Instructions for Use V 2005

Surgical Probe CXS-OPSZB
Control Unit CXS-SG03

CE

This manual serves only for information. All specifications stated herein are subject to changes at any point of time without previous announcement. CRYSTAL GmbH shall not assume any responsibility for direct or indirect damage resulting from the use of the manual or in connection with its use.

Quality System LQP®
certified by DQS
according to ISO 9001
(Reg.-No. 102764-01)

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QUICK SET UP OF CRYSTAL PROBE SYSTEM

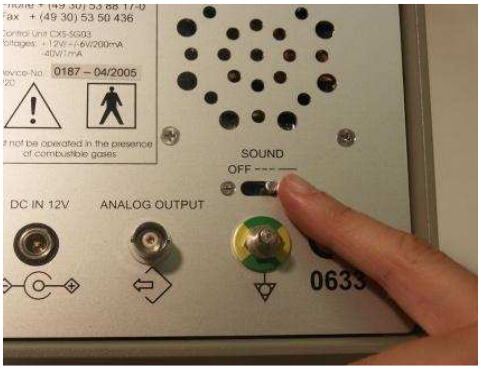
1 Adjust the handle to the desired viewing position.

2 Connect the Surgical Probe Cable to the Control Unit. Only connect or disconnect the Cable while the unit is OFF.

3 Switch the Control Unit ON; after 10 seconds the system is ready.

4 Select the desired Nuclide setting.

5 Adjust Volume.



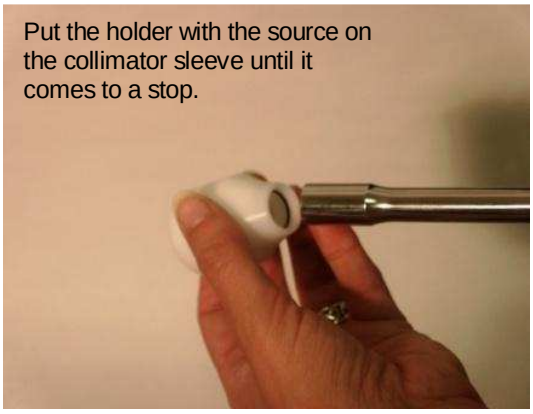
6 Choose the Audio Tone (located on backside of the Control Unit)

7 Set the Sample time to 1s for a one second sample time or to 10s for a ten second sample time.

8 The “counter” audio tone can be set to three different measuring ranges. Beep rate: 1x; 10x; 100x

For complete instructions on the Set Up and Function of the system see 8.5 and 8.6.

Calibration Check with Source Holder



For complete instructions on the Calibration Check see 9.9

2 Introduction

The Crystal Probe System is used for the detection and quantification of gamma radiation. It is used for external and intra-operative detection of radioactivity in the body (i.e. Sentinel Lymph Nodes), where radio-pharmaceuticals are administered.

The hand probe CXS-OPSZB detects radioactive nuclides with energies ranging from 50 keV to over 511 keV.

The interchangeable tungsten collimator sleeves and the nuclide selection knob allows a suppression of the background radiation.

The battery operating control unit CXS-SG03 shows the actual count rate on an LCD screen. The bar graph and two different audio signals give a quick overview of the radiation intensities.

This Instruction Manual describes how to operate the Crystal Probe System.

3 Safety Instructions

The Crystal Probe System is a highly developed measuring system for nuclear medicine. It was developed and manufactured taking maximum precision and security aspects into consideration. Nevertheless some safety instructions must be observed at all times:

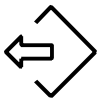
- First connect the Surgical probe cable to the control device before turning on the power
- The control unit CXS-SG03 must be in a stable position
- Do not operate in the presence of combustible gasses
- Do not operate in damp rooms
- Do not operate in the vicinity of high frequency systems (i.e. mobile phones, monitors)
- The control unit and the surgical probe must be used together. The connection to other equipment will severely damage the control unit and probe
- Sterilization of the probe is required (see chapter 8.1)
- Do not perform steam sterilization (see chapter 8.1)

4 Explanation of Symbols and Characters

Protection degree of the application part against an electric shock: Type BF

Observe Operating Manual

Adjustment of the equi-potential bonding



Output signals

DC-charger input

Switch for selecting the acoustic signal:

OFF sound off

--- counter like sound with variable pulse frequency

——— continuous sound with variable pitch

5 Construction and Operating Elements

The CRYSTAL Probe System consists of the control unit CXS-SG03 and the surgical probe CXS-OPSZB.

