Model 1102 Wireless Probe

Operation Manual
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Contains BLUETOOTH Module WML-C40AH (Mitsumi Electric Co., Ltd.)

Contains: FCC: POOWML-C40 / IC: 6820A- POOWMLC4

Class: Part 15 Spread Spectrum Transmitter Bluetooth Module Rule: Parts 15 C

Rx Only

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Made in the U.S.A.

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1. Introduction

<table>
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<tr>
<th>Intended use</th>
<th>Electronic medical device for detecting and quantifying gamma radiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Used externally and intraoperatively to detect radioactive emissions from body tissues or organs where radiopharmaceuticals are administered</td>
</tr>
</tbody>
</table>

This manual:

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Operating the following devices: <em>neoprobe® Gamma Detection System</em> (GDS) Model 1102 Wireless Gamma Detection Probe Model 1131 Serial Port Adapter (required for Model 2000, 2100 and 2200 Control Unit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users</td>
<td>Physicians and operating room staff</td>
</tr>
<tr>
<td>Scope</td>
<td>Supplementary information for users of wireless probes This manual does not provide: System repair and technical documentation Procedures for performing surgery Procedures related to nuclear medicine</td>
</tr>
</tbody>
</table>

2. Equipment Assembly

**Console:**

*Note:* The Model 1131 Serial Adapter is not required for the Model 2300 GDS.

1. If using an older unit (Model 2200 and earlier), connect Model 1131 serial port adapter to data port on rear of console. Secure with thumbscrews.
2. Connect medical-grade power supply (Neoprobe PN 00-1221/Ault Model No. MW117) to receptacle on serial port adapter.
3. Connect 2 medical-grade power cords (Model 2009) to power connectors: one on the console and one on the serial port adapter power supply.
Probes:

⚠️ Remove battery before cleaning and sterilizing probe.

1. Remove Battery Cap

2. Install Battery

3. Install Battery Cap

1. Hold probe firm; turn battery cap counterclockwise until stop; pull battery cap from probe.
2. Install 3V CR 123 lithium battery; either polarity.
3. Hold probe firm; push battery cap into probe and turn clockwise until stop.

<table>
<thead>
<tr>
<th></th>
<th>Disposable</th>
<th>Rechargeable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand</strong></td>
<td>Duracell Ultra 123</td>
<td>UltraLast 123 (North American Battery Company)</td>
</tr>
<tr>
<td><strong>Hours of continuous operation</strong></td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td><strong>Capacity</strong></td>
<td>1550 mAh</td>
<td>750 mAh</td>
</tr>
</tbody>
</table>

*Note: Fully recharge battery before each use*

⚠️ Before installing battery cap, check that o-ring is in place. Ensure o-ring is not missing, cut or damaged.

**Trocar compatibility and Sheaths**
The Model 1102 Gamma Detection Probe is compatible with 11mm or 12mm trocars. Consult instructions for trocar selected. The Model 1102 Gamma Detection Probe with CIVCO Laparoscopic Transducer Cover should be used with 12mm sized trocars.

Using sterile sheaths:

⚠️ For intraoperative use, install the probe in a commercially available sterile sheath, such as:
3. System Operation

Establishing communication:

Before using the wireless probe, follow the next section to establish a BLUETOOTH communication link between the probe and the GDS or serial port adapter (indicated by the blue LEDs on the back of the GDS or serial port adapter and the probe).

**Note:** Link any Model 1131 adapter or Model 2300 GDS with any Model 1102 wireless probe.

<table>
<thead>
<tr>
<th>1. Model 2300 or Adapter’s LED</th>
<th>Description</th>
<th>2. Probe’s LED</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>On</td>
<td>Linked</td>
<td>On</td>
<td>Searching for the link</td>
</tr>
<tr>
<td>Off</td>
<td>Not linked</td>
<td>Blinking</td>
<td>Linked</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Off</td>
<td>Not powered</td>
</tr>
</tbody>
</table>

4. Configuring dynamic or binary pitch mode:

⚠️ For more information, see the Console Operation Manual.

Using aseptic technique, install probe in a sterile sheath. Fold and secure sterile sheath around the probe to create a complete sterile barrier. Follow established hospital procedures to maintain a sterile environment.

Also, probes may be sterilized by EtO, STERIS® 1, V-PRO™ 1, or STERRAD®. Sterile probes do not require a sterile sheath.
• Power on console.

• The console indicates there is no link, as shown.

Press the probe control button to power on the probe.

