# SURGICAL PROBE EUROPROBE 3® SYSTEM CE 0459
# OPERATION MANUAL

**Read the present manual carefully.**
**The warranty only applies if the system has been handled properly. The manufacturer is not liable for any consequence resulting from the non-respect of the recommendations listed in this document .**

**CE marking: 1999/2009**

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# Check list

Before using the **EUROPROBE 3®**, please make sure that no part is missing. If one component is missing please contact your local seller.

- ✔ **EUROPROBE 3® display module**
- ✔ **Detection probes (type and quantity depending on delivery note) see « Compatible probes for Europrobe 3®» on next page.**
- ✔ **Main power cable.**
- ✔ **User manual**

**In option:**

- ✔ **Additional detection probes (**see description of different probes on next page)**.**
- ✔ **Footswitch Steute MKF1S-med .**
- ✔ **Additional collimator.**
- ✔ **Source holder** (for quality insurance test).

# Compatible probes for Europrobe 3®

In order to identify the **EUROPROBE 3®** probes, refer to the marking which appears on the cable of the probe (near the connector) or on the body of the probe.

All the **EUROPROBE 3®** probes have an integrated collimator at the detection head . Additional collimators are available, for more information see «Appendix» section at the end of this manual.

| Reference | Page | Technology | Description | Connections |
|---|---|---|---|---|
| **SOE306** | 26 | CdTe | Short straight probe, low sensitivity special ROLL, 6mm diameter | White connector |
| **SOE311** | 28 | | Short angled probe, 11mm diameter | Blue connector |
| **SOE311-D** | | | Short straight probe, 11mm diameter | |
| **SOE311-AF** | 30 | | Endoscopic probe, 11mm diameter, frontal detection | Grey connector |
| **SOE311-AL** | | | Endoscopic probe, 11mm diameter, lateral detection | |
| **SOE316** | 34 | CsI | Short angled probe, 16mm diameter | Black connector |
| **SOE316-D** | | | Short straight probe, 16mm diameter | |
| **SOE316-7** | 36 | | Short angled probe, high sensitivity, 16mm diameter | |
| **SOE316-7-D** | | | Short straight probe, high sensitivity, 16mm diameter | |
| **SOE314-DON** | 32 | Optical | Optical probe for blue dye detection. | Optical fiber |

# Table of contents

# Warnings

Great care has been given to safety considerations in the design of the **EUROPROBE 3®**.

For a safe and reliable operation, please adhere to the following guidelines.

**Before using the system for the first time, please read this manual carefully**

## In order to avoid serious or fatal injuries:

- To avoid any risk of electric shock, the **EUROPROBE 3®** must only be connected to a mains supply with protective earth.
- Position the **EUROPROBE 3®** on an accessible location in order to easily disconnect the main power supply.
- Connect the probe(s) before turning the system ON.
- Never disconnect the probe when the system is running.
- Use the module only with a waterproof footswitch IPx7 which is supplied as an option.
- If the system or the probe breaks during an impact please do not touch the internal components (risk of electrocution).
- Do not use the system if one of its component appears damaged (cables, connectors, probe, module, power supply).
- Do not dis-assemble or modify the system. The high voltage components might cause an electrocution.
- Do not use the system in presence of a flammable gas (risk of explosion or fire).

- Do not leave any cable near to a heat source (risk of distortion or melt of the insulation).
- During use, in case of excessive heat, smoke, etc…, disconnect immediately the power supply from the plug.
- Do not store the system in a humid or dusty environment.

**In order to avoid injuries or equipment break-down:**

- Do not leave the system near a heat source.
- Do not move the system when it is ON.
- Do not cover the system during use. It would become impossible to evacuate the heat produced.
- In case water or metallic parts penetrate into the system by accident, disconnect immediately the power supply from the plug and stop using the equipment.
- Do not use solvant or benzene to clean the system.
- In case of suspected radioactive contamination of the probes and/or high counting display in the absence of radioactive source perform a de-contamination as specified in Chapter VII.

## Special precautions for the medical field:

- Handle the system like all other sensitive medical instrument.
- The system should only be operated by qualified personnel.
- The **EUROPROBE 3®** is an invasive, surgical device intended for a brief period of use (Class IIa system). The period of use should not exceed 60 minutes on the same patient.
- The display module should not be placed in the patient's environment .
- The operator using probes within the sterile patient zone should not touch the read-out module.
- The **EUROPROBE 3®** conforms with the CEI 60601-1-2 standard. However, please make sure that it is placed away of equipments which may interfere with its function e.g. diathermy cables, some mobile radio-communication devices, etc.
- The probes must ONLY be used after being placed in a sterile biocompatible sheath.
- Prior to use the probe must be decontaminated and the module should be cleaned with alcohol (see section VII). For more information concerning the probes de-contamination and eventual sterilization, please refer to a Chapter VIII.
- No device can be connected to the serial port of Europrobe 3 when the probes are in use on a patient (risk of electrocution).

# Meaning of the symbols used:

| | |
|---|---|
|  | General warning symbol (CEI60601-1) |
|  | Suggestion for proper functioning. |
|  | Identifies type BF applied part and its connection (CEI60601-1) |
| XX | Identifies walking contactor and its connection. |
|  | Systems must be collected, disposed off and treated properly (DEEE directive) |
|  | Manufacturer references (EN980) |
|   | Serial number (EN980) |
|  | Meaning (CEI60601-1) : Consult the operation manual. |

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# I. INTRODUCTION

## 1. GENERAL OVERVIEW OF THE SYSTEM AND ITS APPLICATIONS

The **EUROPROBE 3®** System has been designed for the accurate location during surgery of areas of increased radionuclide uptake. The whole system comes with one read-out module and several detection probes, which are based on the CdTe - CsI technology. (see probes details on page 3)

The **SOE306** and **SOE11-xx** Cadmium Telluride (CdTe or CdZnTe) probes have been designed for lower energy detection (i.e. I-125, Tc-99m, etc…) with an excellent spatial resolution (see pages 26, 28 and 30).

