile field).

- The surgical team should keep the Tethered Probe sterile throughout the duration of the surgery, in particular any part of the product that comes into direct contact with the patient.

⚠ **DO NOT REUSE OR RE-STERILISE THE TETHERED PROBE**

- The Tethered Probe is a single use device. It should not be re-sterilised or reused. The Tethered Probe packaging must be opened in the sterile field.
- Discard the Tethered Probe after first use. The Tethered Probe is not reusable and is for single use only.
- Do not reuse the Tethered Probe on another patient under any circumstances.

⚠ **DO NOT DROP THE TETHERED PROBE. IF THE DEVICE HAS BEEN DROPPED, DO NOT USE**

- The Tethered Probe is fragile. Mechanical shock can result in irreparable damage**.** Care must be taken to avoid damage to the detector window during surgery. If any damage to the Tethered Probe is noticed it should be disposed of and replaced with a new Tethered Probe.

SENSEI® SHOULD ONLY BE USED WITH ^{99M}Tc LABELLED RADIOPHARMACEUTICALS OR A COBALT-57 SEALED RADIATION SOURCE. OTHER TYPES OF RADIOPHARMACEUTICALS INJECTED INTO THE PATIENT ARE NOT APPROVED FOR USE WITH THE DEVICE

- SENSEI® is designed to detect **only** the ^{99m}Tc radionuclide that has been injected into the patient and the device should not be used to attempt to detect any other radionuclides or radioactive sources in the patient.

- SENSEI® will utilise ^{99m}Tc labelled radiopharmaceuticals and therefore local radiation safety guidelines must be adhered to.

- The use of multiple radiopharmaceuticals in a single surgical procedure could impede accurate detection with SENSEI® and should be avoided.

- SENSEI® can be used with a Cobalt-57 (^{57}Co) sealed radiation source to perform a probe check prior to clinical use. The sealed radiation source should be handled carefully and in accordance with local guidelines.

DO NOT USE SENSEI® WITH ANY OF THE FOLLOWING EQUIPMENT:

- **Defibrillator equipment:** SENSEI® is not compatible with defibrillator equipment and the Tethered Probe must be removed from the patient before a defibrillator is used on the patient.

- **Electrocautery and other electrosurgical devices:**

  - SENSEI® should not be put in direct contact with electrocautery or other electrosurgical devices. This may cause damage to the Tethered Probe or result in electrical tracking, resulting in unintended burns.
  - Do not use/activate electrocautery or electrosurgical instruments when in contact with the SENSEI® Tethered Probe as they may cause damage to the device and injury to the patient may occur.
  - It is highly recommended to remove SENSEI® from the patient when electrocautery or electrosurgical devices are being used.

- **Other electrical equipment:** SENSEI® should not come into contact with other electrical equipment during use other than the equipment specified in the IFU.

DO NOT OPEN THE TETHERED PROBE OR CONTROL UNIT ENCLOSURE

- The Tethered Probe and Control Unit are tested and sealed at the factory. Opening the Tethered Probe or Control Unit may result in damage and will void the warranty.

- Do not modify or attempt to change any part of the Tethered Probe or Control Unit.

- SENSEI® contains no user-serviceable parts.

DO NOT STERILISE OR IMMERSE THE CONTROL UNIT

DO NOT PUT THE CONTROL UNIT INTO AN AUTOCLAVE

- No component or part of the Control Unit can be autoclaved. Only use the cleaning methods described in Section 16.1.

- The Control Unit and mains power cord are reusable and non-sterile. The Control Unit is to be set-up outside of the sterile field. Please be advised that any sterile HCP should not come into contact with the Control Unit, as this may result in the loss of their sterility.

DO NOT USE OTHER MANUFACTURER'S PROBES WITH THE CONTROL UNIT. USE OF UNAUTHORISED ACCESSORIES MAY VOID THE WARRANTY WITH THE USER ASSUMING ALL LIABILITIES

- Only use the SENSEI® Tethered Probe and Control Unit together.

DO NOT USE OTHER MANUFACTURER'S CONTROL UNITS WITH THE SENSEI® TETHERED PROBE. USE OF UNAUTHORISED ACCESSORIES MAY VOID THE WARRANTY WITH THE USER ASSUMING ALL LIABILITIES

- Only use the SENSEI® Tethered Probe and Control Unit together.

AVOID CAUSING DAMAGE TO THE TETHER CABLE DURING USE. IF THE TETHER CABLE IS DAMAGED DO NOT USE THE TETHERED PROBE AND REPLACE IT WITH A NEW TETHERED PROBE

SENSEI® SHOULD NOT BE USED WITH FLAMMABLE ANAESTHETICS

SENSEI® SHOULD NOT BE USED IN AN OXYGEN RICH ENVIRONMENT

USE OF THIS DEVICE IN THE VICINITY OF PERSONS UNDERGOING RADIATION THERAPY MAY CAUSE FALSE AND/OR INACCURATE READINGS

DO NOT INSERT THE TETHERED PROBE THROUGH A TROCAR USING A LAPAROSCOPIC GRASPER DURING LAPAROSCOPIC SURGERY. THE TETHERED PROBE SHOULD ONLY BE INSERTED THROUGH A TROCAR USING A GLOVED HAND AND NOT BY MEANS OF ANY OTHER INSTRUMENT

DO NOT INSERT, REMOVE OR USE OTHER INSTRUMENTS OR PRODUCTS, OR ATTEMPT TO REMOVE SPECIMENS, THROUGH THE SAME TROCAR OCCUPIED BY THE TETHERED PROBE

DO NOT REMOVE THE TETHERED PROBE WITHOUT TAKING THE PROBE TO THE BASE OF THE TROCAR, AS THIS WILL RISK CAUSING INTERNAL INJURY TO THE PATIENT

DO NOT REMOVE THE TETHERED PROBE THROUGH A TROCAR BY USING A LAPAROSCOPIC GRASPER DURING LAPAROSCOPIC SURGERY. THE TETHERED PROBE SHOULD ONLY BE REMOVED THROUGH A TROCAR USING A GLOVED HAND AND NOT BY MEANS OF ANY OTHER INSTRUMENT

AVOID ABRASIVE DAMAGE TO THE TETHERED PROBE HEAD AT ALL TIMES. IF DAMAGE IS IDENTIFIED E.G. SURFACE SCRATCHES, STOP USING THE TETHERED PROBE AS THIS MAY INJURE THE PATIENT

7.2.CAUTIONS

To avoid the risk of electric shock, this equipment must only be connected to a mains power supply with a protective earth.

The Tethered Probe is connected to a 3 m tether cable. Avoid entanglement of the tether cable as this could cause injury to the patient or user.

SENSEI® is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

7.3.NOTES

SENSEI® should only be used by trained and qualified personnel.

HCPs, nuclear medicine physicians and surgeons must adhere to local clinical practices when conducting surgical operations and should use the SENSEI® device as per the instructions provided. The Instructions for Use are not designed to assist with, or to be used to reference, surgical procedures or techniques.

No patient data is stored in the SENSEI® Tethered Probe or Control Unit.

8. OPERATING INSTRUCTIONS

Before using the SENSEI® System for the first time please read through the Instructions for Use and watch the training video available at www.senseisurgical.com.

8.1. CONTROL UNIT EXTERNAL FEATURES

Figure 3 - Control Unit front panel

Figure 4 - Control Unit back panel

8.2. CONTROL UNIT VISUAL DISPLAY (TOUCHSCREEN)

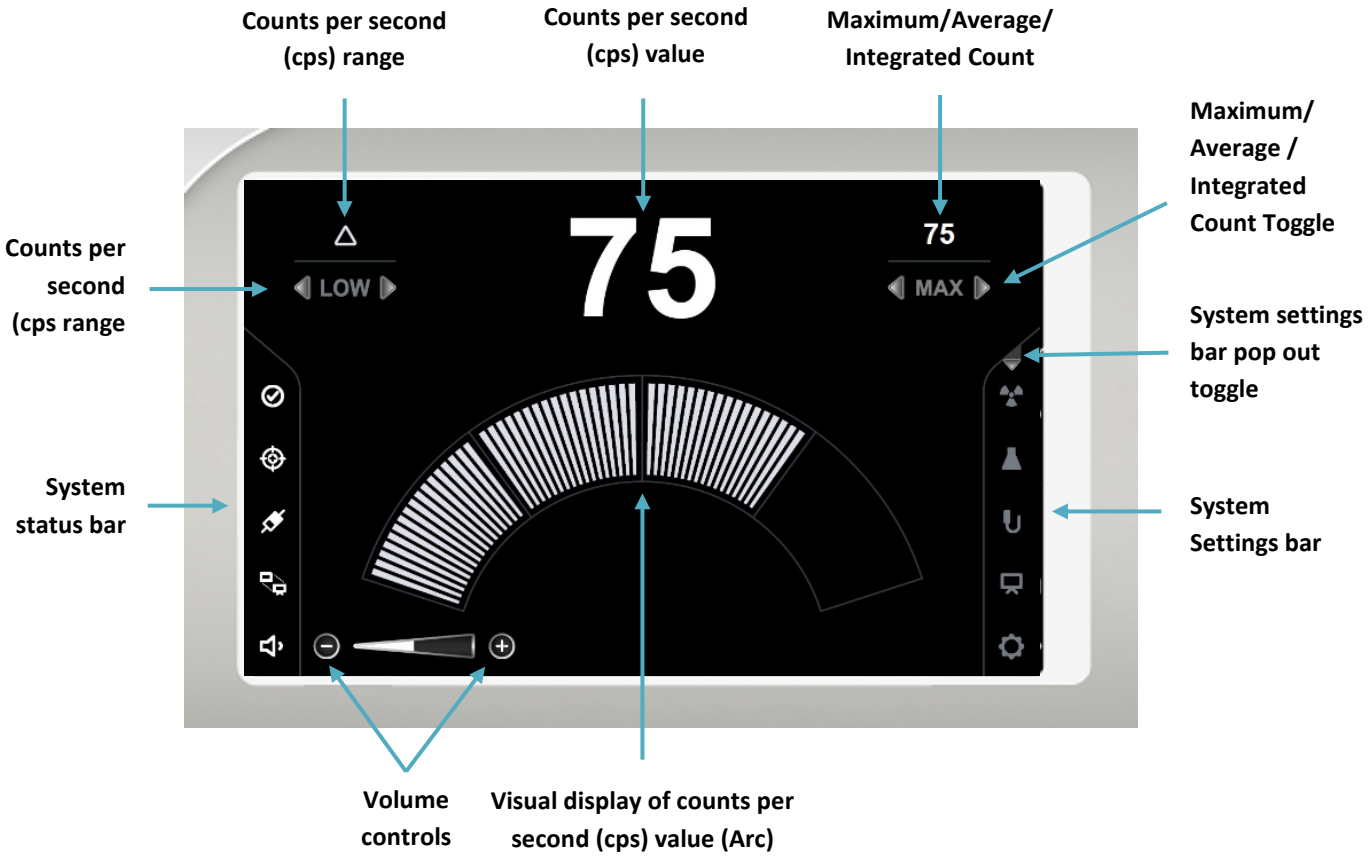


Figure 5 - Control Unit visual display

8.2.1. SYSTEM STATUS BAR SYMBOL MEANINGS

The system status bar shows the overall status of the SENSEI® System and components.

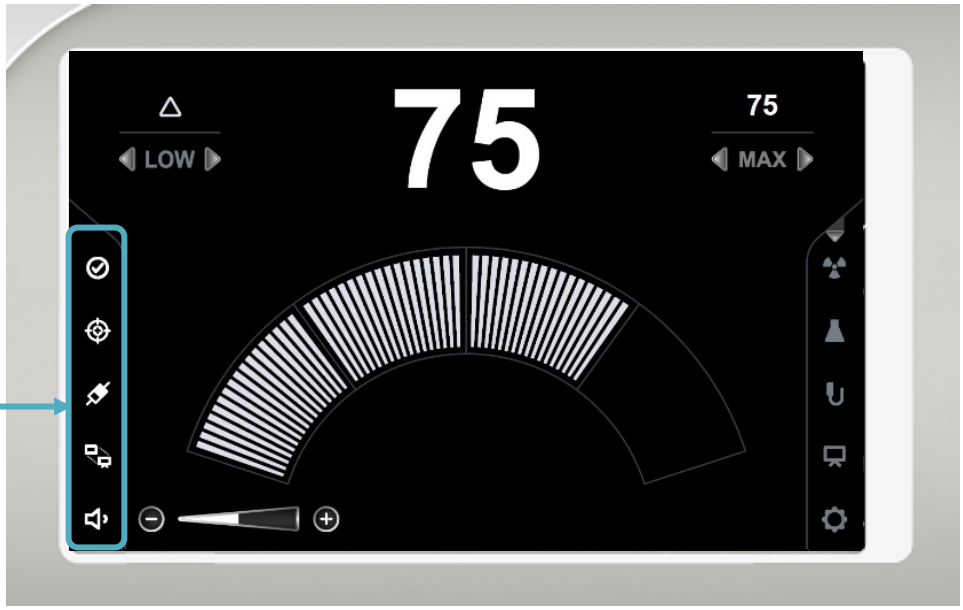
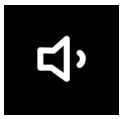


Figure 6 – System status bar symbols

System status bar

Status symbol	Name of symbol	Options	Symbol meaning	Action required
	System status		If pulsing: System ready and working correctly.	No action required.
			If still: System has frozen.	Consult Troubleshooting (Section 15).
			The system is not ready for use, proceed to conduct probe check.	Conduct probe check. Consult Troubleshooting (Section 15).
	Probe check status			Connect SENSEI® Tethered Probe.
			Probe check required, probe check fault.	Conduct probe check. Consult Section 9.3.
			Probe check completed.	No action required.