• The probe LED illuminates (searching for the BLUETOOTH link).

• If the probe is already linked to the console, the console powers on normally, as shown.

• The probe LED blinks and the Model 2300 GDS or adapter LED is on.

If the console indicates there is no link, press and hold the Target Count Button to initiate search.

• The console searches for the BLUETOOTH link, as shown.

**Note:** This is only required if you are using a different wireless probe than was previously attached to the console.

• When the link is established, the system is ready for use.

If the probe detects an input count under 5 counts/second for a 5-minute period, it powers down to conserve power.

• The console indicates there is no link, as shown.

• Probe and Model 2300 GDS or adapter LEDs are off.

To continue using the probe, press and release the probe’s control button.

• The probe powers on.

• The link is established and the probe is ready within 5 seconds.
Monitoring the battery:

If low battery voltage occurs:

- An alarm sounds and the console indicates low batt, as shown.
- Replace the battery as soon as possible.

If the battery voltage falls below a critical level, the probe shuts down and remains off.

Probe operation:

The probe operates like all Neoprobe probes when used intraoperatively to detect and quantify radioactive emissions.

The probe’s control button lets you initiate operations without a second person operating the console outside the sterile field.

### Dynamic pitch operation:

<table>
<thead>
<tr>
<th>Operation</th>
<th>Probe</th>
<th>Console</th>
<th>Activation / Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Count</td>
<td>•</td>
<td>•</td>
<td>Press and release the probe’s control button.</td>
</tr>
<tr>
<td>10-Sec Count</td>
<td>•</td>
<td>•</td>
<td>Press and hold the probe’s control button (&gt;1 sec).</td>
</tr>
<tr>
<td>Background Count</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count Range Select</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Range</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radionuclide Selection</td>
<td>•</td>
<td></td>
<td>Only 4 radionuclides ¹²⁵I, ⁹⁹ᵐTc, ¹¹¹In, ¹³¹I</td>
</tr>
<tr>
<td>Volume Adjustment</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mute Button</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td>•</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Binary pitch operation:

<table>
<thead>
<tr>
<th>Function</th>
<th>Probe</th>
<th>Console</th>
<th>Activation / Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Check (2 sec)</td>
<td>•</td>
<td>•</td>
<td>Press and release the probe’s control button.</td>
</tr>
<tr>
<td>Target Count (6 sec)</td>
<td>•</td>
<td>•</td>
<td>Press and hold the probe’s control button (&gt;1 sec).</td>
</tr>
<tr>
<td>Background Count</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radionuclide Selection</td>
<td>•</td>
<td></td>
<td>Only 4 radionuclides (^{125}\text{I}, ^{99m}\text{Tc}, ^{111}\text{In}, ^{131}\text{I})</td>
</tr>
<tr>
<td>Volume Adjustment</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mute Button</td>
<td>•</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td>•</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Powering down the system:
- Press and release the console’s Power button.
- Unplug the console’s power cord from the wall receptacle.
- If necessary, unplug the adapter’s power cord from the wall receptacle.
- Clean the console, adapter, and power cord(s).
- Using aseptic technique, remove the probe from the sterile sheath. Follow established hospital procedures to discard the sheath.
- Clean the probe as described in this manual.

### 5. Terminology and Symbols

Terms, symbols and graphics used in this manual.

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count Rate</td>
<td>A continuous rate of gamma radiation measured in counts per second and updated every one-half second. Count Rate is displayed on same line of LED screen as Target Count data and Target Check data when these functions are not active.</td>
</tr>
</tbody>
</table>
| Background Count | In Dynamic Pitch Mode: a baseline value in counts per second stored in console and used as threshold to activate sound  
                      In Binary Pitch Mode: baseline value in counts per second stored in console for comparison to Target Count determines if difference in radioactivity between Background Tissue and Target Tissue is statistically significant. |
| Dynamic Pitch | Default mode of operation: baseline value measured in counts per second that is stored in console, and used as threshold at which sound is activated. |
| Binary Pitch | Optional mode of operation: baseline value measured in counts per second that is stored in console for comparison to Target Count determines if difference in radioactivity between Background Tissue and Target Tissue is statistically significant. |
| Target Check | Binary Pitch Mode Only: quick check of level of radioactivity measured in counts per second detected by a probe held stationary for 2 seconds over target tissue; more accurate than Count Rate. Target Check function does not display a calculated Ratio Readout. |
| Target Count | Number indicating level of radioactivity detected by probe when held stationary for 6 seconds over Target Tissue; more accurate than Target Check. Target Count activates |
ITEM | DESCRIPTION
--- | ---
| and displays a calculated Ratio Readout; 6 seconds in Binary Pitch mode; 1 to 6 seconds in Dynamic Pitch mode.