The **SOE16-xx** scintillation probe (CsI scintillator coupled to a silicon photodiode) has been designed for higher energy detection (i.e. In-111, I-131, etc…), but can also be used for Tc-99m detection when high sensitivity is required (see pages 32 and 34).

The **SOE314** has been designed for a blue patent dye optical detection (see page 32)

## 2. PRINCIPLE OF OPERATION

When radio-elements go back to a stable level they emit radiations like gamma rays (photons). These photons are detected by a detector, which transforms each photon into an electrical signal. These signals are amplified through the preamplifier, which is located in the probe. The signals are then transferred to the read-out module where they are processed, counted and displayed. An audible sound, proportional to the detected activity, allows the surgeon to localise the areas of higher activity by sound without requiring visual monitoring of the display.

# 3. READ-OUT MODULE DESCRIPTION

The standard probes SOE306, 311 and 316 can be stored directly in the designated places on the top of the read-out module.

Two probe connectors are available on the front face of the read-out module. All the Europrobe 3 probes (see page 3) can be plugged into any of these two connectors . A button allows the selection of the probe to be used. An advanced function allows an automatic commutation of the probe used. If no probe is detected or if the used probes are not compatible with Europrobe 3, the system emits an error signal.

A large digital display as well as a bargraph are located on the upper part of the module.

Three well distinguished interaction areas are offered to the user:

- The « User area » on the blue colored part of the front panel. It offers all the necessary functions during operation. This area allows the direct access to the basic functions of the system.
- The « Adjustment area » on the black colored part of the front panel. It offers different adjustments possibilities.
- The « Advanced Configuration area » on the right side of the read-out module. It offers the advanced configuration functions. These are designed for experienced users.

A footswitch (optional) allows, as default, to start a timed acquisition without touching the module.

# 4. DETECTION PROBES DESCRIPTION

Since several types of radioisotopes are employed in Nuclear Medicine, which have different gamma-ray spectra, the best-suited detector depends on several parameters, including the energy domain, which has to be covered.

To fulfill the various needs, two different standard probes have been designed. They incorporate a solid state gamma ray detectors and operate at room temperature and low voltages.

The probes must be placed in a sterile biocompatible sheath before use.

## a). SOE306 and SOE311 CADMIUM TELLURIDE PROBES

CdTe or CdZnTe probes have been designed for low to mid energy radiation detection (I-125, Tc-99m, etc...) with an excellent spatial resolution. The detector and the low noise charge preamplifier with high gain FET are mounted in a probe of 11mm diameter (detection head). The collimator is an integral part of the probe.

The **SOE311** standard probe has a angled head to permit easier access to certain tissues. It is connected to the read-out module through a 3.5 m flexible cable.

Different types of SOE311:

| | | |
|---|---|---|
| **SOE306** | Straight ROLL probe | See details page 26 |
| **SOE311** | Short angled probe | See details page 28 |
| **SOE311-D** | Short straight probe | |
| **SOE311-AF** | Endoscopic probe, frontal detection | See details page 30 |
| **SOE311-AL** | Endoscopic probe, lateral detection | |

## b). SOE316 SCINTILLATION PROBES

These scintillation probes, operating without any PMT are best suited for a higher energy range (In-111, I-131, etc...), up to 1.0 MeV photons, but can also be used for the Tc-99m detection if high sensitivity is required.

The detector and the low noise charge preamplifier with high gain FET are mounted in a probe of 16mm diameter (detection head).The collimator is an integral part of the probe.

The **SOE316** standard probe has a angled head to permit easier access to certain tissues. It is connected to the read-out module through a 3.5 m flexible cable.

Different types of SOE316 :

| | | |
|---|---|---|
| **SOE316** | Short angled probe. | See details page 34 |
| **SOE316-D** | Short straight probe | |
| **SOE316-7** | Short angled probe, high sensitivity | See details page 36 |
| **SOE316-7-D** | Short straight probe, high sensitivity | |

## c). SOE314 OPTICAL PROBE

This probe has been designed for an optical detection of the blue patent dye concentration in the tissues.

See page 32 for details.

# II. SYSTEM DESCRIPTION

**Place the module outside the patient's environment when using the system in the surgery room. - Make sure the module is placed on a stable stand. - Do not use the serial port when the probes are used on the patients. - Turn the system OFF to connect the probe(s).**

## 1. INSTALLATION

Probes decontamination (or eventual sterilization) and read-out module cleaning (alcohol) are necessary before each use (see Chapter VIII).

Place the module out of patient environment on a stable stand.

Place the probes in sterile sheaths inside the patient environment.

The system has to be turned OFF while connecting / disconnecting the probes.

Connect the power cable to the read-out module.

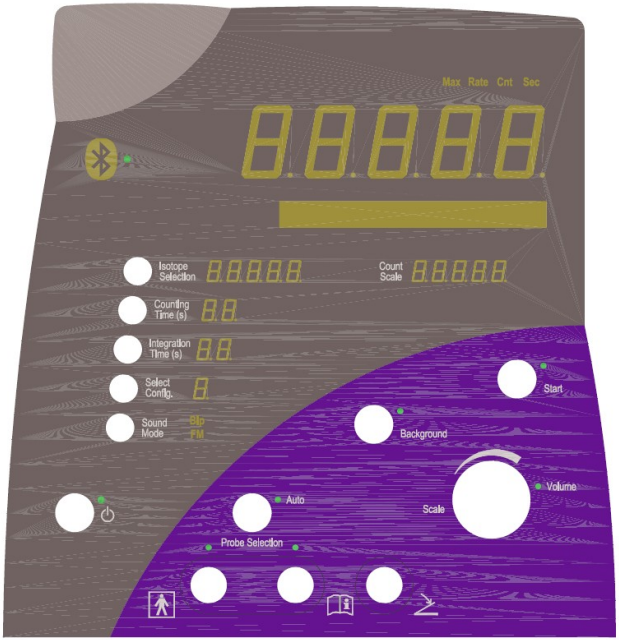
Connect the probe(s) to the front panel of read-out module and turn the system ON. The probes are detected automatically.