	Probe status		Probe not connected.	
				No action required.
			Probe connected, connection and/or probe fault.	Consult Troubleshooting (Section 15).
			No additional display connected.	Connect a DVI-D cable to engage with an additional display.
			Additional display connected.	DVI-D cable is connected to an additional display: Access the additional display settings menu to engage with the additional display.
			Additional display output active	No action required.
			Additional display connected, connection fault.	Consult Troubleshooting (Section 15).
	Volume		Volume, low.	No action required.
			Volume, medium.	No action required.
			Volume, high.	No action required.
			Volume, max.	No action required.
			Audio, muted.	No action required.
			Audio fault.	Consult Troubleshooting (Section 15).

8.2.2. SYSTEM SETTINGS BAR SYMBOL MEANINGS

The system settings bar provides access to set-up tasks, connection to an additional display and other settings.

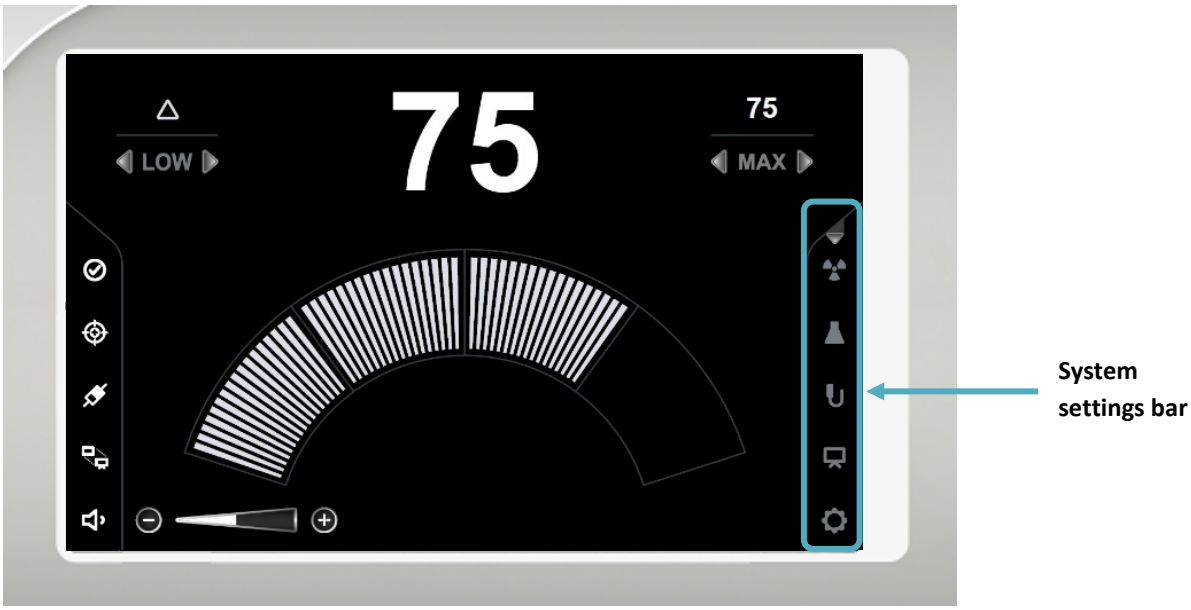
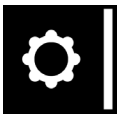


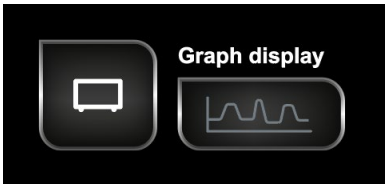
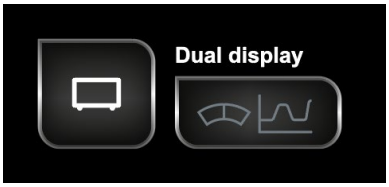
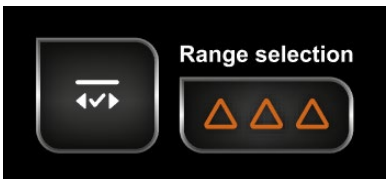
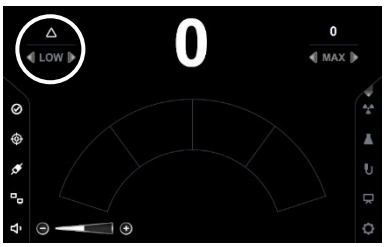
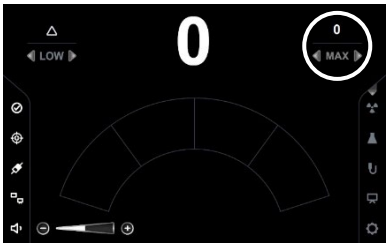
Figure 7 – System settings bar symbols

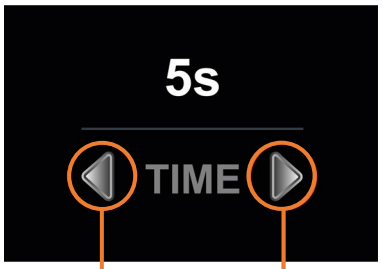
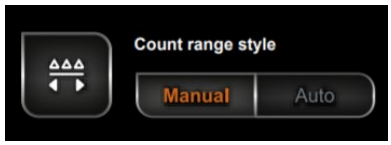
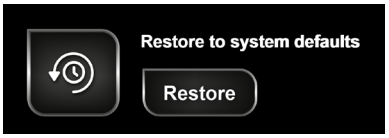
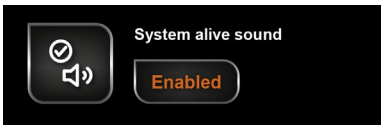
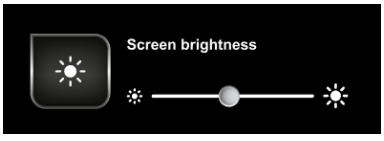
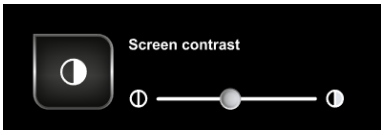
System settings bar

Setting symbol	Name of symbol	Options	Symbol meaning	Action required
	System settings bar minimised		System settings bar is minimised, probe check is required.	Press the up arrow to expand the system settings bar and access the probe settings menu.
				No action required.
	Radiation type selection		Radiation type menu closed.	No action required.
			Radiation type menu open.	No action required.

	Radionuclide selection			No action required.
			Radionuclide menu open.	No action required.
	Probe settings			No action required.
			Probe settings menu open, probe check required.	See Section 9.3 Conduct probe check.
			Probe settings menu open, probe check complete.	
	Additional display settings		Additional display settings screen is closed.	No action required.
			Additional display settings screen is open.	No action required.
	System settings		System settings menu is closed.	No action required.
			System settings menu is open.	No action required.

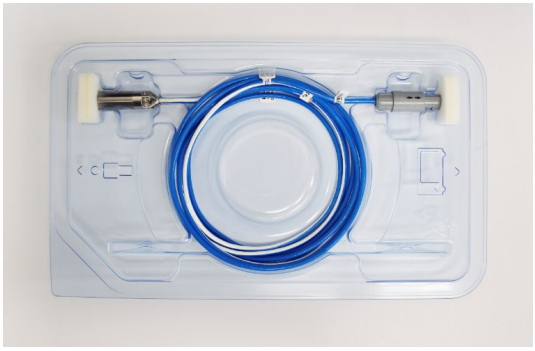
System settings

Additional Setting	Options	Name of symbol	Meaning
Visual display choices 		Arc display (Default).	The main operating screen will show an arc representation of the count rate.
		Graph display.	
		(Both Arc and Graph display).	The main operating screen will show both an arc and a graphical representation of the count rate.
		Range selection (Default on).	The range selection display option on the main operating screen can be either selected (with a tick) or not selected (no tick). If the option is selected, the user will be able to change the range between LOW, MED, HIGH or MAX. If the option is not selected, then the user will not be able to change the range.
			The range selector will appear in the top left-hand corner of the main operating screen. To change between LOW, MED, HIGH or MAX press the left or right-hand arrows.
	 	MAX/ AVG/INT (Default on).	The auxiliary display option on the main operating screen can be either selected (with a tick) or not selected (no tick). If this option is selected, the user will be able to change the auxiliary indication between the Maximum, Average, or Integration (MAX/AVG/INT) count value over a specified time window. If the option is not selected, then the user will not be able to change the auxiliary indication. These functions will appear in the top right-hand corner of the main operating screen. To change between MAX/AVG/INT press the left or right-hand arrows.

	 Press here to engage the time setting of the MAX/AVG/INT controls  Use arrows to swap between MAX/AVG/INT or 1s/5s/10s/60s		To set a time period, press the word 'MAX/AVG/INT' and the word 'TIME' will appear. Then use the left or right-hand arrows to cycle between 1s, 5s, 10s or 60s. To exit press the word 'TIME' to return to the 'MAX/AVG/INT' function selector (the system will return automatically in a few seconds if there is no further control input). • The maximum function can be set to find the maximum cps over the previous 1s, 5 s, 10 s or 60 s time window. (Continuously updated). • The average function can be set to calculate the average cps over the previous 1 s, 5 s, 10 s or 60 s time window. (Continuously updated). • The integration function can be set to calculate the total number of counts in the previous 1 s, 5 s, 10 s or 60 s time window. (Updated after each integration time period e.g., once every 10 seconds if a 10 s time window is selected).
System configuration		Count range style.	*[Manufacturer note/Note to user: Only the 'Manual' mode option is currently available. The 'Auto' mode change option will be greyed out].*
		Graph span time (s). (Default, 10 s).	This setting allows the user to alter the span time of the graph (if the graphical representation of cps is selected). The options are 10, 20 or 30 seconds.
		Restore to system defaults.	
		System alive sound. (Default, enabled).	Enables or disables the 'alive sound'. The 'alive sound' is a low intermittent tone that is present when the Tethered Probe is ready for use, but is not detecting radiation. This will sound every 5 seconds to indicate the system is fully operational.
Screen Adjustments		Screen brightness. (Default, maximum brightness).	Allows the user to alter the visual display brightness for best visibility.
		Screen contrast. (Default, maximum contrast).	Allows the user to alter the visual display contrast for best visibility.

9. SETTING UP THE SENSEI® SYSTEM

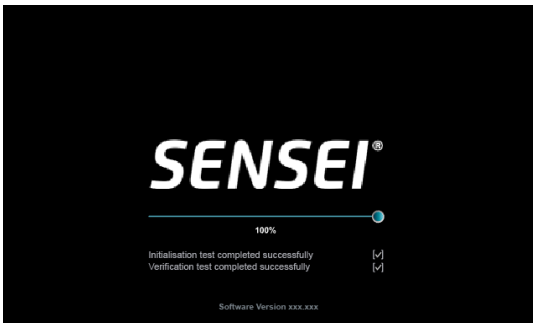
9.1. GATHER ALL COMPONENTS

#	Image	Step	Additional information
	The Control Unit and the power cord are not sterile. All tasks in this section should be performed by a non-sterile member of staff with the Control Unit outside of the sterile field.		
9.1.1		Retrieve the SENSEI® Tethered Probe from storage.	It is advised to take a spare SENSEI® Tethered Probe into the operating room when possible. **DO NOT OPEN** the Tethered Probe packaging until in the sterile field.
9.1.2		Retrieve the SENSEI® Control Unit from storage.	The Control Unit can be carried using the handle if desired.
9.1.3		Place the SENSEI® Control Unit safely on a flat surface, where it can be seen by the intended users e.g., in a laparoscopic stack or on an instrument trolley.	The Control Unit can be angled by positioning the handle underneath the case. To do this: 1. Press the grey buttons on either side of the Control Unit at the same time; this will allow the handle to rotate. 2. Rotate the handle until the angle is satisfactory. 3. Release the buttons and the handle will click into position.

9.2. CONTROL UNIT SET-UP

#	Image	Step	Additional information
		The Control Unit and the power cord are not sterile. All tasks in this section should be performed by a non-sterile member of staff with the Control Unit outside of the sterile field.	
9.2.1		Connect the power cord to the socket on the back of the Control Unit.	Ensure that the isolator switch above the socket is in the 'off' position. Ensure that the power cord is pushed all the way into the socket before continuing. ⚠ Prior to use, inspect the power cord to ensure there is no damage to the cable. If there is any damage **DO NOT USE** it and contact Lightpoint Medical Ltd.
9.2.2		If the power outlet is fitted with a switch, ensure that it is in the 'off' position and plug the power cord into the outlet. Once connected, turn 'on' the outlet.	Ensure that the plug is compatible with the mains socket in the country of use. Ensure that the mains power cord does not cause a trip hazard. ⚠ Cables to and from the SENSEI® System should be arranged so that they do not create obstacles, hazards or interfere with expected movements in the operating room.
9.2.3		Push the isolator switch on the back of the Control Unit to move the isolator switch to the 'on' ('I') position.	

