

# EUROPROBE 3.2 SYSTEM SPECIAL OPERATION MANUAL FOR WIRELESS PROBES



## APPENDIX FOR SOE32xxBT WIRELESS PROBES

Do not use this manual without the main Europrobe 3.2 operation manual

Read the present manual carefully.

This user guide is not intended to be used alone. This is an appendix of the Europrobe 3.2 operation manual. Please read carefully the main Europrobe 3.2 operation manual as it contains important notice for operator and patient safety

CE marking: 1999/2014 (EUROPROBE 3.2)



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### Check list

Before using the **EUROPROBE 3.2** SOE32xx-BT wireless probes, please make sure that no part is missing. If one component is missing please contact your local seller.

- ✓ **SOE3216-BT, SOE3211-AF-BT, SOE3211-AL-BT or SOE3211-AL-45-BT Probe (depending on the version ordered)**
- ✓ **Lithium battery (LiSOC12, 3,6V 1/2AA)**
- ✓ **The EUROPROBE 3.2 manual as well as the present operation manual.**

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## SPECIAL PRECAUTIONS



Be sure you have carefully read the main Europrobe 3.2 Operation manual before using the wireless SOE32XX-BT probe. Otherwise you may expose the operator and the patient to severe injuries.

### In order to avoid injuries due to the lithium battery (fire, explosion, and burn hazard)

- Do not recharge the battery,
- Do not short circuit, crush, disassemble the battery,
- Do not heat the battery above 100°C
- Do not incinerate the battery,
- Do not expose to water,
- Always remove the battery before cleaning the probe.
- Remove battery if the probe is not used for a long time
- Always handle the probe carefully

### Emissions of non ionizing-radiation

- The SOE32xx-BT probes have an embedded radio transmitter in order to exchange wireless data with the Europrobe 3.
- Bluetooth module : FCC ID ED9LMX9838 / ID 1520A-LMX9838.



### **Special precautions for the medical field:**

- Handle the system like all other sensitive medical instrument.
- The system should only be operated by qualified personnel in the operating room.
- Check the good locking of battery cap before use.
- Do not use the probe if the battery cap is open.
- This probe 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 SOE32xx-BT 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.
- Prior to use the probe must be disinfected and the module should be cleaned with alcohol. For more information concerning the probes de-contamination, please refer to « Cleaning and disinfection » section of the Europrobe 3.2 operation manual
- The probe must **ONLY** be used after being placed in a sterile biocompatible sheath.

## Meaning of the symbols used:



General warning symbol (CEI60601-1)



Suggestion for proper functioning.



Identifies type BF applied part and its connection (CEI60601-1)



Systems must be collected, disposed off and treated properly (DEEE directive)



Serial number (ISO 15223-1)



Meaning : emissions of non-ionizing radiations (NIR)

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## 1. TYPES OF WIRELESS PROBE SOE32XXBT

The SOE3216-BT wireless probe can be used for the same application as the standard SOE3216 probe. (see Europrobe 3.2 operation manual)

The SOE3211-AL/-AF/-AL-45 probes BT versions can be used for the same applications as the standard SOE3211-AL/-AF/-AL-45 probes. (see Europrobe 3.2 operation manual)

## 2. DESCRIPTION OF THE USER INTERFACE

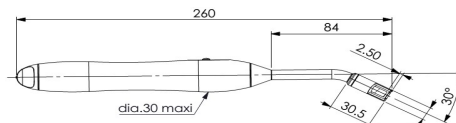
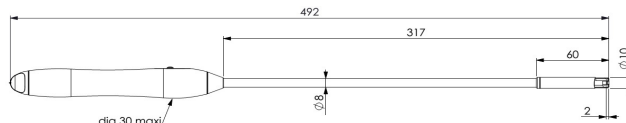
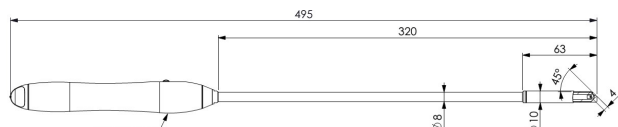
	<p>Left indicator :Shows the state of the data communication with the Europrobe 3.2. Blinks when data are transmitted</p>
	<p>Right indicator: Shows the radio link status. Led is OFF when the radio link is established with the module</p>
	<p>Push button. Allows to wake up the probe. A long push (5sec) puts the probe into standby mode. <i>Pressing briefly enable a start/stop counting. (optional on request)</i></p>