Surgeons using the probes in patient environment cannot manipulate the read-out system for asepsis reason. Another person (out of patient environment) has to adjust the system according to the user's demand.

Read carefully sections III and VII before use.

See on next page the read-out module description.

## 2. FRONT PANEL OF READ-OUT MODULE



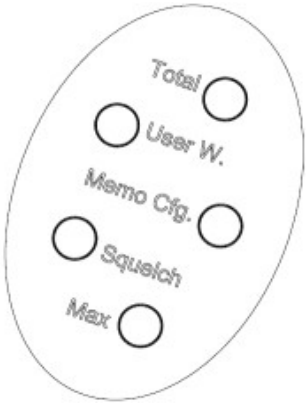

| | |
|---|---|
| **Isotope Selection** | Allows the user to select the isotope to be detected |
| **Counting Time** | Allows the user to adjust the counting time in seconds. |
| **Integration Time** | Allows the user to adjust the integration time in seconds. |
| **Select Config** | Allows the user to select the existing configuration |
| **Sound Mode** | Allows the user to select the sound mode. |
| **Standby** | On / Standby |

| | |
|---|---|
| **Start** | Starts / stops a counting. |
| **Background** | Starts / stops a noise subtraction. |
| **Probe Selection** | Choice of the probe. |
| **Scale / Volume** | Adjusts the scale and sound volume (press). |

| | |
|---|---|
| **Probes Connectors** | Two connectors of applied part BF. |
| **Footswitch connector** | Footswitch connector . |

## 3. READ-OUT MODULE RIGHT SIDE

The buttons of the advanced functions configuration are situated on the right side of the read-out module.




| | |
|---|---|
| **Total** | Opens total energy detection window |
| **User** | Adjusts the energy detection window according to the user choice |
| **Squelch** | Adjusts the threshold for starting the sound |
| **Memo** | Saves configuration. |
| **Max** | Maximum count rate mode. |

## 4. REAR SIDE OF READ-OUT MODULE


| | |
|---|---|
| **Power supply connector** | Mains power supply (100 – 240 V 50-60Hz) |
| **Fuse trap** | Fuse's holder. Two fuses 1,6AT -250V |
| **Serial port IOIOI** | Data transfer for maintenance and updating of system |

**The serial port connector on the rear panel must only be used for the maintenance of the system. It must NOT be used while operating on a patient.**

## 5. POWER OFF

In order to power off the system it is necessary to remove the power supply cable from the power entry module on the backside of the read-out module.

**Place the read-out module to allow easy access to the power connector.**

# III. FUNCTIONS DESCRIPTION

## 1. USER AREA

The « User area » on the blue part of the front panel offers all the necessary functions during operation. This area allows direct access to the basic functions.

### a). Rotary button – Scale / Volume

« **Scale** » : By default, it allows the adjustment of the sensitivity level of bargraph on the following levels positions: 100, 250, 500, 1000, 2500, 5000, 10000 and 50000 cp/s. The 10000 and 50000 positions work in log mode.

When the measured signal gets to the highest level of the given scale, the bargraph is blinking and a beeping noise is heard.

When the counting rate exceeds the system capacity (99999 cp/s) the main display also flashes on and off**.**

« **Volume** »: A single push on the rotary button allows the sound volume adjustment between 0 (silent) and 10 (max).

The button function automatically changes back to «Scale» after 2 seconds of inactivity in « Volume »

### b). Start

Starts a timed count for the timed set determined in « *Counting Time* ». This is adjustable in «Adjustments ».

The main display shows the number of counts accumulated during the counting period. The «*Counting Time* » displays the duration of the count in seconds. A sound signal indicates the counting end.

The counts value is displayed until the « *Start* » or « *Background* » button is pressed again.

Pressing the « *Start* » before the end of the timed count cancels the timed count.

### c). Background

Allows a measured value to be used as a noise threshold level.

Values higher than 10000 cp/s cannot be used for this function.

After setting the background/threshold value the displayed value is the number of counts/s minus the background/threshold value.

This button is only active at the end of counting and as long as the value is displayed (« *Start* »)

The « *Background* » LED is ON when the background deduction is active.

Pressing « *Background* » a second time cancels this function.

In order to register a new background value, leave the « *Background* » function and start a new counting (« *Start* »).

### d). Probe Selection

Allows to select the probe to be used when two probes are connected. The active probe's LED is ON.

Continued pressing (>3sec) of the button « *Probe selection* » allows an automatic selection of the probe (LED « *Auto* »): the system switches automatically to the corresponding probe.

A new pressing of this button allows you to exit the automatic mode.

If no probe is detected or if the probes are not compatible with the system a heavy sound can be heard and « Pro » blinking is displayed.

## 2. ADJUSTMENT AREA

The « *Adjustment* » area on the black part of front panel offers different adjustments.

### a). Isotope Selection

Allows the detection window selection according to the isotope used.

Possible adjustments : $^{99m}$Tc, $^{131}$I, $^{125}$I and $^{18}$F.

### b). Counting Time

Allows to set the count time for the « *Start* ». function.

Possible adjustments : 1, 2, 5, 10, 20 and 50 seconds

### c). Integration Time

Allows the integration time adjustment for the measured signal.

