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1 Introduction

Thank you for choosing the UroShield®. This manual contains general instructions for operation, application, precautions and care. In order to obtain maximum life and efficiency from the UroShield® and to assist in its proper operation, please read and understand this manual thoroughly. This UroShield® is to be used only as directed in this manual.

1.1 Biofilm Formation and Urinary Tract Infections

Catheter-associated urinary tract infection (CAUTI) and other indwelling-device associated infections are a major cause of morbidity and mortality in hospitalized patients.\(^1\) Urinary catheters readily acquire biofilms after insertion; and the longer the catheter remains in place, the greater is the tendency for the formation of biofilms, resulting in urinary tract infections.

The initial step in biofilm formation is the adhesion or attachment of planktonic bacteria to the catheter surface. It is thought that the bacteria use touch sensors to attach to a solid surface.\(^2\) This occurs within a few hours after urinary catheter placement. After attachment the bacteria begin to interlock, a process known as docking. The bacteria then secrete an extra-cellular polymeric matrix (ECM), which allows them to survive and proliferate. The complex of the bacteria and ECM, now adherent to the catheter surface, is known as biofilm. The established biofilm is highly resistant to antibiotics and to the body's immune system.

The UroShield® is intended to prevent bacterial biofilm formation by generating acoustic waves on the surface of the catheter. The waves interfere with the attachment of bacteria (which is the initial step in biofilm formation) and increase antibiotic efficacy against biofilm bacteria.

---

2 Princeton University News- Discovery of bacterial touch sensor could lead to Biofilm treatments. [http://www.princeton.edu/pr/news/02/q1/0205-touchsensor.htm](http://www.princeton.edu/pr/news/02/q1/0205-touchsensor.htm).
1.2 Pain, Discomfort, and Spasm

By means of the same acoustic waves that mitigate against biofilm, the UroShield® also reduces friction between the catheter and the patient’s internal tissues. This decreases the pain, discomfort and spasm associated with indwelling urinary catheters.

1.3 General Safety

Thoroughly read and understand the precautionary and operating instructions before attempting to operate the UroShield®. Observe the precautionary and operational labels on the product. Periodically review the operation procedures and safety precautions outlined in this manual.
2 Indications for Use

The UroShield® is intended for use with indwelling urinary catheters. It addresses the two major problems associated with urinary catheters:

- Urinary tract infection due to biofilm formation
- Pain, discomfort, and spasm

The UroShield® can be used with catheters made of any material and sized 14, 16, 18, 20, or 22 French, for up to 30 days.

Note that the UroShield® is not for use with percutaneous nephrostomy catheters. With these you can use its sister product, Z-Shield: see Appendix F.
3 Safety Warnings and Cautions

- Insertion and removal of catheters and connection, operation, and disconnection of the UroShield® should be performed only by qualified medical staff and in accordance with the relevant medical facilities care guidelines.

- Do not use the UroShield® as a treatment for an active urinary infection.

- Do not use the UroShield® in the presence of flammable materials and liquids. The UroShield® is classified as internally-powered, intermittently-operated, ordinary equipment with a disposable type BF applied part.

- The UroShield® is not MRI compatible and therefore, should be detached from the catheter before entering the MRI suite.

- Use the UroShield® only as instructed in this manual.

- Do not use the UroShield® or any accessory pieces if they appear to be damaged.

- Do not modify the UroShield® in any way.

- The UroShield® has no user serviceable parts. If it is not operating correctly, contact the local representative of NanoVibronix. No part of the UroShield® should be replaced with components or parts other than those supplied by NanoVibronix.
**CAUTION**

- The UroShield® driver is not waterproof. Do not expose it to water.
- Charge the UroShield® only with the supplied charger.
- Do not attempt to open or remove any of the covers of the UroShield®.
- The lithium ion rechargeable battery in the UroShield® must not be disassembled, heated above 100 degrees Celsius, incinerated, or exposed to water.
4  Product Features

4.1  Mains and Battery Operation

The UroShield® can be powered by the mains or by its rechargeable battery. In normal use it should be continuously connected to a mains socket. However, to provide patient mobility it can be powered by the battery for up to 6 hours (when fully charged).

The battery can be fully charged in about 2 hours.

4.2  Operating Cycle

When the UroShield® is ON, it alternates between 2 phases:

- Active phase—the UroShield® generates acoustic waves on the surface of the catheter. This phase is 15 minutes long (a low audible sound is heard).

- Idle phase—the UroShield® does not generate acoustic waves on the surface of the catheter. This phase is 5 minutes long.
5 Product Components

The UroShield® has two components: an actuator and a driver. A power supply/charger is supplied.