**Caution**: see accompanying documents

ISO Symbol: indicates product is nonsterile until properly cleaned, disinfected and sterilized.

Temperature limits

Relative humidity

Atmospheric pressure

Rx Only In the U.S.A., Caution: Federal Law restricts this device to sale by or on the order of a physician.

6. Cleaning, Disinfection and Sterilization

Reprocessing:

- If you detect a high count in the absence of a radioactive source, clean the probe with a radioactive decontamination solution. Follow your institution’s biohazard and radioactive decontamination and waste procedures.

- **Note**: Remove the battery before cleaning and sterilizing.

- After cleaning and before using:

- Before installing the battery cap, check that the o-ring is in place. Ensure that it is not missing, cut or damaged.

- Ensure the battery and probe housing are completely dry.
Cleaning and Disinfection According to EN ISO 17664

| Manufacturer: Neoprobe Corporation | Method: Cleaning/Disinfection | Symbol: NON STERILE
| 425 Metro Place North, Suite 300 Dublin, Ohio 43017-1367 USA | | Model 1100, 1101, 1102 (wireless) |

**Devices(s):** All reusable probes, cables and collimator supplied by Neoprobe Corporation comprising fixed assemblies (no moving parts); sold nonsterile.

| Warning: | During cleaning or drying do not exceed 60ºC for probes and cords. |
| Limitations: | Repeated processing has minimal effect on this device. End of life is normally determined by abrasion, wear, and damage from use. |

**Instructions**

**Point of use:** Remove excess soil and surface contamination with a disposable cloth/wipe.

**Containment and transportation:** Reprocess device as soon as is practical after use.

**Preparation for cleaning:** Warning: Remove the battery before cleaning. To avoid permanent damage, do not immerse the probe with the battery cap loose or removed. NOTE: Remove battery from wireless probe 1100, 1101 and 1102

**Cleaning - Automated:** Does not apply.

**Cleaning: Manual**

| Equipment: enzymatic detergent, brush, soft cloth, running water. |
| Method: Remove the battery. Discard or set aside. |
| Remove excess soil from the device. |
| Using a brush, apply detergent solution to all surfaces. |
| Rinse under clean, running water for 1 minute. |
| Inspect. |
| Repeat steps 2–5 until the device passes inspection. |
| Inspect the battery cap and o-ring. |
| Using a brush or cloth dampened with the enzymatic detergent solution, clean the battery cap and opening. |
| Rinse the battery cap and opening under clean, running water for 1 minute. |
| Inspect. |
| Repeat steps 8–10 until the device passes inspection. |

**Disinfection:** Use disinfectant solution. **Warning:** To avoid health hazards, follow the disinfectant manufacturer’s instructions.

- Prepare soaking mixture according to manufacturer’s instructions.
- Soak the product for 5–20 minutes. Cover all areas including niches and joints.

**Drying:** During cleaning or drying do not exceed 60ºC.

**Maintenance:** Do not use damaged instruments.

**Inspection and function testing:** All instruments: Inspect for damage or wear. Where instruments are part of a larger assembly, check assembly with mating components.

**Packaging:** Singly – use standard packaging material. Ensure that the packaging is large enough to contain the instrument without stressing the packaging seals.

**Sterilization:** See separate instructions for STERIS, V-PRO 1, STERRAD, or EtO.

**Storage:** Protect the device during transport.

**Additional information:** To avoid damage to battery contacts, do not immerse the probe with the battery cap loose or removed.

**Manufacturer contact:** See page 2 of this operation manual.

**Note:** The instructions above were validated by the medical device manufacturer as being capable of preparing a medical device for reuse. It remains the responsibility of the reprocessor to ensure the reprocessing actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires validation and routine monitoring of the process. Any deviation from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.
Ethylene Oxide (EO) Sterilization According to EN ISO 17664

Manufacturer:
Neoprobe Corporation
425 Metro Place North
Suite 300
Dublin, Ohio 43017-1367 US

Method: EO
Symbol: NON STERILE

Model 1100, 1101, 1102 (wireless)
Model 1017, 2059
Model 2021, 2024, 2060
Model 1013

Devices(s): All reusable probes, cables and collimator supplied by Neoprobe Corporation comprising fixed assemblies (no moving parts); sold nonsterile.