The shorter the time the more reactive the system. The longer the time the more precise the measurement.

Possible adjustments : ½, 1, 2 and 4 seconds.

### d). Select Config

Allows to select a pre-registered configuration.

After consecutive pressing of this button the corresponding configurations can be seen on the adjacent display.

Continuous pressing (>3sec) allows to come back to the factory configuration by default: no display

### e). Sound Mode

Allows to choose between two sound modes :

FM : continuous sound: the frequency of this signal is proportional to the counting rate.

BIP : « bips » signal: the frequency of the « bips »signal is proportional to the counting rate.

## 3. ADVANCED CONFIGURATION

« Advanced *Configuration* » area functions are located on the right side of the read-out module.

They should only be used by experienced users. All these functions can be activated after a long time pressing (>3sec) on the corresponding buttons.

### a). Total

Opens the energy detection window. There is no longer any isotope energy window discrimination.

« *Isotope Selection* » in the adjustments area indicates « tot »

To cancel this function, press again the « *Isotope Selection* » button in the adjustments area.

### b). User

Allows the user to determine his own energy window.

To cancel this function, press again the « *Isotope Selection* » button in the adjustments area.

### c). Memo

Allows a configuration to be stored.

Adjusts the system parameters on user's demand.

Press more than 3 seconds the « *Memo* » button, the « Select Config » display will blink.

Press the button « Select Config » in order to select the configuration number for your settings to be saved in.

Once the configuration number is chosen, press the « Memo » button again to save your settings.

### d). Squelch

The « Squelch » function allows to adjust the noise threshold level below which the sound signal will not be active.

This adjustment is a percentage of the scale (5%, 10%, 15%, 20% and 30%)

Consecutive pressing of the « Squelch » button increases the cursor position on the bargraph.

### e). Max

Enable / Disable the maximum display mode. In this mode only the max count value achieved is displayed,

# IV. EXAMPLE OF SETTING UP THE SYSTEM

Before starting read carefully the Chapters II, III and VII.

1. Turn ON the system while pressing the « Standby » button on the front panel of the read-out module.
2. The system is in « Default » configuration (LED of « Select Config » is OFF).
3. If two probes are connected, choose the corresponding probe while pressing « Probe Selection »
4. Parameters :
   - Isotope Selection : « Tc99 ».
   - Scale : 250 counts.
   - Counting Time : 10 seconds.
   - Integration Time : ½ second.
   - Sound Mode : FM
   - Advanced functions are not active.
5. The system is ready to be used. In a first step, the read-out module must be switched OFF, the probe(s) has to be disconnected, placed in the sterile sheath and then reconnected to the read-out module . Switch the read-out module ON. If during use the counting rate reaches the max value of the bargraph (250), it is necessary to change the sensitivity scale by turning the rotary button to the right.

It is recommended to use around 10 seconds acquisition time (the time can vary depending on the protocol which is used). In order to make this measurement, press on « *Start* » and the system will make an acquisition over a 10 seconds period.

# V. SPECIFICATIONS

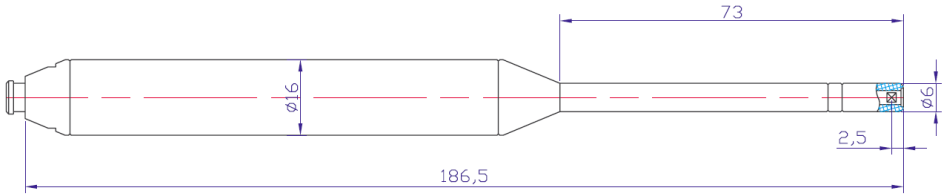
## 1. SOE306 PROBE

These probes are designed for low-mid energy detection: $^{125}I$, $^{99m}Tc$ especially developed for the ROLL (Radio-guided Occult Lesion Localization) method.

### a). Technical specifications

| Parameters | Specifications |
|---|---|
| Crystal | 2x2x2 $mm^3$ CdTe or CdZnTe (Cadmium Telluride or CZT) |
| Energy range | 20 - 170 keV |
| Detector efficiency for I-125 (27-35 keV) | > 80% |
| Detector efficiency for Tc-99m (140 keV) | > 40% |
| Storage temperature | + 1°C to +40°C |
| Operating temperature | +15°C to +40°C |
| Probe size | See drawings on the next page<br>The collimator is an integral part of the probe. |
| Weight | 120 g |
| Max ambient humidity for proper operating | 80% at 40°C |
| IP Protection | IP68 |

## b). Schematics




***SOE306 : Short straight CdTe probe for low energies detection***

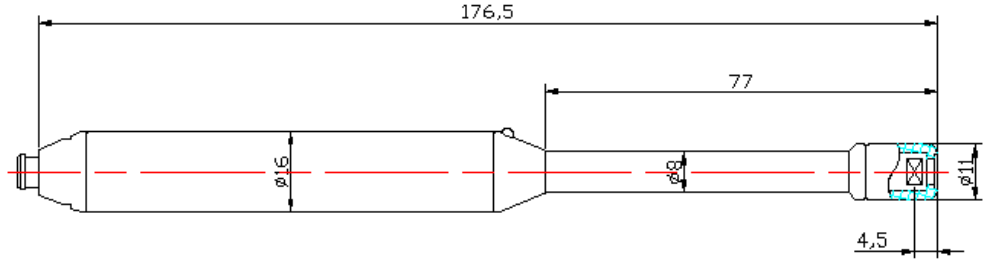
## 2. SOE311 AND SOE311-D PROBES:

These probes are designed for low and mid energies detection: $^{125}I$, $^{99m}Tc$

