FRONT SHEET

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SENSEI® INSTRUCTIONS FOR USE

Document #: LPM_EN_IFU_001_08

PART #: LLC_04000 REV 08

Revision History

Rev	Revision History	ECN	Date
01	First Release	n/a	n/a
02	Updated in line with ECM Technical File Feedback – addition of performance characteristics.	052	19 Nov 2020
03	Updated with recommended nominal voltages (100-240V) and frequency (50-60Hz). Update operating temperature to 10-40°C.	055	13 Jan 2020
04	Updated in line with the changes from the External Design Review held in Mar 2020 to update the statement regarding the control unit not holding patient data, adding additional warnings with regards to the damage to the tether and gamma window and updated missing images throughout the IFU. https://lightpointmedical.box.com/s/99mauld6gpggdcxdk5fzo2duh49crde9	068	24 Apr 2020
05	Updated the Intended Use and Indications for Use in line with changes of the CER.	076	16 Jun 2020
06	Update the front sheet and addition of the part number to the IFU.	081	21 Aug 2020
07	Update the contents of the IFU based on the findings from the summative evaluation. These include: emphasis and format of warnings and enhanced descriptions for the following: insertion, connecting to an additional display, probe check, scanning and removal. The changes were authorised based on the Feedback Register list of Summative Mitigations Actions which proceeds the Summative Evaluation Mitigations Meeting Notes. Add CE mark to the front page of the IFU Amend the Indications for use as per recommendation from ECM (Notified Body)	080 097 098	07 Jan 2021
08	Addition of customer feedback/adverse event reporting information, update to performance test results (sensitivity), addition of Monotype disclaimer and Copyright statements, addition of packaging disposal instructions.	103	19 Feb 2021

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. 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.

1.1. 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 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

2. PERFORMANCE CHARACTERISTICS

2.1. PERFORMANCE SPECIFICATIONS

PARAMETER	VALUE
MAXIMUM COUNT RATE	99,999 Counts per second (CPS)
SENSITIVITY	1200 CPS / MBq at 20mm 680 CPS / MBq at 30mm
ANGULAR RESOLUTION	43 degrees FWHM
LATERAL RESOLUTION	29 mm FWHM at 30mm
BACKGROUND REJECTION	>99.9%

2.2. OPERATING CONDITIONS

SENSEI® will display the count per second rate of the activity detected in a number of the ranges.

RANGE	COUNTS PER SECOND (CPS)
LOW	0 - 99
MED	0 – 999
HIGH	0 – 9,999
MAX	0 – 99,999

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

3. 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 designed to be reusable. The Control Unit does not come into contact with the patient and will be used outside of the sterile field.

3.1. LAPAROSCOPIC TETHERED GAMMA PROBE

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

The Tethered Probe incorporates a scintillator to convert a gamma photon into an optical photon for detection using a semiconductor-based device that converts the photon into an electrical pulse. The Tethered Probe is sensitive to gamma rays emitted by a ^{99m}Tc source, which has 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 12mm 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. For open surgery a suitable grasper (e.g. Allis Tissue or Overholt forceps) can be used. The Tethered Probe has a 3m 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.

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

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

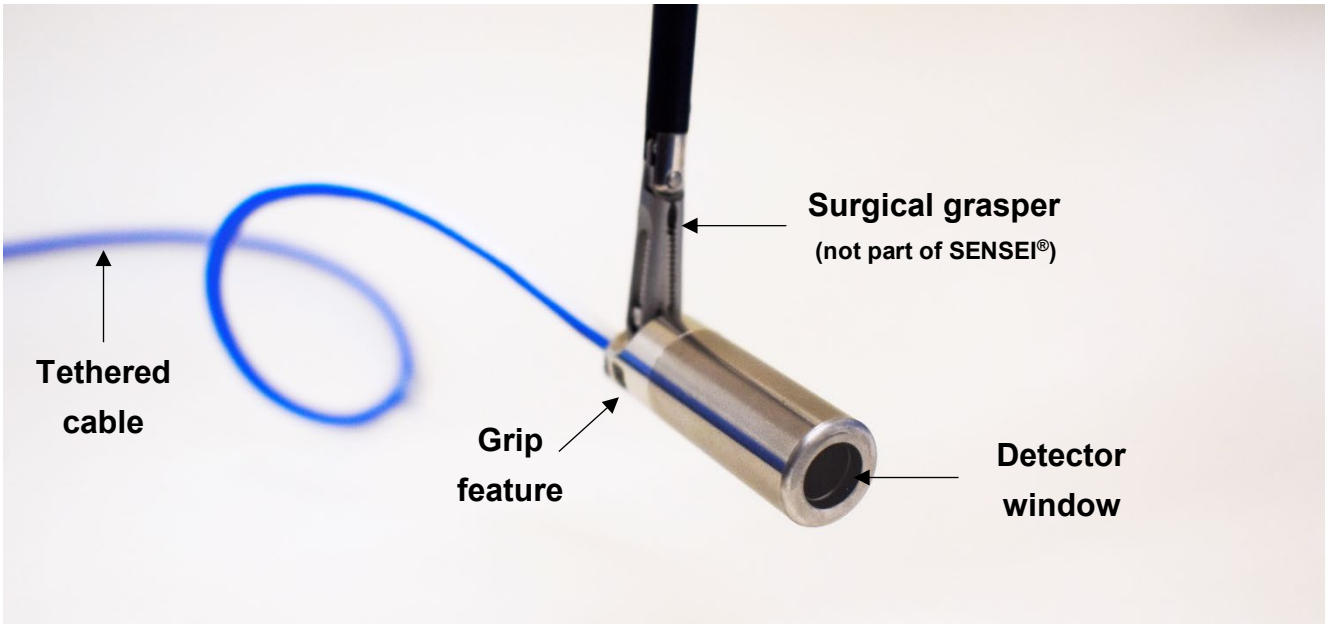


Figure 1 - Image of the Tethered Probe

3.1.1.SPECIFICATIONS

Tethered Probe specifications:

LENGTH OF PROBE	41.1mm
DIAMETER OF PROBE	12mm
LENGTH OF CABLE	3m
DIAMETER OF CABLE	3.2mm
WEIGHT	110g
IP RATING	IP68

3.2.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 device does not display an image of the inside of the body or an image of the distribution of the radiopharmaceutical *in vivo*.

It is possible to use the SENSEI® system in a standalone mode. Alternatively, it can be used with a 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 - Design of the Control Unit

3.2.1 SPECIFICATIONS

Control Unit specifications:

HEIGHT WITHOUT HANDLE	165mm
HEIGHT WITH HANDLE	235mm
WIDTH	320mm
DEPTH	260mm
WEIGHT	4kg
IP RATING	IP21

3.3.POWER SUPPLY/FUSE RATING

Three mains power cables 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 – 250VAC
INPUT CURRENT:	1.22A at 100VAC 0.6A at 250VAC
INPUT FREQUENCY:	50 – 60Hz

Fuses in the Control Unit:

T2A HBC / 250VAC (20mm)

Electromagnetic compatibility (EMC)

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

Phenomenon	Standards	Immunity test levels Professional healthcare facility environment
Electrostatic Discharge	EN 61000-4-2	± 8kV contact ±2kV, ±4kV, ±8kV and ±15kV air
Radiated Immunity	EN 61000-4-3	3V/m 80MHz – 2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communication equipment	EN 61000-4-3	See Frequency & Range Level: RF Wireless Communication Equipment Table (below)
Electrical fast transients / bursts	EN 61000-4-4	±2kV 100kHz
Surge	EN 61000-4-5	±0.5kV, ±1kV and ±2kV
Conducted disturbances induced by RF fields	EN 61000-4-6	3V 0.15MHz – 80MHz 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz

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

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 10ms 0° for all other dips (0% Vn 20ms and 70% Vn 500ms)

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

4. 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 to be used 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 outside of what is described in these Instructions for Use (IFU).

5. 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®.

5.1. 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 the sterile field).

- The surgical team should keep the Tethered Probe sterile throughout the duration of 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 TO BE USED 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 standards 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 unintentionally cauterise nearby tissue.
- **Other electrical equipment:** SENSEI® should not come into contact with other electrical equipment during use.

DO NOT OPEN THE TETHERED PROBE OR CONTROL UNIT

- 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 parts 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 IN AN AUTOCLAVE

- No component or part of the Control Unit can be autoclaved. Only use cleaning methods described in Section 13.1.

- The Control Unit and mains cable are reusable and non-sterile. The Control Unit is to be installed outside 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.

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 INNACURATE READINGS

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

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 FROM A TROCAR BY USING A LAPAROSCOPIC GRASPER DURING LAPAROSCOPIC SURGERY

5.2.CAUTION

Avoid causing damage to the tether cable during use. If the tether cable is damaged STOP using the Tethered Probe and replace it with a new Tethered Probe.

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

The Tethered Probe is connected to a 3m 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.

5.3. 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 or to be used to reference surgical procedures or techniques.

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

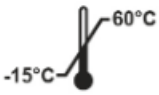
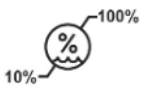
6. DEFINITIONS

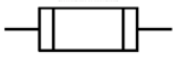
This section defines key terms and symbols used in the Instructions for Use (IFU).

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 for the medical electrical equipment or a medical electrical system to perform its function.
Autoclave	A strong heated container used for chemical reactions 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.
Confidence Signal	This is a test mechanism that checks the entire signal chain during routine use. The result is an audible / visible confidence signal that the system is functioning normally.
Control Unit	Control Unit.
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 Professionals.
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®	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.

