Crystal Photonics

Crystal Probe –automatic-

Intraoperative Gamma Probe System

V

Instruction Manual

Gama detektoriaus remontinis keitimas

Software version 1.6x
January 2025

Instruction Manual
Crystal Probe *-automatic-*

Intraoperative gamma probe system

It is essential to read this instruction manual before using the gamma probe system **Crystal Probe** *-automatic-*.

The system **Crystal Probe** *-automatic-* detects Gamma- and X- ray-radiation. It is intended for the intraoperative detection of radioactive labeled tissue. The following instruction manual is not sufficient for inexperienced users to ensure professional use.. The user must be familiar with the planned surgical procedures, including diagnostics and presurgical planning and/or laboratory procedures. The user is obliged to independently check the products before use and to assess their suitability and applicability for the intended purpose. Contributory negligence on the part of the user leads to the reduction or the complete elimination of the liability of Crystal Photonics GmbH in the event of damage. This is particularly the case if the instruction manual is not read, the warnings are ignored or the device is misused by the user.

The **Crystal Probe** *-automatic-* is manufactured under the strictest accuracy and safety aspects and complies with the essential requirements of the Medical Device Directive 93/42 EEC, Annex I.

The classification and certification is according to class IIa of the Medical Device Directive 93/42/EEC, Annex IX and the German Medical Device Act dated 06.09.1994 as amended in 2007. Declaration of conformity for medical devices according to Annex II, Medical Device Directive 93/42/EEC.

The quality management system of ***Crystal Photonics GmbH*** is certified according to:

ISO 13485 and ISO9001

CE 0633

Table of Contents

1 Advice for Users

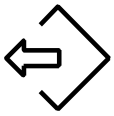
The symbols and signs used in the instruction manual and on the control unit have the following meaning:

Degree of protection of applied parts handled by users against electrical shock: Type B

Degree of protection of applied parts handled by users against electrical shock: Type BF

Read instruction manual

Terminal contact for equipotential bonding (DIN 428011/1)



Output signal

Input socket for charger

Class II Electrical Appliance

IP 20

Degree of protection of control unit

Non ionizing electromagnetic radiation

Read the instruction manual carefully and inform yourself about the operation and functionality of the device and the accessories before using it in the operating room. If you do not follow the instructions in this manual, to the following may occur:

- patient injuries
- injuries to the surgical teams or to the nursing/service staff
- damage to or failure of the device and accessory.

The manufacturer reserves the right that illustrations and technical data deviate slightly from the delivered product due to further developments of products.

The paragraphs marked with the terms **Danger!, Warning!** and **Info!** have a special meaning. Read these sections carefully!

Danger!

The safety of patients, users or third parties is at risk. Observe this warning to avoid injury to the patient, user or third parties!

Warning!

These sections contain information to help the operator use the device or accessories in accordance with their intended use.
Failure to observe the sections marked as such may impair the proper functioning of the gamma probes and void the warranty.

Info!

These sections contain information to clarify the instructions or provide additional useful information.

2 Safety Instructions

Drop down
The control unit CXS-SG04 must always be positioned in such a way that it is fixed and cannot be moved or pulled down by the connecting cable, especially when the probes are moved.

Drop down
Place the probes on a flat, even surface so that they are secured against rolling or falling down. Tubes between device and patient must not be an obstacle. The crystal wireless probe cannot roll down due to its design. A fall can lead to malfunction or damage.

Damp areas
Protect the device from moisture. Do not use the device if liquid or steam has entered the device.

Mains operation and equipotential bonding
When using the gamma probe system with connected power supply during operation (mains operation), only the provided power supply may be used. Otherwise, safety can no longer be guaranteed and the conformity expires!
In addition, the control unit must be connected to the equipotential bonding of the operating theatre.

Start-Up
Before putting the system into operation with a wired probe, one of the specified cable probes must be connected to the control unit. The plug connection between the probe and the control unit CXS-SGO4 must fit securely. The red markings on the plugs must be placed opposite the markings on the control unit and probe housing.

Original basic components
The control unit CXS-SG04 and the various probes are matched to each other and cannot be combined otherwise. If the probe is used with other control units or if external probes are operated on the control unit, safe operation is not guaranteed. The signal input on the control unit is intended exclusively for the CXS-OP-* probes. Connecting other devices can result in the destruction of the probes or the control unit and the conformity expires!

Original Accessories
The use of accessories other than those supplied or purchased by Crystal Photonics (e.g. power supplies, storage and transport case) is prohibited and will void the warranty and CE marking.

Danger!

Interdependencies
The probes must not be used in close proximity of monitors, television sets and HF systems (mobile phones, X-ray systems, etc.), as interactions and thus incorrect measurements cannot be ruled out.

Danger!

Explosion hazard
The device is not explosion-proof. Do not operate the device near explosive anesthetic gases or oxygen enriched environments.

Danger!

Sterile components
All probes may only be used in a sterile condition during a surgery. The possible sterilization methods are described in section 7.3.

Danger!

Sterilization of probes
Steam sterilization is unsuitable for some probes and leads to the destruction of the probe.
Please refer to the table for suitable sterilization methods in section 7.3.

Danger!

Cleaning the control unit
The control unit must not be treated with cleaning, disinfection and/or sterilization methods which may allow steam or liquid to penetrate.
Do not clean the control unit while it is activated and/or connected to the mains.

Danger!

Contamination
Decontaminate the device and accessories to protect the service personnel before dispatch. Follow the instructions in this manual. If this is not possible,

- mark clearly the contaminated product with a reference to the contamination and
- seal it twice in a safety plastic foil.

The manufacturer may refuse to accept the repair of contaminated products.

Danger!

Contamination
Never use the device and/or accessories if there are signs of contamination. Secure the device and/or accessories from further use until checked by a service technician.

Danger!

Techniques and Procedures
Only the physician can decide whether the use of the device is indicated on the patient from a clinical point of view. The physician must determine the technique and procedure to be used to achieve the desired clinical effect.

Danger!

Check all the default settings

The device has default settings for the following items, which are automatically set via probe detection when switched on:

-Nuclide choice

-Gate-Time

-Pitch

These default settings are not prescriptions for the surgeon. The surgeon is responsible for all settings that affect the surgical conditions.

Danger!

Professional Qualification

The instruction manual does not contain a description or procedure for surgical techniques. It is also not intended to introduce a surgeon to surgical techniques. Medical instruments and devices may only be used in designated facilities and by surgeons or medical professionals who have the appropriate professional qualifications.

Danger!

System failures

If you suspect a system failure, the use of the system is prohibited. This also applies to obvious defects and damages, in particular to the mains plug and mains cable.

Danger!

Installation site

The device must be set up in such a way that it is possible to observe the display values and the device functions as well as to access the control elements at any time.

Danger!

Danger

Different presetting of the warning signals for the same or similar devices in the operating theatre may cause a hazard by confusing the warning signals.

Danger!

Disclaimer of liability

The manufacturer assumes no liability for any direct or indirect damage and the warranty expires if

- the control unit, probes and/or accessories are used, processed or maintained improperly,
- instructions and regulations in the instruction manual are not observed,
- unauthorized persons perform repairs, adjustments or changes to the device or accessories,
- unauthorized persons open the device,
- the specified inspection and maintenance intervals are not observed.

The provision of technical documentation does not constitute authorization to repair or modify the equipment or accessories.

Danger!

Opening the housing
Modifications to the electronics of the control unit or the probe can lead to destruction of the gamma probe system. Furthermore, there is danger risk of electric shock. Unauthorized opening of the probe housing or the control unit CXS-SGO4 will void the warranty and CE-mark.

Danger!

Replacing fuses or battery
Only replace the fuses or battery following the instructions provided by and with explicit approval of Crystal Photonics GmbH.
When replacing the fuse (see section 9.2), make sure that the correct type is used.

Danger!

Disposal
Electronic waste must not be disposed as domestic or medical waste but must be collected separately. Please contact the manufacturer or an authorized disposal company regarding the disposal of the equipment at the end of its lifetime or in case of irreparable damage.

Danger!

The applicable regulations for handling radioactive materials must be observed.

Danger!

Check whether the available mains voltage corresponds to the mains voltage indicated on the power supply unit. Incorrect voltage may result in malfunction or destruction of the unit.

Warning!

Before the device is switched on, sufficient time must have passed to adapt to the room conditions.

Warning!

Switch the device off and on again at the latest after 24 hours of continuous operation so that the self-test of the device can be carried out.

Warning!

Anyone who connects additional devices to signal outputs is a system configurator and is therefore responsible for compliance with the IEC 60601-1 / EN 60601-1 standard.

Warning!

During the development and testing of the device, care was taken to ensure that any electrical interference with other devices is almost excluded. Nevertheless if you suspect such influences, they can be prevented by the following measures:

- Changing the place of the device, the place of the other

devices, or both
- Increasing the distance between the devices used
- Consult medical technology specialist

Warning!

The device must not be used in conjunction with a defibrillator, as it does not have any appropriate protection systems. In this case, the manufacturer accepts no liability whatsoever for any damage that may occur.

Warning!

Avoid overheating the device. Ensure that there is free air circulation especially to the bottom and the back of the device (rear panel gap at least 10cm).

Warning!

Battery change wireless probe

The Li-battery of the Crystal Wireless Probe must be replaced in such a way that no short circuit can occur at the Li-cell. The battery should be used and recycled in accordance with the battery manufacturer's instructions.

3 Introduction to the Crystal Probe -*automatic*-

The gamma probe system **Crystal Probe** -*automatic*- is a highly developed intraoperative detection system for the localization of radioactive concentrations in tissue. The system consists of the SG04 control unit and at least one or more of the probes listed in Section 5.

3.1 Scope

The **Crystal Probe** -*automatic*- is used intraoperatively to detect radioactively marked tissue. It meets all technical and usability requirements for performing a sentinel lymphonodectomy (SLNE, sentinel lymph node surgery). It is also able to localize nuclide accumulations at the borders of marked primary tumors (ROLL), in the thyroid gland and in other organs.

The **Crystal Probe** -*automatic*- indicates the detected gamma radiation by an acoustic signal and synchronously via a numerical value in cps (counts per second) on the display, which is proportional to the activity level.

3.2 Essential performance

The device has no essential performance.

3.3 Intended use and Contraindication

3.3.1 Intended use

The applications of the **Crystal Probe** -*automatic*- in the clinical field include the extra- and intraoperative detection of tumor cell groups in oncology areas as well as the detection of distribution areas of radioactively labeled substances. This includes, for example, the localization of the first draining lymph node (sentinel node) in malignant melanoma (skin cancer) or breast cancer.

3.3.2 Contraindication

The **Crystal Probe** -*automatic*- is not suitable for dosimetric applications, detection of radiation other than gamma-radiation and detection of radiopharmaceuticals with radiation energy outside the defined energy range.

3.4 User requirements

This instruction manual is intended for the proper operation of the system, but does not contain any description or procedural instructions for surgical techniques and is in no way intended to impart such knowledge to a surgeon. The gamma probe system **Crystal Probe** -*automatic*- is a medical device. For medical applications in the surgical field or in diagnostics, it may only be used in designated facilities and by surgeons or medical professionals who have the appropriate professional qualifications and can decide whether, from a clinical point of view, its use on the patient is necessary and how it should be performed.

3.5 **Scope of Delivery**

The gamma probe system is delivered in a stable hard-shell case which contains the following components:

- Control unit SG04
- At least one probe (See Section 5. Probes)
- Power supply for the control unit SG04
- Nuclide holder for daily functional tests (for all probes included)
- Spare fuses
- Additional probe(s) (optional)
- PET-collimator (optional)
- Packing list
- Declaration of conformity
- Instruction manual
- Final Checking report

Inspection on delivery
Check the device and optional accessories for completeness and possible damages immediately after receipt. The manufacturer will only consider claims for compensation that have been forwarded to a sales representative or authorized Service Company.