⚠️ WARNING:
Do Not exceed 60ºC for probes and cables during cleaning or drying cycles.

Limitations on reprocessing:
Repeated processing has minimal effect on these instruments. End of life is normally determined by abrasion, wear and damage due to use.

INSTRUCTIONS:

Point of use:
Detach the external collimator from the probe, if used. Remove the excess soil and surface contamination with disposable cloth/paper wipe.

Containment & Transportation:
Loosely coil the cable and place in plastic container to protect the probe, cable and collimator from damage during transport. No particular requirements. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

Preparation for cleaning:
⚠️ WARNING: to avoid electrical shock disconnect probe and cable from control unit before cleaning. DO NOT disconnect the probe from the cable at this time. NOTE: Remove battery from wireless probe 1100, 1101 and 1102.

Cleaning - Automated: Automated cleaning does not apply to these instruments. See manual cleaning below.

Cleaning: Manual
Equipment: enzymatic detergent, brush, running water.

Method:
1. With the cable still attached to the probe, rinse outside surfaces with brisk stream of water. Wipe with soft cloth soaked with enzymatic cleaner suitable for surgical instruments. Repeat process separately for collimator cleaning.
2. Visually inspect cable and probe for contaminated areas.
3. Repeat Steps 1 and 2 until visual inspection reveals instrument is clean. Detach probe from cable.
4. Rinse probe, cable and collimator with a brisk stream of water for 30 seconds and dry with clean soft cloth.
5. Repeat steps 1 to 4 until visual inspection assures instrument is clean.

Disinfection:
Disinfectant solution may be used in accordance with label instructions.

⚠️ WARNING: to avoid health hazards comply with the disinfectant manufacturer’s instruction.
1. Prepare mixture according to manufacture’s instructions.
2. Apply mixture for at least 5 minutes but not more than 20 minutes. Cover all area including niches and joints. DO NOT soak the probe or cable connectors.
3. The connector ends should be swirled in 100 milliliters of clean enzymatic solution for at least one minute, but no more than two minutes.
4. Rinse with brisk stream of tap water for approximately 30 seconds and dry with clean soft cloth.

Drying:
When drying is achieved as part of disinfection cycle, do not exceed 60ºC.

Maintenance:
Do not use damaged instruments.

Inspection & Function Testing:
All instruments: Visually inspect for damage or wear. Where instruments form part of a larger assembly, check assembly with mating components.

Packaging:
Singly – a standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the package seals.

Sterilization:

<table>
<thead>
<tr>
<th>EO Process Phase</th>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preconditioning</td>
<td>Temperature</td>
<td>48.9 to 54.4 ºC set point of 55 ºC</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Pressure</td>
<td>690 to 827 hPa gauge (10 to 12 PSIG)</td>
</tr>
<tr>
<td></td>
<td>Humidity</td>
<td>&gt; 70 % RH</td>
</tr>
<tr>
<td></td>
<td>Humidity Dwell</td>
<td>30 – 45 minutes</td>
</tr>
<tr>
<td></td>
<td>Sterilant Gas</td>
<td>100% EO</td>
</tr>
<tr>
<td></td>
<td>EO Gas Concentration</td>
<td>883 ± 30 mg/L</td>
</tr>
<tr>
<td></td>
<td>Exposure time</td>
<td>48 – 60 minutes</td>
</tr>
<tr>
<td></td>
<td>Post-vacuum</td>
<td>1.93 – 2.91 PSIA (3.93 – 5.92 inches Hg)</td>
</tr>
<tr>
<td></td>
<td>Time/Temperature</td>
<td>≥12 hours at 50 to 57.2ºC or 7 days at</td>
</tr>
</tbody>
</table>
Storage: No particular requirements. Protect during transport between cleaning and sterilization. Once sterilized, protect from contamination.

Additional Information: When sterilizing multiple instruments in one sterilizer equipment, do not exceed the sterilizer’s maximum capacity. Do not immerse the connector of the probe in fluids.

Manufacturer Contact: See brochure for telephone and address of local representative or telephone (+1) 614-793-7500, extension 167.

NOTE: The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a medical device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials, and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

STERRAD Sterilization According to EN ISO 17664

Manufacturer: Neoprobe Corporation
425 Metro Place North
Suite 300
Dublin, Ohio 43017-1367 US

Method: STERRAD
Symbol: Model 1100, 1101, 1102 (wireless)
Model 1017, 2059
Model 2021, 2024, 2060

Devices(s): All reusable intraoperative probes and cables supplied by Neoprobe Corporation comprising fixed assemblies (no moving parts); sold non-sterile.