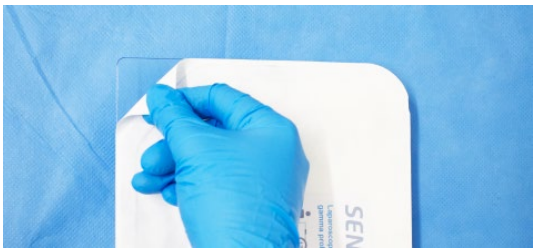
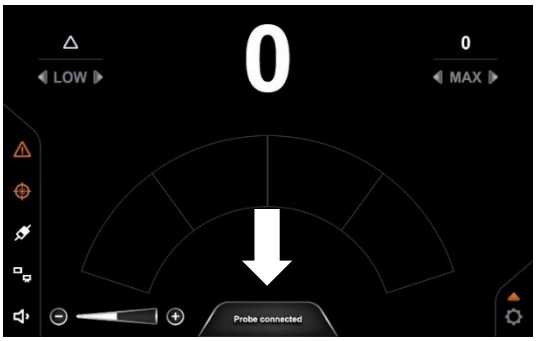
<table>
<tr><td>9.2.4</td><td> 
</td><td>Push the operate button on the front of the Control Unit.</td><td>A green light will appear on the operate button and the visual display on the device will light up during normal operation.

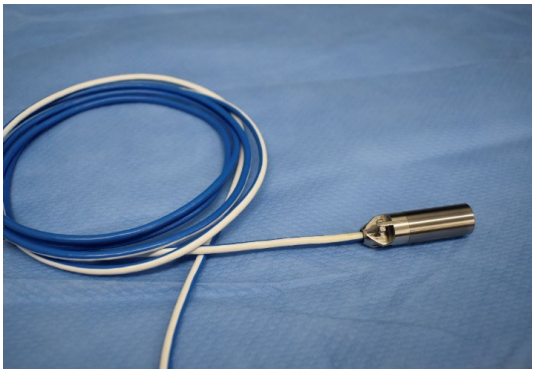
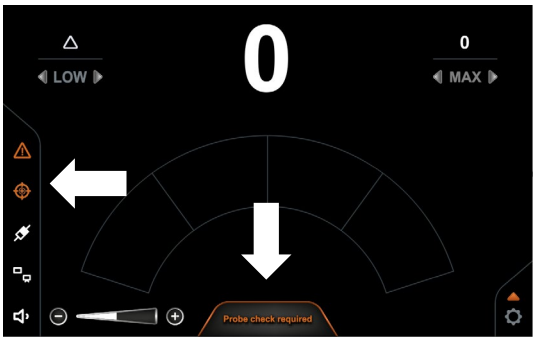
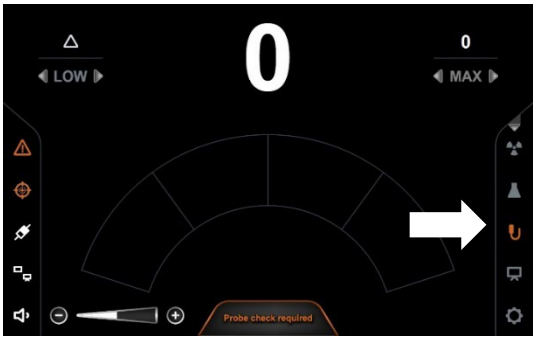
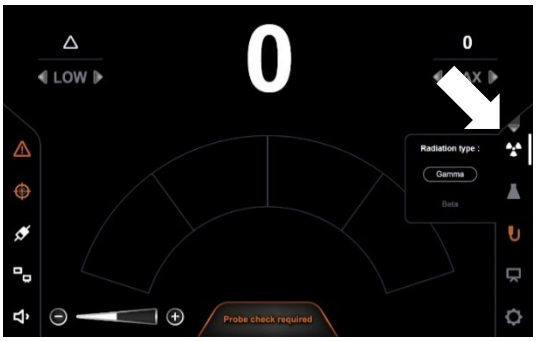
If the operate button is flashing red, consult Troubleshooting (Section 15).</td></tr>
<tr><td>9.2.5</td><td> 
</td><td>The system will run through a series of set-up checks as the device starts up.

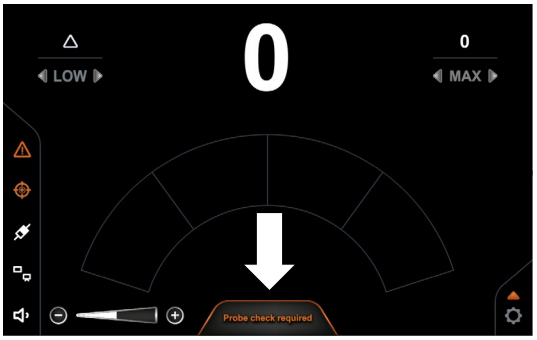
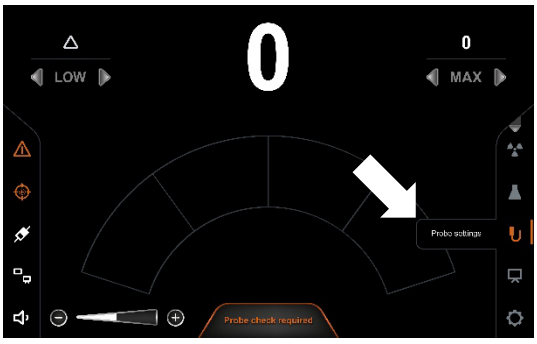
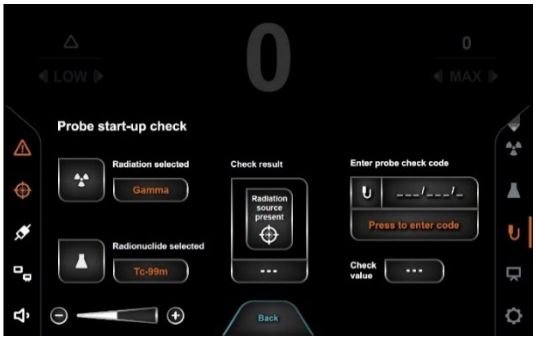
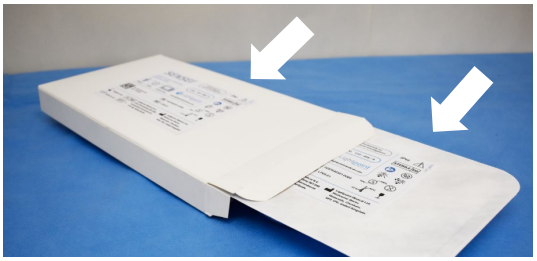
Following the set-up checks, the status will be displayed.</td><td rowspan="2">In the event the Control Unit runs into a system error, the device is not suitable for use and should be powered down, see the Shutdown procedure (Section 13).

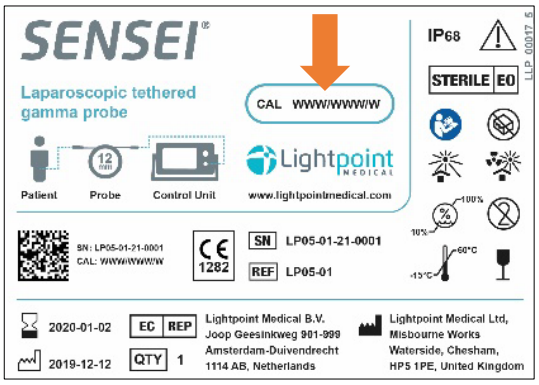
If the start-up screen displays a warning message, consult Troubleshooting (Section 15).</td></tr>
<tr><td></td><td> 
</td><td></td></tr>
<tr><td>9.2.7</td><td> 
</td><td>In the event the system does not pass all of the start-up checks the visual display will show a warning message and instructions.</td><td></td></tr>
</table>

9.3. CONDUCT A PROBE CHECK

#	Image	Step	Additional information
⚠	**The Control Unit and the power cord are not sterile. The Tethered Probe is a sterile device and must remain sterile at all times. Be aware that a non-sterile member of staff and a sterile member of staff must work together to complete the probe check described in this section.**		
9.3.1		**Task performed by <u>non-sterile</u> member of staff.** Remove the SENSEI® Tethered Probe from the cardboard sleeve.	The paper leaflet contains a quick start guide.
9.3.2	 	**Task performed by <u>non-sterile</u> member of staff.** Whilst holding the plastic portion of the SENSEI® Tethered Probe blister pack, pull back on the membrane tab.	It is recommended that users wear gloves when unpacking the Tethered Probe. It is recommended that the user opening the Tethered Probe blister pack holds the packaging with the patient symbol facing the sterile user, while they retrieve the Tethered Probe. **Always maintain the sterility of the Tethered Probe.**
9.3.3	  	**Task performed by <u>non-sterile</u> member of staff.** Open the Tethered Probe input port cover to expose the socket. Remove the tether connector from the blister pack and push it into the socket on the front of the Control Unit. Once connected a 'Probe connected' message will be displayed on the visual display of the Control Unit.	Ensure that the tether connector is aligned with the connector on the Control Unit and push it into the socket, until it locks. Inspect the Tethered Probe prior to use. **<u>Do not use</u>** if there are any visible signs of damage. If there is any damage, replace the Tethered Probe. Please return the damaged Tethered Probe to Lightpoint Medical. Refer to Section 20 for details. **Always maintain the sterility of the Tethered Probe.**

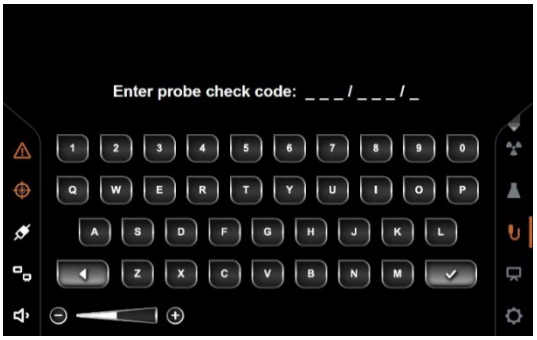
9.3.4		**Task performed by <u>sterile</u> member of staff.** Once the tether is connected to the Control Unit, the sterile user is able to remove the Tethered Probe head from the blister pack.	Ensure that the sterile user is wearing gloves and that the probe head and cabling remain sterile at all times. **Always maintain the sterility of the Tethered Probe.**
9.3.5		**Task performed by <u>sterile</u> member of staff.** Carefully place the Tethered Probe head on a sterile surface ready for use. Make sure that there is no draping cable between the sterile field and the Control Unit.	It is recommended that the tether cable is not placed under tension during the operation of SENSEI®. **Always maintain the sterility of the Tethered Probe.**
9.3.6		A 'Probe check required' message will appear after the 'Probe connected' message and the probe check status symbol should be highlighted.	
9.3.7		**Task performed by <u>non-sterile</u> member of staff.** Open the system settings bar. The 'Probe start-up check' icon will be highlighted.	
9.3.8		**Task performed by <u>non-sterile</u> member of staff.** Press the 'Radiation type' selection symbol and from the menu select the correct radiation type.	Gamma radiation will be set as the default, and this should be confirmed by entering the menu.

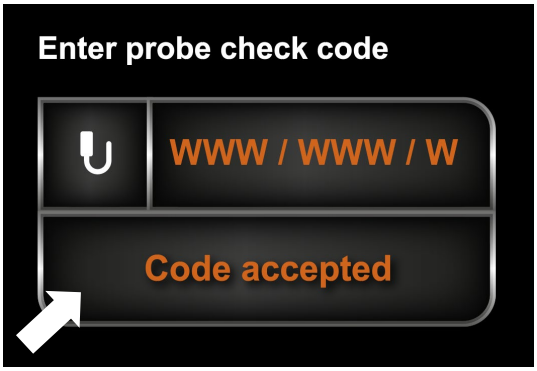
9.3.9		**Task performed by <u>non-sterile</u> member of staff.** Press the 'Radionuclide' selection symbol and from the menu select the correct radionuclide.	Technetium-99m (^{99m}Tc) will be set as the default and this should be confirmed by entering the menu.
9.3.10	  	**Task performed by <u>non-sterile</u> member of staff.** To access the 'Probe start-up check' menu, press either the 'Probe check required' pop-up message on the main operating screen or press the probe settings symbol.	
9.3.11	 	**Task performed by <u>non-sterile</u> member of staff.** Locate the unique probe check code, which can be found on the probe label, on the blister pack label and on the cardboard sleeve label.	Each probe check code can be identified by the word 'CAL' next to a 7-character alphanumeric code. Each code is unique to each Tethered Probe. The correct code for the Tethered Probe being used must be entered to ensure normal operation. .



Note that the probe check code shown in the image is an example only. The code will be different for each probe used.

9.3.12





Task performed by <u>non-sterile</u> member of staff.

Enter the probe check code by pressing the text ‘Press to enter code’. This will open a keyboard.

Enter each alphanumeric character of the code using the keyboard and complete the entry by using the ‘tick’ button.