Returning the device
If it is necessary to return the unit, use the original packaging. The manufacture does not bear liability for transport damages, which are caused by insufficient transport packaging.
Please make sure, the following information is included:

- Name of owner
- Address of owner
- Type of device
- Serial number (see device label)
- Detailed description of defects

Use the return form provided (enclosed with the case or on request from the manufacturer).

4 The Control Unit CXS-SG04

Kontrolinis įrenginys CXS-SG04

The control unit CXS-SG04 has the following functions:

- Evaluation of the incoming signals of the probe – indication of the count rate visually on the display and acoustically via the loudspeaker
- Control elements for adjustment of
  - Nuclide
  - Audio signal: Type, volume and pitch
  - Gate time
- Selection of nuclides that may be used during the operation
- Power supply for wired probe
- Settings of the wireless probe
- Semi-automatic execution of the daily functional test

Operating, Transport and Storage Conditions

	Temperature	Humidity	Pressure
Operation	15°C to 40°C	30 % to 70 %	700 hPa to 1060 hPa
Storage	-20°C to 45°C	10 % to 85 %	700 hPa to 1060 hPa
Transport	-20°C to 60°C	10 % to 85 %	700 hPa to 1060 hPa

Carrying Handle

The carrying handle can be adjusted by simultaneously pressing the buttons on the joints and locking in a variety of fixed positions.
The following positions are typical:

- Carrying handle vertically upwards: Easy transport of the control unit
- Carrying handle horizontally to the front: Stowing the control unit in transport case
- Carrying handle diagonally forward and down: Positioning of the control unit with display tilted upwards for good visibility during the operation

Installation site:

- Non sterile operating area
- Flat stable surface with enough space to reach all operating elements and to see all display elements
- When used with a wired probe: Check the stability, so that even if the cable is accidentally pulled, it cannot be displaced.
- In case of mains operation, set it up in such a way that it can be disconnected from the mains as quickly as possible in the event of a failure. Protection against overheating: leave at least 10cm of free space behind the control unit so that the air can circulate

Maintenance and Cleaning:

The control unit CXS-SG04 requires no maintenance from the user.
In case of a malfunction, contact the manufacturer as described in section 11 or your local distributor.

The control unit CXS-SG04 should be regularly wiped with cleaning solution and disinfectant. Make sure the control unit is not connected to mains or turned on during cleaning and that no liquid enters the interior of the control unit.

Danger!

- Probes CXS-OP-* and the control unit CXS-SG04 are matched to each other and must not be combined in any other way (neither with the predecessor model nor with products of external companies), as otherwise the safe function is not guaranteed and the control unit or the probe can be destroyed
- Mains operation only with connection to equipotential bonding
- Only switch on after adaptation to the room climate
- Avoid direct sunlight
- Do not use, if steam or liquid has penetrated the system
- Prevent shocks, vibrations or falls
- Do not use the control unit or probe in the event of obvious defects or damage, in particular to the mains plug and mains cable
- Do not operate in the vicinity of explosive gases or in oxygen-enriched environments (no explosion protection)
- Whoever connects additional devices to signal outputs is system configurator and responsible for the compliance to the standards IEC 60601-1 / EN 60601-1

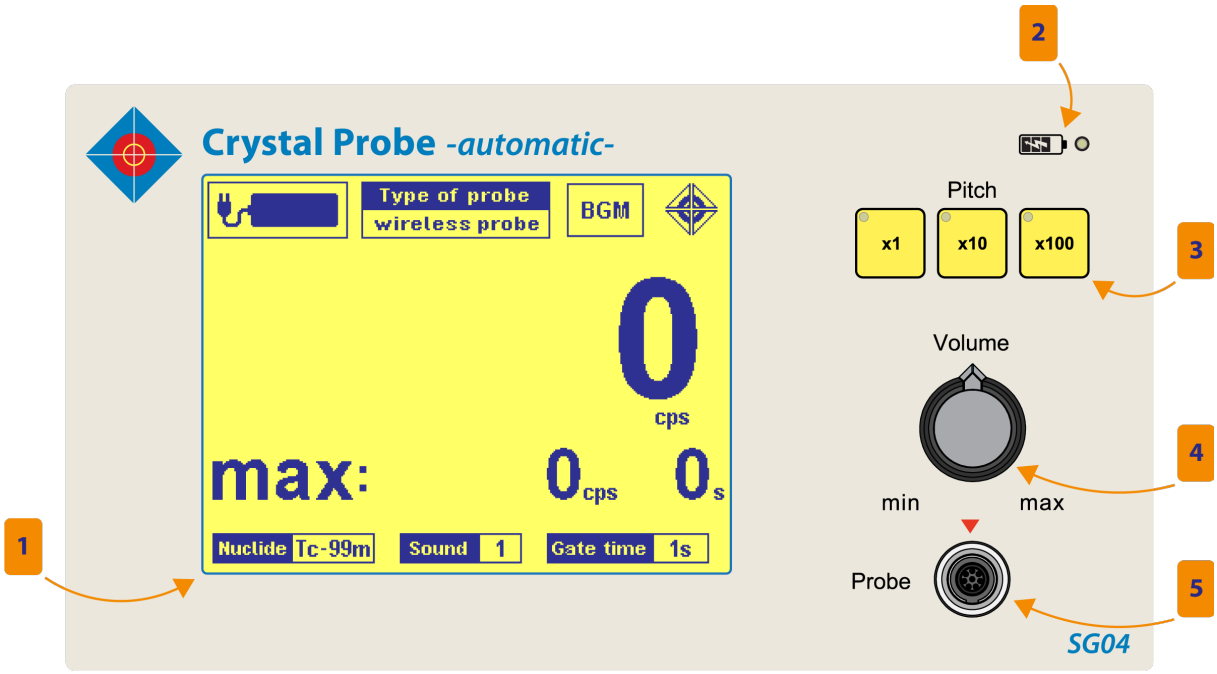
Info!

Functionality

In the Control Unit SG04 the settings “Nuclide choice“, “Gate Time“ and “Pitch“ are called up by default and are not mandatory specifications for the surgeon. These settings are freely selectable by the user depending on the operating conditions.

After switching on, an automatic system check is performed. Possible malfunctions are indicated and the type of probe is recognized. When the type of probe is detected, an automatic nuclide selection is made, which is a suggestion for the nuclide setting for the intended application. For all gamma probes, the nuclide Tc-99m is set. It can be changed at any time by the manual selection of nuclides, which is the responsibility of the operating surgeon or the accompanying nuclear physician.

4.1 Explanation of the operating and display elements - Front panel



1	**Display** *(see 4.2)*
2	**Charging indicator light** The charging indicator light is used to indicate the state of charge during recharging of the internal accumulator when the device is switched off and the other display elements are not activated. If the control unit is switched off and charging is in progress at the same time, the charging indicator light flashes evenly. If it lights continuously, the accumulator is fully charged and the power supply unit can be removed. If the charging indicator light only flashes briefly, there is a malfunction in the battery charge. If the control unit is switched on, the charging indicator light is out of operation and the state of charge is indicated by the active charging indicator on the display.
3	**Pitch** Depending on the pressed key "x1", "x10" or "x100", either every individual, every 10th or every 100th count is signaled acoustically. At very high count rates, the acoustic signals are rapidly consecutive which makes accurate localization difficult. The keys are used to adapt the acoustic signal to the measured count rate and thus help with the search. The pressed key is indicated by the respective key LED. *The range switch is not effective on "Sound 3" because it is a continuous tone that changes its tone pitch depending on the count rate.*
4	**Volume control** Rotary knob used to adjust the volume of the acoustic signals to the operating conditions. Turning the knob to the left (min) will make the signal quieter and to the right (max) louder. The speaker is located on the back panel of the control unit.

Probe connection port

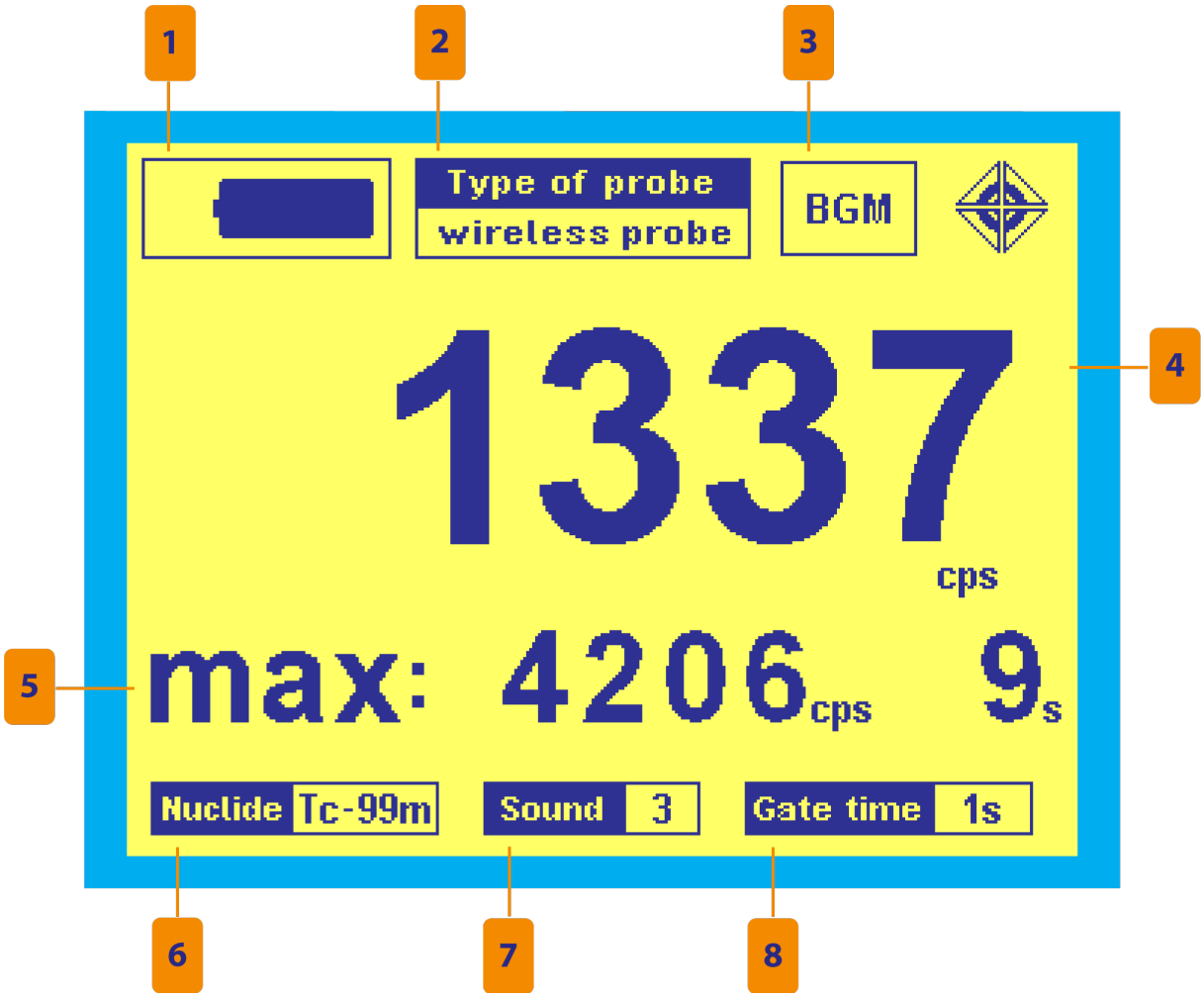
The socket is used to connect probe and control unit.

5

Warning!

The plug and socket are marked for orientation of the plug in the socket. The plug can only be inserted if the red triangle above the socket matches the red dot on the plug! Violent incorrect insertion of the plug leads to destruction of the plug pins and thus to failure of the probe!