7. SYMBOLS

Symbol	Definition	Symbol	Definition
	**Manufacturer** LIGHTPOINT MEDICAL LTD. MISBOURNE WORKS, WATERSIDE, CHESHAM, HP5 1PE UNITED KINGDOM		**WEEE Symbol**
	**Date of Manufacture** YYYY-MM-DD		**Storage and Transit Temperature** Example ranges between -15°C – 60°C
EC REP	**Authorised Representative** LIGHTPOINT MEDICAL B.V. JOOP GEESINKWEG 901-999 AMSTERDAM-DUIVENDRECHT 1114 AB, NETHERLANDS		**Storage and Transit Humidity** Example ranges between 10% – 100%
	**Use By** YYYY-MM-DD		**Keep away from sunlight**

SN	**Serial Number** 0123456789-1234 (Tethered Probe) LP06-01-YY-123456 (Control Unit)		**Protect from heat and radioactive sources**
REF	**Model** LP05-01 (Tethered Probe) LP06-01 (Control Unit)		**Keep dry**
QTY	**Quantity of item(s)** 1 or 10		**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.		**Type BF**
	**Caution**		**Video Output** (DVI Connection to Additional display)
STERILE EO	**Sterilized using ethylene oxide**	IPN_2N_0	**IP Rating** IP68 (Tethered Probe) IP21 (Control Unit)
	**Protective earth (ground)**		**Equipotentiality**
	**Fuse Rating**		**Fragile, handle with care**
	**Do not use if package is damaged**	CE 1282	**CE Mark, Class IIa**

8. OPERATING INSTRUCTIONS

8.1. CONTROL UNIT EXTERNAL FEATURES

Figure 3 - Control Unit front panel

Figure 4 - Control Unit rear panel

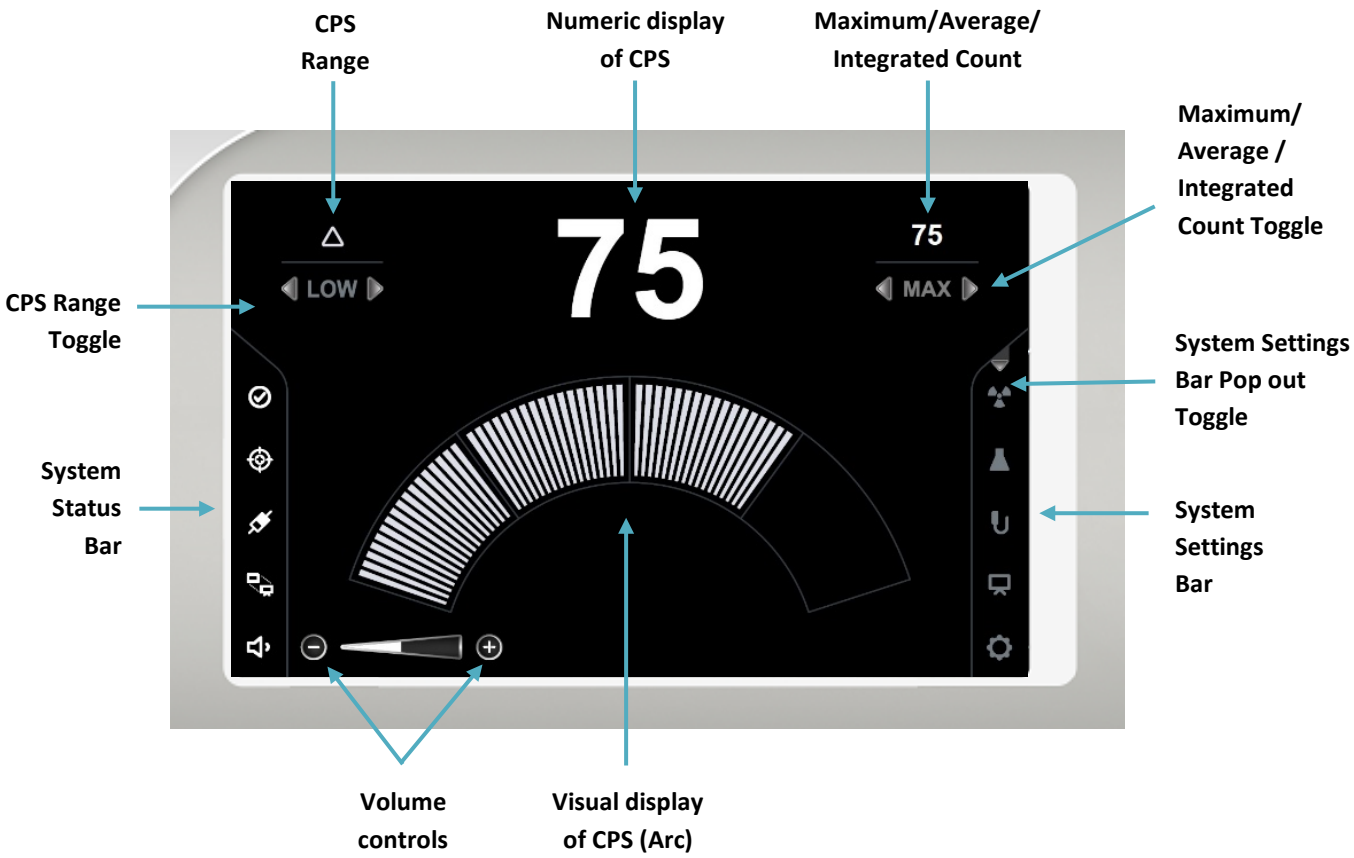
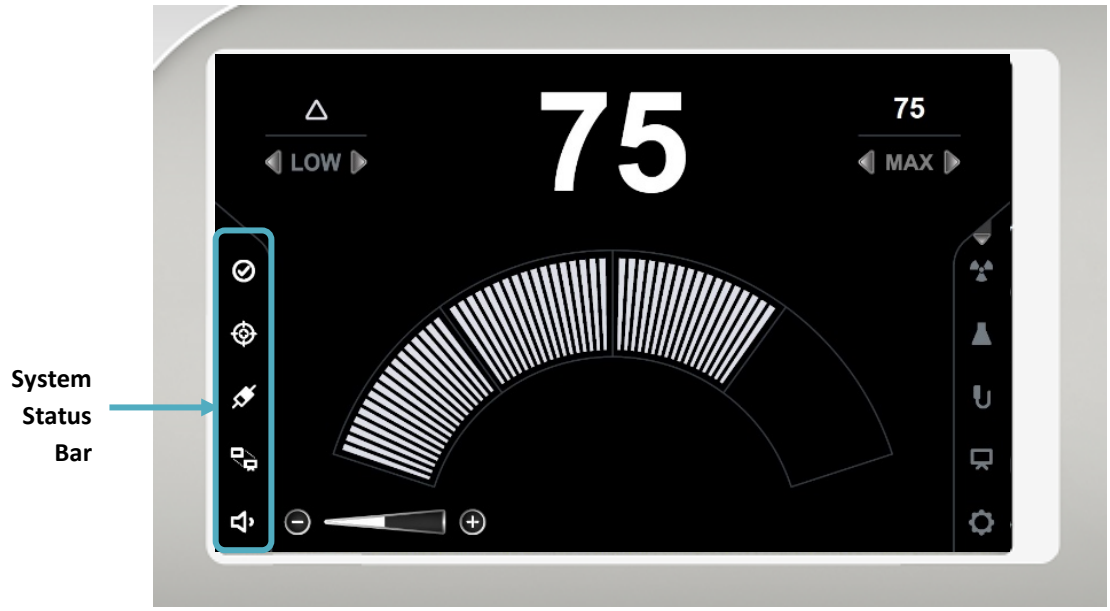


Figure 5 - Control Unit visual display

8.2.CONTROL UNIT TOUCHSCREEN INTERFACE

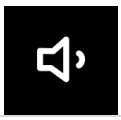
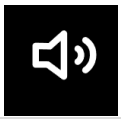
8.2.1.SYSTEM STATUS BAR SYMBOL MEANINGS

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



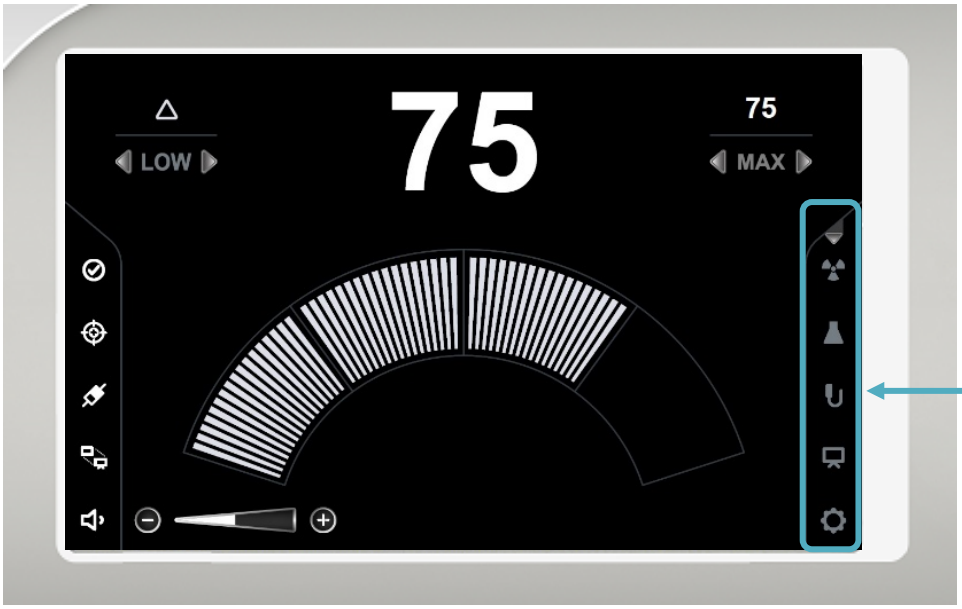
System status bar

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 12)
			The system is not ready for use, proceed to conduct probe check	Conduct probe check. Consult Troubleshooting (section 12)
	Probe check status		Probe not connected and probe check not completed	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		No probe connected	Connect SENSEI® Tethered Probe
			Probe connected	No action required
			Probe connected, connection fault	Consult Troubleshooting (section 12)
	Additional display status		No additional display connected	Need to connect a DVI cable to engage with an additional display
			Additional display connected	DVI cable is connected to an additional display: Access the Additional display settings menu
			Additional display projected onto the connected additional display	No action required
			Additional display connected, connection fault	Consult Troubleshooting (section 12)
	Volume		Volume, low	No action required
			Volume, medium	No action required
			Volume, high	No action required
			Volume, max	No action required
			Volume, muted	No action required
			Audio fault	Consult Troubleshooting (section 12)

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.



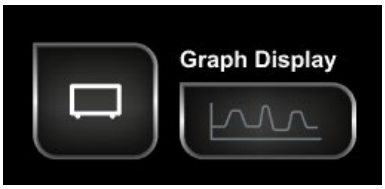
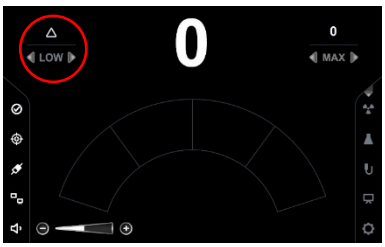
System settings bar

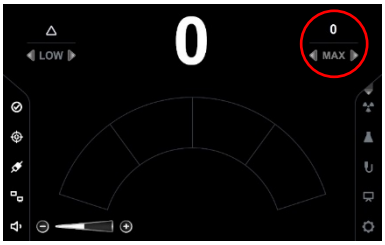
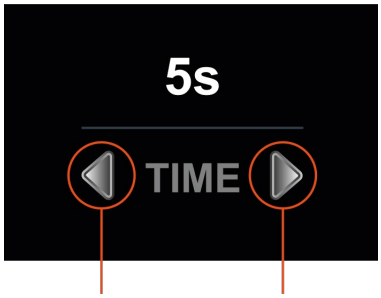
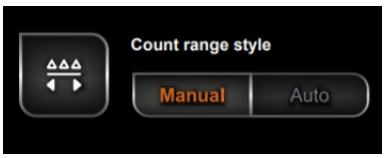
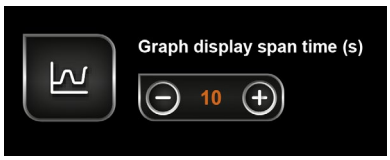
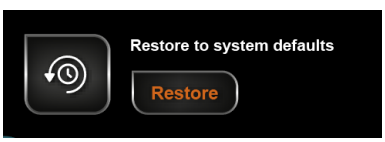
Setting Symbol	Name of Symbol	Options	Symbol meaning	Action required
	System settings bar minimised		System settings bar is minimised, probe check is required	Press button to expand system settings bar to conduct probe check
			System settings bar is minimised, probe check is completed	No action required
	Radiation type selection		Radiation type menu closed	No action required
			Radiation type menu open	No action required