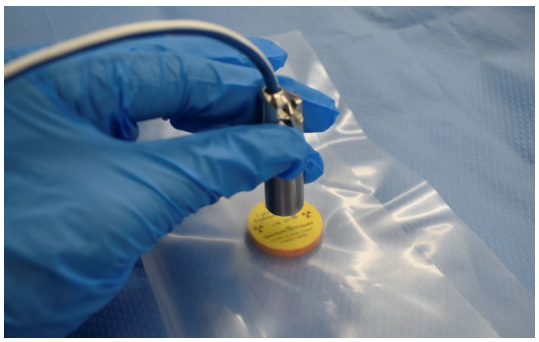
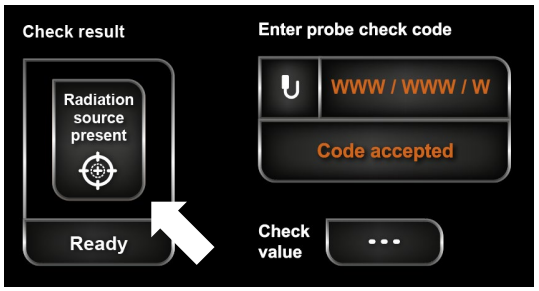
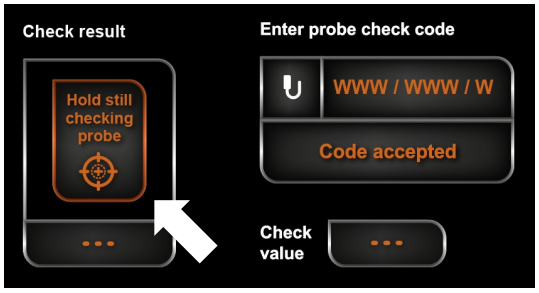
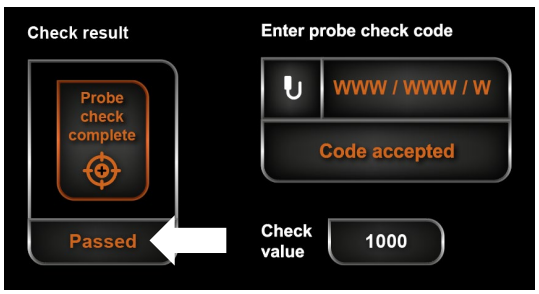
A ‘Code accepted’ message will appear.

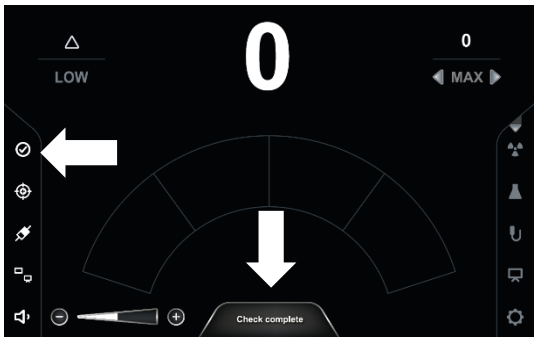
Characters can be deleted using the ‘back’ arrow button on the keyboard.

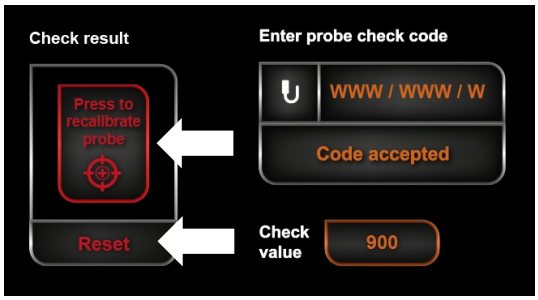
Ensure that the entered Tethered Probe check code matches the code exactly as displayed on the label or on the packaging.

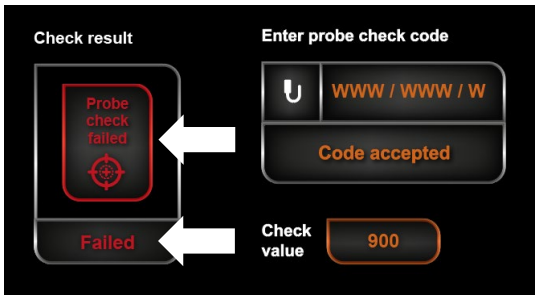
If the code is entered incorrectly a ‘Code rejected’ message will be displayed. To re-enter the correct code, press the text ‘Code rejected’ and the keyboard will reappear.

Note that the probe check code of ‘WWW/WWW/W’ shown in the image is an example only. The code will be unique for each probe used.

9.3.13		**The <u>non-sterile</u> member of staff should handle the radiation source. The <u>sterile</u> member of staff should handle the sterile membrane.** **Retrieve a Cobalt-57 radiation source from storage, following local radiation safety guidelines.** **Cover the sealed source with a sterile membrane.**	**The sealed radiation source should be handled carefully and in accordance with local radiation safety guidelines. Refer to the local radiation safety/protection officer for guidance.** **Ensure that the radiation source is covered with a sterile membrane before allowing it into the sterile field.** **Always maintain the sterility of the Tethered Probe.**
9.3.14		**The <u>sterile</u> member of staff should handle the Tethered Probe. The <u>non-sterile</u> member of staff should interact with the Control Unit.** Position the probe head in direct contact with the sterile membrane, over the centre of the sealed source. Press the 'Radiation source present' button on the Control Unit.	
9.3.15		**Task performed by <u>sterile</u> member of staff.** Keep the probe head as still as possible whilst the Control Unit checks the probe.	This will take approximately 30 seconds.
9.3.16		Once successfully completed, the Control Unit will display a 'Passed' message. The SENSEI® System is now ready for use.	Note that the check value of '1000' shown in the image is an example only. This may be different each time a probe check is conducted.

<table>
<tr>
<td>9.3.17</td>
<td> 
</td>
<td>Task performed by <u>non-sterile</u> member of staff.

Upon exiting the settings menu, a ‘Check complete’ message will be displayed, an audible ‘Alive signal’ will begin to sound, and the system status icon will be white and pulsing.</td>
<td>The ‘Alive signal’ is a low intermittent tone present when the Tethered Probe is ready for use, but not detecting radiation. This will sound every 5 seconds to indicate the system is fully operational.</td>
</tr>
<tr>
<td>9.3.18</td>
<td> 

 
</td>
<td>If completed unsuccessfully, the Control Unit will display a red ‘Press to recalibrate probe’ message.

The device is not ready for use and the check value displayed remains orange and not white.

The SENSEI® System will allow one further attempt to complete the probe check.

Task performed by <u>sterile</u> member of staff.

Position the probe head in direct contact with the sterile membrane, over the centre of the sealed source as described in 9.3.13 and 9.3.14.

Task performed by <u>non-sterile</u> member of staff.

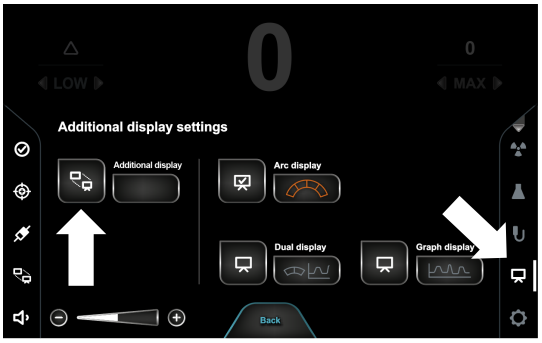
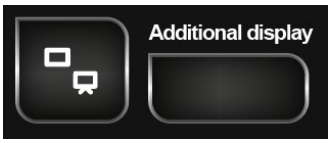
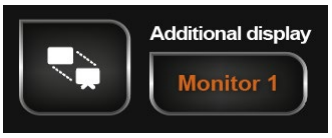
Press the ‘Press to recalibrate probe’ button on the Control Unit.

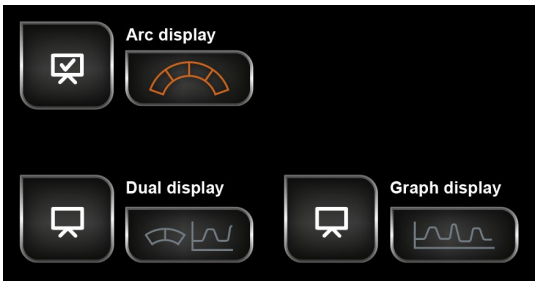
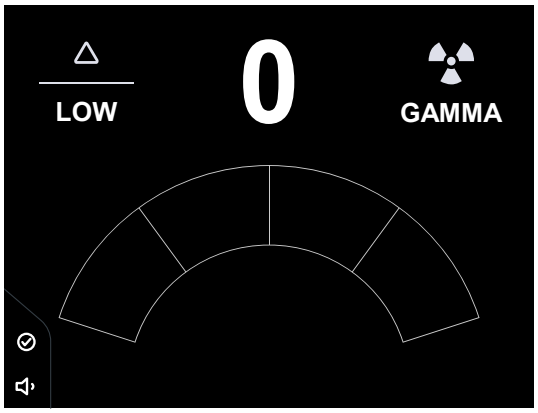
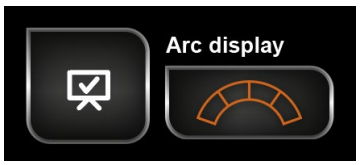
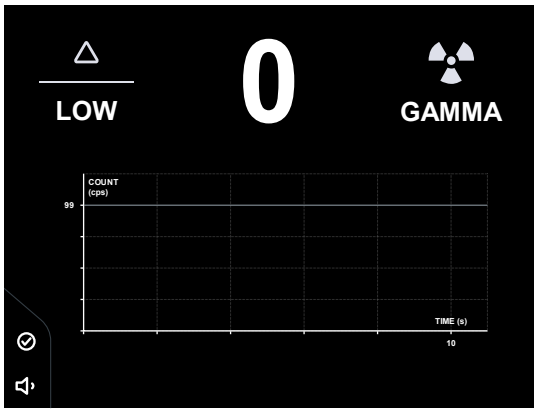
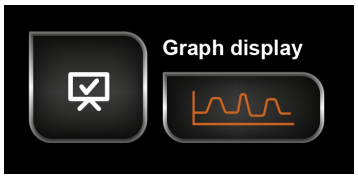
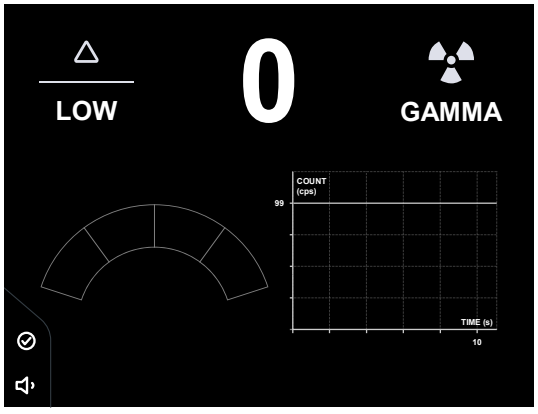
Follow steps 9.3.15 to 9.3.17.</td>
<td>If completed unsuccessfully on the second attempt the Control Unit will display a red ‘Probe check failed’ message.

The device is not ready for use and the check value displayed remains orange and not white.

Consult Troubleshooting (Section 15).</td>
</tr>
</table>

9.4. CONNECT TO AN ADDITIONAL DISPLAY

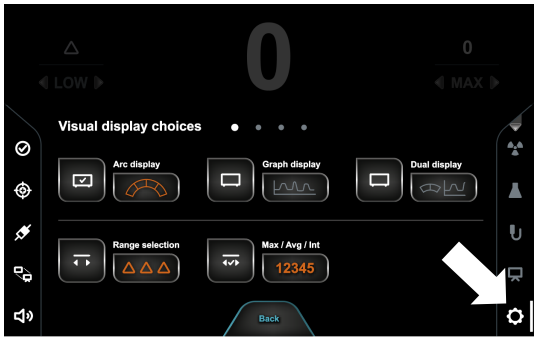
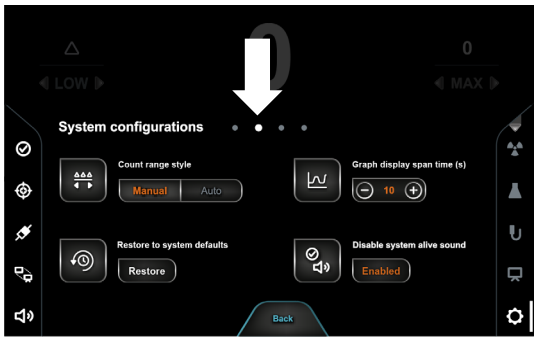
#	Image	Step	Additional information
9.4.1		To connect the SENSEI® System to an additional display e.g., the Intuitive Surgical da Vinci® TilePro™, connect a DVI-D cable to the additional display output on the rear of the Control Unit. Details of the DVI-D cable can be found in Section 17.	Ensure that the other end of the DVI-D cable is connected to a suitable additional display. Consult the manufacturer's Instructions for Use, where necessary. ⚠ Cables to and from the SENSEI® System should be arranged so that they do not create obstacles, hazards or interfere with expected movements in the operating room.
9.4.2		Open the system settings bar and select the additional display settings icon to open the 'Additional display settings' menu.	⚠ This step must be conducted to connect to an additional display.
9.4.3	 1. NO DVI-D cable is connected  2. DVI-D cable connected  3. Additional display has been engaged	To turn on an additional display, press the screen icon next to the title 'Additional display' (Image 2). This will change to a connected screen symbol and the words 'Monitor 1' will be seen in the box on the right (Image 3).	⚠ This button must be pressed to connect to an additional display. To switch off the additional display, press the connected screen icon (Image 3). This will change to the not connected screen symbol (Image 2).