4.2 Display



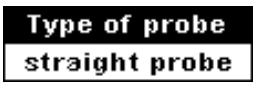
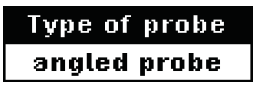
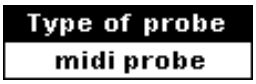
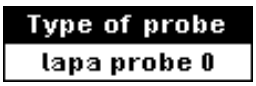
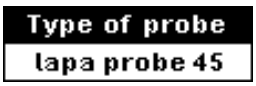
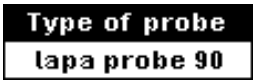
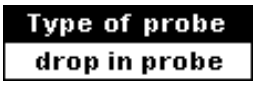
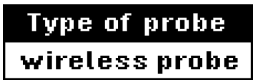
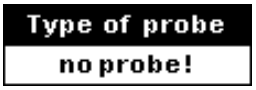
1

Type of power supply
The symbol indicates whether the control unit receives power via the power supply unit or is operated with the battery. The battery charge status is also visible. The progress of charging is indicated by the symbol.

	Battery fully charged
	Battery half empty
	Battery empty
	Mains operation, battery fully charged
	Mains operation, battery charging

2

Type of probe
The Symbol indicates the probe connected to the control unit.

	Straight Probe
	Angled Probe
	Midi Probe
	0° Laparoscopic Probe
	45° Laparoscopic Probe
	90° Laparoscopic Probe
	Drop-In Probe
	Crystal Wireless Probe
	No probe connected

3

BGM (background-measurement)
The measurement of the background radiation is useful if the measurement signal can be distorted by superimposed background radiation. This function can block the output of the acoustic signal below a measured threshold.
Press the „Background" key to activate the function: see section 4.3, point 8.

		Function switched off
	(flashes)	Background radiation is being measured
		Function activated, Background measurement performed, Value saved

4

Count rate

The count rate is the actual measurement signal of the gamma probe system and the local radioactive enrichment is detected with the "maximum detection" during operation. The value is indicated by a five-digit numerical value and shows the sum of all detected counts within the set gate time. With a "gate time" of 1 s **cps** (counts per second) are specified, with 10 s it means **counts**.

To change the Gate time: see section 4.3, point 9.

If the count rate is greater than 99999, the number 99999 stops and starts flashing.

5

Maximum cps-value of the last 30 s

The display **max**: always shows the highest cps value measured within the last 30 seconds. If a value higher than the currently displayed is measured within a 30-second cycle, this value is displayed while the adjacent countdown starts counting from the beginning (30 s downwards). If no higher value is measured within this period, the countdown starts again. If there is no measurable activity, the value jumps to 0 cps after 30 seconds.

This feature is only active at a Gate time of 1 s, not in 10 s mode.

Info!

6

Nuclide

The currently set nuclide is displayed.

To change the nuclide, press the button „Nuclide": see Section 4.3, point 6.

	Technetium-99m
	Lutetium-177
	Indium-111
	Iodine-131
	PET-Nuclide with energy 511 keV
	all energy values >20 keV
	Dual Mode Simultaneous detection of Tc-99m and I-125 with a changed display *See section 4.4 Dual-Mode for details*
	Iodine-125
	Cobalt-57
	No Probe connected

7

Sound (acoustic signal)

There are three different audio signals to choose from.

Sound 1 and 2 are single tones that, depending on the pitch setting (section 4.1, point 3), indicate every 1st, every 10th or every 100th count.

With Sound 3, the pitch depends on the count rate (low = low count rate, high = high count rate). The selected sound is retained after device restart.

The ideal sound type is the one that differs from similar or identical sounds in the OR and thus prevents confusion.
To change the sound type: see section 4.3, point 7.

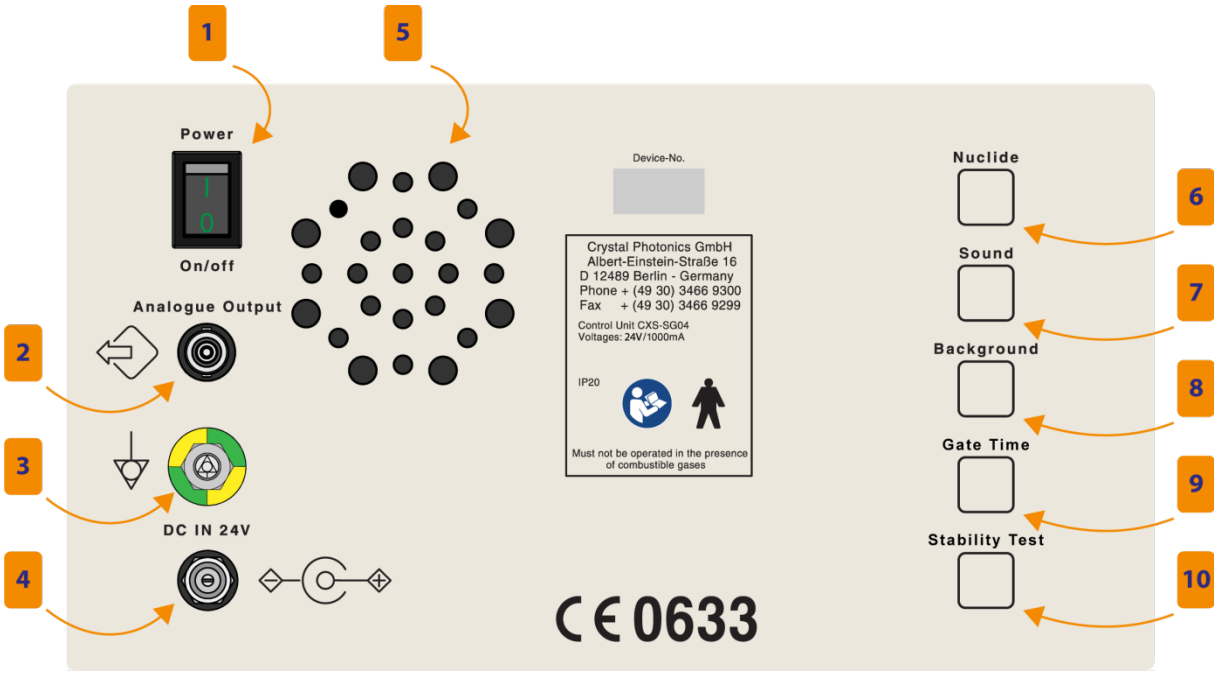
Sound 1	Single tone-1
Sound 2	Single tone-2
Sound 3	Continuous tone

8

Gate time (current measurement time)
Two measurement periods are available. If this is 1 s, the count rate is updated every half second (but a value related to one second is displayed), at 10 s the total number of counts measured appears after the corresponding period. The value in brackets counts down, from 9 to 0 every second. With the change from 0 to 9 the updated count value appears.
To change the gate time: see section 4.3, point 9.

Gate time 1s	Measuring period 1 s	unit: cps
Gate time 10s	Measuring period 10 s	unit: Counts

4.3 Explanation of the operating and display elements – Rear panel



1	**Power switch** Switch for turning on or off the control unit.
2	**BNC-connection** (for analog output signal) When connecting an oscilloscope, the individual pulses are displayed. The connection of a spectrometer (MCA) allows the control of the actually measured energy spectrum of the detected radiation. When a Crystal Wireless Probe is used, no analog signal is generated by the control unit.
3	**Connection for equipotential bonding** In order to avoid the risk of electric shock, the control unit may only be used in mains operation if the equipotential bonding is connected via the plug provided for this purpose. (DIN428011/1)
4	**Power Connector** The supplied mains adapter can be connected to this socket in order to use the system in mains operation or to charge the accumulator.

Danger!

Use only the original power supply and charger. Other power supplies and chargers can cause serious problems with the probe system and endanger patients!
The use of a different power supply will void the warranty and CE-mark.

Danger!

In order to avoid the risk of electric shock, this device may only be used in mains operation if the equipotential bonding is connected via the plug provided for this purpose.

5 **Speaker** (for the acoustic signal output)

6 **Nuclide**
The automatic probe recognition activates the nuclide preset for these probes. By simply pressing the "Nuclide" key, a different nuclide can be selected from the nuclide table corresponding to the application.
A list of the preprogrammed nuclides is available in point 6 of section 4.2.
This button is also used to enter and leave the Dual-Mode: *see section 4.4.*

7 **Sound**
Button to set the sound output. Three different sound sequences can be selected. The last selected sound setting remains saved for the next operation after the control unit is turned off.

8 **Background**
Pressing this key starts the background measurement (BGM) and activates the operating mode "Working with background suppression". Activating this function enables a more differentiated localization of radioactively marked objects, since measurements in the background radiation range are only reproduced visually, but not acoustically.

Activation of BGM-Mode for suppression of background radiation

(1) The whole system must be in operating mode and the displayed average count rate should be more than 5 cps.
(2) Place the probe that there is no nuclide enrichment in the field of view of the probe.
(3) Press the "Background" button on the back of the control unit.
(4) A measurement of the current count rate is made for 10 s. The countdown in progress is indicated instead of the count rate and "seconds" will be displayed below the countdown display. The **BGM** display appears alternatively with a dark or neutral background and the RUN symbol also lights up.
(5) When the measurement is finished, the mean value of the measured background count rate is displayed for a short time. This is accompanied by the black **BGM** and the STOP symbol.
(6) The control unit continues normal operation. The audible signal will disappear on all subsequent measurements up to the mean of the measured count rate, but not the numeric display.
(7) To deactivate the function, press the "Background" key again or switch the control unit off and on again.

Warning! The measurement of background events should be performed close to the person being operated on, but not in the immediate vicinity of the injection site as this will distort the measured values. With low background radiation, this function should not be activated.

Warning! This function is not available in Dual-Mode.

Info!

Single pulse rejection – SPR:
This is a permanently installed function for the acoustic suppression of random events (e.g. cosmic radiation). These events, which usually occur individually, are shown on the display, but there is no sound output. The sound output starts at a count rate> 5 cps. When the BGM function is used, the function SPR is deactivated.

9 **Gate Time** (to change the measurement period from 1s to 10s: *see section 4.2*)

Warning!

This function is not available in Dual-Mode.

10 **Stability Test** (to start the constancy test: *see section 6.4*)

Warning!

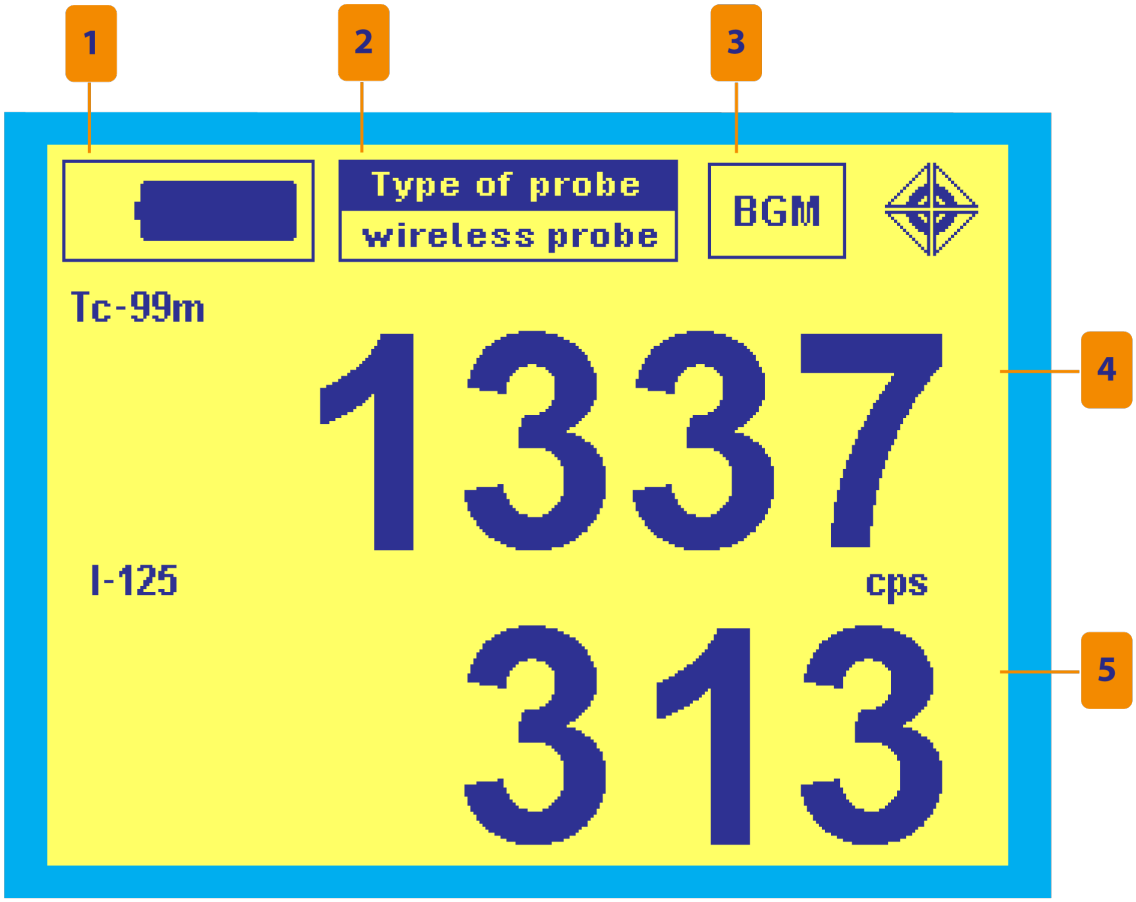
This function is not available in Dual-Mode.