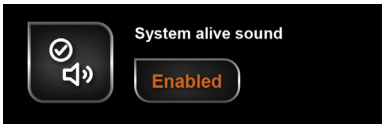
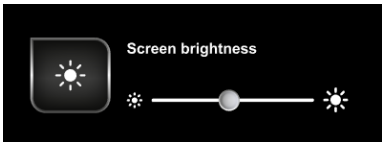
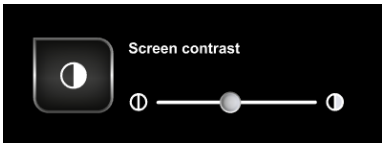
	Radionuclide selection		Radionuclide menu closed	No action required
			Radionuclide menu open	No action required
	Probe settings		Probe check required	A probe check needs to be conducted. See Section 9.3 Conduct probe check
			Probe check complete	No action required
			Probe settings menu closed	No action required
	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 not selected	No action required
			System settings menu is open	No action required

8.2.3. SYSTEM SETTINGS MENU

System settings

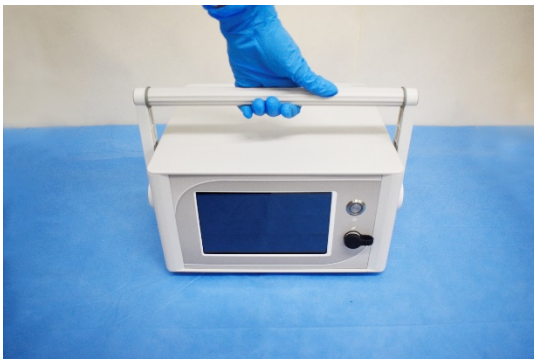
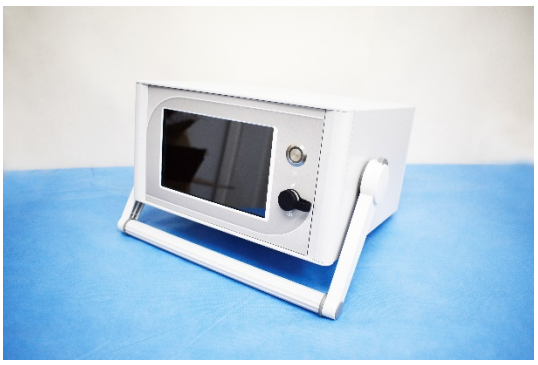
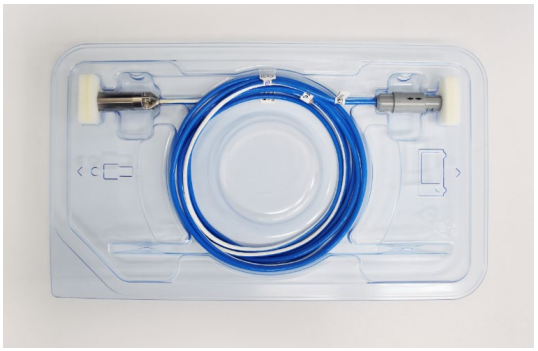
Additional Setting	Options	Name of Symbol	Meaning
Visual display choices 		Arc Display (Default)	The front screen will show an arc representation of the count rate
		Graph Display	The front screen will show a graphical representation of the count rate
		Both Arc and Graph Display	The front screen will show both an arc and a graphical representation of the count rate
		Range Selection (Default)	The range selection option 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 normal operating screen. To change between LOW, MED, HIGH or MAX press the left or right hand arrows
		MAX/AVG /INT (Default)	The Maximum/Average/Integration option 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 Maximum, Average or Integration. 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 side of the normal 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 in a few seconds if there is no further control input). • The maximum function can be set to find the maximum counts per second over the previous 1s, 5s, 10s or 60s time window. (Continuously updated) • The average function can be set to calculate the average counts per second over the previous 1s, 5s, 10s or 60s time window. (Continuously updated) • The integration function can be set to calculate the total number of counts in the previous 1s, 5s, 10s or 60s time window. (Updated after each integration time period e.g. Once every 10 seconds if a 10s time window is selected)
System configuration		Count range style	The count range style can be selected to be “Manual” or “Auto” (automatic). “Manual” mode will require the user to press one of the toggle buttons to change between ranges.
		Graph span time (s)	This setting allows the user to alter the span time of the graph (if the graphical representation of counts per second is selected). The options are 10, 20 or 30 seconds
		Restore to system defaults	Resets the system back to original settings

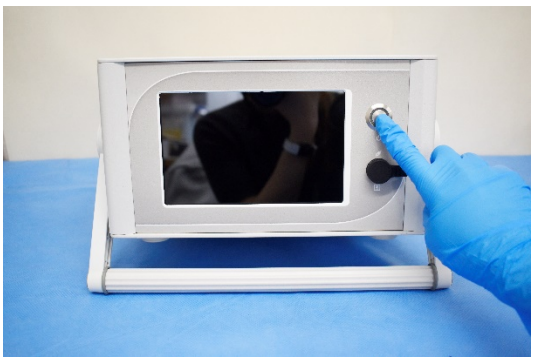
		System alive sound	Enables or disables the low tone audio confidence signal
Screen Adjustments 		Screen brightness	Allows the user to alter the screen brightness for best visibility
		Screen contrast	Allows the user to alter the screen contrast for best visibility

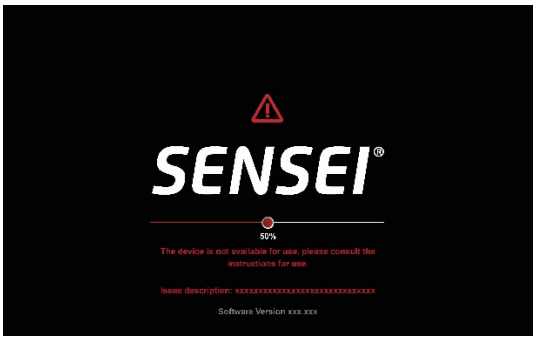
9. SETTING UP THE SENSEI® SYSTEM

9.1. GATHER ALL COMPONENTS

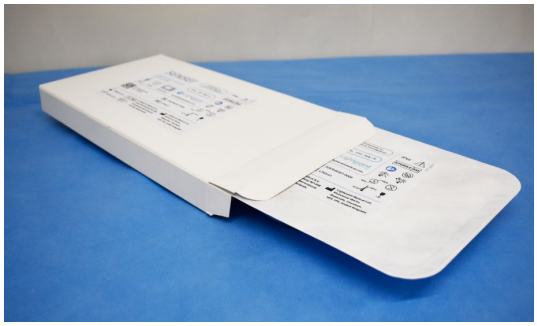
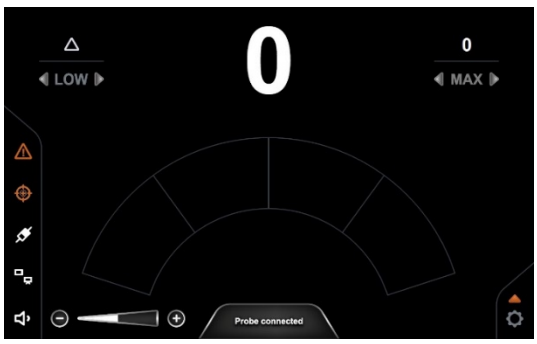
#	Image	Step	Additional Information
9.1.1		**Retrieve the SENSEI® Control Unit from storage.**	The Control Unit can be carried using the handle if desired.
9.1.2		**Place the SENSEI® Control Unit safely on a flat surface, where it can be seen by the intended users e.g. in a laparoscopic stack or on an instrument trolley.**	The Control Unit can be angled by positioning the handle underneath the case.
9.1.3		**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.

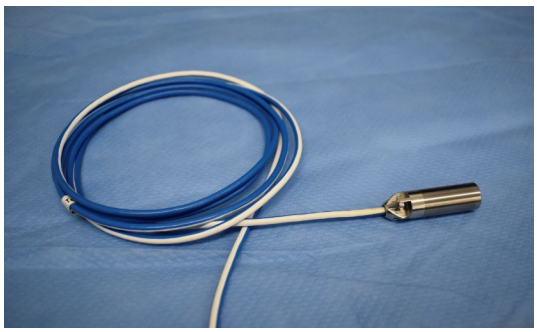
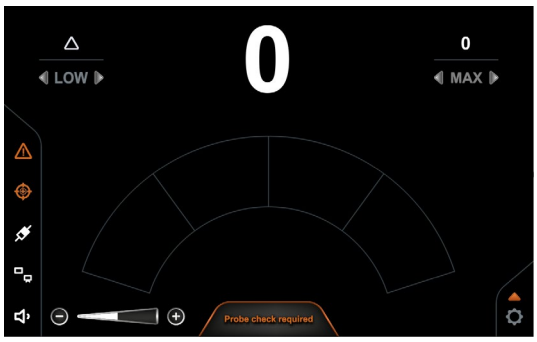
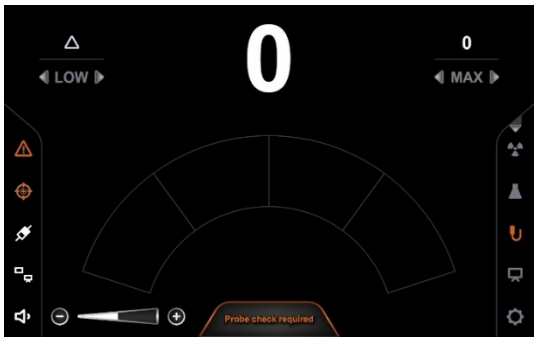
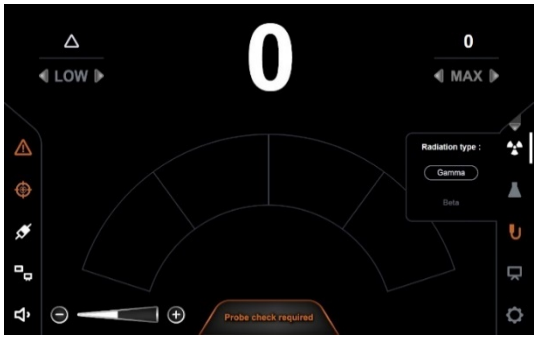
9.2.CONTROL UNIT SET-UP