### 3. TECHNICAL SPECIFICATIONS

	Paramètres	Spécifications
SOE3216-BT	Crystal Energy range Efficiency for Tc-99m (140keV) Efficiency for In-111 (245 keV) Efficiency for I-131 (364 keV)	CsI crystal, diameter = 5mm, length = 10mm coupled to a 25 mm <sup>2</sup> Silicon photodiode 140 keV to 1 MeV (can also be used from 100 to 140 keV, but the detection efficiency within this range is better with the CdTe probe) > 80% > 70% > 45%
SOE3211-xx-BT	Crystal Energy range Efficiency for I-125 (27-35 keV) Efficiency for Tc-99m (140 keV)	8,6x8,6x3 mm <sup>3</sup> CdTe or CdZnTe 20 - 170 keV (can also be used from 170 to 364 keV, but the detection efficiency within this range is better with the CsI probe) > 80% > 60%
	Storage conditions Operating conditions Final size of the probe Poids Maximum ambient humidity IP protection Power Wireless module	1 to 40°C, 10 to 95 rH, 500-1060hPa 10 to40°C, 30-75% rH, 700-1060hPa See drawings. The collimator is an integral part of the probe. 200g 80% à 40°C IP64 battery Li-SOCL <sup>2</sup> 1/2AA 3,6V SAFT LS14250 battery lasting : continuous use : 10 hours; standby 3 months Module bluetooth ID : ES9LMX9838



Schematics : :

**SOE3216-BT : Wireless probe for high energy detection****SOE3211-AF BT : long wireless probe with frontal detection****SOE3211-AL BT : long wireless probe with lateral detection****SOE3211-AL-45-BT : long wireless probe with 45° detection**

### 4. WIRELESS MODE OPERATION

- Turn on the Europrobe 3.2 module.
- Turn the probe ON by pressing it's button.
- On the probe, two leds will turn on
- When the orange led turns off, the probe is connected with the Europrobe 3.2 module
- You can then use the probe.
- *Pressing briefly on the probe's button enables a start/stop counting. (optional on request)*
- If the probe is left for more than 5 minutes without counting it will switch to the standby mode. Press once on the button to activate the device.

### 5. WIRELESS MODE PRECAUTIONS & LIMITATIONS

- Please refer to « Cleaning and disinfection » section in the « Service and maintenance » chapter of the Europrobe 3.2 operation manual.
- As this probe uses wireless communication to send data to the module, it can be disturbed by other electrical equipment like electrocautery devices.
- The wireless probe can be used with a 'wired' probe connected to the Europrobe 3.2 module.
- The following Europrobe 3.2 functions are not available with wireless probe : « User », «Max» and «Total» modes, « Auto Selection » of probe and energy spectrum.

## 6. INSTALLING THE BATTERY

- Remove the battery cap at the rear of the probe (turn counter clockwise)
- Remove the empty battery
- Put the new battery with its positive pole toward the front of the probe
- **Use only a SAFT 1/2AA LS14250 Li-SOC<sup>2</sup> battery**
- Put the battery cap in place by screwing it gently. Ensure correct positioning of the o-ring.

## 7. 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 any lumps melted parts, smoke, discolouration etc. which might be caused by an electrical short circuit. The connectors and cables of the module 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).**

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

### 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  $^{99m}\text{Tc}$  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 $^{57}\text{Co}$ at 3cm through air (Cp/s/MBq)
SOE316-BT	>700
SOE3211-AF/AL/AL45-BT	>200

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

## **8. CLEANING AND DISINFECTION**

Please refer to « Cleaning and disinfection » section in the « Service and maintenance » chapter of the Europrobe 3.2 operation manual.

## **. NOTICE OF INFORMATION**

(Please complete in case of an incident with the **EUROPROBE 3.2** system)

**NAME:**

**ADDRESS**

**PHONE:**

**FAX:**

**E-MAIL:**

**DESCRIPTION OF THE INCIDENT (Thank you to specify if it is a serious incident):**

**Please send this notice back to:**

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