4.4 Dual-Mode

The Dual-Mode is a special mode for the simultaneous detection of Tc-99m and I-125 that can be selected via the nuclide selection.

Warning!

Due to the redesigned display, a number of functions and display elements are not available in this mode.



1	**Type of power supply**
2	**Type of probe**
3	**BGM** As described in section 4.2 Display.
4	**Countrate for Tc-99m** This five-digit display of the countrate for Tc-99m matches the display of the countrate in normal operation mode, as described in section 4.2 Display, though it is limited to the display of the gate time of 1 s in **cps**. The nuclide association is indicated at the left side of the display above the countrate. The acoustic signal in Dual-Mode corresponds to the countrate of Tc-99m at all times.

5

Countrate for I-125
This five-digit display of the countrate for Tc-99m matches the display of the countrate in normal operation mode, as described in section 4.2 Display, though it is limited to the display of the gate time of 1 s in **cps**.
The nuclide association is indicated at the left side of the display above the countrate.
The fraction of the signal that is generated by Tc-99m in the energy range of I-125 is subtracted from the countrate.
There is no acoustic output for the countrate of I-125.

The Dual-Mode is selected and left via the nuclide selection, as described in section 4.3 Explanation of the operating and display elements – Rear panel.
In Dual-Mode, the countrates for Tc-99m and I-125 are displayed simultaneously; one below the other, the acoustic signal corresponds to the countrate of Tc-99m.

Warning!

The following functions are not available in Dual-Mode:

- Background
- Gate Time
- Stability Test

Warning!

If a connected wireless probe looses contact or is turned off and on again, the nuclide selection is reset to automatic and the Dual-Mode has to be reselected.

4.5 Battery and mains operation

The gamma probe system **Crystal Probe** *-automatic-* can be used in mains as well as in battery operation mode. Both modes are safe for use during surgery as confirmed by the CE mark approval procedure.

4.5.1 Mains Operation

For mains operation, connect both the power supply and the equipotential bonding at the correct connectors of the control unit (see section 4.3) before turning on the control unit.
Mains operation is possible even with a discharged, defective or removed battery.

Danger!

Power supply
When using the gamma probe system with connected power supply during operation (mains operation), only the provided power supply may be used. Otherwise, safety can no longer be guaranteed and the conformity expires!
In addition, the control unit must be connected to the equipotential bonding of the operating theatre.

Correct equipotential bonding ensures that all connected devices in the operation room are on the same potential, so no currents can flow between them and through the patient, the user or a third party.

4.5.2 Battery Operation

The control unit contains a battery for up to 12 hours of continuous operation without recharging.
For battery operation, simply turn on the control unit without connecting the power supply and equipotential bonding.

This way, the gamma probe system is isolated from other devices and no current can flow through it and through the patient, the user or a third party.

Charging the battery of the control unit properly and regularly ensures a long service life and trouble-free operation.
We recommend that you start charging immediately after using the device or at the end of each working day.
The battery cannot overload or cause any damage.

Warning!

Only the power adapter supplied with the device is permitted to use for charging the battery or for mains operation! The using of any other power supply is prohibited and lead to the loss of any warranty and the conformity. The power supply unit must not be operated on DC voltages and the available mains voltage must match that specified on the power supply unit.

4.5.3 Change between battery- and mains operation (during an operation)

The change between battery and mains operation takes place automatically as soon as the control unit is connected to or disconnected from the mains via the supplied mains adapter. This allows for uninterrupted operation.

Danger!

When switching to mains operation, the device must first be connected to the equipotential bonding of the OR via the provided socket.

In battery mode, when the battery voltage drops below the minimum battery voltage value, the symbol ERROR flashes in the upper right corner of the display. At this point at the latest, the control unit should be operated via the power supply and it must also be connected to the equipotential bonding in the OR. If this does not happen, a large-scale request is made across the entire display to charge the control unit.

Please charge immediately !!

At this time, further operation is no longer possible for safety reasons. If the power supply is not connected within a reasonable time, the control unit will turn off with a loud beep.
If the device is switched to mains operation, it returns to normal operation.
This measure prevents the deep discharge of the internal battery!

5 Probes

The probes belonging to the gamma probe system **Crystal Probe** *-automatic-* detect the radioactive radiation, which is displayed and evaluated by the control unit SG04. According to different applications and tasks different probes belong to the gamma probe system. The different types of probes are designed for special operational requirements and applications. The following table lists the medical-technical properties of the Crystal Probes.

Tiesus daviklis

	Crystal wireless probe	Straight Probe	Angled Probe	Laparoscopic Probes	Midi Probe	Drop-In Probe
Sensitivity	$> 25.000 \frac{cps}{MBq}$	$> 17.000 \frac{cps}{MBq}$	$> 17.000 \frac{cps}{MBq}$	$> 17.500 \frac{cps}{MBq}$	$> 16.500 \frac{cps}{MBq}$	$> 17.500 \frac{cps}{MBq}$
Collimator FOV	45°	45° Standard other FOV on request	45°	0°-Probe: 45° 45°-Probe: 77°/62° * 90°-Probe: 77°/65° *	45°	50°
Local resolution (in 1 cm)	$< 14\ mm$	$< 17\ mm$	$< 17\ mm$	$< 20\ mm$	$< 20\ mm$	$< 15\ mm$
Energy range	20 to 600 keV					
Energy resolution	$< 15\ keV$					
Side shielding in optimal energy range	99,95 % (140 keV, ^{99m}Tc)	99,95 % (140 keV, ^{99m}Tc)	99,95 % (140 keV, ^{99m}Tc)	99 % (140 keV, ^{99m}Tc)	99 % (140 keV, ^{99m}Tc)	99 % (140 keV, ^{99m}Tc)
Special Characteristics	Battery life up to 12 hours, CR123A Battery		Head angled 30° from handle	Three lines of sight (to the probe axis) possible: 0°, 45° and 90° Viewing direction labeled on the hand piece		Connection to the control unit via additional dongle
Main application area	All standard procedures			Minimally invasive surgery	All standard procedures	Robot-assisted minimally invasive surgery
Diameter of probe head	$15\ mm$	$13\ mm$	$14\ mm$	$10\ mm$	$10\ mm$	$10\ mm$
Dimensions	$L = 220mm$ $D = 23mm$**	$L = 220mm$ $D = 20mm$**	$L = 220mm$ $D = 20mm$**	$L = 510mm$ $D = 20mm$**	$L = 240mm$ $D = 20mm$**	$L = 70mm$ $D = 10mm$
Mass	$210g$	$220g$	$200g$	$190g$	$180g$	$210g$
Housing material	Medical stainless steel (1.4301)					
Cable length	n.a.	$3\ m$				
Max. Distance to control unit	$10\ m$	n.a.				
Nuclide library	^{125}I, ^{57}Co, ^{99m}Tc, ^{177}Lu, ^{111}In, ^{131}I, PET, DUAL Mode - ^{125}I & ^{99m}Tc simultaneous					

*) The 45°- and 90°-Probes have an elliptical field of view with a long axis parallel to the probe and the short axis perpendicular to the probe

**) Diameter of handpiece

5.1 Wired probes

All wired probes are connected to the control unit via an exchangeable cable. The cable is fitted with non-interchangeable connectors and can be processed alongside the probes.

5.1.1 Straight Probe CXS-OP-SP-AC

Tiesus daviklis: CXS-OP-SP straight probe

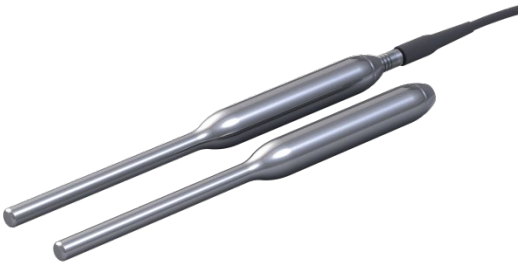
The standard probe CXS-OP-SP-AC is intended for open surgery..

5.1.2 Angled Probe CXS-OP-AP-AC

The angled probe CXS-OP-AP-AC is intended for open surgery. The probe head is angled 30° against the handle and allows better access than the straight probe in certain regions of the body.

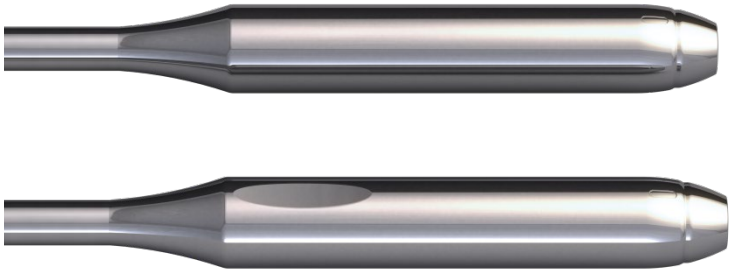
5.1.3 Midi Probe CXS-OP-MP

The applications of the Midi Probe CXS-OP-MP are the same as for the Straight Probe. In favor of a longer and slimmer neck, this probe has a lower spatial and angular resolution.



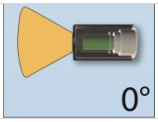
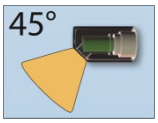
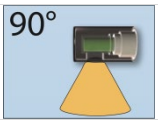
5.1.4 Laparoscopic Probes

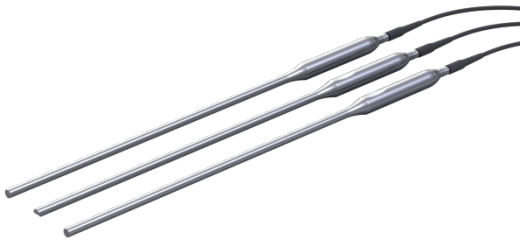
The long and narrow laparoscopic probes are particularly suitable for minimally invasive procedures, whereby the probes must be inserted through a trocar. There are three different versions, which differ in the "directions of view". The CXS-OP-LP-0 is sensitive in the axial direction (corresponds to 0°), the CXS-OP-LP-45 is sensitive at 45° to the axial direction (corresponds to 45°), and the CXS-OP-LP-90 is sensitive at 90° to the axial direction (corresponds to 90°).



There is a mark on the hand piece of the 45° and 90° probe, which marks the viewing direction of the probe. It is arranged offset by 180° to the radiation entrance window of the probe, so the probe always "looks" in the direction opposite to the mark. At the head of the 90° probe, a marker signals the position of the radiation entry window.