WARNING: Do Not exceed 60ºC for probes and cables during cleaning or drying cycles.

Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is normally determined by abrasion, wear and damage due to use.

INSTRUCTIONS:

Point of use: Detach the external collimator from the probe, if used. Remove the excess soil and surface contamination with disposable cloth/paper wipe.

Containment & Transportation: Loosely coil the cable and place in plastic container to protect the probe and cable from damage during transport. No particular requirements. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

Preparation for cleaning: WARNING: to avoid electrical shock disconnect probe and cable from control unit before cleaning. DO NOT disconnect the probe from the cable at this time. NOTE: Remove battery from wireless probe 1100, 1101 and 1102.

Cleaning - Automated: Automated cleaning does not apply to these instruments. See manual cleaning below.

Cleaning: Manual
Equipment: enzymatic detergent, brush, running water.

Method:
6. With the cable still attached to the probe, risk outside surfaces with brisk stream of water. Wipe with soft cloth soaked with enzymatic cleaner suitable for surgical instruments NOTE: no cable used with/wireless probe.
7. Visually inspect cable and probe for contaminated areas.
8. Repeat Steps 1 and 2 until visual inspection reveals instrument is clean. Detach probe from cable
9. Rinse with a brisk stream of water for 30 seconds and dry with clean soft cloth.
10. Repeat steps 1 to 4 until visual inspection assures instrument is clean.

Disinfection: Disinfectant solution may be used in accordance with label instructions.

WARNING: to avoid health hazards comply with the disinfectant manufacturer’s instruction.
5. Prepare mixture according to manufacturer’s instructions.
6. Apply mixture for at least 5 minutes but not more than 20 minutes. Cover all area including niches and joints. DO NOT soak the probe or cable connectors.
7. The connector ends should be swirled in 100 milliliters of clean enzymatic solution for at least one minute, but no more than two minutes.
8. Rinse with brisk stream of tap water for approximately 30 seconds and dry with clean soft cloth.

Drying: When drying is achieved as part of disinfection cycle, do not exceed 60ºC.

Maintenance: Do not use damaged instruments.

Inspection & Function Testing: All instruments: Visually inspect for damage or wear. Where instruments form part of a larger assembly, check assembly with mating components.

Packaging: Singly – a standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the package seals.
### Sterilization: STERRAD:

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vacuum</td>
<td>20 minutes</td>
</tr>
<tr>
<td>1st Injection, Diffusion &amp; Plasma</td>
<td>17 minutes</td>
</tr>
<tr>
<td>2nd Injection, Diffusion &amp; Plasma</td>
<td>17 minutes</td>
</tr>
<tr>
<td>Vent</td>
<td>1 minute</td>
</tr>
<tr>
<td>Aeration or cool down</td>
<td>0 (not required)</td>
</tr>
<tr>
<td>Full Cycle time</td>
<td>55 minutes</td>
</tr>
</tbody>
</table>

### Storage:
No particular requirements. Protect during transport between cleaning and sterilization. Once sterilized, protect from contamination.

### Additional Information:
When sterilizing multiple instruments in one sterilizer equipment, do not exceed the sterilizer’s maximum capacity. Do not immerse the connector of the probe or cable in fluids.

### Manufacturer Contact:
See product brochure for telephone and address of local representative or telephone (+1) 614-793-7500, extension 167.

### NOTE:
The instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials, and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

### STERIS Sterilization According to EN ISO 17664

<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>Method: STERIS</th>
<th>Symbol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neoprobe Corporation</td>
<td></td>
<td>[Image]</td>
</tr>
<tr>
<td>425 Metro Place North</td>
<td></td>
<td>[Image] Model 1100, 1101, 1102 (wireless)</td>
</tr>
<tr>
<td>Suite 300</td>
<td></td>
<td>Model 1017, 2059</td>
</tr>
<tr>
<td>Dublin, Ohio 43017-1367 US</td>
<td></td>
<td>Model 1013</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Model 2021, 2024, 2060</td>
</tr>
</tbody>
</table>

| Devices(s): | All reusable intraoperative probes with cables supplied by Neoprobe Corporation comprising fixed assemblies (no moving parts); sold non-sterile. |

#### WARNING:
Do Not exceed 60ºC for probes and cables during cleaning or drying cycles.

#### Limitations on reprocessing:
Repeated processing has minimal effect on these instruments. End of life is normally determined by abrasion, wear and damage due to use.