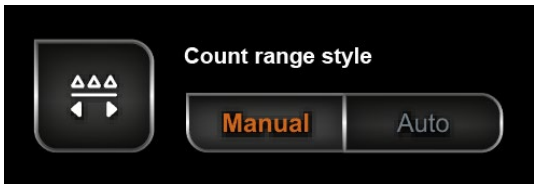
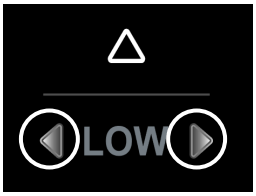
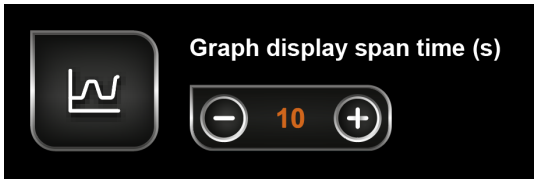
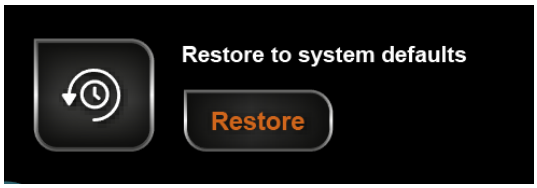
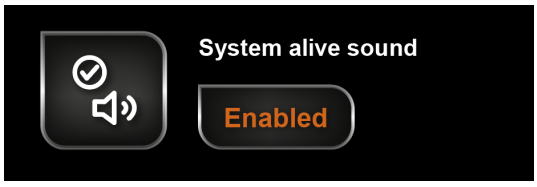
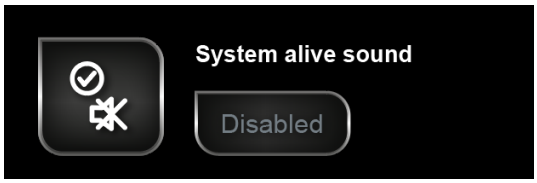
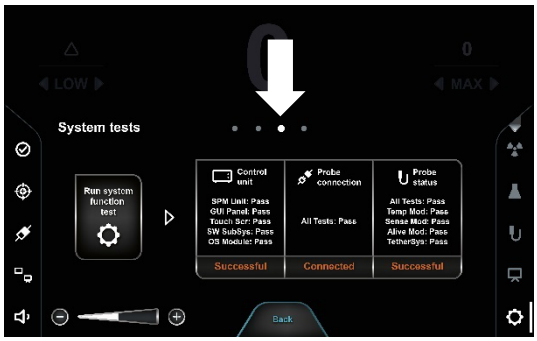
9.4.4		To select the presentation style to send to the additional display, select either ‘Arc’, ‘Dual’ or ‘Graph’, by pressing the appropriate icon.	The selected screen icon will change from an empty screen symbol to a screen with a tick.
9.4.5		If the ‘Arc display’ is selected this image will be displayed on the additional display.	
9.4.6		If the ‘Graph display’ is selected this image will be displayed on the additional display.	
9.4.7		If the ‘Dual display’ is selected this image will be displayed on the additional display.	

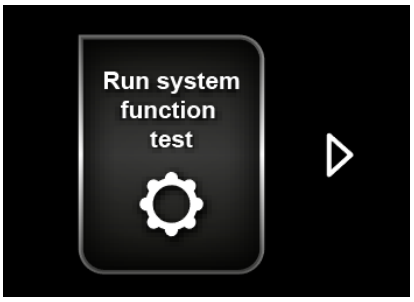
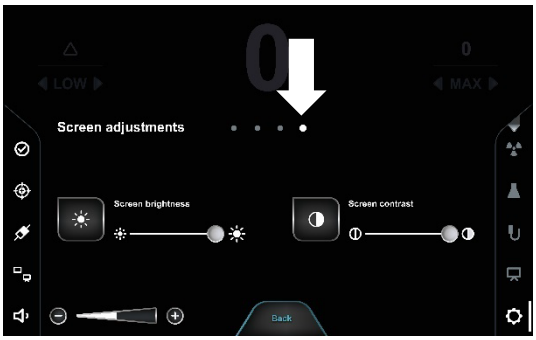
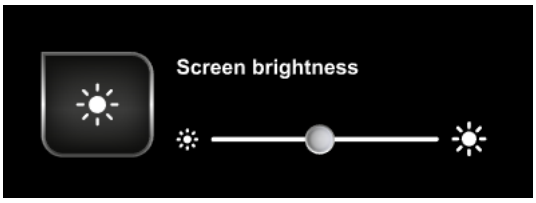
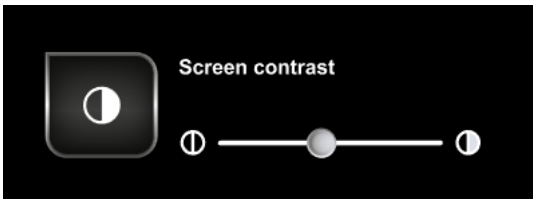
There may be other steps that need to be conducted on the additional display that is being used to allow it to accept an input from SENSEI®.

Please refer to the individual manufacturer’s Instructions for Use. For example, when using the Intuitive Surgical, da Vinci® Surgical System, the TilePro™ must also be turned on to see this screen.

9.5. CONFIGURE SYSTEM SETTINGS

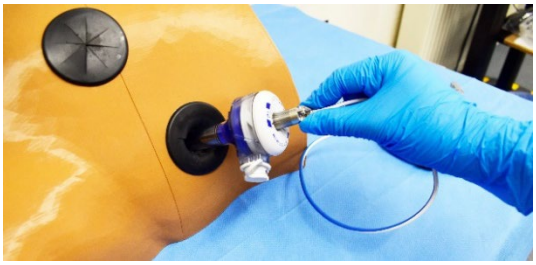
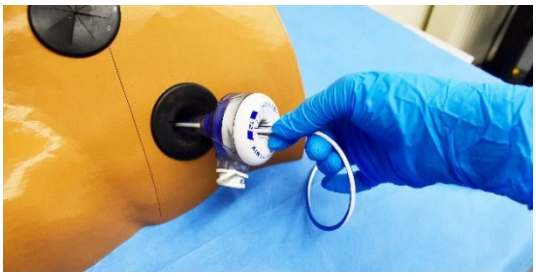
#	Image	Step	Additional information
9.5.1		To alter the system settings, open the system settings bar and press the 'System settings' icon. The first page shows the 'Visual display choices' for the Control Unit.	To navigate between setting screens, press one of the small dots in the middle of the screen.
9.5.2		In the 'Visual display choices' screen, the top row of buttons configures the Control Unit visual cps representation to show either an 'Arc', a 'Graph' or 'Dual' displays. The default is the 'Arc' display.	To select an alternative display, press on the icon to select the preferred display type.
9.5.3		In the 'Visual display choices' screen, the bottom row of buttons configures the accessory toggles to show the range and the MAX/AVG/INT selectors. The default is that both the range and MAX/AVG/INT selectors are displayed.	To select the accessory toggles to configure what is displayed on the main operating screen, press the icon next to the accessory toggle. Each choice is explained in Section 8.2.3.
9.5.4		To access the 'System configurations' screen, press the second dot. 	

9.5.5	 	To alter whether the count range change is set to 'Manual' or 'Auto' mode, press on the word 'Manual' or 'Auto' to select the desired option. The default is 'Manual' mode.	'Manual' mode will require the user to press one of the toggle buttons to change between ranges. *[Manufacturer note/note to user: Only 'Manual' mode is currently available. The 'Auto' mode is not accessible and will be greyed out].*
9.5.6		To alter the count rate 'Graph display span time', to display 10, 20 or 30 seconds of data, select the desired value. The default is 10 seconds.	To switch between 10, 20 or 30 seconds, use the plus and minus buttons either side of the number.
9.5.7		To restore the system to original factory default settings, press the 'Restore' button.	Be aware that this will reset all of the changes that have been made during the set-up of the Control Unit **including resetting the probe check code.**
9.5.8	 	To disable the 'System alive sound' press the button so that it states 'Disabled'. The default is 'Enabled'.	
9.5.9		To access the 'System tests' screen, press the third dot. 	

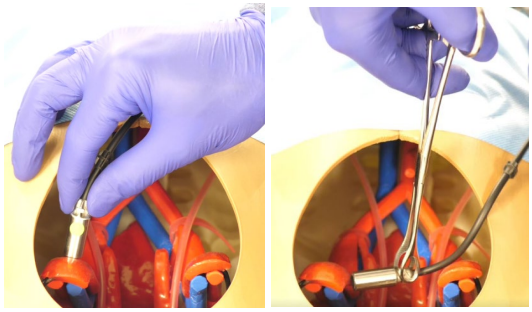
9.5.10		To manually test the system, press the 'Run system function test' button.	The Control Unit test results will either be 'Successful' or 'Unsuccessful'. The Probe connection test results will either be 'Connected' or 'Not connected'. The Probe status test results will either be 'Successful' or 'Unsuccessful'. For troubleshooting, consult Troubleshooting (Section 15).
9.5.11		To access the 'Screen adjustments' screen, press the fourth dot. 	
9.5.12		To alter 'Screen brightness', slide the toggle on the bar either to the left or to the right. The default is maximum brightness.	Alternatively, press the small sun icon on the left to reduce the brightness or press the large sun icon on the right to increase the brightness.
9.5.13		To alter 'Screen contrast', slide the toggle on the bar either to the left or to the right. The default is maximum contrast.	Alternatively, press the contrast icon on the left to reduce the contrast or the contrast icon on the right to increase the contrast.

10. INSERTING THE SENSEI® TETHERED PROBE INTO A PATIENT

10.1. INSERTING THE TETHERED PROBE DURING LAPAROSCOPIC SURGERY

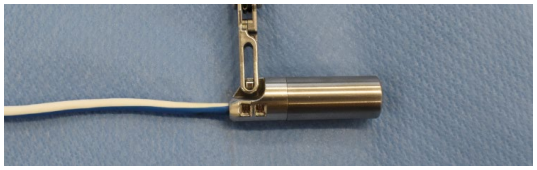
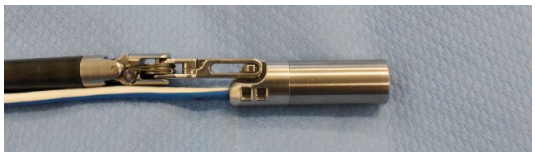
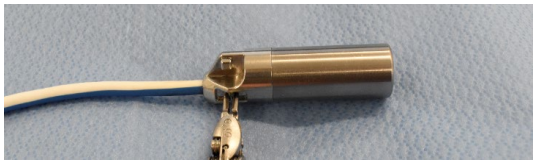
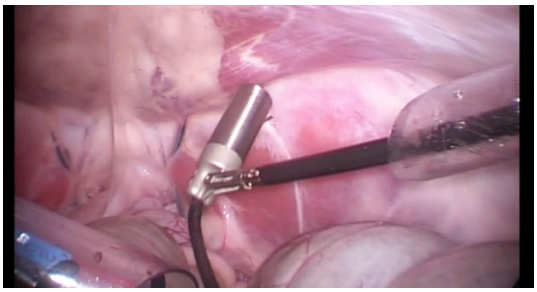
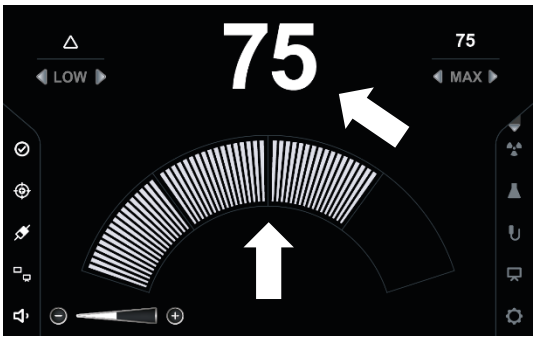
#	Image	Step	Additional information
10.1.1	 	To insert the Tethered Probe through a trocar, place the probe head into the opening of the trocar and gently push it through the trocar, using the tether cable. **Do not insert the Tethered Probe using a laparoscopic grasper.** **Do not insert, remove, or use other instruments, products or attempt to remove specimens through the same trocar occupied by the Tethered Probe.** See Section 17 for a list of compatible trocars that can be used with SENSEI®.	If the device is used with a valved trocar, slightly more pressure may need to be applied, to push the probe head through the valve. Take care to ensure that the Tethered Probe is not used in a way that may compromise insufflation pressure. Be careful not to cause any injury to the patient through excessive force. Minimise any additional force when inserting the Tethered Probe.
10.1.2		When inserting the Tethered Probe, maintain vision of the inner end of the port using the laparoscopic camera.	This will ensure that the user can see the Tethered Probe at all times and observe its orientation before grasping onto the device.

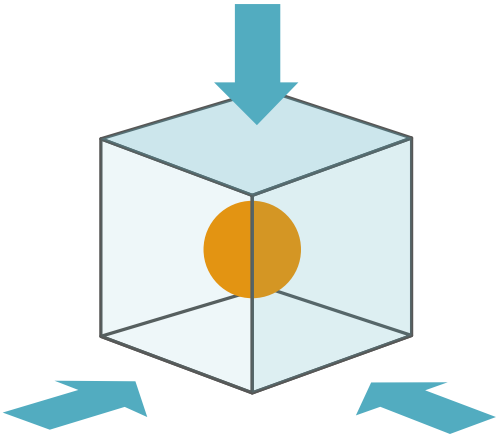
10.2. INSERTING THE TETHERED PROBE DURING OPEN SURGERY

#	Image	Step	Additional information
10.2.1		To insert the Tethered Probe through an open cavity incision, place the Tethered Probe directly into the body cavity using a gloved hand (left image) or one of the recommended instruments (right image) listed in Section 17.	Grip onto the Tethered Probe outside of the patient before inserting it into the cavity. Ensure that the user can see the Tethered Probe at all times.