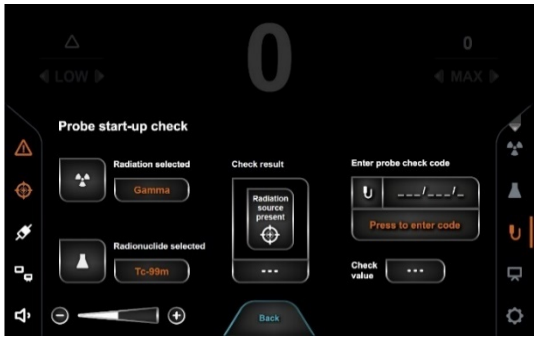
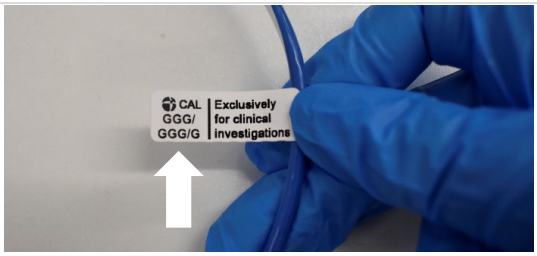
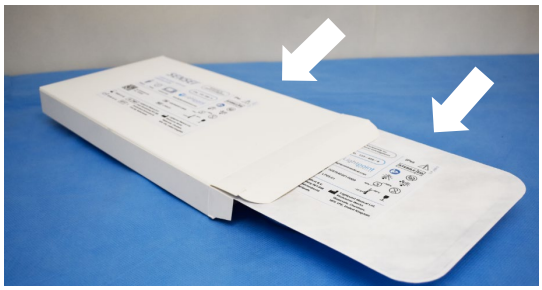
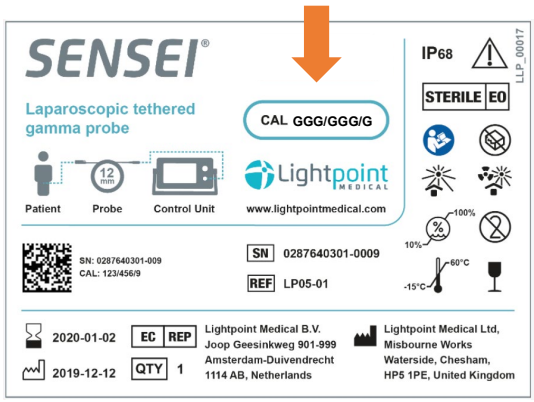
#	Image	Step	Additional Information
9.2.1		**Connect the power cord to the socket on the back of the Control Unit.**	Ensure the isolator switch above the socket is in the 'off' position. Ensure the power lead is pushed all the way into the socket before continuing. Note: Prior to use, inspect the mains cable to ensure there is no damage to the cable. If there is any damage **DO NOT USE** and contact Lightpoint Medical Ltd. Ensure the mains power cable does not cause a trip hazard.
9.2.2		**If fitted with a switch, with it in the "off" position, plug the power cord into a mains socket. Once connected, turn on the mains.**	Ensure that the plug is compatible with the mains socket. If fitted with a switch, ensure that the mains socket is turned off before plugging the power cord in.
9.2.3		**Switch the isolator switch on the back of the Control Unit to the "on" ("1") position.**	
9.2.4		**Push the operate button on the front of the Control Unit.**	A green light on the button will appear and the touchscreen on the device light up during normal operation. If the operate button is flashing red, consult Troubleshooting (section 12).

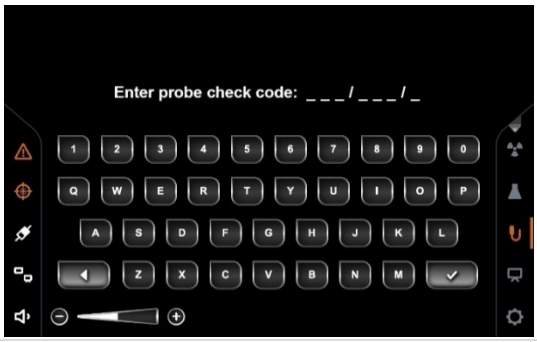
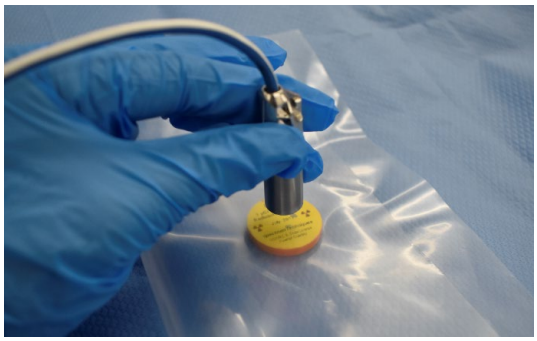
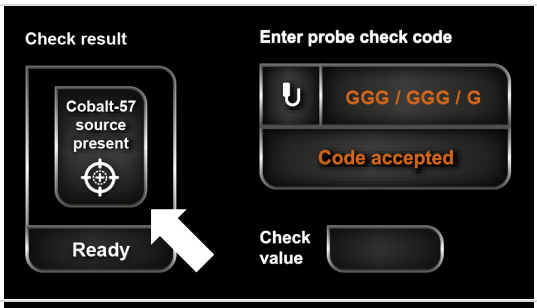
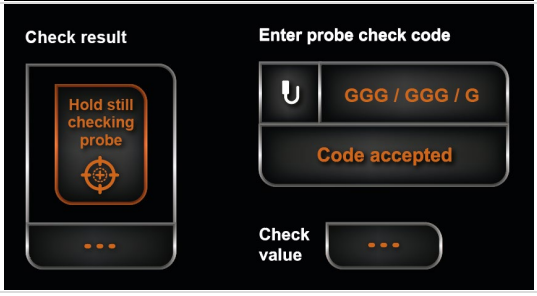
9.2.5		**The system will run through a series of set up checks as the device starts up.** **The status following the set up checks will be displayed.**	In the event the system runs into a system error the device is not suitable for use and should be powered down, see the Shutdown procedure (section 11). If the start-up screen displays a warning message, consult Troubleshooting (section 12).
9.2.6		**In the event the system does not pass all start up checks the screen will display a warning message and instructions.**	
9.2.7		**The SENSEI® Control Unit should enter the normal working screen as shown.**	

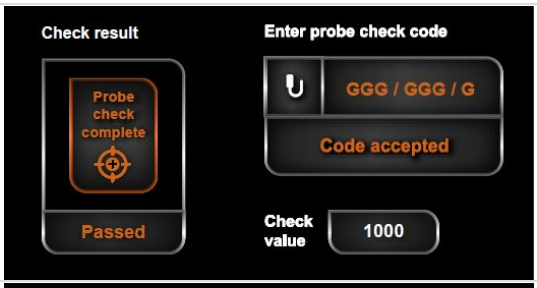
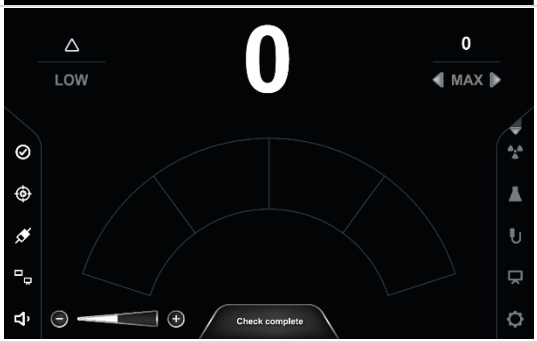
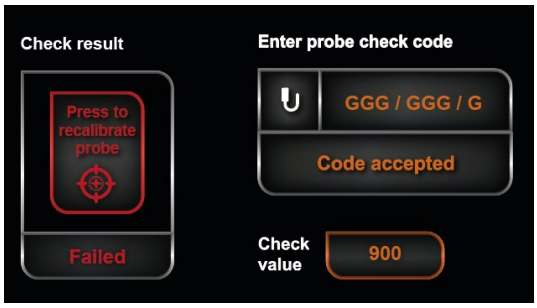
9.3.CONDUCT PROBE CHECK

#	Image	Step	Additional Information
9.3.1		**Remove the SENSEI® Tethered Probe from the cardboard sleeve.**	The paper leaflet contains a quick start guide.
9.3.2		**Whilst holding the plastic portion of the SENSEI® Tethered Probe blister pack, pull back on the Tyvek tab.** ⚠ **Always maintain the sterility of the Tethered Probe.**	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 retrieving the Tethered Probe.
9.3.3	 	**Remove the tether connector from the packaging and push it into the socket on the front of the Control Unit.** **Once connected a "Probe connected" message will be displayed on the touchscreen of the Control Unit.** ⚠ **Always maintain the sterility of the Tethered Probe.**	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. **Do not use** 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 Ltd.

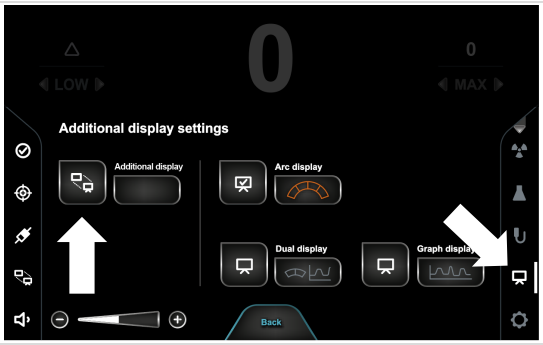
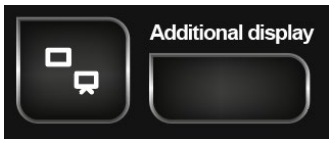
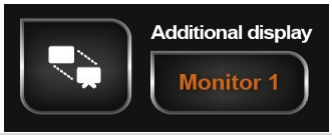
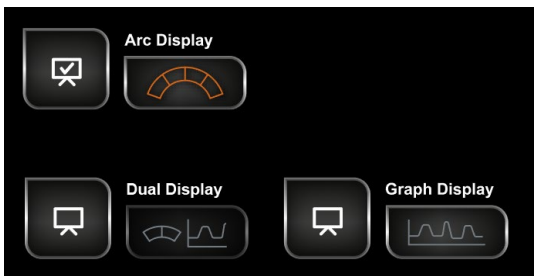
9.3.4		**Once connected, a sterile user is able to remove the probe head from the packaging.** **Always maintain the sterility of the Tethered Probe.**	Ensure that the sterile user is wearing gloves and that the probe head and cabling remains sterile at all times.
9.3.5		**Carefully place the Tethered Probe head on a sterile surface ready for use.** **Always maintain the sterility of the Tethered Probe.**	Ensure that the Tethered Probe is removed from the packaging and placed securely on a sterile surface, making sure that there is no draping cable between the sterile field and the Control Unit. It is recommended that the tether cable not be placed under tension during the operation of SENSEI®.
9.3.6		**When returning to the Control Unit a "Probe check required" message will appear, and the probe check status symbol should be highlighted.**	
9.3.7		**Open the system Settings bar. The probe settings icon will be highlighted.**	
9.3.8		**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		**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		**Press the probe settings symbol.**	
9.3.11	  	**Locate the unique probe check code, which can be found on the probe label, on the blister packaging label and on the cardboard sleeve label.**	Each probe check code will be identified by “CAL” being next to a 7 character alphanumeric code. Each code is unique to each Tethered Probe so ensure that the correct code is entered for the Tethered Probe being used. Note that the probe check code of ‘GGG/GGG/G’ shown in the image is a placeholder and will be different for each probe used.