5.1 Control Unit CXS-SG03

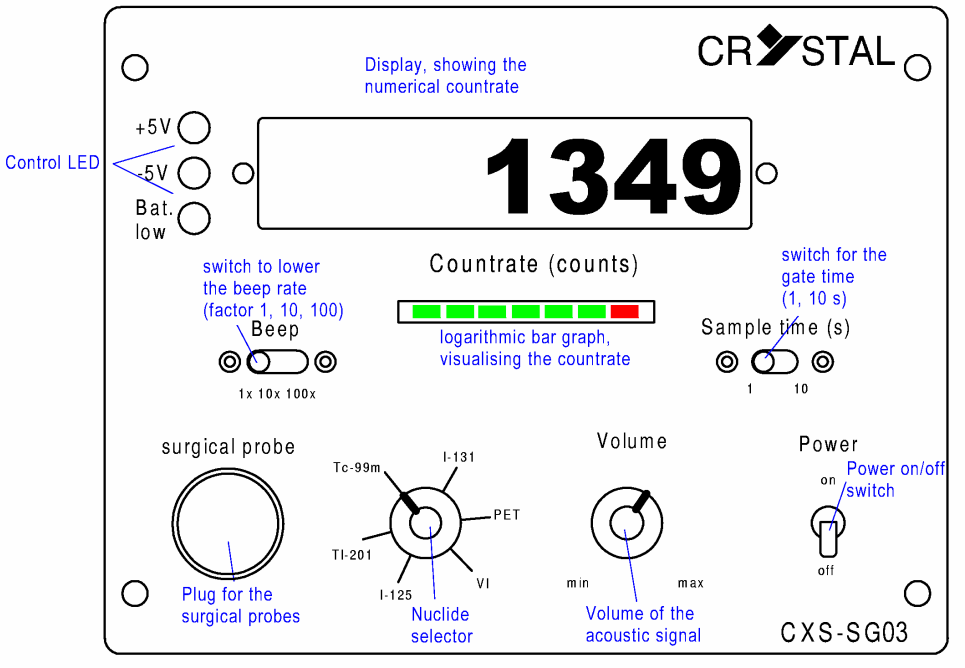


Fig. No.1: Front panel of the control unit CXS-SG03

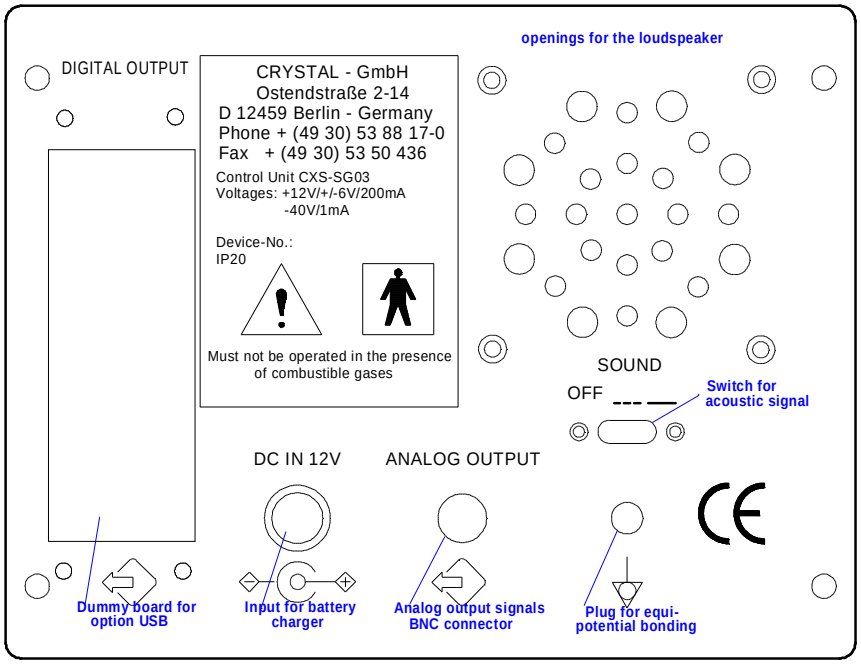


Fig. No.2: Back panel of the control unit CXS-SG03

5.2 Surgical Probe CXS-OPSZB

The housing of the surgical probe is made of surgical stainless steel with a tungsten collimator inside the tip of the collimator sleeve. The collimator sleeve can be screwed off (Fig. No. 3).