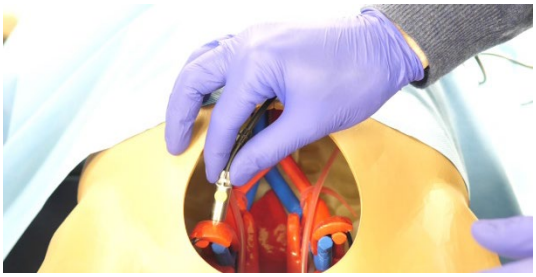
11.SCANNING A PATIENT USING THE SENSEI® SYSTEM

11.1.SCANNING A PATIENT DURING LAPAROSCOPIC SURGERY

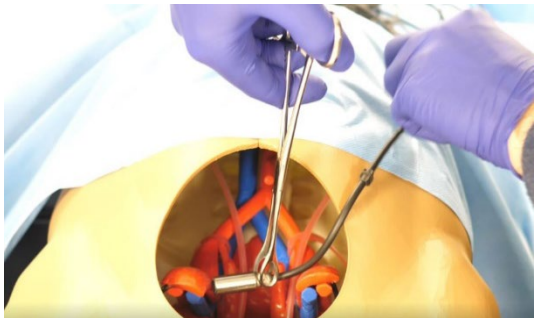
#	Image	Step	Additional information
⚠ Before scanning with the device, ensure that there is slack in the tether and that the tether is placed in a position where it will not get tangled with the patient or any other equipment.			
11.1.1	 	**Primary grip feature** Once inserted into the patient, grasp onto the Tethered Probe in one of the orientations shown, using a recommended instrument listed in Section 17.	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether. Only grip onto the Tethered Probe using the grip features.**
		To alternate between grips, use the side pockets on the probe head.	⚠ **If any damage to the tether is seen, stop using the device and replace it with a new Tethered Probe.**
11.1.3	 	Point the probe at the tissue to be scanned and move carefully and slowly along the area of interest. ⚠ Ensure that the probe detector window is in direct contact with and is perpendicular to the tissue. The numeric count rate will show the cps value detected by the Tethered Probe. The cps value will increase as greater uptake of the target radiopharmaceutical is detected. The graphical representation of the cps value e.g., the 'Arc display', will show the cps value in a visual format within the specified range. For example, the 'Arc display' when in 'LOW' range will show full scale deflection (arc completely filled) at 99 cps. The audio signal (high pitched 'beeps') will get faster as the cps value increases as this is linked to the graphical representation of the cps value. For example, the audio signal when in 'LOW' range will fully saturate at 99 cps and will generate 'beeps' at a consistently fast pace. ⚠ Be aware of potential background sources when scanning (e.g., the injection site).	

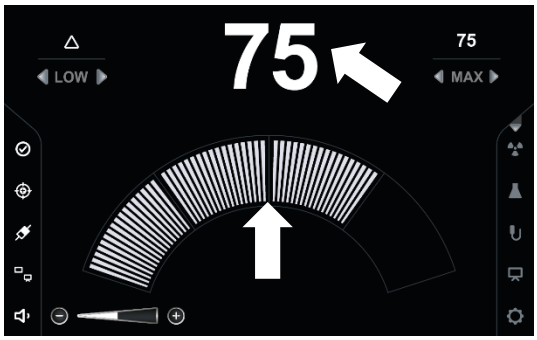
11.1.4		To confirm the location of a suspected area of increased activity it is recommended that that the user triangulates the signal. To do this, re-orient the probe so that it is pointing at the suspect area from several different angles. The visual and audio feedback will increase the closer the Tethered Probe is to the radiation source.	⚠ Be aware of potential background sources when scanning (e.g., the injection site). ⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether. Only grip onto the Tethered Probe using the grip features.** ⚠ **If any damage to the tether is seen, stop using the device and replace it with a new Tethered Probe.**

11.2.SCANNING A PATIENT DURING OPEN SURGERY

#	Image	Step	Additional information
⚠ Before scanning with the device ensure that there is slack in the tether and that the tether is placed in a position where it will not get tangled with the patient or any other equipment.			
11.2.1		Grasp onto the Tethered Probe with a gloved hand or one of the recommended instruments listed in Section 17.	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether. When using surgical instruments, only grip onto the Tethered Probe using the grip features.** ⚠ **If any damage to the tether is seen, stop using the device and replace it with a new Tethered Probe.**
11.2.2		To alternate between grips, use the side pockets on the probe head, or the user can use their hands.	

11.2.3





Point the probe at the tissue to be scanned and move carefully and slowly along the area of interest.

Ensure that the probe detector window is in direct contact with and is perpendicular to the tissue.

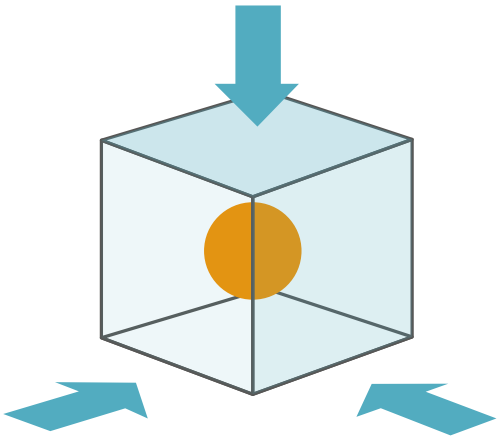
The numeric count rate will show the cps value detected by the Tethered Probe. The cps value will increase as greater uptake of the target radiopharmaceutical is detected.

The graphical representation of the cps value e.g., the 'Arc display', will show the cps value in a visual format within the specified range. For example, the 'Arc display' when in 'LOW' range will show full scale deflection (arc completely filled) at 99 cps.

The audio signal (high pitched 'beeps') will get faster as the cps value increases as this is linked to the graphical representation of the cps value. For example, the audio signal when in 'LOW' range will fully saturate at 99 cps and will generate 'beeps' at a consistently fast pace.

Be aware of potential background sources when scanning (e.g., the injection site).

11.2.4



To confirm the location of a suspected area of increased activity it is recommended that that the user triangulates the signal.

To do this, re-orient the probe so that it is pointing at the suspect area from several different angles.

The visual and audio feedback will increase the closer the Tethered Probe is to the radiation source.

Be aware of potential background sources when scanning (e.g., the injection site).

Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether. When using surgical instruments, only grip onto the Tethered Probe using the grip features.

If any damage to the tether is seen, stop using the device and replace it with a new Tethered Probe.

11.3.CHANGING RANGE

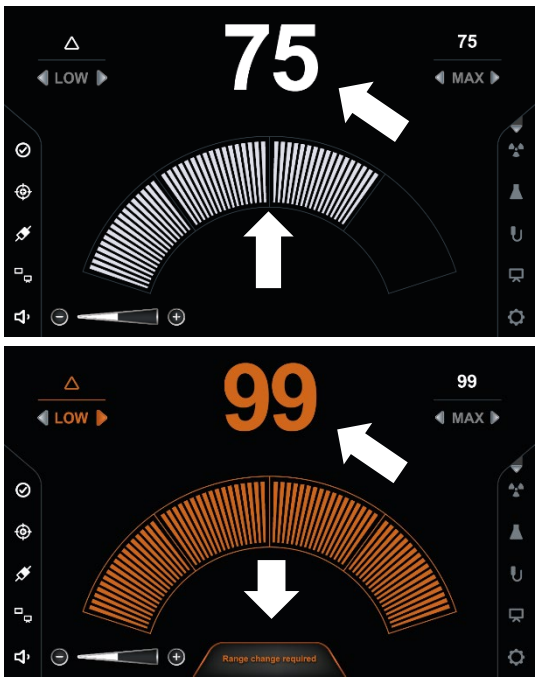
The SENSEI® System has four selectable ranges accessed via the left and right facing arrows on the top-left hand side of the Control Unit visual display. The ranges will affect the graphical representation of the cps value and the audio signal ONLY. The numeric cps value will always provide an accurate reading even if the range has been exceeded.

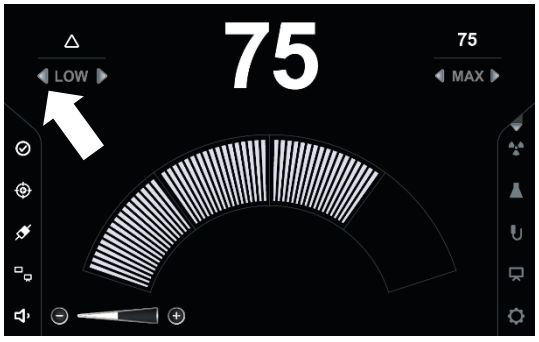
It is very important to understand that if the device enters an 'over-range' state, this does NOT indicate a 'hot' area. It only indicates that the system should be switched to the next range. The device will remain in an over-range state until this is corrected by the user.

Range	Cps value
LOW	0-99
MED	0–999
HIGH	0–9,999
MAX	0–99,999

Please note that the explanation below applies to the 'Manual' range change mode only. The 'Auto' range change mode will not require a user to manually change between ranges.

[Manufacturer note/Note to user: Only the 'Manual' mode option is currently available. The 'Auto' mode change option will be greyed out].

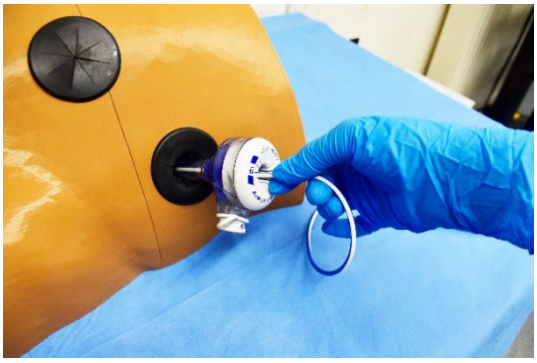
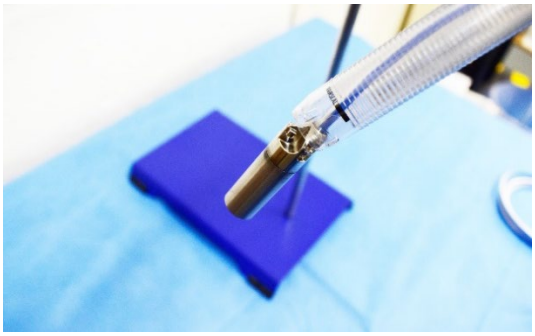
#	Image	Step	Additional information
11.3.1	**When the device enters an over-range state there are specific changes to look for.**		
11.3.2		The numeric count rate, the graphical representation and range accessory toggle will change from white to orange. A message indicating 'Range change required' will also appear at the bottom of the screen. The graphical representation will have reached the maximum rate for the given range. The audio signal will have reached the maximum rate for the given range and will generate 'beeps' at a consistently fast pace.	The numeric count rate will always provide an accurate reading. The graphical representation will have saturated and will no longer be accurately reflecting the numeric count rate. The audio representation will have saturated and will no longer be accurately reflecting the count rate.

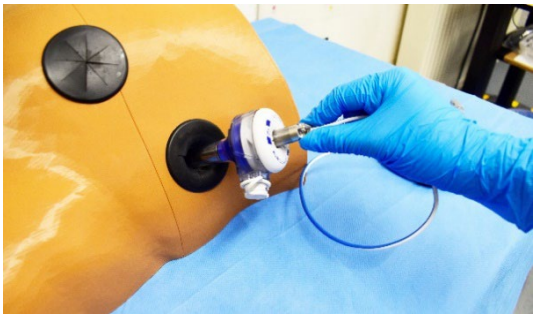
11.3.3	  	The user will be required to press the 'right arrow' on the range selector accessory toggle. This will move to the next range, i.e., change from a lower range to a higher range, e.g., from 'LOW' to 'MED'. When the 'right arrow' is pressed, a 'range change up' audio signal will be generated, indicating the change has been made.	When the range is changed, the graphical and audio representation will again accurately reflect the level of radiation. Each range will have a different audio signal. As the user selects higher ranges, from 'LOW' – 'MED' – 'HIGH' – 'MAX', the pitch of the audio signal will also increase for each range selected.
The device will not notify the user that the system should be moved to operate in a lower range.			
11.3.4	  	To adjust the range downwards, a user is required to press the 'left arrow' on the range selector accessory toggle. This will change from the higher range to a lower range, e.g. from 'MED' to 'LOW'. When the 'left arrow' is pressed, a 'range change down' audio signal will be generated indicating the change has been made.	Each range will have a different audio signal. As the user selects lower ranges, from MAX – HIGH – MED – LOW, the pitch of the audio signal will also decrease for each range selected.