9.3.12	 	**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 using the 'tick' button.** **A "Code accepted" message will appear.**	Characters can be deleted using the 'back' arrow button. Ensure that the 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.
9.3.13		**Retrieve a Cobalt-57 radiation source from storage, following local radiation safety guidelines.** **Wrap the sealed source with a sterile plastic sheet.** ⚠ **Always maintain the sterility of the Tethered Probe.**	The sealed radiation source should be handled carefully and in accordance to local guidelines. Refer to the local radiation safety/protection officer for guidance. Ensure that the radiation source is covered and remains sterile before allowing it into the sterile field.
9.3.14		**Position the probe head above the middle of the sealed source.** **When ready press the "Radiation source present" button on the Control Unit.**	
9.3.15		**Keep the probe head as still as possible whilst the Control Unit checks the probe.** **This will take a few seconds.**	

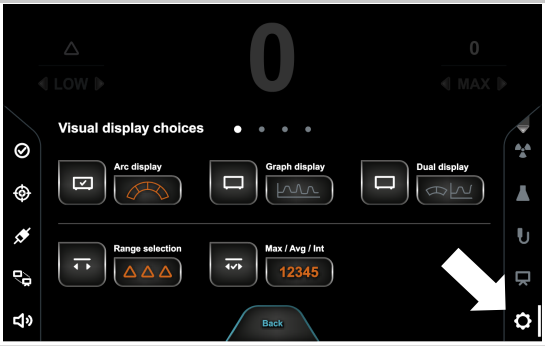
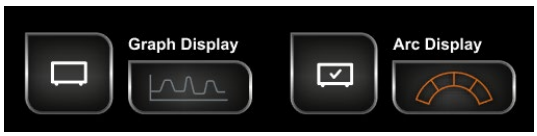
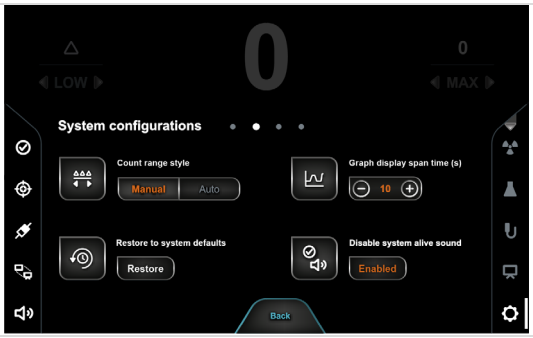
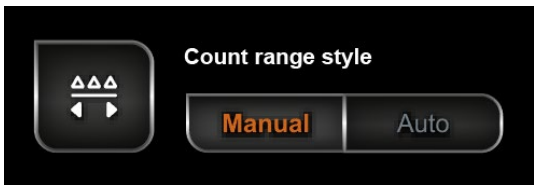
9.3.16		**Once successfully completed, the Control Unit will display a "Passed" message.** **The SENSEI® system is now ready for use.**	Note that the check value of '1000' shown in the image is a placeholder and may be different each time a probe check is conducted.
9.3.17		**Upon exiting the settings menu, a "Check complete" message will be displayed and a "Confidence signal" audio signal will be presented.**	The confidence signal is a low intermittent tone. This will sound every 5 seconds to indicate the system is fully operational.
9.3.18		**If completed unsuccessfully, the Control Unit will display a red "Failed" message.** **The device is not ready for use and the check value displayed is orange and not white.**	Consult Troubleshooting (section 12).

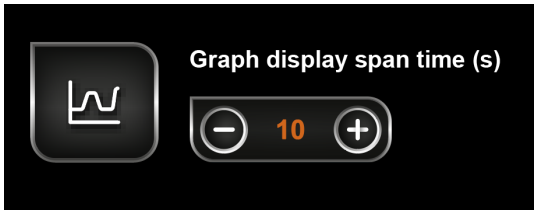
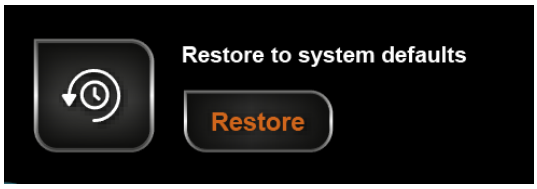
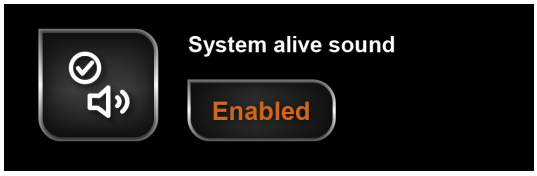
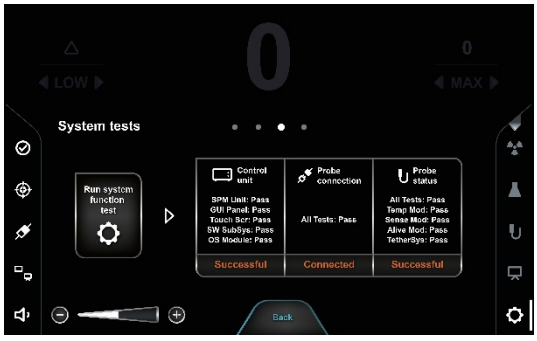
9.4.CONNECT TO AN ADDITIONAL DISPLAY

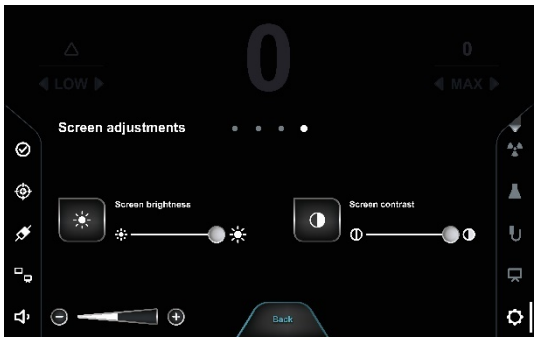
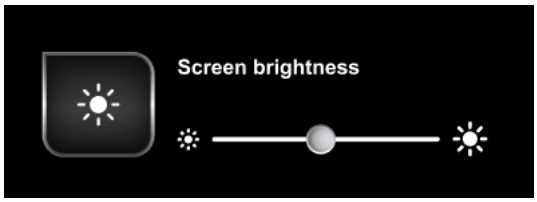
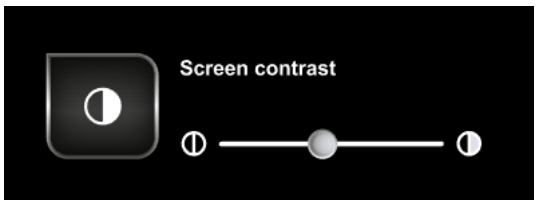
#	Image	Step	Additional Information
9.4.1		**To connect to an additional display, connect a DVI cable to the rear of the Control Unit.**	Ensure that the other end of the DVI connector is connected to a suitable additional display. Consult the manufacturer's Instructions for Use.
9.4.2		**Open the System Settings bar and select the Additional display settings icon to open the Additional display settings menu.** ⚠ **You must conduct this step to connect to an additional display.**	
9.4.3	 **1. <u>NO</u> DVI cable is connected**  **2. DVI 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" should be seen in the box on the right (image 3).** ⚠ **You must press this button 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.

⚠ **There may be other steps that need to be conducted on the additional display that is being used. 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 ADDITIONAL SETTINGS

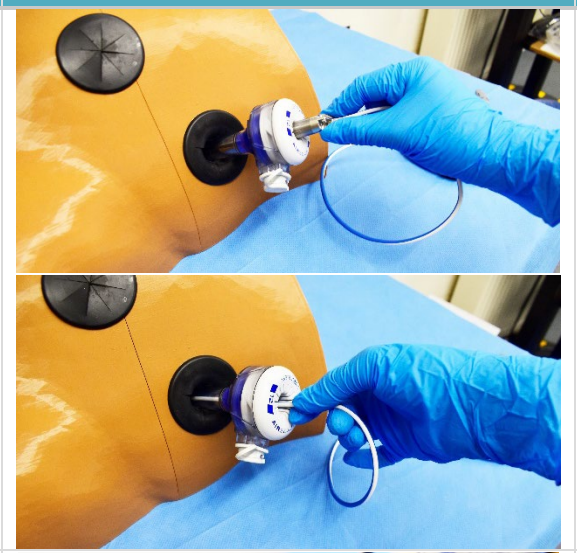
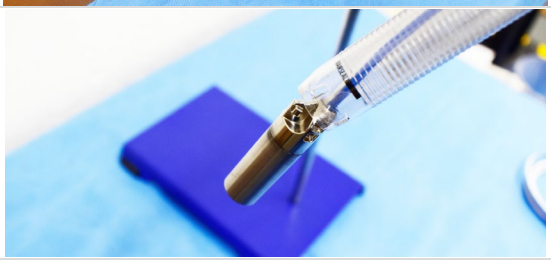
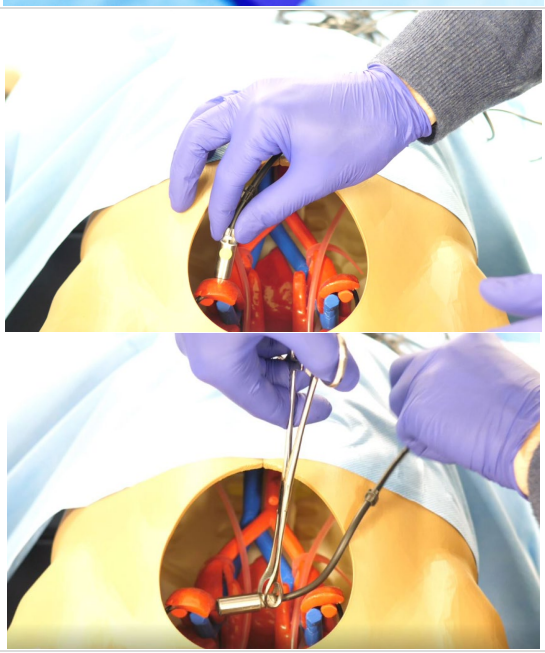
#	Image	Step	Additional Information
9.5.1		**To alter system settings, open the System Settings bar and press the System settings icon.** **The first page shows the visual display choices for the Control Unit.**	To navigate between setting screens, press the small dots in the middle of the screen.
9.5.2		**In the visual display choices screen, the top row of buttons configures the Control Unit visual count rate presentation to show either an Arc, a Graph or Dual displays.**	To select an alternative display press on the icon to select the preferred display type. The default is the Arc display.
9.5.3		**In the visual display choices screen, the bottom row of buttons configures accessory toggles to show the range and the MAX/AVG/INT selectors.**	To select the accessory toggles to be displayed on the main screen press the icon next to the accessory toggle. Each choice is explained in section 8.2.3. The default is that both the range and MAX/AVG/INT selectors are displayed.
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.**	"Manual" mode will require the user to press one of the toggle buttons to change between ranges. **"Manual" mode will be set as a default and this should be confirmed by entering the menu.** *[Only the "Manual" mode option is currently available. The "Auto" mode change option will be greyed out]*

9.5.6		**To alter the count rate graph span time to display 10, 20 or 30 seconds of data, select the desired value.**	To switch between 10, 20 or 30 seconds, use the plus and minus buttons either side of the number. The default is 10 seconds.
9.5.7		**To restore the system to default settings, press the "Restore" button.**	Be aware that this will reset all of the changes that have been made during the setup of the Control Unit **<u>including resetting the probe check code.</u>**
9.5.8		**To disable the system alive sound press the button so that it states "Disabled".**	
9.5.9		**To access the system test screen, press the third dot.**	
9.5.10		**To run the system function tests, 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 12).