#### INSTRUCTIONS:

##### Point of use:
Detach the external collimator from the probe, if used. Remove the excess soil and surface contamination with disposable cloth/paper wipe.

##### Containment & Transportation:
Loosely coil the cable and place in plastic container to protect the probe and cable from damage during transport. No particular requirements. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

##### Preparation for cleaning:

1. **WARNING:** to avoid electrical shock disconnect probe and cable from control unit before cleaning. DO NOT disconnect the probe from the cable at this time. NOTE: Remove battery from wireless probe 1100, 1101 and 1102.

##### Cleaning - Automated:
Automated cleaning does not apply to these instruments. See manual cleaning below.

##### Cleaning: Manual
Equipment: enzymatic detergent, brush, running water.

1. Method:
   1. With the cable still attached to the probe, risk outside surfaces with brisk stream of water. Wipe with soft cloth soaked with enzymatic cleaner suitable for surgical instruments
   2. Visually inspect cable and probe for contaminated areas.
   3. Repeat Steps 1 and 2 until visual inspection reveals instrument is clean. Detach probe from cable
   4. Rinse with a brisk stream of water for 30 seconds and dry with clean soft cloth.
   5. Repeat steps 1 to 4 until visual inspection assures instrument is clean.

##### Disinfection:

1. **WARNING:** to avoid health hazards comply with the disinfectant manufacturer’s instruction.
   1. Prepare mixture according to manufacturer’s instructions.
   2. Apply mixture for at least 5 minutes but not more than 20 minutes. Cover all area including niches and joints. DO NOT soak the probe or cable connectors.
   3. The connector ends should be swirled in 100 milliliters of clean enzymatic solution for at least one minute, but no more than two minutes.
   4. Rinse with brisk stream of tap water for approximately 30 seconds and dry with clean soft cloth.
Drying: When drying is achieved as part of disinfection cycle, do not exceed 60ºC.

Maintenance: Do not use damaged instruments.

Inspection & Function Testing: All instruments: Visually inspect for damage or wear. Where instruments form part of a larger assembly, check assembly with mating components.

Packaging: Singly – a standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the package seals.

Sterilization: STERIS: Always follow the sterilizer equipment manufacturer’s specific operator instructions in the correct application of the STERIS System 1 equipment.

1. Place the cleaned probe in the appropriate STERIS Rack.
2. Process the device in accordance with the instructions in your STERIS System 1 Operator’s Manual.

Storage: No particular requirements. Protect during transport between cleaning and sterilization. Once sterilized, protect from contamination.

Additional Information: When sterilizing multiple instruments in one sterilizer equipment, do not exceed the sterilizer’s maximum capacity. Do not immerse the connector of the probe in fluids.

Manufacturer Contact: See product brochure for telephone and address of local representative or telephone (+1) 614-793-7500, extension 167.

NOTE: The instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials, and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

V-PRO 1 (STERIS) Sterilization According to EN ISO 17664

Manufacturer: Neoprobe Corporation
425 Metro Place North, Suite 300
Dublin, Ohio 43017-1367 US

Method: STERIS

Symbol:

![NON STERILE](Model 1100, 1101 (wireless))

![Model 1017, 2059](Model 1013)

![Model 2021, 2024, 2060](Model 2021, 2024, 2060)

Devices(s): All reusable intraoperative probes with cables supplied by Neoprobe Corporation comprising fixed assemblies (no moving parts); sold non-sterile.

⚠️ WARNING: Do Not exceed 60ºC for probes and cables during cleaning or drying cycles.

Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is normally determined by abrasion, wear and damage due to use.

INSTRUCTIONS:

Point of use: Detach the external collimator from the probe, if used. Remove the excess soil and surface contamination with disposable cloth/paper wipe.

Containment & Transportation: Loosely coil the cable and place in plastic container to protect the probe and cable from damage during transport. No particular requirements. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

Preparation for cleaning: ⚠️ WARNING: to avoid electrical shock disconnect probe and cable from control unit before cleaning. DO NOT disconnect the probe from the cable at this time. NOTE: Remove battery from wireless probe 1100, 1101 and 1102.

Cleaning - Automated: Automated cleaning does not apply to these instruments. See manual cleaning below.

Cleaning: Manual

Equipment: enzymatic detergent, brush, running water.