12.REMOVING THE SENSEI® TETHERED PROBE FROM A PATIENT

12.1.REMOVING THE TETHERED PROBE DURING LAPAROSCOPIC SURGERY

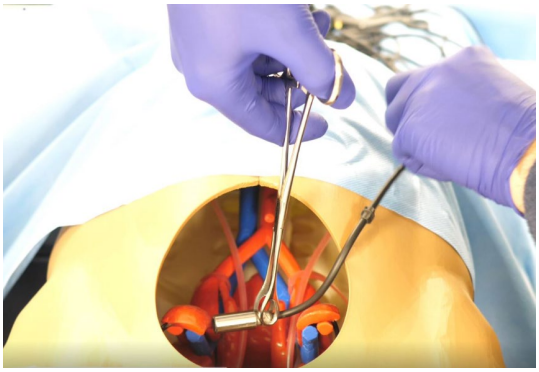
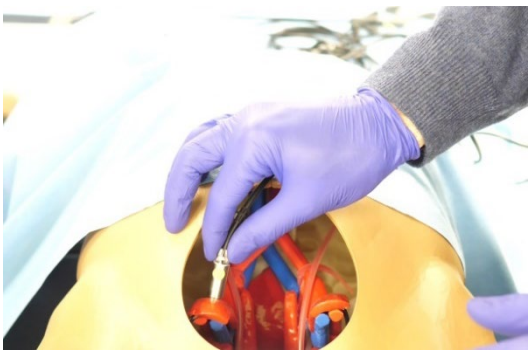
Always ensure the user has sight of the Tethered Probe. Do not attempt to remove the Tethered Probe without it being in line of sight as this may risk causing injury to the patient.

#	Image	Step	Additional information
12.1.1		To remove the Tethered Probe during laparoscopic surgery, take the probe to the base of the trocar and disengage all instruments from all grip sites on the probe head. Pull back gently on the tether so that the device is positioned in the base of the trocar. Take care to ensure that the Tethered Probe is not used in a way that may compromise insufflation pressure.	**This must be conducted using laparoscopic camera guidance.** **Do not remove the Tethered Probe without taking the probe to the base of the trocar, otherwise this will risk causing internal injury to the patient.** **Do not remove the Tethered Probe by using a laparoscopic grasper.**
12.1.2		Once the Tethered Probe reaches the trocar, be careful to ensure that the Tethered Probe does not get caught on the lip of the trocar.	If the Tethered Probe gets caught on the trocar, twist the tether so that the whole grip feature is within the trocar. It may be necessary to release tension on the tether slightly and then re-approach the trocar. **Avoid gripping onto the tether at all times. Only grip onto the Tethered Probe using the grip features. Do not use any surgical tools to grip the tether directly.**

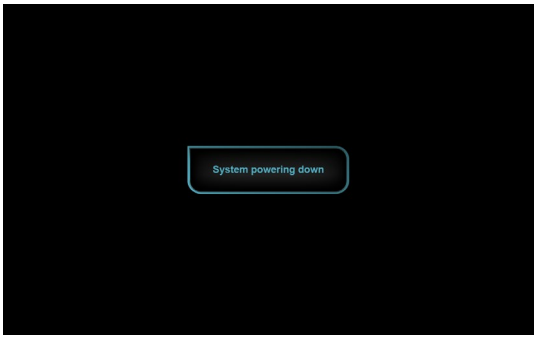
		When the Tethered Probe is inside the trocar, pull back gently until reaching the trocar exit.	⚠ If the device is used with a valved trocar, slightly more pressure may need to be applied, to remove the probe head through the valve. ⚠ Be careful not to cause any injury to the patient through excessive force. Minimise any additional force when removing the Tethered Probe.
12.1.3	Once removed from the trocar and the procedure is complete, the Tethered Probe may be disposed of.		See Section 19 for disposal information.

12.2.REMOVING THE TETHERED PROBE DURING OPEN SURGERY

⚠ **Always ensure that the user has sight of the Tethered Probe. Do not attempt to remove the Tethered Probe without it being in line of sight as this may risk causing injury to the patient.**

#	Image	Step	Additional information
12.2.1		For the Tethered Probe to be removed during open surgery the user is encouraged to keep any recommended instruments attached to the Tethered Probe. This will assist removal.	If the Tethered Probe is dropped or becomes detached from an instrument, gently pull on the tether to retrieve the Tethered Probe. ⚠ If any resistance is detected, stop pulling on the tether and check for any obstruction.
12.2.2		Gently remove the Tethered Probe from the open cavity with the instrument attached. If using gloved hands to hold the Tethered Probe, maintain a grip on the Tethered Probe and remove it from the open cavity.	⚠ **Ensure that the Tethered Probe is not caught on tissue or other internal structures.** ⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**
12.2.3	Once retrieved from the open cavity, and the procedure is complete, the Tethered Probe may be disposed of.		See Section 19 for disposal information.

13. SHUTDOWN PROCEDURE

#	Image	Step
Once a user has finished using the Control Unit and the Tethered Probe, follow the instructions below.		
	The Control Unit and the power cord are not sterile. All tasks in this section should be performed by a non-sterile member of staff with the Control Unit outside of the sterile field.	
13.1.1	 	Press the operate button on the front of the Control Unit. The visual display will report 'System powering down'. After a few seconds the light on the button will no longer be illuminated and the visual display will change from 'System powering down' to a blank display.
13.1.2		To remove the Tethered Probe from the Control Unit, pull backwards on the grey plastic sleeve on the tether connector to disengage the lock.
13.1.3		Push the isolator switch on the back of the Control Unit to move the isolator switch to the 'off' ('0') position.
13.1.4		If the mains socket is fitted with an 'on/off' switch, change the switch from the 'on' to the 'off' position.

13.1.5		To remove the power cord from the Control Unit, pull back on the red toggle (locking mechanism) and then remove the connector from the socket. The power cord cannot be sterilised and should only be cleaned as per the instructions in Section 16.1.

14. TECHNICAL ALARM / SYSTEM FAULT

In the event the SENSEI® Control Unit detects a problem with the SENSEI® System whilst in use, a Technical Alarm will occur, this condition can be identified visually and audibly.

#	Image	Step
If the SENSEI® System enters a Technical Alarm condition, the following will occur:		
14.1		**Control Unit** The visual display will show a red box entitled 'SYSTEM FAULT'. It will detail the type of fault e.g., 'Control Unit Fault' and an instruction for the user to follow e.g., Consult the Instructions for Use. The operate button will change from steady green to a red pulsing light. The loudspeaker will produce the Technical Alarm sound, which is a dual tone, repetitive sound.
14.2		**Additional display** If connected, the additional display will show a red box entitled 'SYSTEM FAULT'. It will provide an instruction for the user to follow i.e., 'Refer to the Control Unit for details'.

⚠ **The SENSEI® System cannot be used when a Technical Alarm is present, and it is not possible to suppress the Technical Alarm.**

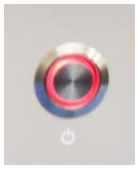
If a Technical Alarm occurs:

- **Observe the instructions on the visual display and, if connected, any additional display.**
- **Restart the system following the shutdown procedure in Section 13, followed by starting the device up as shown in Section 9.2. Be aware that when restarted the system will be restored to the original factory default settings and any user settings will need to be re-entered after the restart, this includes performing the probe start-up check again.**

- **If the problem persists, contact Lightpoint Medical Ltd. or the supplier.**

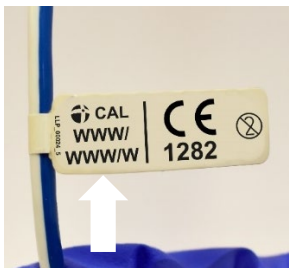
15. TROUBLESHOOTING

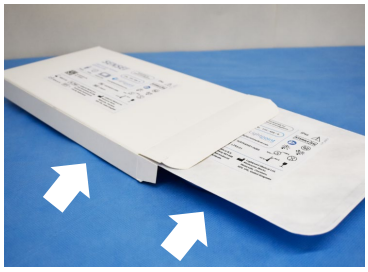
Problem	Image	Possible causes	Actions
1. The white 'system status' icon is not pulsing on the Control Unit and/or the additional display. What does this mean?		The system has frozen.	Please restart the device by following the shutdown procedure in Section 13, followed by starting the device up as shown in Section 9.2. Be aware that when restarted the system will be restored to the original factory default settings and any user settings will need to be re-entered after the restart, this includes the probe start-up check. If this problem persists, please contact Lightpoint Medical Ltd. or the supplier.
2. The 'probe check status' icon looks like this. What does this mean?		This symbol means that a probe check is required or that there is a fault with the probe check.	If a probe check has not been conducted, please follow the instructions in Section 9.3. If a probe check has been conducted, then confirm that the correct probe check code has been entered. If a probe check code has been entered correctly, but the system still displays a fault, please replace the faulty Tethered Probe with a new probe. Please return the faulty Tethered Probe to Lightpoint Medical Ltd. Refer to Section 20 for details.
3. The 'probe status' icon looks like this. What does this mean?		This symbol means that there is a probe connected but that there is a fault in the connection or the probe.	If a Tethered Probe has been connected, but the system still displays a fault, please replace the faulty Tethered Probe with a new probe. Please return the faulty Tethered Probe to Lightpoint Medical Ltd. Refer to Section 20 for details.
4. The 'Additional display status' icon looks like this. What does this mean?		This symbol means that there is no additional display connected or that there is a fault in the connection.	Check that the DVI-D cable is connected to the additional display output on the rear of the Control Unit and that the DVI-D cable is connected to the additional display. If no additional display is required, disable the additional display output. See Section 9.4. If the problem persists, contact Lightpoint Medical Ltd. or the supplier.

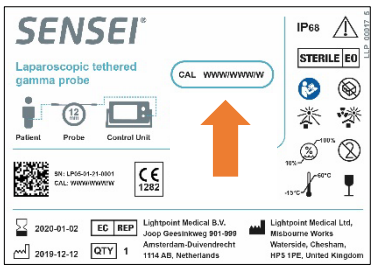
5. The 'volume' icon looks like this. What does this mean?		This symbol means that there is a fault in the audio system.	Contact Lightpoint Medical Ltd. or the supplier.
6. In the radiation type selection menu, the symbol is orange. What does this mean?		If the symbol is orange, this means that the radiation type is not selected.	Please select a radiation type.
7. In the radionuclide selection menu, the symbol is orange. What does this mean?		If the symbol is orange, this means that a radionuclide is not selected.	Please select a radionuclide.
8. In the probe settings menu, the symbol shows orange. What does this mean?		This means that a probe check has not been completed successfully.	Please refer to Section 9.3 to carry out a probe check.
9. The operate button on the front panel of the Control Unit, is flashing red. What does this mean?		This means there is a system fault.	Restart the system by following the shutdown procedure in Section 13 followed by starting the device up as show in Section 9.2. Be aware that when restarted the system will be restored to original factory default settings and any user settings chosen will need to be re-entered after the restart, this includes the probe start-up check. If the problem persists, contact Lightpoint Medical Ltd. or the supplier.

10. Where can I find the probe check code?

Location:



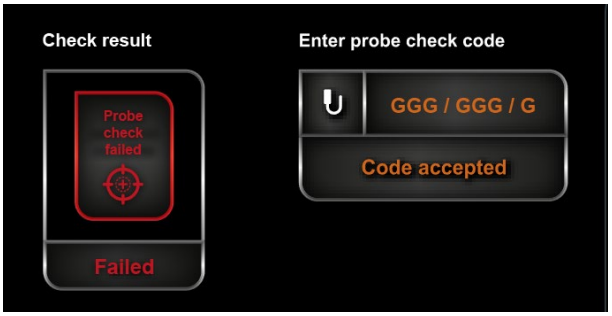


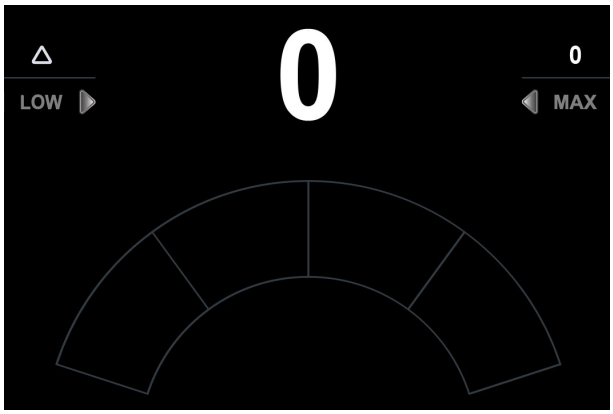


This is on the Tethered Probe label (located on the cable near the connector end) and it is also on the blister pack label and on the cardboard sleeve label, that the blister pack was supplied in.

11. When starting up the Control Unit, the system does not pass the start-up check and displays a warning.	
	
What is the cause?	• There is a system fault.
What action to take?	• Restart the system following the shutdown procedure in Section 13 followed by starting the device up as shown in Section 9.2. • Please note, when restarted the system will be restored to original factory default settings and any user settings chosen will need to be re-entered after the restart, this includes the probe start-up check. • If the problem persists, contact Lightpoint Medical Ltd. or the supplier.

12. The Control Unit visual display is blank, or the additional display is blank.	
The visual display shows:	
What is the cause?	• The Control Unit is not turned on correctly. • The additional display is not engaged correctly. • There is a system fault.
What action to take?	• Power down the Control Unit and check the power connections to the Control Unit are correct, according to Section 9.1 and 9.2. • Check that the DVI-D cable is connected to the additional display output on the rear of the Control Unit, that the DVI-D cable is connected to the additional display. Ensure that the additional display is turned on and that the additional display has been engaged in the additional display settings menu on the SENSEI® Control Unit. (See Section 9.4). If the error persists, replace the DVI-D cable. • If the problem persists, contact Lightpoint Medical Ltd. or the supplier.