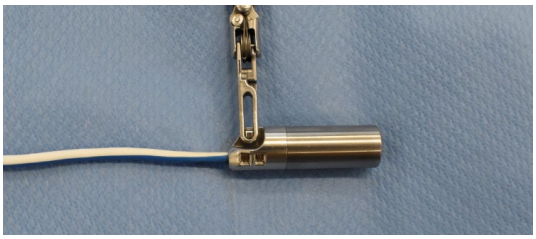
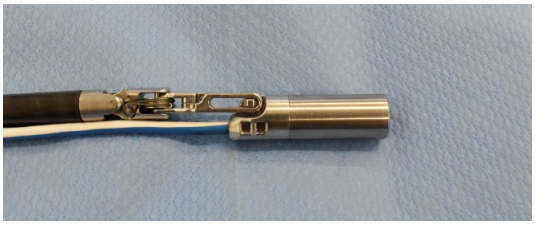
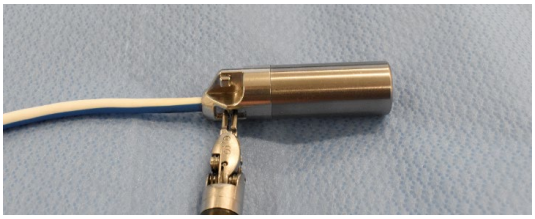
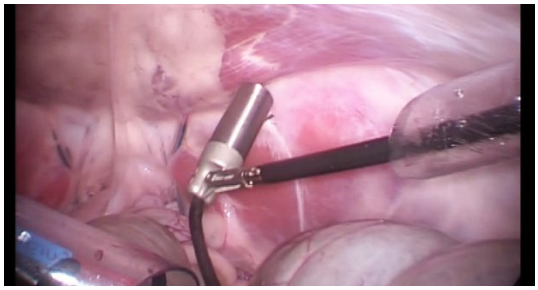
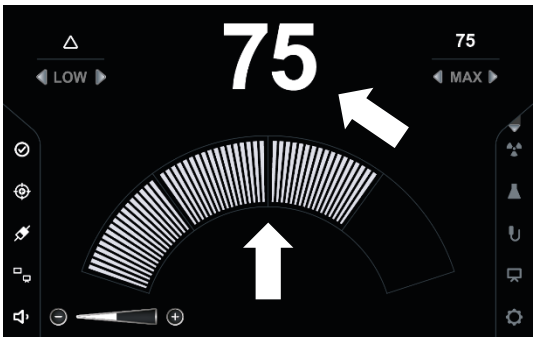
9.5.11		**To access the screen adjustment screen, press the fourth dot.**	
9.5.12		**To alter screen brightness, slide the toggle on the bar either to the left or to the right.**	Alternatively, press the sun icon on the left to reduce the brightness or press the sun icon on the right to increase the brightness.
9.5.13		**To alter screen contrast, slide the toggle on the bar either to the left or to the right.**	Alternatively, press the contrast icon on the left to reduce the contrast or the contrast icon on the right to increase the contrast.

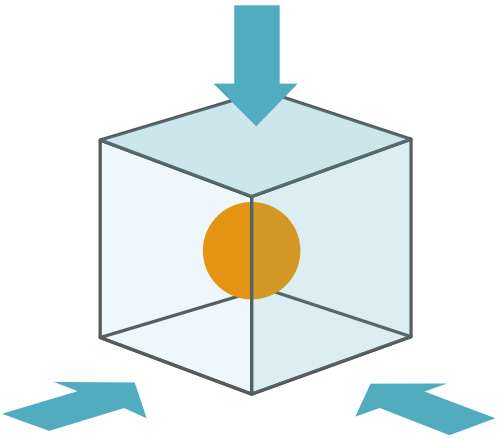
10.SCANNING USING THE SENSEI® SYSTEM

10.1.INSERTING THE TETHERED PROBE INTO A PATIENT

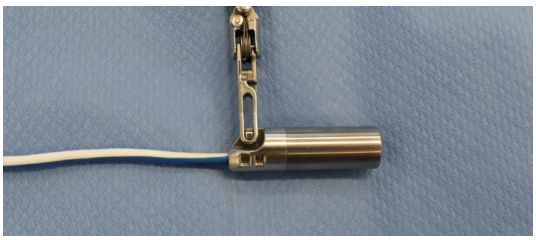
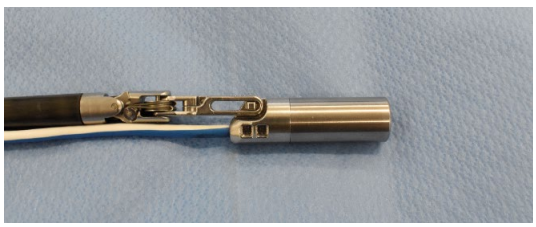
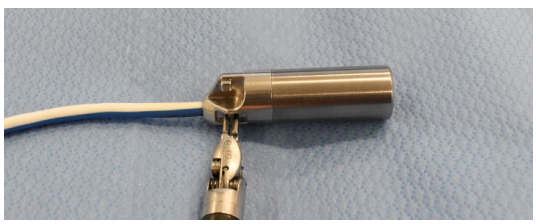
#	Image	Step	Additional Information
10.1.1		**To insert the Tethered Probe through a trocar, place the probe head into the opening of the trocar and gently push through the trocar, using the tether cable.** **⚠ Do not insert the Tethered Probe using a laparoscopic grasper.**	If the device is used with a valved trocar, slightly more pressure may need to be applied, to push the probe head through the valve. ⚠ Be careful not to cause any injury to the patient through excessive force. Minimise any additional force when inserting the Tethered Probe. See section 14 for a list of compatible trocars that can be used with SENSEI®.
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.
10.1.3		**To insert the Tethered Probe through an open cavity incision, place the Tethered Probe directly into the body cavity using a gloved hand or an approved instrument.**	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.

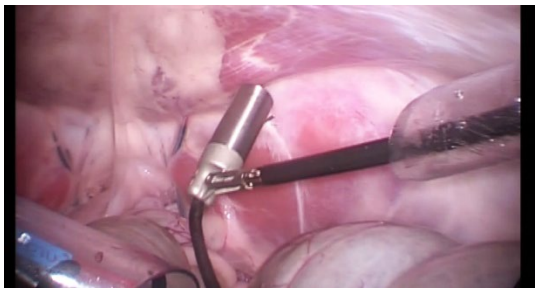
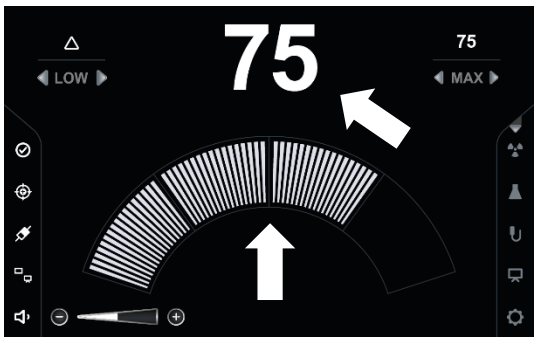
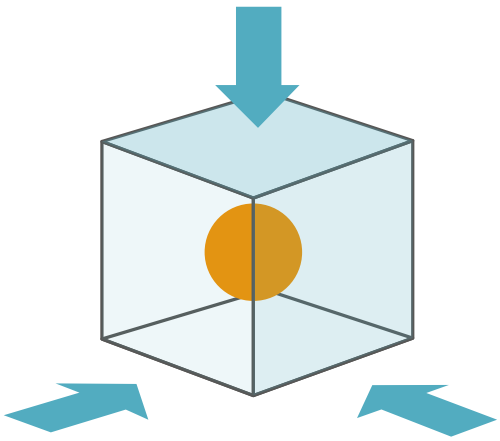
10.2.SCANNING A PATIENT USING THE TETHERED PROBE – ROBOTIC ASSISTED LAPAROSCOPIC SURGERY

#	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.			
10.2.1	 	**Once inserted into the patient, grasp onto the Tethered Probe in one of the shown orientations using one of the approved instruments in section 14.**	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**
10.2.2		**To interchange between grips, use the side pockets on the probe head.**	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**
10.2.3	 	**Point the probe at the tissue to be scanned and move carefully and slowly along the area of interest.** **The numeric count rate will show the counts per second being captured by the probe.** **The graphical representation of the count rate will show the same information.** **The audio signal will get faster as the count rate increases.**	⚠ Make sure the probe detector window is in contact with the tissue and the probe detector window is perpendicular to the tissue. ⚠ Be aware of potential background sources when scanning (e.g. the bladder or injection site).