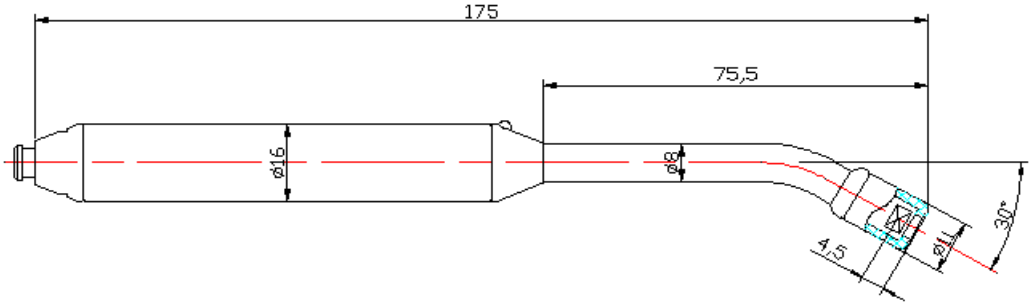
### a). Technical specifications

| Parameters | Specifications |
|---|---|
| Crystal | 5x5x3 mm³ CdTe or CdZnTe (Cadmium Telluride or CZT) |
| Energy range | 20 - 170 keV<br>(can also be used from 170 to 364 keV, but the detection efficiency within this range is better with the CsI probe) |
| Detector efficiency for I-125 (27-35 keV) | > 80% |
| Detector efficiency for Tc-99m (140 keV) | > 60% |
| Storage temperature | + 1°C to +40°C |
| Operating temperature | +15°C to +40°C |
| Probe size | See drawings on the next page<br>SOE311-D : Straight probe.<br>SOE311 : Angled probe to permit easier access to certain tissues. The collimator is an integral part of the probe. |
| Weight | 140 g |
| Max ambient humidity for proper operating | 80% at 40°C |
| IP Protection | IP68 |

## b). Schematics




***SOE311-D : CdTe straight probe for low and mid energies detection***




***SOE311 : CdTe angled probe for low and mid energies detection***

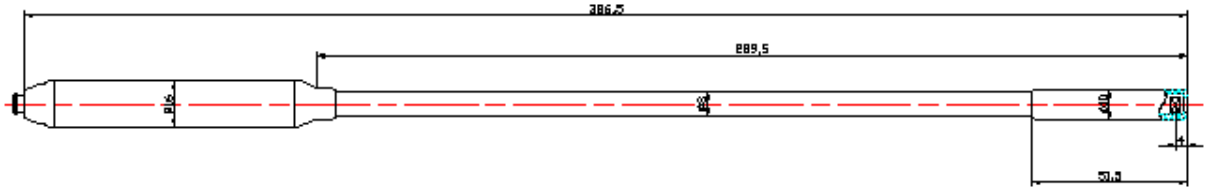
## 3. SOE311-AL AND SOE311-AF ENDOSCOPIC PROBES

These probes are straight in order to allow an endoscopic use. Depending on the application, the detection can be frontal or lateral. These probes are designed for low to mid energies levels : $^{125}I$, $^{99m}Tc$.

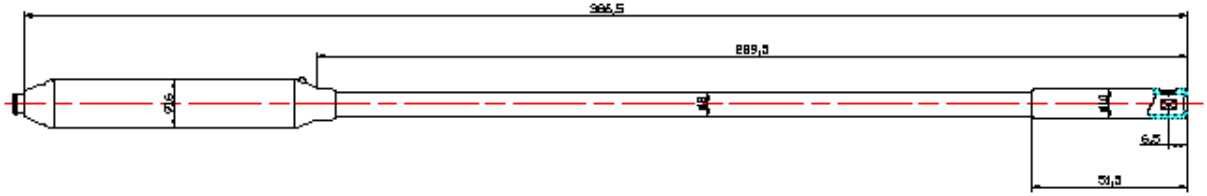
### a). Technical specifications

| Parameters | Specifications |
|---|---|
| Crystal | 5x5x3 $mm^3$ CdTe |
| Energy range | 20 - 170 keV<br>(can also be used from 170 to 364 keV, but the detection efficiency within this range is better with the CsI probe) |
| Detector efficiency for I-125 (27-35 keV) | > 80% |
| Detector efficiency for Tc-99m (140 keV) | > 60% |
| Storage temperature | +1°C to +40°C |
| Operating temperature | +15°C to +40°C |
| Probe size | See drawings on the next page.<br>SOE311-AF : Frontal detection window.<br>SOE311-AL : Lateral detection window<br>The collimator is an integral part of the probe. |
| Weight | 170 g (excluding cable) |
| Maximum ambient humidity for proper operation | 80% at 40°C |
| IP Protection | IP66 |

## b). Schematics




***SOE311-AF, CdTe Endoscopic frontal detection probe***




***SOE311-AL : CdTe Endoscopic lateral detection probe***

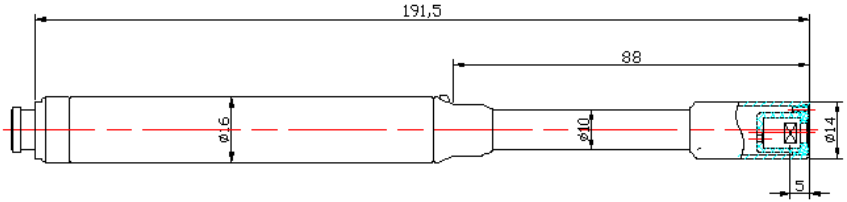
## 4. SOE314-DON PROBE

This probe is designed for blue dye detection in tissues.