Recommended areas of application for Laparoscopic Probes

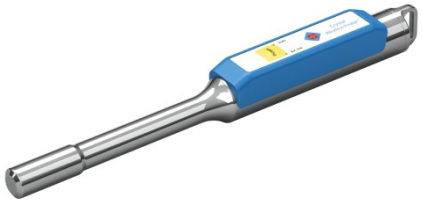
	• for general use in the stomach area
	• for use in the urological field • Example: cervix, uterus, ovary, pancreas, liver, large intestine
	• Example: Prostate, Penis, Lungs



5.1.5 Drop-In Probe CXS-OP-DP

The Drop-In Probe CXS-OP-DP is a probe for the gamma probe system **Crystal Probe** *-automatic-* designed for use in robot assisted minimally invasive surgery.
For this purpose, the probe is especially compact and parts of the electronics are housed in a separate dongle that is interposed between the probe and the control unit.
The probe body has gripping areas for typical tools of surgical robots to enable a precise and secure manipulation.

5.2 Crystal Wireless Probe



The Crystal Wireless Probe CXS-OP-WP is cordless connected to the control unit. It offers the highest level of comfort for the user as no connection cable interferes with the freedom of movement. It can be used in all parts of the body for open surgery.

5.2.1 Indicator Elements and Operating Mode

Indicator elements of the keypad:

- green LED to display operating mode („State“)
- red LED to display malfunction or battery status („Bat. low“)

Switching on and off:

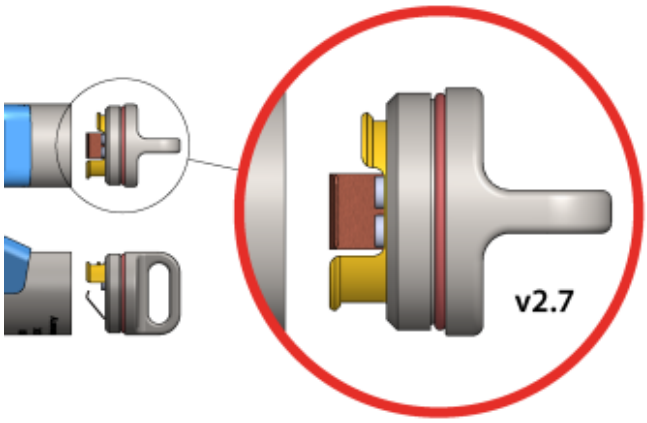
1. **Turn on the control unit,** so it is ready to use.
2. **Switch on the wireless probe:** Press the “Power”-key briefly. The green LED begins to blink. If the battery charge is less than a specific value, then the probe will not turn on.
3. **Logging in the probe (connection setup):** If the probe is switched on, its transmitter immediately searches for the remote station (receiver) located in the CXS-SG04 control unit.
   The radio modules of the probe and the controller only work as a pair. This means a connection can only be established between them without risk of a mix-up.
   If the transmitter has found the remote station, this is indicated by the transition of the green LED from flashing mode to the permanently lit mode. If no receiver is found, the LED continues to flash.
4. **Internal Operation Check:** Immediately after switching on the probe checks all internal operating voltages. In the event of a deviation, it signals an error by means of the flashing red LED. The operating parameters are constantly monitored during normal operation.
5. **Operating mode of the Probe:** If the probe is operating in normal operating mode, the green LED must be constantly lit, the red LED is off or steady. The latter means that the charge capacity of the battery has fallen below a certain value and has to be exchanged after a maximum of one hour of operation. If the count rate detected by the probe is below 5 cps for longer than 60 minutes, it turns off automatically.
6. **Switch off Probe:** Press the "Power"-key for at least 2s without interruption. The green LED turns off. Both LEDs are switched off.

5.2.2 Battery change

Warning!

The Crystal Wireless Probe must always be equipped with a non-rechargeable **CR123A Li-battery from Panasonic®, Varta® or Duracell®**. If other batteries or rechargeable batteries are used, all warranty claims expire!
Handling of the Li-battery must be according to the manufacturer's instructions! In particular, no short circuit may occur at the connecting poles in order to exclude a risk of fire or explosion.

1. Switch off probe.
2. Unscrew cap to the left and remove it.
3. Angle the probe, let the empty battery slide out and dispose of it according to the manufacturer's instructions.
4. Push the new battery with the "+ pole" forward into the battery compartment until it stops.
5. Insert the electrical contacts into the corresponding groove and screw the cap to the right until it stops.



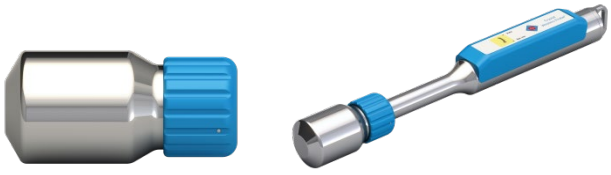
Warning!

When closing, place the lid neatly and make sure it turns easily. Otherwise, the thread may be damaged.

6. A time of at least 20s must be observed for the battery change and the resulting reset of the electronics. Be sure to exceed this time otherwise the probe may not turn on.
7. After the battery has been used up, the probe switches off automatically.

5.2.3 PET-Collimator

The PET-Collimator is an additional accessory for the Crystal Wireless Probe. It serves to adapt the side shielding and collimation to the higher energy gamma radiation of PET nuclides.

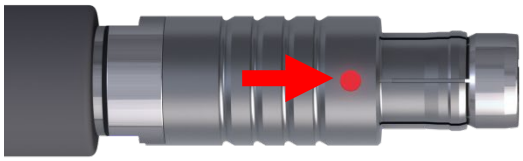


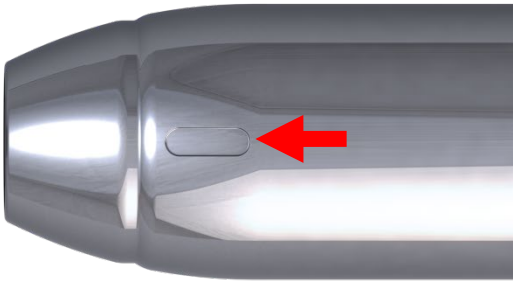
To use, slide the PET Collimator over the probe tip and tighten the mounting nut. Select PET using manual nuclide selection.
To change the Nuclide, press the button „Nuclide": see section 4.3, point 6.

6 Use of the Crystal Probe *-automatic-*

6.1 Operation with wired Probes

1. The power switch on the control unit is set to "0".
2. Connect the wired probe to the control unit.
   a. **Attach probe cable to probe:** The markings on the connector and the probe housing have to be aligned.





   b. **Attach probe cable to control unit:** The markings in the connector and the control unit have to be aligned.

Danger!

The specified procedure of connecting the probe and switching on the control unit must be strictly observed.
Otherwise, there is a risk of short circuit via the contacts in the plug, which could lead to injury of the user or damage to the device.

Warning!

There are red dots on the plugs of the probe cable. The plugs must always be inserted in the socket on the CXS-SG04 control unit and the probe so that the dot on the plug faces the red marking on the control unit or the probe respectively. If this is not observed, the plug can be damaged!

3. Set the power switch to "I". The company name, logo and contact data appear on the display for 15s (self-test and initialization of the electronics).
   The control unit has default values for the following settings, which are automatically selected via the probe recognition when the system is turned on.
   - Nuclide Choice
   - Gate Time
   - Pitch
4. The battery indicator must indicate sufficient battery charge. Otherwise, connect the power adapter to the mains and set up equipotential bonding via the provided connector.

Danger!

Mains operation and equipotential bonding
When using the gamma probe system with connected power supply during operation (mains operation mode), only the provided power supply is permitted. Otherwise, safety can no longer be guaranteed and the conformity expires!
In addition, the control unit must be connected to the equipotential bonding of the operating theatre.

5. If no error message appears, the system is ready for use. The control unit has detected the type of probe and automatically set the corresponding operating parameters.
6. Use the button on the back panel of the Control Unit to set the desired tone.

6.2 Operation with Drop-In Probe

1. The power switch on the control unit is set to "0".
2. Connect the Drop-In Probe to the control unit.
    a. **Attach probe cable to dongle:** The markings on the connectors have to be aligned.
    b. **Attach dongle to control unit:** The markings in the connector and the control unit have to be aligned.

Warning!

The connectors have to be plugged into the socket on the control unit and the cable connector at the dongle so that the red dots on the connectors face the red markings on their respective counterparts.
If this is not observed, the plug can be damaged!

3. Set the power switch to "I". The company name, logo and contact data appear on the display for 15s (self-test and initialization of the electronics).

The control unit has default values for the following settings, which are automatically selected via the probe recognition when the system is turned on.

- Nuclide Choice
- Gate Time
- Pitch

4. The battery indicator must indicate sufficient battery charge. Otherwise, connect the power adapter to the mains and set up equipotential bonding via the provided connector.

Danger!

Mains operation and equipotential bonding
When using the gamma probe system with connected power supply during operation (mains operation mode), only the provided power supply is permitted. Otherwise, safety can no longer be guaranteed and the conformity expires!
In addition, the control unit must be connected to the equipotential bonding of the operating theatre.

5. If no error message appears, the system is ready for use. The control unit has detected the type of probe and automatically set the corresponding operating parameters.
6. Use the button on the back panel of the Control Unit to set the desired tone.

6.3 Operation with Crystal Wireless Probe

1. Set the power switch to "I". The company name, logo and contact data appear on the display for 15s: This serves as a self-test and the initialization of the electronics.
2. The battery indicator must signal a sufficient charge. Otherwise, connect the power adapter to the mains and set up equipotential bonding via the connector provided.
3. If no error message appears, the system is operationally functional. If no wired probe is connected, the display show "00000" for the count rate. In addition, in the display for the probe "**no probe**" appears, and the nuclide display is empty.
4. Switch on the Crystal Wireless Probe with the key. After the electronics have been initialized and the connection to the control unit has been established, the green LED on the probe lights up continuously, the red LED is off. If a wired probe is also connected to the control unit, it will now be switched off. In the window for the probe display "wireless probe" appears. This signals the successful connection; automatically the default ^{99m}Tc nuclide is also selected. The count rate measured is shown on the control unit display.

Warning!

Take the Crystal Wireless Probe like a pen! Never cover the plastic top, otherwise the radio connection to the control unit can break off and the status LEDs are no longer visible!

6.4 Constancy test

Some authorities demand regular monitoring of the functionality of medical devices. This "constancy test" has to be performed and documented every working day to guarantee the adequate probe quality. The constancy test of the **Crystal Probe** *-automatic-* works semi automatically.
The constancy check ensures that the sensitivity and the zero effect of the probe remain constant; deviations of these characteristics may be indications of probe malfunctions.
Therefore the constancy test included two steps:

1. Checking the sensitivity of the probe
2. Checking the “Zero-effect” of the probe

The procedure is designed for use with a Co-57 test source.
.

6.4.1 Constancy Test Table

The following instructions refer to the table with the following structure, which is available via Crystal Photonics.

Crystal Photonics

Protocol for constancy test according to DIN 6855-1

Instruction (in all Fields with H you can get help by using the mouse pointer) H
ENTRIES PLEASE ONLY IN THE GRAY CELLS AND NAMES OF THE EXAMINER

Probe:		**CXS-OP-xx s/n xxxx**	
SG04:		**s/n xxxx**	
Co-57 source name:			
Date of source Certificate:			H
Activity in source cerfificat (kBq):			H
Reference value probe sensitivity(cps/MBq):			H
Reference value zero effect (counts/min):			H
Maximum permitted tolerance of sensitivity [%]		*5*	H
Maximum permitted zero effect:		*20*	H

Current Date:	19.06.19
Clinic:	
Dept.:	
Room	
V.:	
MTK:	
Renew MTK!	

Date H	Age of source	Activity	Display value after 100s WITHOUT source H	Display value after 100s WITH source H	Mean sensitivity	Sensitivity variance H	H	Name / signature of examiner
	(days)	(kBq)	(counts/min)	(cps)	(cps/MBq)	(%)		

6.4.2 Straight Probe

1. Open the Excel table and (once) enter the data for the test source in cells F6- F8 (as specified in the source certificate). It is important to enter the reference date for the source activity and not the issue date of the certificate. When replacing the test emitter, the table must be set up again. Line 15 of the table serves as a reference line for all further constancy checks. If this is not completed, no constancy check can be carried out.
2. Enter the current date in the first column so that the current activity of the test spotlight is calculated.

Info!