Method:
6. With the cable still attached to the probe, risk outside surfaces with brisk stream of water. Wipe with soft cloth soaked with enzymatic cleaner suitable for surgical instruments
7. Visually inspect cable and probe for contaminated areas.
8. Repeat Steps 1 and 2 until visual inspection reveals instrument is clean. Detach probe from cable
9. Rinse with a brisk stream of water for 30 seconds and dry with clean soft cloth.
10. Repeat steps 1 to 4 until visual inspection assures instrument is clean.

Disinfection: Disinfectant solution may be used in accordance with label instructions.

⚠️ WARNING: to avoid health hazards comply with the disinfectant manufacturer’s instruction.
5. Prepare mixture according to manufacturer’s instructions.
6. Apply mixture for at least 5 minutes but not more than 20 minutes. Cover all area including
7. Maintenance

User maintenance is restricted to battery and battery cap replacement.

There are no user serviceable components or items on the Model 1102 wireless probe.

Do not attempt to repair damaged battery contacts, or any other damage to the probe.

**WARRANTY**

New equipment manufactured by Company is warranted against defects in workmanship and materials for a period of one year from the date of shipment by Company to buyer, subject to the limitations hereinafter set forth. Should any defects be found and reported during that period, company, at its option, will repair or replace such defective equipment provided that Buyer ship the product containing the defect to the Company, transportation charges prepaid, with notice of the defect and representation that the equipment will be shipped C.I.P. from the Company’s plant. The terms of this product warranty do not extend to any product or part thereof, which, under normal usage, has an expected useful life of less than one year. This warranty shall not apply to any equipment where the installation, calibration or servicing of such equipment is improper, or where equipment is operated above rated load capability, or subjected to accident, tampering, alteration, or abuse.

**THE COMPANY'S LIABILITY UNDER THIS WARRANTY OR ANY OTHER WARRANTY WHETHER EXPRESS OR IMPLIED IN LAW OR FACT SHALL BE LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE MATERIAL AND WORKMANSHIP, AND IN NO EVENT SHALL THE COMPANY BE LIABLE FOR CONSEQUENTIAL OR INDIRECT DAMAGES. THIS WARRANTY CONTAINS THE ENTIRE OBLIGATION OF NEOPROBE CORPORATION AND NO OTHER WARRANTIES INCLUDING, WITHOUT LIMITATION, WARRANTIES EXPRESSED, IMPLIED, OR STATUTORY ARE GIVEN.**
### 8. Probe Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystal</td>
<td>Cadmium Zinc Telluride, CdZnTe</td>
</tr>
<tr>
<td>Energy Range</td>
<td>27-364 keV</td>
</tr>
<tr>
<td>Detector Efficiency</td>
<td>&gt;90% 125I</td>
</tr>
<tr>
<td></td>
<td>&gt;76% 99m Tc</td>
</tr>
<tr>
<td></td>
<td>&gt;60% 111In</td>
</tr>
<tr>
<td></td>
<td>&gt;25% 131I</td>
</tr>
<tr>
<td>Weight</td>
<td>175 grams</td>
</tr>
<tr>
<td>Side/Rear Shielding</td>
<td>&gt;99.99% 125I</td>
</tr>
<tr>
<td></td>
<td>&gt;99.5% 99m Tc</td>
</tr>
<tr>
<td></td>
<td>&gt;90% 111In</td>
</tr>
<tr>
<td></td>
<td>&gt;80% 131I</td>
</tr>
<tr>
<td>Operating Temperature Range</td>
<td>15° to 40° C (59° to 104° F)</td>
</tr>
<tr>
<td>Storage/Transit temperature</td>
<td>-20° to 60° C (-4° to 140° F)</td>
</tr>
<tr>
<td>Storage/Transit humidity</td>
<td>10 to 95%</td>
</tr>
<tr>
<td>Storage/Transit atmospheric pressure</td>
<td>500 hPa to 1060 hPa (7.3 psia to 15.4 psia)</td>
</tr>
<tr>
<td>Frequency Band/Range</td>
<td>2402.0 – 2408.0 MHz</td>
</tr>
<tr>
<td>Harmonized standard(s)</td>
<td>ETSI EN 300 328 v1.6.1:2004</td>
</tr>
<tr>
<td></td>
<td>ETSI EN 301 489-17:2002</td>
</tr>
<tr>
<td>Modulation</td>
<td>FHSS (GFSK)</td>
</tr>
<tr>
<td>Channel Spacing</td>
<td>79 channels</td>
</tr>
<tr>
<td>Max Transmit Power Limit</td>
<td>0.01382 Watts</td>
</tr>
<tr>
<td>Duty cycle</td>
<td>Variable (hops = 1600/sec)</td>
</tr>
<tr>
<td>Type of antenna</td>
<td>Chip</td>
</tr>
<tr>
<td>Duplex direction</td>
<td>Full duplex</td>
</tr>
</tbody>
</table>

**Equipment Classification:**

For more information, see the neo2000 Operation Manual.