### a). Technical specifications

| Parameters | Specifications |
|---|---|
| Crystal | N/A |
| Energy domain | N/A |
| Optical fiber diameter | 1mm |
| Storage temperature | + 1°C to +40°C |
| Operating temperature | +15°C to +40°C |
| Probe size | See drawings on the next page<br>The collimator is an integral part of the probe. |
| Weight | 100 g |
| Maximum ambient humidity for proper operation | 80% at 40°C |
| **IP Protection** | IP68 |

## b). Schematics




***SOE314-DON : Optical probe, blue dye detection***

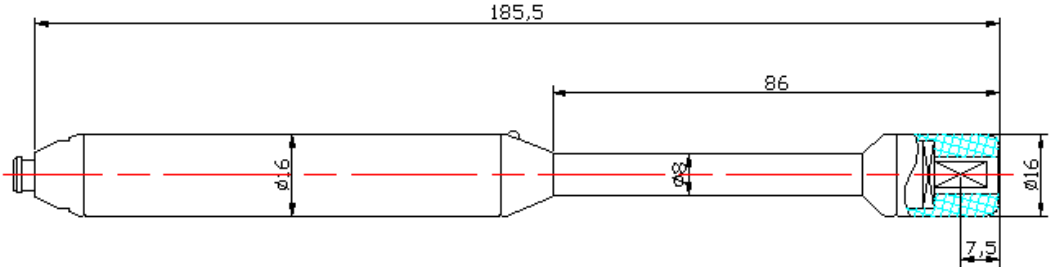
## 5. SOE316 AND SOE316-D PROBES

These probe are designed for higher energies levels : $^{111}In$, $^{131}I$.

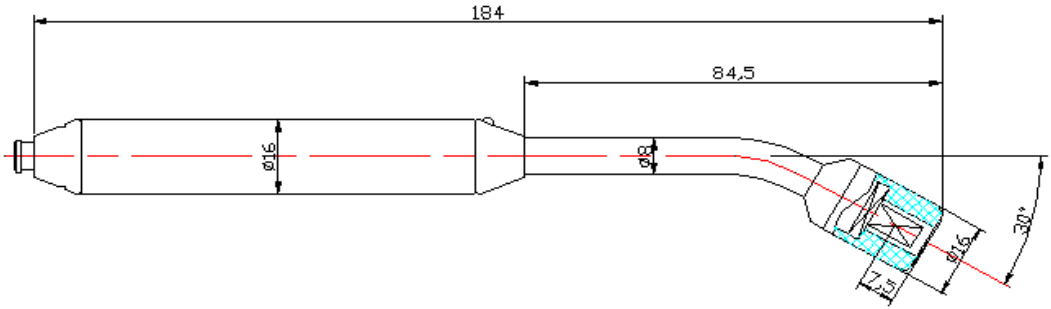
### a). Technical specifications

| Parameters | Specifications |
|---|---|
| Scintillator | CsI crystal, diameter = 5mm, length = 10mm coupled to a 25 $mm^2$ Silicon photodiode |
| Energy range | 150 keV to 1 MeV |
| Detector efficiency for Tc-99m (140keV) | > 80% |
| Detector efficiency for In-111 (245 keV) | > 70% |
| Detector efficiency for I-131 (364 keV) | > 45% |
| Storage temperature | + 1°C to + 40°C |
| Operating temperature range | + 15°C to + 40°C |
| Final size of the probe | See drawings on the next page<br>SOE316-D : Straight probe.<br>SOE316 : Angled probe to permit easier access to certain tissues. |
| Weight | The collimator is an integral part of the probe. |
| Maximum ambient humidity for proper operation | 175g<br>80% at 40°C |
| IP Protection | IP68 |

## b). Schematics




***SOE316-D : CsI straight probe for higher energies detection***




***SOE316 : CsI angled probe for higher energies detection***

## 6. SOE316-7 AND SOE316-7-D PROBES

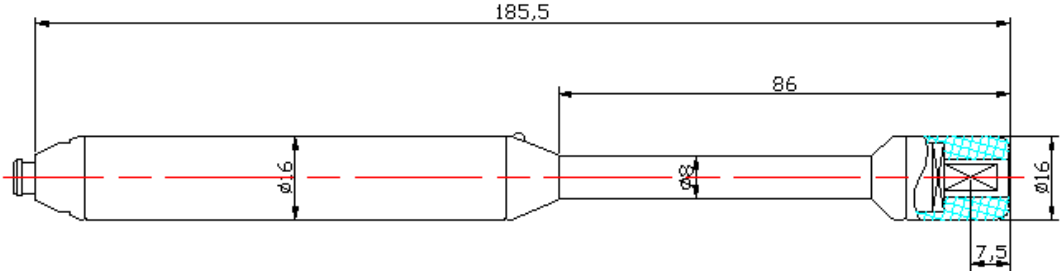
These probes are designed for higher energy levels $^{111}In$, $^{131}I$ with increased sensitivity.

### a). Technical specifications

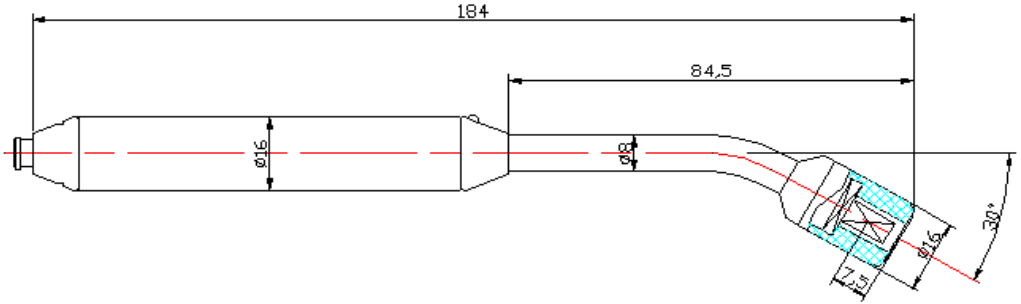
Scintillation probes of high efficiency

| Parameters | Specifications |
|---|---|
| Scintillator | CsI crystal, diameter = 7mm, length = 10mm coupled to a 25 $mm^2$ Silicon photodiode |
| Energy range | 150 keV to 1 MeV |
| Detector efficiency for Tc-99m (140keV) | > 80% |
| Detector efficiency for In-111 (245 keV) | > 70% |
| Detector efficiency for I-131 (364 keV) | > 45% |
| Storage temperature | + 1°C to + 40°C |
| Operating temperature range | + 15°C to + 40°C |
| Final size of the probe | See drawings on the next page<br>SOE316-7-D : Straight probe<br>SOE316-7 : Angled probe to permit easier access to certain tissues.<br>The collimator is an integral part of the probe. |
| Weight | 175g |
| Maximum ambient humidity for good operation | 80% at 40°C<br>I |
| Protection IP | P68 |