The activity of the nuclide used should be between 10 kBq and 200 kBq.
If activity falls below this range, switching to a new nuclide is recommended.
When changing the nuclide, a new table must be set up.

3. Enter name in the last column of the same row.
4. Fix the test radiation source into the supplied nuclide holder and place them on the probe (always keep the measuring geometry exactly the same, i.e. the test radiation source must always point to the probe with the same side (writing side facing the probe). If the nuclide is rotated by 180 °, the measurement is different via measuring geometry, which is not completely comparable. Insert nuclide holder on the probe as far as it will go. Switch on the control unit with connected probe and wait about 15 s during initialization of the system.
5. Press the "Stability Test" button (on the back of the control unit).
6. Control unit starts the measurement and displays the remaining time on the display (countdown: 100 s).
7. The measurement result will be shown on the display after the countdown has finished. Enter this value in the table (column E). The result is shown in “counts/s” (cps). Press any "Pitch" button to return to normal operating mode.
8. Remove the nuclide and nuclide holder from the probe. If the test radiation sourcer is only used for the gamma probes, it can remain in the nuclide holder (no accidental twisting possible). Place both together in the lead protection container.
9. The probe rests on the table and don’t “look” to any radiation source.
10. Press the stability test button again for the “Zero-effect” measurement.
11. The control unit restarts the measurement and displays the remaining time on the display (countdown: 100 s).
12. Enter the measurement result, which is shown on the display after the countdown has ended, in the table (column D). The result is shown in “counts/ min”(cpm).
13. Press any "Pitch" button to return to normal operating mode.
14. The deviation of the detected probe sensitivity is automatically displayed in column G.
    a. If the cell is highlighted in green, the deviation is within tolerable limits. In this case, save and close the table.
    b. If the deviation is too high, the cell is highlighted in red and an error message is displayed. The zero effect may be max. 20 cpm. If this is exceeded, the cell is also marked in red.
    Warning: If after the zero effect measurement (without nuclide) the result is given with the unit cps, the value is too high!
    Repeat the measurement process to exclude possible errors in measurement.

If the error remains: do not use the system and contact the technical support of ***Crystal Photonics GmbH***: +49 (0)30 34 669 294.

Warning!

During the constancy test, avoid shocks and make sure that there are no sources of radiation and high frequency nearby.

6.4.3 Angled Probe

Proceed analogously to 6.4.2, but use special source holders for the angled probe.

6.4.4 Laparoscopic Probes, Midi Probe and Drop-In Probe

Proceed analogously to 6.4.2, but use special source holders for the respective probes.

6.4.5 Crystal Wireless Probe

Proceed analogously to 6.4.2, but use special source holders for the Wireless Probes.

6.5 Detection of nuclide concentrations

Distance to activity centre
The count rate is approximately inversely proportional to the square of the measuring distance. The probe should therefore be as close as possible to the suspected activity center.

Info!

Accuracy of Values:
Due to the nature of the processes involved the measurements performed with the **Crystal Probe** *-automatic-* can only show relative values and are not fit for measuring the absolute activity of nuclide accumulations. As such, no error margin can be given for values acquired during the intended use of the device.
The constancy of the measurements is ensured via the constancy testing as described in section 6.4.

Info!

Single pulse rejection – SPR:
This is a permanently installed function for the acoustic suppression of random events (e.g. cosmic radiation). These usually single events are shown on the display, but there is no sound output. The sound output starts at a count rate >5 cps. When the BGM function is activated, the function SPR is suspended.

Spatial Resolution
The location-dependent maximum count rate serves to localize the activity center. However, this count rate also depends on the angle of the probe to the activity center. The superposition of both dependencies can lead to the wrong localization of the maximal activity. Therefore, it is usually appropriate to change the position at a constant angle or to change the angle at a constant position. It is recommended to train this technique in a model experiment.

Misinterpretation of Count Value
The lymph nodes to be localized are often close to the site of injection, especially in the sentinel lymph node of breast cancer, with the activity taken up by the lymph node being about 2-3 orders of magnitude below the activity of the injection site. To determine the lymph node location, the probe should be guided so that the injection activity is not within the sensitive area of the probe and is completely shielded by the collimator.

Registration of Count Value
The acoustic count value output serves for qualitative orientation and is a reliable source of information for the surgeon. The volume of the audio signal can be changed with the rotary knob. For quantitative statements, the numeric signal output should be used on the display.

6.6 Switching off the Crystal Probe -*automatic*-

1. Set the power switch of the control unit to "0". Thus, the measuring system is disconnected from the internal supply voltage, there is no more operating voltage and the screen turns off.
2. Disconnect the wired probes from the control unit (unlock the connectors by pulling and then remove it from the control unit and the probe). For the Crystal Wireless Probe, press the button until the green LED turns off (about 2 s). Clean, disinfect and sterilize probes as well as probe cable.
3. Replace the battery of the Crystal Wireless Probe (depending on the battery status) with a new one.
4. Connect the control unit with the mains adapter to the mains (charge the battery).

7 Cleaning, Disinfection and Sterilization of Probes

7.1 General

All types of medical gamma probes of the "Crystal Probe" brand from Crystal Photonics GmbH for intraoperative use must be cleaned, disinfected and sterilized, before they may be used in surgery.

Danger!

Any unprotected contact with the untreated probe must be prevented by appropriate protective measures.
In particular, the preparation of the probes must always be carried out with suitable protective procedures and devices (gloves, etc.).

Danger!

The use of unsuitable procedures can cause damages to the probes and endanger patients.
Only use procedures marked as suitable for your probe.

The dongle for Drop-In Probes CXS-OP-DP has to be treated similar to the control unit. It is not suitable for submersion of any kind.

7.2 Cleaning and Disinfection

Cleaning the probe is necessary:

- immediately after each surgery or other uses, immediately in the operation theatre if possible
- before each disinfection and sterilization
- before each return to the manufacturer (e.g. after a test sample, or for repairs)

7.2.1 Information on cleaning solutions

In principle, all medically approved neutral or alkaline cleaning agents can be used for cleaning. Alkaline cleaning solutions should be given preference.

Warning!

Do not use cleaning or disinfection agents that act corroding to steel, as these may damage the probe.
Never use an ultrasonic bath for cleaning the probe as this damages the probe!

Info!

The effectiveness of the cleaning with the typical cleaning agents of the clinic should be validated on the probe.

Info!

Some manufacturers offer products that cover the treatment steps of cleaning and disinfection in an overall process (e.g. Tristel Trio Wipes). In such systems, the procedure may differ from this manual. Specifications and exposure times of the manufacturer should be followed in any case.

7.2.2 Automated Cleaning and Disinfection

Wired probes with detachable cable are suitable for automated cleaning and processing.

- Cleaning:
  - in Accordance with ISO 15883
- Disinfection:
  - Thermal disinfection at 90°C, 10 min or A_0-value of 3000
- Drying:
  - Automated at 110°C or
  - Medical compressed air

Warning!

Do not use cleaning or disinfection agents that act corroding to steel, as these may damage the probe.
Never use an ultrasonic bath for cleaning the probe as this damages the probe!

Warning!

Only the following Probes and their corresponding cables are suitable for automated cleaning and disinfection:
CXS-OP-SP-AC: standard straight probe
CXS-OP-MP: Midi-Probe
CXS-OP-AP-AC: Angled Probe
CXS-OP-LP-0°: 0° Laparoscopic Probe
CXS-OP-LP-45°: 45° Laparoscopic Probe
CXS-OP-LP-90°: 90° Laparoscopic Probe
CXS-OP-DP: Drop-In Probe

7.2.3 Manual Cleaning and Disinfection

7.2.3.1 Cleaning

7.2.3.1.1 **Wired Probes** (CXS-OP-SP-AC, CXS-OP-MP, CXS-OP-AP-AC, CXS-OP-LP-0°,-45°,-90°, CXS-OP-DP)

- Remove the sterile sleeve from the probe (if it used with a sterile cover)
- Hold the probe with the tip down and rinse the probe in clean water for two minutes.
- Dry the probe with a soft cloth.
- Clean the surface of the probe by placing it in a cleaning solution and then with a soft cloth, sponge or soft brush soaked in cleaning solution. Make sure to remove any adhering contamination, especially if the probe was used without a sterile sleeve or if the sterile cover was damaged
- Hold the probe with the tip down and rinse the probe in clean water for two minutes.
- Dry the probe with a soft cloth and perform a visual inspection. Repeat the cleaning procedure if any residue is visible on the probe.
- After drying, the probe is ready for disinfection.

The probe cable can be treated using the same procedure.

Warning!

The whole cable of the Drop-In Probe CXS-OP-DP has to be included in this procedure.

7.2.3.1.2 **Crystal Wireless Probe** (CXS-OP-WP)

Warning!

Do not allow liquid to enter the battery compartment of the probe. This can cause electrical short circuits in the probe electronics and render the probe unusable.

- Remove the sterile sleeve from the probe.
- Hold the probe with the battery compartment upwards on the handle and rinse the probe for 2 minutes under running tap water. Then wipe the rear end of the probe with a wet cloth. Make sure that no water gets to the plug or the battery compartment.
- Dry the probe with a soft cloth.
- Clean the probe with a soft cloth or sponge soaked in cleaning solution. If there is any noticeable residue on the rear end of the probe, it can also be removed with the cleaning cloth or sponge. Make sure to remove any remaining contamination.
- Hold the probe with the battery compartment upwards on the handle and rinse the probe for 2 minutes under running tap water. Then wipe the rear end of the probe with a wet cloth. Make sure that no water gets to the plug or the battery compartment.
- Dry the probe with a soft cloth and inspect visually. Repeat the cleaning procedure if any residue is visible on the probe.
- After drying, the probe is ready for disinfection.

7.2.3.1.3 PET-Collimator

- Remove the sterile sleeve from the probe with PET collimator.
- Remove the PET-Collimator from the Probe to clean it separately (see 7.2.3.1.1 and 7.2.3.1.2).
- Hold the PET collimator and the fastening nut individually by hand under running tap water and rinse for 2 minutes from all sides.
- Dry both parts with a soft cloth.
- Clean both parts with a soft cloth or sponge soaked in cleaning solution or in a basin filled with cleaning solution using a soft cloth or sponge. Be sure to remove any remaining contamination, especially if the probe was used without a sterile sleeve.
- Hold the PET collimator and the fastening nut individually by hand under running tap water and rinse for 2 minutes from all sides.
- Dry both parts with a soft cloth and perform a visual inspection. Repeat cleaning if any residue is visible on the parts.
- After drying, the parts of the PET-Collimator are ready for disinfection.

7.2.3.2 Disinfection

The following fundamental disinfection methods are suggested:

	Wired probes CXS-OP-SP-AC, CXS-OP-MP, CXS-OP-AP-AC, CXS-OP-LP-0°, -45°, -90°	**Wireless Probe** CXS-OP-WP	**PET-Collimator**	**Drop-In Probe** CXS-OP-DP
Wipe disinfection	+	+	+	+
Immersion disinfection	+[1]	(+)[2]	+	+
Trophon-EPR-System	+[3]	+	-	-

Legend	
Suitable	+
Unsuitable	-

Table 1: Overview of the appropriate disinfection methods for your probe

7.2.3.2.1 Wipe or spray disinfection

- Wrap the probe, the cable or the parts of the PET Collimator with a lint-free cloth soaked in a suitable disinfectant solution. Make sure that the entire surface is wetted by the disinfectant solution.
- At the end of the exposure time, remove the cloth and wipe the probe, the cable or the parts of the PET Collimator with a clean, lint-free cloth soaked in clean water. Make sure that no water enters the battery compartment.
- Dry the probe or the parts of the PET collimator with a lint-free, clean cloth. The probe is now ready for use with sterile cover or for sterilization.

Info!

Tristel Trio Wipes, a combined system of cleaning and disinfection wipes, was validated for use with our probes.
Adhere to the manufacturer's instructions for correct use.

7.2.3.2.2 Immersion disinfection

Warning!