The detector electronics are located in the hand piece of the probe. Use the plastic protection sleeve to protect the detector electronics when the collimator sleeve is detached.

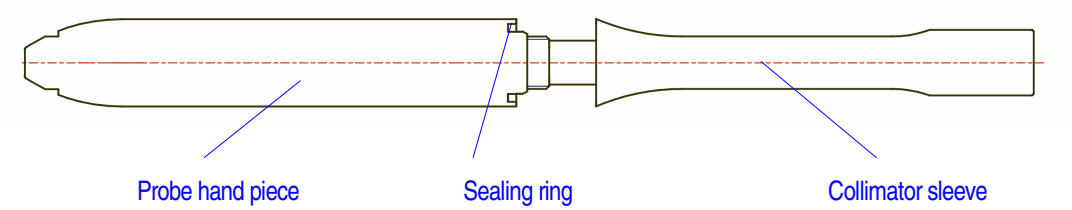


Fig. No.3: Hand probe CXS-OPSZB

6 Charging the Battery

The batteries will be delivered not fully charged, it is necessary to charge them for at least 12 hours before using the System (see 8.4).

7 Installation Location

The control unit CXS-SG03 should be positioned on a flat, stable surface. Observe that sufficient space is available to reach all operating elements. In connection with the probe CXS-OPSZB ensure that the control unit stands firmly during the application and cannot be shifted. The control unit CXS-SG03 should not be exposed to excessive heat or humidity.

Ambient temperature:	5℃ to 35℃
Relative air humidity:	10% to 85%

The following instructions must be observed:

- Avoid direct sun rays
- Avoid the vicinity of strong electromagnetic fields (i.e. mobile phones, monitors)
- Do not operate the control unit in damp rooms
- Avoid shocks and vibrations of the system
- The control unit must stand firmly on a flat and horizontal surface
- Dropping the control unit and/or surgical probe may lead to malfunction

8 Operating the Crystal Probe System

8.1 Disinfecting the Probe

The following sterilization methods are recommended:

- The collimator sleeve (see Fig. No.3, page 5) can be screwed off and further sterilized with one of the usual methods (plasma sterilization, 150℃ water vapor at 4 bar). The cable and hand piece must be coated for intra operative application with a sterile protective coating. The transition between sterile sleeve and the protective coating is covered with a sterile tape.
- Use of sterile sleeves, e.g. latex sleeves from ultra-sonic diagnostics.
- With the help of the ethylene oxide method, the complete surgical probe including cable can be sterilized.

Other sterilization methods are NOT suitable for the surgical probe!

Non-observance of the above instructions and the use of other sterilization methods can lead to a destruction of the probe!

8.2 Cleaning the Probe CXS-OPSZB

The surgical probe can be wiped with a damp cloth using conventional disinfecting agents.

For disinfecting and cleaning, the collimator sleeve can be screwed off the hand piece. If the sleeve is pulled off the probe, the sensitive probe parts are laid bare and are easily accessible. The set-up must not be exposed in an open state to any mechanical or chemical loads. This can lead to severe damages to the CXS-OPSZB probe.

After having screwed off the collimator sleeve it is recommended to screw on the delivered plastic protector sleeve to protect the detector head from damage.

A circular sealing between the collimator sleeve and hand piece (see fig. No. 3, page 5) prevents a penetration of fluids. If it is necessary to clean the detector head, make sure the sealing ring is put back in place. The collimator sleeve must be screwed firmly to the hand piece, without using any mechanical tools. This is the only way to guarantee the function of the sealing ring.