## b). Schematics




***SOE316-7-D : CsI straight probe of high sensitivity***




***SOE316-7 : CsI angled probe of high sensitivity***

# 7. READ-OUT MODULE

| | |
|---|---|
| Main power | 100-230VAC ~ 50/60Hz, 110mA-60mA |
| Connection | Power supply cable to the backside of module |
| Fuses | 2x 1,6AT 250V |
| Electrical protection class | Class I |
| Applied parts | BFType |
| Laser Diode(in option) | Class 3A ; 2.8mW / 635nm |
| Power consumption | Max. 15 watts |
| Maximum counts rate | 99999 cps/s |
| Operating temperature | +15°C to +40°C |
| Storage temperature | +1°C to +40°C 10 at 95% RH without condensation |
| Height | 245 mm |
| Width | 233 mm |
| Length | 270 mm |
| Weight | 3,5kg |

| | |
|---|---|
| Footswitch Steute MFK1S-MED / Eurorad | IPx7, approved EN60601-1 |

# VI. QUALITY INSURANCE PROCEDURES

**NOTE : A visual inspection of the system should be made on every occasion the system is used. The module should not show and lumps melted parts, smoke dicolouration etc…which might be caused by an electrical short circuit. The connectors and cables should also be inspected. They should not be damaged or cut, the cables should be well connected into connectors. If you are not 100% satisfied with these inspections DO NOT USE THE SYSTEM (the electrical safety might be defective).**

## 1. PROBES VERIFICATION PROCEDURE

These Quality Assurance procedures can be used periodically to monitor the system function. They can be used before an operation or when the system has not been in use for a prolonged period of time. The Quality Assurance procedures can also be used to check for Probe damage.

These tests can be done with Eurorad's source holder. It permits an optimal placing of the source in front of the probe.

### a). Efficiency test

Place the source in front of the probe (in probe's axis) at 3 cm distance or use Eurorad's source holder (optional). The counting rate should not exceed 10000 Bq in order to avoid a system saturation.

- Select $^{99m}$Tc isotope
- Select a 50 seconds « Counting time »

- Press the « Start » button to start the measurement
- Read the displayed value and calculate the number of counts per second and per MBq
- Determine the sensitivity error by comparing this result to the reference value which was determined when making the initial measurement
- Remove the radiation source and perform a background measurement in the same experimental conditions.

| Probes | Sensitivity $^{57}$Co at 3cm through air (Cp/s/MBq) | Sensitivity $^{57}$Co at 1cm through air (Cp/s/MBq) |
|---|---|---|
| SOE306 | >40 | >300 |
| SOE311 / SOE311-D | >250 | >1800 |
| SOE311 AF / AL | >200 | >1600 |
| SOE316 / SOE316-D | >800 | >5000 |
| SOE316-7 / SOE316-7D | >1600 | >8000 |

*Probe sensitivity example. Tests done with a $^{57}$Co source of less than 3,7MBq activity.*

# VII. OPERATIONAL PRECAUTIONS & LIMITATIONS

The EUROPROBE 3® system has to be treated like all other sensitive medical equipment. If you observe the following instructions your system should provide trouble free operation

## 1. BEFORE USE

Before using the system on a patient please make sure that :

- No part of the system, cable or connector are damaged.
- The EUROPROBE 3® is safely connected to mains power.
- The display module is not placed in the patient's environment.
- The chosen detection probe is correctly connected and has been selected on the read-out module.
- The probes have been decontaminated and eventually sterilized and placed in a sterile, biocompatible sheath.
- The isotope selection is correct.
- The quality assurance procedures have been fulfilled (see section VI).

## 2. DURING USE

When the system is in operation please ensure yourself that :

- The sound mode has been correctly selected and the volume set to the desired level.
- The time selection has been made.
- The system is not used on the same patient for more than 60 minutes at one time.

## 3. LIMITATIONS

**With the SOE306 and SOE311probes:**

These probes should be used for energies between 20 and 170 keV. Over 170 keV the detection efficiency will be much better using the CsI probe. The operating temperature range goes from +15°C to + 40°C and the ambient humidity should not exceed 80% at 40°C.

**With the SOE316 probes:**

The energy range for this probe is 100 keV to over 1 MeV. The operating temperature range goes from + 15°C to + 40°C and the ambient humidity should not exceed 80% at 40°C.

**With the SOE314 probe:**

This probe is convenient for blue dye detection. The operating temperature range goes from + 15°C to + 40°C and the ambient humidity should not exceed 80% at 40°C.

# VIII. HAZARDS

The hazard level for use of a surgical probe is considered minimal.

## 1. ELECTRICAL

The system has been developed following all existing security standards. It is mains powered and is mounted in a plastic box in order to ensure a complete security during use (security of the user & the patient is ensured).

## 2. MECHANICAL

The EUROPROBE 3® System has to be treated like all sensitive medical equipments. The most sensitive parts are the two probes. In case they are dropped, follow the quality assurance procedures before re-using them on a patient, to ensure that they are functioning properly.