13. The probe check has failed.	
The visual display shows:	 *Note that the probe check code of 'GGG/GGG/G' shown in the image is an example only. The code will be unique for each Tethered Probe used.*
What is the cause?	• There is a system fault or a problem with the probe check function.
What action to take?	• If a probe check has been conducted, then confirm that the correct probe check code has been entered, see Section 9.3. • If the probe check code has been entered correctly, but the system still displays a fault, please replace the Tethered Probe with a new probe. • Please return the faulty Tethered Probe to Lightpoint Medical Ltd. Refer to Section 20 for details.

14. The Control Unit does not seem to be detecting radiation.	
The visual display shows:	
What is the cause?	• The Tethered Probe is not pointed at a radiation source. • The probe check has not been conducted. • There is a system fault.
What action to take?	• Point the Tethered Probe at a radiation source e.g., a Cobalt-57 source. • If a probe check has not been conducted, please follow instructions in Section 9.3. • If a probe check has been conducted, then confirm that the correct probe check code has been entered. • If the probe check code has been entered correctly, but the system still does not detect radiation, please replace the Tethered Probe with a new probe. • If the problem persists, contact Lightpoint Medical Ltd. or the supplier.

16. MAINTENANCE

This section discusses procedures for the maintenance of SENSEI®.

DO NOT OPEN THE TETHERED PROBE OR CONTROL UNIT

- The Tethered Probe and Control Unit are tested and sealed during manufacture. Opening the Tethered Probe or Control Unit may result in damage and will void the warranty.

Maintenance is limited to:

- External cleaning
- Fuse replacement
- Conducting functional diagnostics

16.1. CLEANING PROCEDURES – CONTROL UNIT

This section discusses the cleaning procedures for the **Control Unit only**.

The Tethered Probe is a single use device, therefore should be disposed of as clinical radioactive waste.

DISCONNECT THE MAINS POWER SUPPLY FROM THE CONTROL UNIT BEFORE CLEANING

THE CONTROL UNIT SHALL NOT BE STERILISED

The external surfaces of the Control Unit and power cord may be wiped down using hospital cleaning agents (e.g., Clinell® wipes or Sprint H 200 solution) and can be cleaned using standard hospital cleaning procedures before and after use.

Care should be taken to ensure that the visual display on the Control Unit does not become contaminated with any bodily fluids. If the visual display comes into contact with bodily fluids, ensure that the whole Control Unit is cleaned.

16.2.SYSTEM DIAGNOSTICS

The SENSEI® System contains a number of diagnostic mechanisms, some of which run when the unit is first started and others that run in the background during normal use.

There is a ‘power on self test’ system that operates during the start-up sequence, which checks that the hardware and software are all performing within specified limits. This test can be performed on just the Control Unit or on a Control Unit and Tethered Probe together, so that the Tethered Probe is also checked. This test provides a simple pass / fail output.

There is also an option for a user to instigate a manual test of the system using the built in test equipment. As with the ‘power on self test’ system, this checks that the hardware and software are all performing within specified limits. This manual test can also be performed on just the Control Unit or on a Control Unit and Tethered Probe together. This manual test provides a user with more detailed diagnostic information. See Section 9.5.

A third diagnostic process runs continuously during routine use, to check that the system is functioning normally. This test checks and confirms that the signal chain from the sensor in the Tethered Probe to the output to the user is fully operational. The user is continually kept informed as to the health of the system, by way of a visual and audible alive signal.

16.3.HOW TO USE THE GROUNDING CONNECTION ON THE CONTROL UNIT

The equipotential ground bond point mounted on the rear of the Control Unit may be used when there is a requirement for the Control Unit to be held at the same electrical potential as other bonded metal objects in the operating room.

The equipotential ground bond point can be identified by the equipotential bonding symbol and should be connected using a suitable socket.

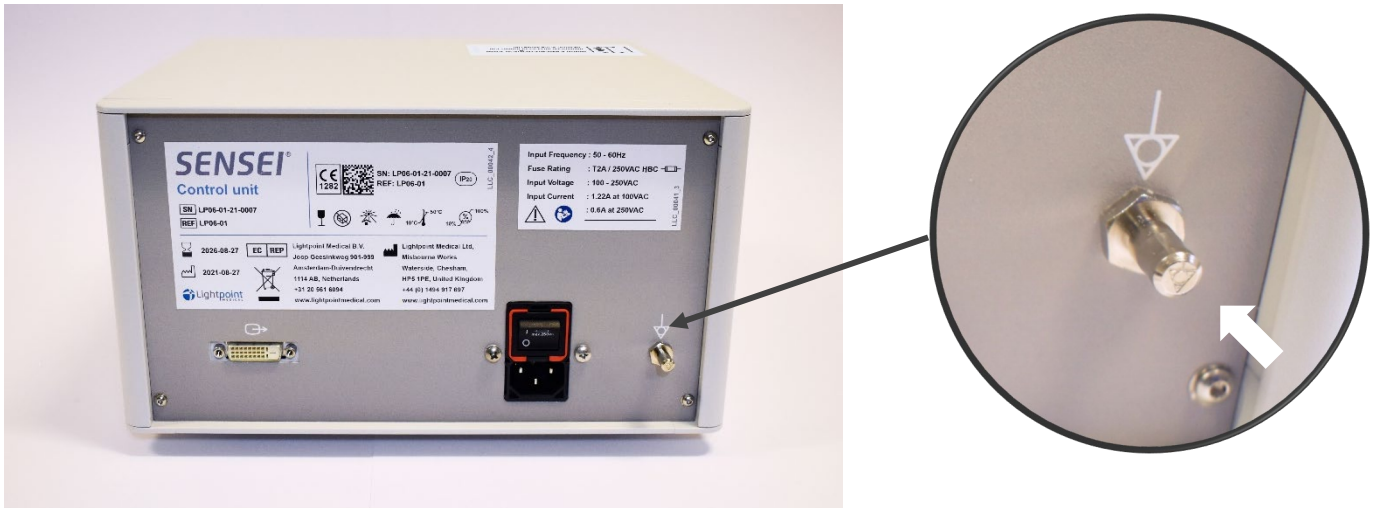


Figure 8 – SENSEI® Control Unit equipotential ground bond point

16.4.REPLACEMENT OF FUSES

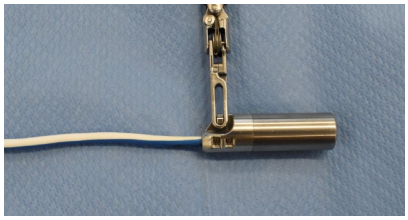
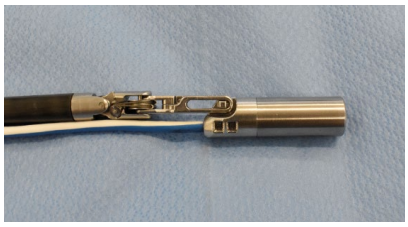
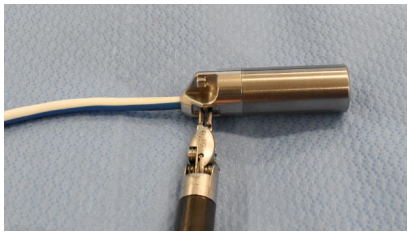
The information below explains how to change the mains line fuses. See Section 5.3 for further information. The fuses are mounted in a holder inside the power socket on the rear of the Control Unit. A competent person should perform this task to ensure that it is conducted safely and correctly.

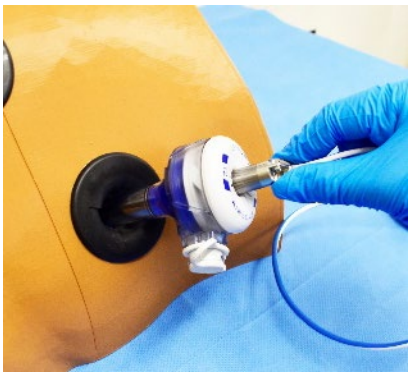
#	Step	Image
16.4.1	Push the isolator switch on the back of the Control Unit to move the isolator switch to the 'off' ('0') position and remove the power cord as per Section 13. **Ensure that the Control Unit is not connected to the mains power supply.**	
16.4.2	To remove the fuse holder unit, use a simple tool to eject the carriage from the assembly at the points shown in the image.	
16.4.3	Slide the fuse holder out of the assembly, as shown in the image.	
16.4.4	Replace the 2 in line fuse(s). Note that there is a spare fuse provided on the underside of the carriage. If used, ensure that the spare is replaced. **Only use the correct fuse type as specified in Section 5.3.**	
16.4.5	Slide the fuse holder back into the assembly until it is again securely 'locked' into place.	

17. RECOMMENDED COMPATIBLE EQUIPMENT

The SENSEI® Tethered Probe and Control Unit have been designed to work optimally with specific devices, platforms, and instruments, which may be commonly found in robotic-assisted laparoscopic, laparoscopic, or open surgery:

Any instruments that are not recommended in the Instructions for Use are used at the discretion and liability of the user. Take care if using equipment that is not listed below.

SENSEI® Tethered Probe – Recommended compatible equipment		
 	**Tissue Grasper(s) / Johan Grasper(s)**	**Recommended robotic instrument(s):** Intuitive Surgical da Vinci® EndoWrist® ProGrasp® Intuitive Surgical da Vinci® EndoWrist® Cadiere forceps
		LaproSurge® Johan LG006-T/ LG007-T Ethicon® ENDOPATH® Babcock 5BB
		Recommended open instrument(s): Aesculap® Allis Tissue Forceps
	**Needle Holder(s)**	**Recommended robotic instrument(s):** Intuitive Surgical da Vinci® EndoWrist® Large Needle Drivers
		Recommended laparoscopy instrument(s): The SENSEI® Tethered Probe is designed to work with standard needle holders. Take care when using with an instrument that has not been recommended for use with the SENSEI® System.
		Recommended open instrument(s): Aesculap® Halsted/Nissen Forceps Aesculap® Overholt Forceps



Trocar(s)

Recommended trocar(s):

Surgiquest®/ConMed® AirSeal®
Ethicon® ENDOPATH® Xcel®
Covidien®/Medtronic® VersaOne™

The SENSEI® Tethered Probe has an outer diameter of 12 mm, therefore a suitable trocar should be identified to accommodate the Tethered Probe.

Surgical equipment, such as trocars, should be placed in accordance with standard laparoscopic techniques giving specific regard to the anatomy of the patient to assure that the Tethered Probe has access to the areas if interest.

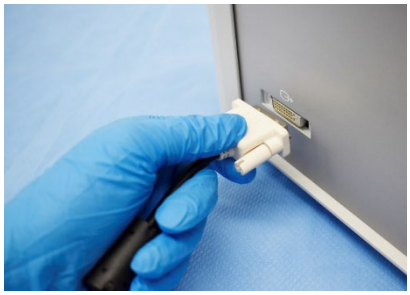
Additional display

Recommended robotic platform(s):

Intuitive Surgical da Vinci® Surgeon Console Si
Intuitive Surgical da Vinci® Surgeon Console X
Intuitive Surgical da Vinci® Surgeon Console Xi

Recommended laparoscopy platform(s):

The SENSEI® System is designed to include a connection for an additional display via a DVI-D connection. Take care when connecting to an additional display that has not been recommended for use with the SENSEI® System.



DVI-D cable specifications

A cable is required to connect the SENSEI® System to an additional display. The additional display output on the back of the Control Unit is a DVI-D output. The input port on the additional display will depend on the equipment being used. Consult the manufacturer's Instructions for Use for details about the additional display.

Select a cable that provides a suitable distance between the SENSEI® Control Unit and the additional display, taking into consideration the working environment.

Connector type	Resolution	Frame Rate
DVI-D	1024 x 768	38 fps

18. STORAGE AND HANDLING

SENSEI® System component	Condition	Temperature	Humidity
Tethered Probe	Non-operational	-15-60°C	10-100% RH (non-condensing)
Control Unit	Non-operational	-15-60°C	10-100% RH (non-condensing)

19. DISPOSAL OF THE SENSEI® SYSTEM

The user shall not dispose of any part of the medical system as unsorted municipal waste.

The Tethered Probe is a single use device and the responsible organisation (e.g., Hospital) is required to dispose of it in radioactive clinical waste.

The Control Unit may be sent to Lightpoint BV in Amsterdam (address below) for disposal.

Lightpoint Medical B.V.
Joop Geesinkweg 901-999,
Amsterdam-Duivendrecht,
1114 AB, Netherlands
www.lightpointmedical.com

The blister packaging for the Tethered Probe is made out of plastic and cannot be reused and must be disposed of in standard waste. All cardboard packaging is recyclable and can be disposed of as recyclable waste.

20. CUSTOMER FEEDBACK, REPORTING OF COMPLAINTS OR ADVERSE EVENTS AND RETURNING SENSEI® DEVICES.

20.1. CUSTOMER FEEDBACK AND REPORTING OF COMPLAINTS OR ADVERSE EVENTS

Your opinions are important to us and all feedback from our customers helps us improve our products and services. If you have any questions, comments or complaints about the product or user documentation, please use the contact details below to share your views. Please also notify us in the event of any adverse incident.

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feedback@lightpointmedical.com

20.2. RETURNING SENSEI® DEVICES

Faulty and/or damaged SENSEI® Control Units and Tethered Probes should be returned to Lightpoint Medical Ltd. Refer to the Lightpoint Medical website for detailed return instructions: www.lightpointmedical.com