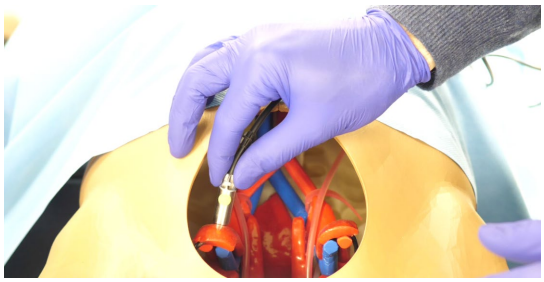
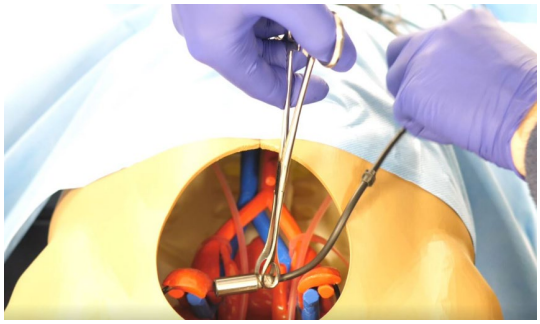
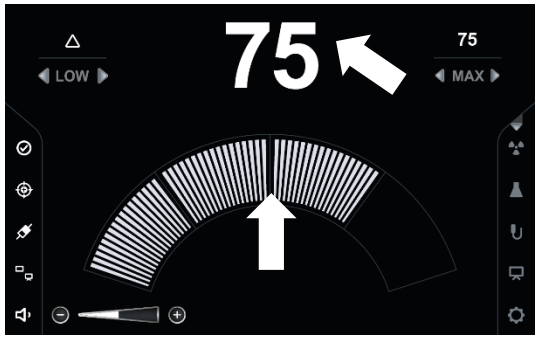
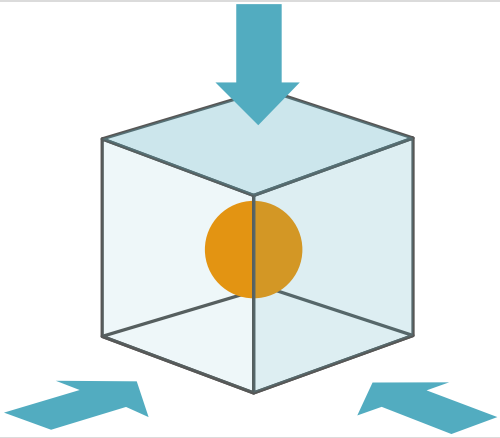
10.2.4		**It is recommended that to confirm the location of a suspected area of increased activity that the user triangulates the signal.** **To do this, re-orient the probe so that it is pointing at the suspect area from several different angles.**	⚠ Be aware of potential background sources when scanning (e.g. the bladder or injection site). ⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**

10.3.SCANNING A PATIENT USING THE TETHERED PROBE – 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.			
10.3.1	 	**Once inserted into the patient, grasp onto the Tethered Probe in one of the shown orientations using one of the approved instruments in section 14.**	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**
10.3.2		**To interchange between grips, use the side pockets on the probe head.**	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**

10.3.3	 	**Point the probe at the tissue to be scanned and move carefully and slowly along the area of interest.** **The numeric count rate will show the counts per second being captured by the probe.** **The graphical representation of the count rate will show the same information.** **The audio signal will get faster as the count rate increases.**	⚠ Make sure the probe detector window is in contact with the tissue and the probe detector window is perpendicular to the tissue. ⚠ Be aware of potential background sources when scanning (e.g. the bladder or injection site).
10.3.4		**It is recommended that to confirm the location of a suspected area of increased activity 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.**	⚠ Be aware of potential background sources when scanning (e.g. the bladder or injection site). ⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**

10.4.SCANNING A PATIENT USING THE TETHERED PROBE – OPEN SURGERY

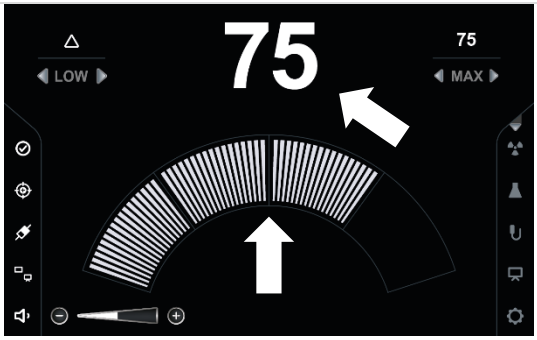
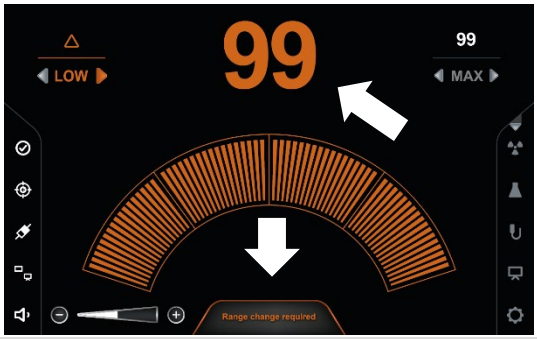
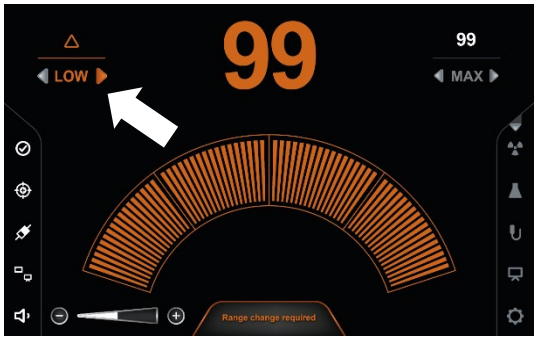
#	Image	Step	Additional Information
⚠ Before scanning with the device ensure that there is slack in the tether and that the tether is placed in a position where it will not get tangled with the patient or any other equipment.			
10.4.1		**Grasp onto the Tethered Probe with a gloved hand or one of the approved instruments in section 14.**	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**
10.4.2		**To interchange between grips, use the side pockets on the probe head, or the user can use their hands.**	⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**
10.4.3	 	**Point the Tethered Probe at the tissue to be scanned and move carefully and slowly along the area of interest.** **The numeric count rate will show the counts per second being captured by the probe.** **The graphical representation of the count rate will show the same information.** **The audio signal will get faster as the count rate increases.**	⚠ Make sure the probe detector window is in contact with the tissue and the probe detector window is perpendicular to the tissue.
10.4.4		**It is recommended that to confirm the location of a suspected area of increased activity 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.**	⚠ Be aware of potential background sources when scanning (e.g. the bladder or injection site). ⚠ **Avoid gripping onto the tether at all times. Do not use any surgical tools to grip onto the tether.**

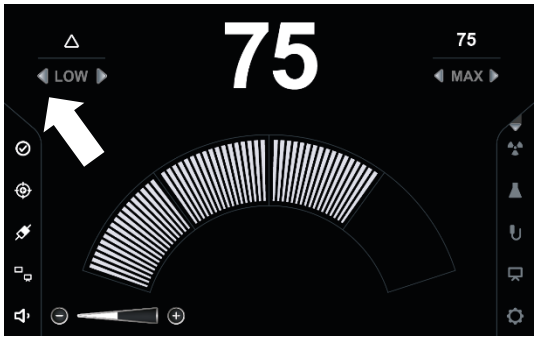
10.5.CHANGING RANGE – "MANUAL" MODE

Please note that this explanation is given for the "Manual" range change mode. The "Auto" range change mode will not require a user to manually change between ranges.

[Only the "Manual" mode option is currently available. The "Auto" mode change option will be greyed out]

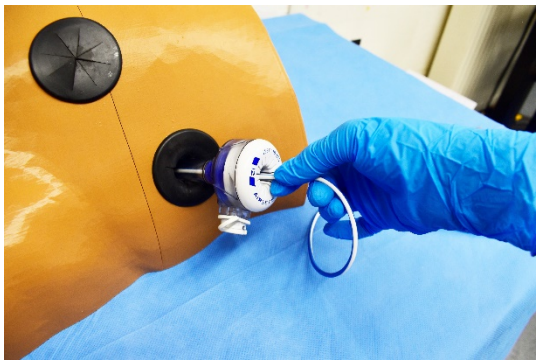
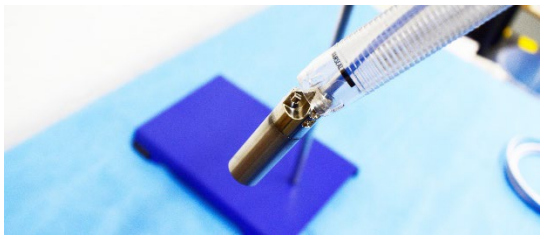
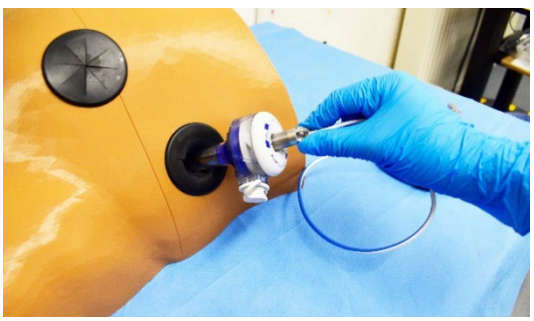
It is very important to understand that just because the device enters an over-range state, that this does not indicate a "hot" area. It only indicates that the system should be changed to the next range. The device will remain in an over-range state until corrected by the user.

#	Image	Step	Additional Information
10.5.1	**When the device enters an over-range state there are specific changes to look for.**		
10.5.2	 	**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 audio signal will have reached the maximum rate for the given range and will be almost constant.**	⚠ 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.
10.5.3	  	**The user will be required to press the "right arrow" on the range selector accessory toggle. This will 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 played indicating the change has been made.**	When changed, the graphical 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 audio signal pitch 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.**			
10.5.4	  	**A user will be 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 played 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 audio signal pitch will also decrease for each range selected.

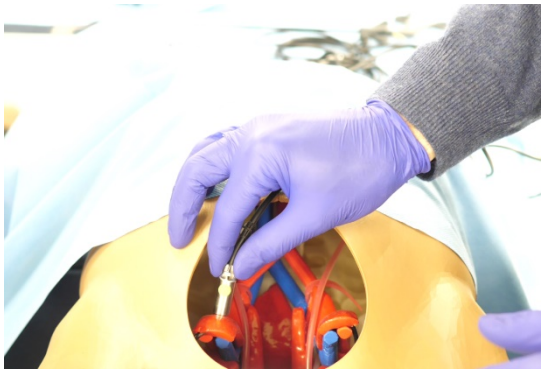
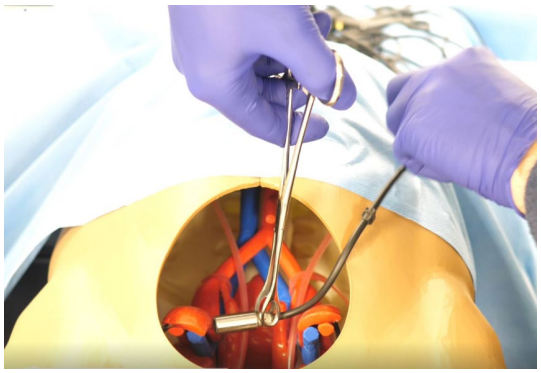
10.6. REMOVING THE TETHERED PROBE FROM THE PATIENT – LAPAROSOPIC SURGERY (INCLUDING ROBOTIC ASSISTED LAPAROSCOPIC SURGERY)

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

#	Image	Step	Additional Information
10.6.1		**For the Tethered Probe to be removed during laparoscopic surgery, take the probe to the trocar and disengaged all instruments from all grip sites on the probe head.** **Pull back gently on the tether so that the device begins to move towards the trocar.**	**This must be conducted using laparoscopic camera guidance.** **<u>Do not</u> remove the Tethered Probe without taking the probe to the trocar, otherwise this will risk causing internal injury to the patient.** **<u>Do not</u> remove the Tethered Probe by using a laparoscopic grasper.**
		**Once the Tethered Probe reaches the trocar, carefully 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. Do not use any surgical tools to grip onto the tether.**
10.6.3		**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.
10.6.4	**Once removed from the trocar, the Tethered Probe may then be disposed of.**		See section 16 for disposal information.

10.7. REMOVING THE TETHERED PROBE FROM THE PATIENT – OPEN SURGERY

Always ensure that the user has sight of the Tethered Probe. Do not attempt to remove the Tethered Probe without vision as this may risk causing injury to the patient.