**Type of protection against electrical shock:**

- Console: Class 1

**Degree of protection against electrical shock:**

- Applied Part: (wireless probe)
  - Type CF

**Protection against the harmful ingress of liquids:**

- Probe: IPX8

- Radio Transmitter:
  - Europe: 99/5/EC R&TTE Directive Class I

**Use only detachable power cords that comply with one or more agency approvals:**

- 100VAC/50-60Hz: Dentori
- 125VAC/60Hz: CSA, UL
This device complies with Part 15 of the FCC Rules. Operation is subject to:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

**Declaration of Conformance:**

Hereby, Neoprobe Corporation declares that this “Wireless Probe” is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

[Česky][Czech] Neoprobe Corporation tímto prohlašuje, že tento “Wireless Probe” je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 1999/5/ES.

[Dansk][Danish] Undertegnede Neoprobe Corporation erklærer herved, at følgende udstyr “Wireless Probe” overholder de væsentlige krav og øvrige relevante krav i direktiv 1999/5/EF.


[Español][Spanish] Por medio de la presente Neoprobe Corporation declara que el “Wireless Probe” cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 1999/5/CE.

[Ελληνική][Greek] ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Neoprobe Corporation ΔΗΛΩΝΕΙ ΟΤΙ “Wireless Probe” ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΙΑΠΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 1999/5/ΕΚ.

[Francés][French] Par la présente Neoprobe Corporation déclare que l'appareil “Wireless Probe” est conforme aux exigences essentielles et aux autres dispositions pertinentes de la directive 1999/5/CE.

[Italiano][Italian] Con la presente Neoprobe Corporation dichiara che questo “Wireless Probe” è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 1999/5/CE.


[Nederlands][Dutch] Hierbij verklaart Neoprobe Corporation dat het toestel “Wireless Probe” in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 1999/5/EG.


[Magyar][Hungarian] Alulírott, Neoprobe Corporation nyilatkozom, hogy a “Wireless Probe” megfelel a vonatkozó alapvető
9. Warnings, Cautions and Notes

This information supplements the Console Operation Manual.

⚠️ Warning:

- Only properly trained and qualified personnel should use the system.
- Execute universal precautions when handling components that are exposed to blood or blood components. Before using or storing, clean all components used during intraoperative applications.
- Always remove battery from wireless probe before reprocessing (cleaning, disinfecting or sterilization).
- To avoid permanent damage, do not immerse the probe with the battery cap loose or removed. Clean the probe’s surface with a soft brush.
- Before cleaning, inspect the probe to ensure the battery is not exposed.
- To ensure compliance with IEC 601-1, use only the battery type or power components listed in this document. Using other items may compromise the device’s safety or operation.
- Use the probe only where the target tissue can be adequately viewed and accessed.
- Use only the Serial Port Adapter (Model 1131 adapter) provided by Neoprobe. Do not co-locate or operate the transmitter with any other antenna or transmitter.
- Do not use an electrocautery or other electrosurgical devices in the patient when the probe is in the patient. Doing so may increase the risk of patient injury if the electrosurgical devices contact the probe.

- Do not sterilize the probe by e-beam or gamma sterilization. Use only recommended cleaning and sterilization methods.

**Caution**

- The probe is a delicate surgical instrument. To avoid permanent damage, do not drop it.
- Completely dry the probe’s battery and housing before use. Wet contacts may short the battery.
- Modifications not expressly approved by Neoprobe Corporation will void your authority to operate the equipment.
- Using this device near X-ray-producing devices may cause false counts.
- Using this device near persons undergoing radiation therapy may cause false counts.

![Warning]

Properly dispose of used batteries and electromechanical products. Neoprobe uses recyclable products and materials wherever possible. If you dispose of components, parts or accessories, follow all local, governmental and/or international laws and regulations. If you cannot find a proper means of disposal, contact Neoprobe at +1 614-793-7500 to arrange for return of material(s) for proper disposal.

**Notes**

- The probe is intended to operate on battery power for \( \leq 10 \) hours.
- If the device is not used for an extended time, remove the battery.