## 3. CLEANING / DECONTAMINATION

Before each use, the probes should be decontaminated and the read-out module cleaned-up with alcohol. In case of contamination, the probes can be sterilized with ethylene oxide gas. **DO NOT USE A HIGH TEMPERATURE PROTOCOLE**

**The probe must be placed in a sterile, biocompatible sheath before each use (for more information, please contact your local reseller).**

If a radioactive contamination is supposed, clean the probes and cables with a decontamination solution foreseen for radioactive materials (RadiacWash® type).

**a). Cleaning method:**

After use remove the probe from the sterile sheath.

Clean all the visible contamination using a disinfectant impregnated cleaning tissue.

Clean the probe and cable with piece of tissue soaked with alcohol.

Brush the surfaces with an enzymatic detergent.

Place the probe and the cable (not the connector) during 1 to 2 minutes into an enzymatic detergent solution.

Clean with water and dry with soft tissue.

**b). Sterilization**

The choice of a sterilization method has to be based on the following conditions: No humidity (without condensation) – Maximal temperature below 60°C – No pressure, an example is the ethylene oxide method.

## 4. LONG TERM STABILITY

Long term stability and reproducibility of the unit can be monitored by using a standard source (not provided) to detect any drift or calibration change (see section VI).

# IX. SERVICE & MAINTENANCE

The **Europrobe 3®** system is covered by a one year limited warranty, under normal conditions of use. Damages due to an accident, an external factor, an impact, an incorrect use, etc… will not be covered by the warranty.

In the event of a malfunction, please return the unit to your distributor who will send it back to EURORAD for service and or repair.

Every five years, the system should be returned to the manufacturer for a complete verification.

Hospital maintenance/electrical engineering personnel are not qualified to repair neither the read-out unit nor the detector probes. The only maintenance accessible to this personnel and /or user is the replacement of the fuses and the exchange of the power supply cable.

## 1. REPAIRING

| Problem | Reason | Solution |
|---|---|---|
| The system is OFF | Defect fuse | Change the fuse. If the problem still exists, contact the After Sale Service. |
| The probe is not working | Bad probe selection | Select the probe correctly with the « Probe Selection » button |
| The system is emitting continuously « bip » sound.<br><br>On display « Pro » can be read. | No probe is connected<br>Probe is non compatible<br><br>Probe was disconnected during use. | Connect the probe<br>Use only the probes SOE306, 311, 314 or 316<br>Turn OFF the system and connect the probe correctly. |

## 2. FUSE REPLACEMENT

The fuses are placed on the rear part of the read-out module (in the fuses holder which is placed inside the module's power entry). They can be replaced by the user.

**Always disconnect the power supply cable from power supply entry module before fuses replacement..**

**In order to avoid any risk of fire, always replace both fuses with new equivalent ones.**

- With a screwdriver, lift the fuses holder at the rear part of the module.
- Replace both fuses by new equivalent ones. (1,6AT-250V)
- Close the fuse holder.

## 3. POWER SUPPLY CABLE REPLACEMENT

If the power supply cable is damaged or showing signs of general wear and tear replace it by an identical one.

Power supply cable characteristics:

- 3 conductors cable H05VV-F 3G 1mm² (or 0,75mm²)
- Connector IEC320 / C13 female for the connection to the power supply entrance of the module.
- Connector CEE7 (for all Europe except UK) for the connection to the power supply net. (For countries outside Europe, refer to the connectors used localy)

**The power supply cable must have a protective earth conductor.**

**To avoid any potential risk of fire ALWAYS replace the power supply cable with the same model or an equivalent model.**

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# X. STORAGE AND HANDLING CONDITIONS

The **Europrobe 3®** system must be stored in a dry environment, at ambient temperature, in its case.

During transportation, please specify to the carrier that the system should be maintained at ambient temperature or between +1°C and +40°C.

Whenever the system has been stored in a cool surrounding (temperature below 15°C), please keep it minimum for 4 hours at ambient temperature (25°C) prior to use.

The handling of the system does not require any particular condition. It should be treated like all other sensitive medical equipment. Please always pack the system in its carrying case (provided)

The used, broken, damaged Europrobe 3 module can not be considered as a common waste. It has to be collected, disposed off and treated in a manner adequate to directive concerning the electrical or electronic wastes (WEEE).

The **EUROPROBE 3®** probe contains components with cadmium telluride which have to be disposed off and treated properly.

In any case Eurorad's advise is to strictly follow all local and/or international regulations. In case of a problem, contact Eurorad or its representatives.

# XI. APPENDIX

## 1. FOOTSWITCH

The Europrobe3 can be delivered with a footswitch (optional).

This footswitch, MKF1S-MED from Steute has been especially desined for medical use. It is waterproof IPx7.

**The Europrobe 3® cannot work with any other footswitch than the one supplied by Eurorad or one of its appointed distributors.**

## 2. PROBES & ADDITIONAL COLLIMATORS

Eurorad has developed a wide range of probes for use with different isotopes and techniques. Additional collimators are also available which are very easy to use as they are just clipped on the probes.

Eurorad can also develop customized probes (other shapes, other dimensions, other materials, etc…).

# XII. NOTICE OF INFORMATION

(Please complete in case of a problem with the **EUROPROBE 3®** system)

**NAME:**

**ADDRESS**

**PHONE:** **FAX:** **E-MAIL:**

**PROBLEM ENCOUNTERED:**

**Please send this notice back to:**
**EURORAD S.A. Mme KAZANDJIAN 2, rue Ettore Bugatti - 67201 Eckbolsheim - FRANCE**
**Tel : +33 (0)3 88 26 81 30 Fax : +33 (0)3 88 28 45 48 E-mail : info@eurorad.com Web : www.eurorad.com**