Only use immersion disinfection with a suitable probe. Table 1 provides an overview of which probes are suitable for immersion disinfection.
The Crystal Wireless Probe can only be immersed up to the handle.
(See Warning! under 7.2.3.1.2)
The whole cable of the Drop-In Probe CXS-OP-DP has to be included in this procedure.

- Prepare the disinfectant solution according to the respective manufacturer's instructions and fill in a suitable container.
- Immerse the probe, the cable or the parts of the PET-collimator in the disinfectant solution and leave in the solution for the exposure time specified by the manufacturer.
- Then remove the probe, the cable or parts of the PET Collimator from the solution and rinse thoroughly with clean water.
- Dry the probe, the cable or both parts of the PET-collimator with a clean, soft, lint-free cloth, and then place or hang them on a soft cloth on a stable surface with the connectors or the thread facing downwards for 10 minutes, so that the water can drain from the interior. Then dry the parts again with a clean, soft, lint-free cloth.

The Probe, cable or PET-Collimator is now ready to be sterilized or used with sterile sleeve (see table of appropriate methods of sterile uses).

[1] Current models. Immersion disinfection is not possible for older probes. Immersion disinfection for straight and angled probes is possible for serial numbers 1320 and above. Probes with fixed cable may only be immersed up to the cable outlet to prevent liquids from entering the interior of the probe.
[2] The Crystal Wireless Probe can only be immersed up to the handle.
[3] Except Laparoscopic Probes CXS-OP-LP-0°, -45°, -90°

7.2.3.2.3 Disinfection in Trophon EPR System

With the Trophon EPR system, automated disinfection of gamma probes, apart from laparoscopic probes, is possible. For implementation, the corresponding instructions of the manufacturer must be observed; the maximum process temperature must not exceed 60 °C.

Info!

The effectiveness of the cleaning with the typical cleaning agents of the clinic should be validated on the probe.
The Disinfection using the Trophon system was validated for use with our probes and is suitable for CXS-OP-SP-AC, CXS-OP-MP, CXS-OP-AP-AC and CXS-OP-WP.

7.3 Sterilization

Before any medical use of the probes sterility must be ensured.
The following table summarizes the suitability of typical sterilization procedures for probes from Crystal Photonics:

	Wired probes CXS-OP-SP-AC, CXS-OP-MP, CXS-OP-AP-AC, CXS-OP-LP-0°, -45°, -90°	**Wireless Probe** CXS-OP-WP	**PET-Collimator**	**Drop-In Probe** CXS-OP-DP
Autoclave	+	-	+	-
Low Temperature-Plasma-(LTP) Sterilization	+	+	+	+
Sterile sleeve [4]	+	+	+	-

Legend	
Suitable	+
Unsuitable	-

Table 2: Overview of the appropriate sterilization methods for your probe

7.3.1 Autoclave

All wired probes with detachable cables, the corresponding cables and the PET-Collimator are suitable for Sterilization by autoclave in accordance with EN 554/ISO 17665-1.
Process Parameters:
135°C, 5min

Warning!

Do not use Temperatures above 135°C. This can cause damage to the probe electronics and render the probe unusable.

Warning!

The number of sterilization cycles is limited to 200.
The probe must then be sent to the manufacturer for inspection. This check is also performed if the probe was sent to the manufacturer in connection with a medical technical check (MTK). This means that the probe must be checked by the manufacturer after 200 sterilization cycles or after 2 years for the MTK, depending on which event occurs sooner.
Cables have to be replaced after 200 cycles.

7.3.2 LTP-Sterilization

The probes of the brand Crystal Photonics can be sterilized by the low temperature plasma method. Follow the instructions from the manufacturer of your sterilizer. The maximum process temperature must never exceed 60 °C!

Warning!

Sterilize the probe using the low temperature plasma procedure only or use a sterile sleeve. Other methods work with high humidity and may damage the probe. Damage caused by the use of unsuitable sterilization methods voids the warranty.

[4]) see also: Sentinel-Node Biopsy in Breast Cancer – an Interdisciplinary Consensus of the German Breast Cancer Society for the implementation of a Quality Assurance Protocol for Routine Clinical Use

Warning!

The number of sterilization cycles is limited to 200 (40 for Drop-In Probe).
The probe must then be sent to the manufacturer for inspection. This check is also performed if the probe was sent to the manufacturer in connection with a medical technical check (MTK). This means that the probe must be checked by the manufacturer after 200 sterilization cycles **(40 for Drop-In Probe)** or after 2 years for the MTK, depending on which event occurs sooner.
Cables have to be replaced after 200 cycles.

7.3.3 Sterile sleeve

- The sterile sleeve must reach from the sterile area to the non-sterile area and incorporate the entire connection cable. The control unit must be in the non-sterile area.
- The rules for sterility compliance in the operating room must be strictly observed.
- Basically, all sterile covers made of latex or similar material can be used, which are also used for endoscopes. The probe must be used sterile during the entire operation. The sterile cover must not be removed until after the operation.
- When laparoscopic probes are inserted for minimally invasive surgery through a trocar, special sterile covers are required. These can be obtained from special retailers or from Crystal Photonics.

Danger!

Before using gamma probes with a sterile sleeve, the probe has to be cleaned and disinfected using a suitable method.

- **The following are examples for suitable sterile sleeves:**

Name	**Notes**	**Practical uses**	**Article-number at Crystal Photonics**	**Package size**
Sterile sleeve for gamma probes	8x244 folded	Wired Gamma-Probes	200188	20
Sterile sleeve for gamma probes	10x38 folded	Wireless Gamma- Probes	200257	20
Sterile sleeve for laparoscopic gamma probes; without latex	15,2x244 cm	Wired Gamma- Probes (Laparoscopic Probes)	200222	12
Double-layer sleeve for gamma probes	9x37	Wireless Gamma-Probes	200261	100

Info!

The effectiveness of the sterilization with the typical sterilization methods of the clinic must be validated.
Sterile sleeves should be checked for strength.

7.4 Storage

7.4.1 Sterile Storage

After Sterilization using the LTP method, the probes can be packaged in sterile packaging.
Make sure all components stored that way are fully dry before sealing the packaging.

Danger!

If the sterile packaging (peel bag) is damaged, the sterility of the products contained therein may be compromised

7.4.2 Non Sterile Storage

After cleaning and disinfecting, store the probe together with the other components of your gamma probe system in the supplied carrying case. This case contains adapted recesses in the foam material, which optimally protects all devices from external influences. To transport the gamma probe system, please always use the supplied carrying case.

Danger!

Before using the device on patients, it must be cleaned, disinfected and sterilized again!

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8 Technical Data

8.1 Control Unit Power Supply

Low-gas, maintenance free Pb-batteries:	1x12 V/5 Ah
Operating time at maximum charge:	>10 h at maximum load >14 h at normal load
Charging with power supply type included:	XP-POWER VEP24US24
Input:	80...264 V AC, 47...65 Hz, 600 mA
Output:	24V DC, 1000 mA
Power consumption at full load:	24 W
Charging time for maximum charge:	8-10 h
Maximum power consumption:	1000 mA
Classification of the control unit CXS- SG04:	IP20
Degree of protection of the applied part against electric shock:	Type B
Micro fuses:	on power supply/audio board: 2x1 A (T 1 A; Size: h=7,2 mm x d=8,5 mm; Operating speed: T; Breaking capacity: 35 A) 1x(T 630 mA; Size: h=7,2 mm x d=8,5 mm; Operating speed: T; Breaking capacity: 35 A)

8.2 Crystal Wireless Probe Power Supply

Nominal voltage / -capacity of the Li-ion battery TypeCR123A (Panasonic®, Varta® or Duracell®)	3 V/1350 mAh
Operating time in working mode: Operating time in "Bat-low"-Mode:	>10 h Maximum 1 h
Power consumption "Probe logged in":	approx. 0,28 W
Maximum consumption in login mode:	150 mA
Degree of protection of the applied part against electric shock:	BF
SMD- Fuses:	1x 500 mAF , 4x200 mAF

8.3 Electromagnetic Compatibility

Medical, electrical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (referred to as EMC).
The **Crystal Probe** *-automatic-* should only be used for the purpose described in the instruction manual.

8.3.1 Interactions with other devices

The probes must not be used in the immediate vicinity of monitors, televisions and HF systems (mobile phones, X-ray equipment or similar), as interactions and thus incorrect measurements cannot be ruled out.

If such an influence is suspected, the following measures help:

- Change the spatial allocation of the system, the other devices or both (minimum distance 30cm)
- Increase the distance between the devices used
- Consult a medical technician.

Defibrillator: The system should not be used in conjunction with a defibrillator because it has no appropriate protective devices. In this case, the manufacturer assumes no liability for any damages that may occur.

Output power of transmitter [W]	**Safety distance dependent on the transmission frequency [m]**		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	80 MHz to 800MHz $d=1,2\sqrt{P}$	800MHz to 2,5 GHz $d=2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum rated power is not specified in the above table, the recommended safe distance d in meters [m] can be calculated using the equation associated with each column, where P is the transmitter maximum power rating in watts [W] as specified by the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz the higher frequency range applies.
Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorption and reflection of buildings, objects and people.

8.3.2 Electrical Connections

Electrical connections with this warning should not be touched. 
First perform ESD protection measures, and then make connections between these plugs and sockets.

- Apply equipotential bonding
- Exclusive use of the specified accessories

Inform or train the technical staff in the hospital about the ESD protection measures.

8.3.3 Guidance and Manufacturer's declaration / Electromagnetic emissions

The **Crystal Probe** *-automatic-* is intended for use in an environment as specified below. Users must ensure that these requirements are met

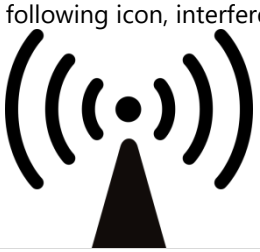
Emitted Interference measurements	**Electromagnetic Environment Guideline**
HF emission according to CISPR 11 (Match: Group 1)	The **Crystal Probe** *-automatic-* uses RF energy exclusively for its internal function. The emission of RF energy is below legal requirements, so that a disruption of adjacent electronic devices is excluded.
HF emission according to CISPR 11 (Match: class B)	The **Crystal Probe** *-automatic-* is suitable for use in all facilities, including those in the home and those directly connected to a public utility network that also supplies buildings used for residential purposes.
Transmission of harmonics to IEC 61000-3-2 (Match: class A)	
Emissions of voltage fluctuations/flickers according to IEC 61000-3-3 (matches)	

8.3.4 Guidelines and manufacturer's declaration/ Electromagnetic immunity

The **Crystal Probe** *-automatic-* is intended for use in an electromagnetic environment as described below. Users must ensure that these requirements are met.

Immunity testing	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic environment/guideline**
Discharge of static electricity according to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. For synthetic flooring, the relative humidity must be at least 30 %.
Fast transient electrical disturbances/ bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines Modulation 100 kHz	±2 kV for power lines ±1 kV for input and output lines Modulation 100 kHz	The quality of the supply voltage should correspond to a typical business or hospital environment.
Surge voltages according to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	The quality of the supply voltage should correspond to a typical business or hospital environment.
Voltage drops, short-term interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	<5 % U_t * (>95 % drop of U_t) for ½ cycle 40 % U_t (60 % drop of U_t) for 5 cycles 70 % U_t (30 % drop of U_t) for 25 cycles <5 % U_t (>95 % drop of U_t) for 5 cycles	<5 % U_t* (>95 % drop of U_t) for ½ cycle 40% U_t (60 % drop of U_t) for 5 cycles 70% U_t(30 % drop of U_t) for 25 cycles <5 % U_t(>95 % drop of U_t) for 5 seconds 0 % U_t; ½ cycle at 0°, 45°, 90°, 135°, 225°, 270° and 315° 0 % U_t; 1 cycle and 70 % U_t; 25/30 cycles single phase: at 0° 0 % U_t; 250/300 cycles	The quality of the supply voltage should correspond to a typical business or hospital environment. If the user of the system requires continued operation even when the power supply is interrupted, it is recommended to feed the device from an uninterruptible power supply.
Magnetic field at The supply frequency (50Hz or 60Hz) after IEC 61000-4-8	30 A/m	30 A/m	Grid frequency magnetic fields should conform to the typical values to be found in the business and hospital environment.