#	Image	Step	Additional Information
10.7.1		**For the Tethered Probe to be removed during open surgery it is encouraged to keep any approved instruments attached to the Tethered Probe to help 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.
10.7.2		**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 it 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.**
10.7.3	**Once retrieved from the open cavity, the Tethered Probe may then be disposed of.**		See section 16 for disposal information.

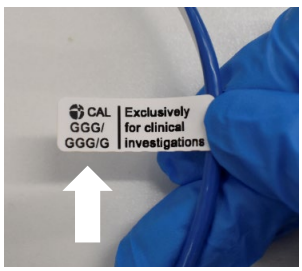
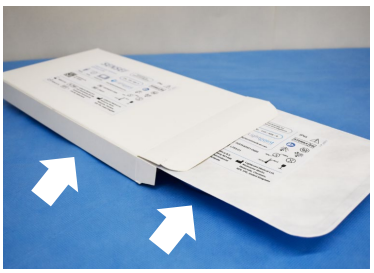
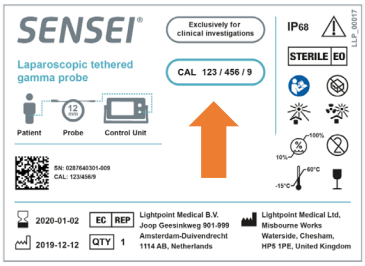
11.SHUTDOWN PROCEDURE

#	Image	Step
Once a user has finished using the Control Unit and the Tethered Probe, follow the instructions below.		
11.1		**Press the operate button on the front of the Control Unit. The light on the button will no longer be illuminated and the touchscreen will go dark.**
11.2		**To remove the Tethered Probe from the Control Unit, pull backwards on the grey plastic sleeve on the tether connector to disengage the lock.**
11.3		**Switch the isolator switch on the rear of the Control Unit from the 'on' ("1") position to the 'off' ("0") position.**
11.4		**If fitted with a switch, switch the mains socket from the 'on' to the 'off position.**

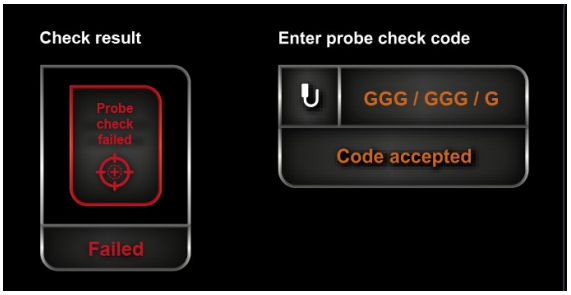
12.TROUBLESHOOTING

Problem	Image	Possible Causes	Actions
1. ***The system status icon is not pulsing. What does this mean?***		The system has frozen.	Please proceed to restart the device by following the shutdown procedure in section 11, followed by starting the device up as shown in section 9.2. If this problem persists, please contact Lightpoint Medical Ltd. or the supplier.
2. ***The probe check status shows. What does this mean?***		This symbol means that a probe check is required or there is a fault in 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.
3. ***The probe status shows. What does this mean?***		This symbol means there is a probe connected but there is a fault in the connection.	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.
4. ***The additional display status shows. What does this mean?***		This symbol means that there is no additional display connected or there is a fault in the connection.	Check that the DVI cable is connected at the rear of the Control Unit and that the DVI cable is connected to the additional display. If the error persists, replace the DVI cable. If no additional display is required, disable the additional display output. See section 9.4.3. If the problem persists, contact Lightpoint Medical Ltd. or the supplier.
5. ***The volume control shows. 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. 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.	Remove the Tethered Probe and switch off the isolator switch on the rear of the Control Unit. Restart the system following the steps in section 9.2 with the Tethered Probe connected. If the problem persists repeat the above without first connecting the Tethered Probe. If the problem persists, contact Lightpoint Medical Ltd. or the supplier.

10. *What is the problem?*	***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 packaging label and the cardboard sleeve label, that the blister pack was supplied in.
11. *What is the problem?*	***During the set up of the Control Unit, the system does not pass the start-up check and displays a warning.***

The screen shows:	
What is the cause?	This means there is a system fault.
What is the best course of action?	Remove the Tethered Probe and switch off the isolator switch on the rear of the Control Unit. Restart the system following the steps in section 9.2 with a Tethered Probe connected. If the problem persists repeat the above without first connecting the Tethered Probe. If the problem persists, contact Lightpoint Medical Ltd. or the supplier.

13. What is the problem?	***The Probe check has failed.***
The screen shows:	
What is the cause?	This means there is a system fault.
What is the best course of action?	If a probe check has not been conducted, please follow instruction 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 displays a fault, please replace the faulty Tethered Probe with a new probe. Please return the faulty Tethered Probe to Lightpoint Medical Ltd.

13.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 at the factory. 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

13.1.CLEANING PROCEDURES

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 SHOULD NOT BE STERILISED.

The Control Unit and power cord maybe 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 touchscreen on the Control Unit does not become contaminated with any bodily fluids. If the touchscreen does come into contact with bodily fluids, ensure the whole system is cleaned.

13.2.SYSTEM DIAGNOSTICS

The SENSEI® system contains a number of diagnostic mechanisms, some 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, where the Tethered Probe is also checked. This test provides a simple pass / fail output.

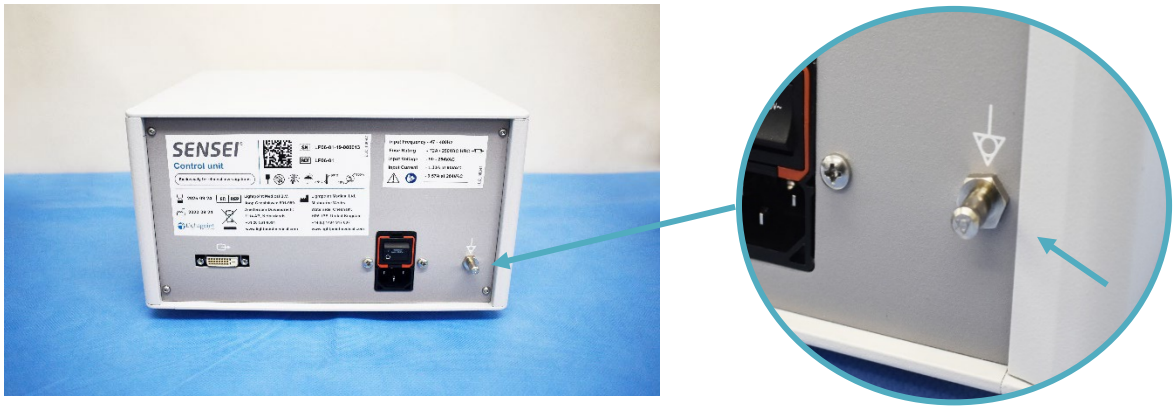
There is an option whereby a user can instigate a manual test of the system using the built-in test equipment. As with the power on self-test system, this checks that the hardware and software are all performing within specified limits. This test can be undertaken on just the Control Unit or on a Control Unit and Tethered Probe. This manual test provides a user with more detailed diagnostic information. See section 9.5.9 and 9.5.10.

There is also a process that runs continuously during normal use, which checks the system is functioning normally. This test checks and confirms that the entire 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 confidence signal.

13.3.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.



The bond point should be connected using a suitable socket.

13.4.REPLACEMENT OF FUSES

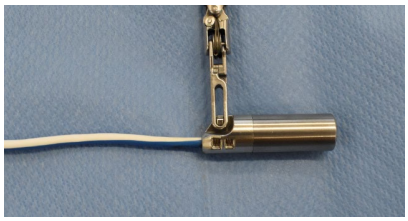
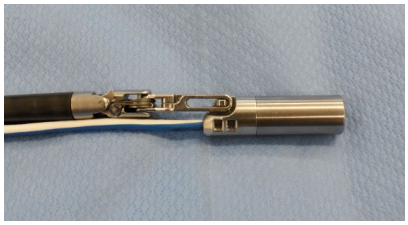
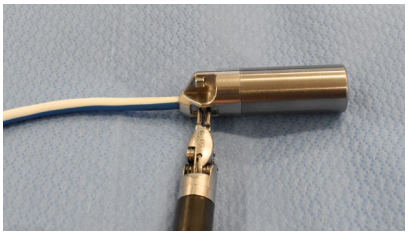
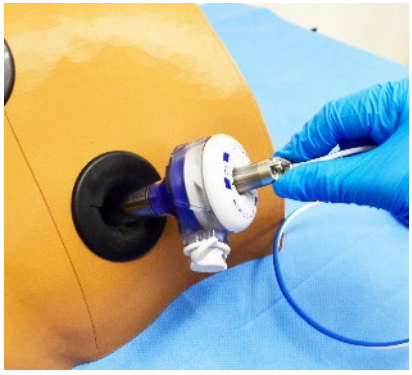
The below provides information regarding changing the mains line fuses. See section 3.3 for further information.

The fuses are mounted in a holder inside the power socket at the rear of the Control Unit.

#	Step	Image
13.4.1	Switch the isolator switch located at the rear of the Control Unit from the 'on' ("1") position to the 'off' ("0") position and remove the power cord. **Ensure the Control Unit is not connected to the mains power supply.**	
13.4.2	To remove the fuse holder unit, use a simple tool to eject the carriage from the assembly at the points shown in the image.	
13.4.3	Slide the fuse holder out of the assembly, as shown in the image.	
13.4.4	Replace the fuse(s) with the spare(s) provided in the rear of the fuse carriage. **Only use the specified fuse type.**	
13.4.5	Slide the fuse holder back into the assembly until it is securely located.	

14. RECOMMENDED COMPATIBLE EQUIPMENT

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

SENSEI® Tethered Probe – Recommended compatible equipment		
 	**Tissue Grasper(s) /Johan Grasper(s)**	**Recommended robotic instrument(s):** • Intuitive Surgical da Vinci EndoWrist® ProGrasp® **Recommended laparoscopy instrument(s):** • Laparosurge 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 tested **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™ 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 Tethered Probe access to the target locations.

SENSEI® Control Unit – Recommended compatible equipment		
	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 connection. Take care when connecting to an additional display that has not been tested.

15. STORAGE AND HANDLING

Condition	Temperature	Humidity (%RH)
Non-operational	-15-60°C	10-100% (non-condensing)

16. DISPOSAL OF SENSEI®

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 (Hospital) is required to dispose it in radioactive clinical waste.

The Control Unit may be sent to the 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 of 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.

17. CUSTOMER FEEDBACK AND REPORTING OF COMPLAINTS OR ADVERSE EVENTS

The following contact information may be used for customer feedback including the reporting of complaints or adverse events.

Lightpoint Medical Ltd.
Misbourne Works
Waterside
Chesham
United Kingdom
HP5 1PE

+44 (0) 1494 917 697

feedback@lightpointmedical.com

Input from our customers helps us improve our products and services. Your opinions are important to us. If you have comments about the product or user documentation, please write to us at the email address above. We would like to hear from you.