Alcohol or usual disinfecting agents can be used to clean the instrument. Acids, alkali, and other solvents can lead to a destruction of the probe.

IMPORTANT NOTE:

The detector head that is normally protected by the collimator sleeve is not allowed to be sterilized by any liquids. If sterilization by solvents cannot be avoided please note the following instruction:

The end of the detector head has to be sealed properly by adhesive tape. The probe must be held with its head downwards. Now a careful disinfecting with a wad is possible. However, damage of the probe cannot be excluded.

Generally only the surgical probe's collimator sleeve should be sterilized. THE COLLIMATOR SLEEVE MUST BE COMPLETELY DRY BEFORE SCREWING BACK ON THE PROBE!

8.3 Optional Collimator Sleeves

The probe CXS-OPSZB offers the opportunity to vary the geometric entry angle of the γ-sensitivity with the help of optionally available collimator sleeves of 20° and 60°. The standard collimator sleeve supplied with the system has an opening angle of 40° FWHM. In order to change the opening angle the standard collimator sleeve has to be removed and the required collimator sleeve has to be screwed on the probe's hand piece.

Excessive mechanical loads can damage the probe. It is recommended to protect the sensitive parts of the probe always by a collimator sleeve or the plastic protection sleeve. The collimator sleeve must be screwed tightly - but without applying any mechanical tools - to the probe hand piece. Otherwise the function of the sealing ring is no longer guaranteed.

8.4 Charging the Battery

Proper charging of the battery, which is in the control unit, guarantees a long life time and a disturbance free operation. The life cycle of the battery is 4-5 years.

The battery is only to be charged by the delivered battery charger.

Make sure that your actual mains voltage is the same as displayed on the battery charger, otherwise the charger is only to be used in connection with the delivered converter.

If the LED signal "Bat. low" lights up while operating the probe or when switching on the control unit, the voltage supply of the battery has sunk below the limit. Continued operation is possible by connecting the system to the mains voltage over the battery charger. For that purpose first switch off the control unit CXS-SG03. Then connect the circular plug of the battery charger with the socket on the rear wall of the control unit. Now the charger can be connected to the mains voltage.

It takes approximately 12 hours to fully charge the battery. A longer charging time will not damage the battery or the control unit.

To maintain the life time use of the battery, we suggest starting the recharging process immediately after having used the system and keep it charging for 12 hours minimum.

8.5 System Set Up

1. Set the power supply to OFF

2. Connect the surgical probe cable to the control unit

3. Switch ON the control unit. After 10 seconds the control unit is ready to use.
   NOTE: The green control LEDs for operating voltages +5V and –5V light up. In the event that the "Bat. low" lights up, connect the battery charger.
   The system must be set to the nuclide to be detected using the nuclide selector (see 11).

4. Select desired the nuclide setting

5. Select the desired acoustic signal with the switch on the back side of the control unit:
   - Left position: acoustic signal is off
   - Mid position: “counter“ like sound with changing frequency of the pulses; there are 3 different measuring ranges for this signal set by the beep rate switch on the front of the control unit.
   - Right position: permanent sound with changing pitch

6. Function test with the help of a radioactive nuclide according (see 8.6) at least once a month. Fill in the table (see 12.1) with the results of the measurements.

8.6 Function Test

In order to check if the system is functioning properly, test the system with a radioactive point source ^{57}Co or ^{99m}Tc (Ø3mm, activity < 500 kBq).

1. Set the nuclide switch to position **VI** (or position **Tc-99m** with the use of ^{99m}Tc) and the sample time with the switch on the front side of the control unit to “**1**”. Use the permanent sound with varying pitch (with the SOUND switch on the backside of the control unit) and set the volume knob to a middle position.

2. After switching on the system the 2 green LEDs must shine indicating that the ±5V for the electronics are supplied. The yellow LED “Bat. Low” must not shine.

3. The system is ready for use after 15 seconds, and the signal output can be tested. For that purpose move the test nuclide in various distances in front of the radiation entrance window of the probe. The different signal outputs (sound, digital LCD and analogue LED display) are supposed to vary accordingly. The signals must reach a minimum with the source beyond the 40° opening angle of the probe. D o the same test also with the pulsed sound (switch on the backside of the control unit). The measuring range must be adjusted with the switch “BEEP” at the front of the control unit according to the radiation intensity, i.e. low intensity beep rate at 1x, high intensity beep rate at 100x.