*Note: U_t is the AC line voltage before applying the test levels.

Immunity testing	IEC 60601-1-2 test level	Compliance Level	Electromagnetic environment/guideline
Guided RF interference according to IEC 61000-4-6 Radiated RF interference according to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz	Portable and mobile radios should in principle be used in the recommended safety distance, which is calculated according to the equation applicable to the transmission frequency. Recommended protection distances: d=1,2$\sqrt{P}$ for 150 kHz to 80 MHz d=1,2$\sqrt{P}$ for 80 MHz to 800 MHz d=2,3$\sqrt{P}$ for 800 MHz to 2,7 GHz Where P is the maximum nominal power of the transmitter in watts [W] according to the transmitter manufacturer. d is the recommended safety distance in meters [m]. An examination a location[a] should be done to verify that the field strength of stationary radio transmitters at all frequencies is below the agreement level[b]. In the vicinity of devices bearing the following icon, interference is possible. 

Note 1: At 80 MHz and 800 MHz the higher frequency range applies.

Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is influenced by adsorption and reflections of buildings, objects and people.
a: The field strength of stationary transmitters, such as Base stations of wireless telephones and radio telephones, amateur radio stations, AM and FM radio and television channels cannot be theoretically accurately determined. In order to determine the electromagnetic environment with respect to the stationary transmitters, a study of the location should be considered. If the field strength measured at the location where the **Crystal Probe** *-automatic-* is used exceeds the above compliance levels, the system should be observed to demonstrate proper function. For unusual features, additional measures may be required, such as a changed orientation or another location, for example.

b: Within the frequency range 150 kHz to 80 MHz the field strength should be less than 3 V/m.

9 Conduct in case of failure

9.1 Manufacturer's liability

For the safety, reliability and usability of the **Crystal Probe** *-automatic-* the manufacturer only considers itself responsible if

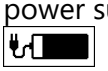
- installation, extensions, new hires, modifications or repairs are only carried out by persons authorized by the manufacturer,
- the electrical installation of the room in question complies with the applicable requirements and the system is used as described in the instruction manual.

Disposal of the Crystal Probe *-automatic-*
At the end of its life cycle, ***Crystal Photonics GmbH*** accepts the gamma probe system and accessories to dispose of it properly. The user is responsible for transport to the manufacturer. If the user decides to carry out the disposal by himself, the regional and municipal legal disposal regulations must be observed.

9.2 Possible Error Causes and Repairs

Do not interfere with the electronics of the control unit or probe. Do not open the probe housing or the control unit unauthorized. Failure to do so will void the warranty. There is a risk of electric shock and the system may be destroyed. Authorization to open the case is provided exclusively by the technical support of ***Crystal Photonics GmbH***. If the fuse is replaced, the prescribed type must be used.

Malfunction	**Cause and Correction of Errors**
Crystal Wireless Probe does not work (green LED does not show)	• Probe not switched on -> switch on • Probe not screwed down correctly • discharged battery in the probe, replace with new one *Otherwise: Troubleshooting by the manufacturer*
Crystal Wireless Probe does not log in (green LED flashes)	• System still initializing -> wait a few seconds • Control unit not switched on -> switch on • If you own more than one system (using the wrong control unit?) -> replace the controller • The hand completely surrounds the plastic mounting -> Hold the probe like a pencil *Otherwise: Troubleshooting by the manufacturer*
Crystal Wireless Probe: red LED flashes constantly during operation of the probe	• one or more supply voltages are out of bounds *Troubleshooting by the manufacturer*
Crystal Wireless Probe: green LED starts to flash intermittently, interruption of the connection	• Distance between probe and controller may be too large -> reduce distance • Hand temporarily wraps around the plastic attachment -> Hold the probe like a pencil *Otherwise: Troubleshooting by the manufacturer*

Malfunction	Cause and Correction of Errors
Control unit does not work (no display)	• check whether the control unit is switched on (it may have switched off automatically, in which case the device must first be switched off and then on again) • Check miniature fuses on power supply board and replace if necessary, if agreed with the manufacturer *Otherwise: Troubleshooting by the manufacturer*
No indication of the count rate in the Display	• Radiation intensity equal to zero • the wrong nuclide was accidentally set using manual nuclide selection • System is still in initialization routine (15 s) *Otherwise: Troubleshooting by the manufacturer*
Alarm signal	Acoustic error signal -> Follow error message
Error display ERROR 	• battery heavily discharged -> Charge • Error message persists despite charging -> Check fuse *Otherwise: Troubleshooting by the manufacturer*
Background- sensitivity too high	• Remove interfering radiation sources near the probe • Contamination of the probe head or the surroundings *Otherwise: Troubleshooting by the manufacturer*
Partial interruption of the measuring function	• Check plug connections for correct fit *Otherwise: Troubleshooting by the manufacturer*
Erratic, Extremely high and unexpected count rates	• remove strong electromagnetic fields nearby *Otherwise: Troubleshooting by the manufacturer*
Permanently extremely high rates	• Check nuclide setting -> correct if necessary *Otherwise: Troubleshooting by the manufacturer*
During the constancy test, lower readings occur than expected	• Nuclide does not sit correctly in the nuclide holder (lettering facing the probe) or not directly on the probe tip • Use another nuclide and modification of the Excel table of the constancy check *Otherwise: Troubleshooting by the manufacturer*
During the constancy test, higher readings occur than expected	• Remove electromagnetic fields nearby • Avoid vibration or shock during the measurement • Contamination of the probe head or the environment • Use of another nuclide *Otherwise: Troubleshooting by the manufacturer*
Background sensitivity too high	• Remove interfering radiation sources near the probe • Contamination of the probe head or the environment *Otherwise: Troubleshooting by the manufacturer*
No mains indication despite connected power supply 	• no voltage from the power supply unit on the control unit -> check whether mains voltage (220 V) is present and the plug connections are in the correct position *Otherwise: Troubleshooting by the manufacturer*

Malfunction	Cause and Correction of Errors
Error display ERROR HV	• Damage in the probe *Troubleshooting by the manufacturer*
Error display ERROR ERROR +5 -5	• Damage in the control unit *Troubleshooting by the manufacturer*

10 Components and Accessories

Accessory part	Article number
Control Unit CXS-SG04	200127
Straight Probe	200266
Angled Probe	200283
Midi Probe	200086
Laparoscopic Probe 0°	200080
Laparoscopic Probe 45°	200082
Laparoscopic Probe 90°	200084
Sterilisable Cable for wired probes	200267
Drop-In probe	200269
Dongle for Drop-In probe	200270
Crystal Wireless Probe	200103
Charging power supply unit for the SG04 control unit	120541
Adapter Charger EU	120542
Adapter Charger US/JP	120543
Adapter Charger UK	120544
Nuclide holder for the daily constancy test - Straight Probe	200276
Nuclide holder for the daily constancy test - Angled Probe	200284
Nuclide holder for the daily constancy test – Crystal Wireless Probe	200147
Nuclide holder for the daily constancy test – Laparoscopic Probe 0°, Midi Probe and Drop-In Probe	200149
Nuclide holder for the daily constancy test – Laparoscopic Probe 45°	200150
Nuclide holder for the daily constancy test – Laparoscopic Probe 90°	200151
PET-Collimator	200176
Case with Trolley	200275

11 Service

The service of ***Crystal Photonics GmbH*** ensures at all times the continued availability of the **Crystal Probe** *-automatic-*.

11.1 Technical Support

Highly qualified service specialists and development engineers provide solutions:
Monday to Friday: from 9:00h to 16:00h CET

11.2 Metrological Test

The test is carried out every two years by the manufacturer, who thus contributes to the quality assurance of the facility. For the duration of the test, a loan system may be available free of charge, so that operations can be carried out as usual.
The **Crystal Probe** *-automatic-*, including the original power supply, has to be sent in its original case.

A test badge on the top of the control unit will show the last test and provide information on the time of the next inspection.

The MTK includes:

- Safety check (discharge resistors)
- Functional check (mechanics, acoustics, battery test)
- Calibration (sensitivity, spectral position of the photopeak)
- Endurance test
- Test protocol
- optional: tests according to DIN EN 62353 (leakage current, mains voltage, load current, power)

11.3 Repair

When used as intended the **Crystal Probe** *-automatic-* will operate reliably over its entire life cycle. For the customer, only the constancy check on every working day is required.

Crystal Photonics GmbH guarantees that all necessary spare parts will be available for necessary repairs within a period of eight years from the date of purchase.

In case of faults and defects:

1. Contact ***Crystal Photonics GmbH*** or the local distributor
2. The customer may receive the option for a loan system. The **Crystal Probe** *-automatic-* to be repaired (in its own original suitcase) is sent back using the return receipt provided by ***Crystal Photonics GmbH*** or the local distributor.
3. A cost estimate will be sent by email.
4. Confirmation of the reimbursement ensures the repair.
5. The customer receives the repaired system and the manufacturer the loan system (see point 2) back.

11.4 **Warranty**

The warranty period starts with the delivery day and lasts two years.

Any damage that may have occurred during transport or due to other influences, except improper use by the purchaser, and found by him during the examination of the system must be made known to the manufacturer within two weeks, otherwise the warranty will expire.

Warranty shall be effective in the event of malfunctions due to defects in material and workmanship and shall not include any damage resulting from improper use, incorrect operation, unauthorized meddling, accidents or operation in unsuitable environments.

11.5 **Contact**

Technical Support

Monday – Friday:	from 9:00h to 16:00h CET
Telephone:	+49 (0)30 34 66 92 94
Fax:	+49 (0)30 34 66 92 99
Email:	service@crystal-photonics.com

Sales

Telephone:	+49 (0)30 34 66 93 01
Fax:	+49 (0)30 34 66 92 99
Email:	sales@crystal-photonics.com

Website: http://crystal-photonics.com

Address: Crystal Photonics GmbH
Albert-Einstein-Straße 16
12489 Berlin
GERMANY

Crystal Photonics GmbH
Albert-Einstein-Str. 16
12489 Berlin
Germany

Phone: +49 30 34669-300
Fax: +49 30 34669-299
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Crystal Photonics GmbH · Albert-Einstein-Str. 16 · 12489 Berlin Germany

MB PROTINGI MEDICINOS SPRENDIMAI
Slėnio g. 5, Grikienių km., Sudervės sen.
14202 Vilnius r.
LITHUANIA

Date: 23.07.2024

To whom it my concern

Authorization/ Declaration of Distributorship and Service

We, the company Crystal Photonics GmbH, Albert-Einstein-Straße 16, D-12489 Berlin, Germany, hereby declare, that the company:
MB PROTINGI MEDICINOS SPRENDIMAI, Slėnio g. 5, Grikienių km., Sudervės sen.
14202 Vilnius r.; LITHUANIA

***TEL.:+* +370 687 77849**

is Crystal Photonic's authorised official distributor for our products:

1. Gamma Probe System „CRYSTAL PROBE"
2. Gamma Probe System "CRYSTAL PROBE – automatic"
3. the hand-held gamma-camera "CrystalCam"
4. all needed spare parts and accessories

in the Republics of Lihuania and Latvia.

We declare that the company **MB PROTINGI MEDICINOS SPRENDIMAI** is authorized by Crystal Photonics GmbH to participate at all tenders regarding the products 1. to 4. in ***LITHUANIA and LATVIA***.

We declare, that we give the company **MB PROTINGI MEDICINOS SPRENDIMAI** all needed support and will provide all spare parts, new information and training for initial operation, maintenance and repairing regarding the products 1. to 4. in ***LITHUANIA*** and ***LATVIA*** now and in the future!
This declaration is valid up to 31.12.2026.

For and behalf of Crystal Photonics GmbH

Crystal Photonics GmbH
Albert-Einstein-Str. 16
12489 Berlin
Tel.: +49 30 34669 93 00

Klaus Schwenkenbecher
CEO Crystal Photonics GmbH