4. Perform the function test also at 10 seconds sample time (switch at the front of the control unit, position “10”). With unchanged geometry between probe and point source the LCD display must show a value roughly 10 times higher than the measurement at sample time switch position “1”. The different acoustic signals are not affected by changing the sample time. Last, test the function of the volume knob with any signal.

Please see to it before using the probe system for an operation that the nuclide switch is reset to the then used nuclide (mostly ^{99m}Tc).

8.7 Measuring with the Crystal Probe System

After a successful function test set the energy threshold for the used nuclide. The probe is positioned on the skin surface or into the patient's wound. To find locations with maximum nuclide enrichment, the probe has to be moved in vertical position in the assumed sector. Enrichments lying at a deeper position are more easily found by also compressing the tissue layers by exerting pressure.

The two different audio signals change with the intensity of the measured radiation. The volume of the audio signal is easily set by a knob on the front of the control unit. The selection of the different audio signal is done by a switch on the back of the control unit. The counter like audio signal can be set to 3 different measuring ranges: When the signal cannot be resolved any longer because of the high radiation intensity another measuring range (1:10 or 1:100) can be selected by the Beep rate switch on the front side of the control unit.

As a rough orientation, short measurement times (sample time 1s) and quick probe movements are suitable. For a more exact localization of the maximum activities, the measurement period should be extended. It is advantageous to use the Countrate bar graph. The function between the count rate and the full light emission of the LEDs is:

Count rate [cps]	5	20	30	50	80	100	200	500
Number of shining LEDs	LED1	LED2	LED3	LED4	LED5	LED6	LED7	LED8

NOTE: The LED1/LED2/LED3, etc. start blinking at four counts before reaching the count rates 5/20/3, etc..

If the audio signal reaches its maximum, the beep rate can be lowered by using the selector switch on the front panel (1:10 or 1:100).

To reduce the influence of counter statistics on the activity measurements, a sample time of 10s is recommended. It is important to ensure that the probe is not moved during the measurement. Position and location to the patient must remain constant.

8.8 Switching off the System

1. Switch off control unit with the ON/OFF switch.
2. Separate the surgical probe from the control unit.
3. Disinfect the Probe (see 8.1)

9 Maintenance, Function, and Calibration Checks

9.1 Maintenance

A regular service or maintenance for the functional safety of the system is not necessary.

The Crystal Surgical Probe System does not need servicing.

For Technical Support:

Nuclear Fields USA Corp.

1645 S. River Road Suite 5

Des Plaines, Illinois 60018 USA

Tel. 847-299-8450

Fax. 847-299-8452

9.2 Function Check

To check if the system works properly see 8.6

9.3 Calibration check

The probe CXS-OPSZB and the control unit CXS-SG03 are subject to a calibration check according to the decree regarding the set up, operation, and usage of medical equipment (MPBetreibV) §11.

A Calibration check must to be done at least once a year according to the following steps:

1. The calibration check requires a complete probe system and a radioactive spot marker ^{57}Co or ^{99m}Tc (Ø3mm, activity < 500 kBq). Set the nuclide switch to position **VI** with the use of ^{57}Co or position **Tc-99m** with the use of ^{99m}Tc.
2. Place the test nuclide ^{57}Co (spot marker Ø1") with the printed side down in the delivered source holder and screw on the lid properly. Put the holder with source onto the collimator sleeve of the probe until it comes to a stop.
3. Set the sample time with the switch on the front side of the control unit to "**10**". Ignore the first measurement and record only the second measurement. Record at least 10 measurements and calculate the average. Transfer this value into the table of paragraph 12.1, column "cps". The current activity of the used ^{57}Co test nuclide can be estimated with sufficiently high accuracy by means of the date and the starting activity printed on the label and the natural loss of activity of the test nuclide (graph, par. 12.2). Transfer this estimated value into the column "Activity A of the used test nuclide in kBq". In order to calculate the counting rate related to 1MBq, multiply the value of column "cps" by 1000 and divide by the estimated activity "A".

NOTE: In case of deviations between the cps/MBq value and the target value 10000 cps/MBq of more than 25% contact technical support.

10 Responsibility and Disturbances

10.1 Responsibility of the Manufacturer

The manufacturer is responsible for the safety, reliability and operability of the device only if:

- The System is operated according to the Instructions for Use Manual
- Assembly, extensions, new settings, modifications or repairs are only carried out by persons explicitly authorized for this purpose

10.2 Disturbances

Disturbance	Troubleshooting
No counting rate is shown in the display	• radiation intensity equals to zero, **no defect** when display is lit up • system is within the 15 seconds initialization routine after switching on the system
Yellow "Bat. low" signal lights up, beep with steady intensity	• Charge the battery
Partial interruption of the measurement function (control LEDs still light up)	• Check plug-in connections to ensure proper fit
One or both control LEDs do not light up	• Check and exchange the fuses of the power supply
Background sensitivity too high	• Remove disturbing radiation in the vicinity of the probe
Erratic and extremely high unexpected counting rate	• Strong electromagnetic fields (e.g.) in the vicinity
Permanent extremely high counting rates	• Batteries are low

NOTE: Do not open or tamper with the control unit and/or surgical probe. Doing so will forfeit the warranty. Contact Crystal Probe technical support (see 9.1).

11 Technical Data

Classification of the system

Class IIa according to Directive 93/42/EEC and §13 Medical Devices Act of 09/08/1994

Certification of the system

EC Verification Certificate according to Annex IV, Directive 93/42/EEC

Power supply

Maintenance-free lead storage batteries	2x6 V/3.0 Ah
Operation time with maximum charge	10 hours at maximum load 13 hours at normal load
Charging with the delivered battery charger	Type: FRIWO FW 1299 Part-No.: 1811809 Input: 230V AC, 15…..39 mA Output: 12V DC, 300mA
Power consumption at full load:	8.5W
Charging period for maximum charge	12 hours
Operation voltages	±5 V / 100 mA
Classification of the control unit CXS-SG03:	IP20
Protection degree of the application part against electric shock:	Type BF
Fuses	2x500mAT on the power supply board 1x100mAT on the bar graph circuit board

Probe CXS-OPSZB

Detector	CsI: Tl-Scintillator, Si-photodiode
γ-energy measurement range	50 keV...>511 keV

Background sensitivity

Zero effect < 0,3 cps = 18 c/min

Energy discrimination

Discriminator Threshold	Nuclides	Switch Position
20 keV	^{125}I	^{125}I
60 keV	^{201}Tl, ^{58}Co, ^{67}Ga	^{201}Tl
120 keV	^{99m}Tc, ^{123}I, ^{111}In	^{99m}Tc
310 keV	^{131}I, ^{113m}In	^{131}I
430 keV	PET-nuclide	PET
100 keV	for tests with ^{57}Co	VI

Collimator

Material:	Tungsten, lateral 3.15 mm wall thickness (with the use of the standard collimator sleeve), rear 5 mm wall thickness
Angle of view:	40°FWHM (standard)

Visual and acoustic signals

8-element LCD display:	Count rate in counts per second (digital)
Bar graph:	Count rate (analogue, logarithmic)
Sound:	2 different acoustic signals, variable according to the radiation intensity, volume adjustable, one signal set to different measuring ranges

Output signals

Analogue voltage signal; output voltage max. 3.5V, output impedance ≥ 5kΩ

Weight

Control unit CXS-SG03:	4.0 kg
Probe CXS-OPSZB (incl. 3 m cable):	0.4 kg

Dimensions

Control unit CXS-SG03 (B x H x T):	185 x 155 x 270 mm³
Probe CXS-OPSZB	
Length	220 mm
Diameter handle	20 mm
Diameter entrance window	15 mm

12 Enclosures

12.1 Table for recording data of the calibration check

Date	Activity **A** of the used test nuclide in kBq	Counting rate		Signature
		cps (average of 10 measurements)	related to one MBq (cps*1000/A) **(Target: >10000cps/MBq)**	

12.2 Time dependent activity loss of ^{57}Co