5.1 The Actuator

The small, lightweight actuator clips onto the urinary catheter after the catheter’s insertion into the patient’s bladder. When the UroShield® is active, the actuator generates acoustic waves on the surface of the catheter. The actuator itself does not have contact with the patient’s skin. It is for single use only: that is, for use with one catheter only (until the catheter is replaced or for a maximum of 30 days).
5.2 The UroShield® Driver

The driver supplies electrical signals to the actuator. It has the following parts:

- Built-in rechargeable battery
- Charging port
- Connection cable
- ON/OFF button
- Operational display screen

The driver is small and lightweight and can be placed on the patient’s bed. When the patient needs to be mobile, it can be placed in a pocket or on a belt.
6 Operation

6.1 Connecting the UroShield®

1. Make sure that UroShield application occurs shortly following catheter insertion into the bladder.

2. Gently pull on the catheter until you feel slight resistance.

3. Remove the actuator from its packaging.

4. Peel off the protective strips from the inside of both halves of the actuator.
5. Place the actuator on the catheter in accordance with the following:
   - In females, make sure that there are 2 to 3 cm between the actuator and the point where the catheter exits the body.
   - In males, make sure that there are 5 to 10 cm between the actuator and the point where the catheter exits the body.
   - Make sure that the direction of the actuator connection cable is towards the patient.
   - Make sure that the patient’s clothing is between the actuator and the patient’s skin.
   - Attach the actuator to the catheter so that the catheter enters and exits the actuator through the grooves at either end of the actuator.

6. Carefully close the actuator so that the two halves snap together.

7. Make sure that the catheter is not pinched or deformed at either end of the actuator.
8. Insert the actuator cable plug into the driver cable socket, making sure to orient the plug correctly in relation to the socket, and also making sure that the plug is fully inserted and secured.

9. Connect the supplied charger to the driver charging port.

10. Plug the charger into the mains.

The driver display shows the following screens in quick succession:

After about 1 minute, the display dims.
The UroShield® is now charging and is ready to be switched on (you do not need to wait for the battery to charge fully, which takes about 2 hours).

6.2 Switching the UroShield® ON or OFF

To switch the UroShield® ON or OFF, press the ON/OFF button for 2–3 seconds.

About 30 seconds after you switch the UroShield® ON, the driver display shows the status of the battery and actuator connection as shown in the following screen:

![Battery and Actuator Status Screen](image)

If another screen appears instead of the above, see section 6.4.2 Alarms and Troubleshooting.

After another 3 minutes, the display dims and shows the screensaver:

![Screensaver](image)

Note: when the screensaver is shown, you can return to the battery/actuator status and brighten the screen by pressing the ON/OFF button briefly (that is, for less than 2 seconds).
6.3 Instructing the Patient

Instruct the patient as follows:

- The patient should not pull or open the actuator.
- The patient should not disconnect the actuator from the driver.
- The patient should not press the ON/OFF button.
- The patient should inform medical staff if an alarm is heard.
- The patient should not expose the driver to water: see section 0

Showering and Bathing
6.4 Monitoring the UroShield®

6.4.1 Driver Display Icons during Normal Functioning

The table below explains the icons and text that may be shown on the driver display during normal functioning of the UroShield®.

<table>
<thead>
<tr>
<th>Icons/Text Shown</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Manufacturer’s name" /></td>
<td>Manufacturer’s name  (shown briefly when you plug the UroShield® into the mains or switch it ON).</td>
</tr>
<tr>
<td><img src="image2" alt="Product name. Software version number" /></td>
<td>Product name. Software version number  (shown briefly after the manufacturer’s name).</td>
</tr>
<tr>
<td><img src="image3" alt="Battery charge indicator." /></td>
<td>Battery charge indicator.  The battery is charging. The UroShield® is OFF. The battery icon fills gradually to show charging progress. If the screen has dimmed, you can brighten it by pressing the ON/OFF button briefly (that is, for less than 2 seconds).</td>
</tr>
</tbody>
</table>
1. Battery charge indicator
2. Actuator status = correctly connected and correctly working

The UroShield® is ON.

Screensaver. The display is dimmed.

The UroShield® is ON.

You can show the battery charge indicator and actuator status (and brighten the screen) by pressing the ON/OFF button briefly (that is, for less than 2 seconds).

6.4.2 Alarms and Troubleshooting

When the UroShield® requires attention, an audible alert sounds and the driver display flashes. The icon on the display will indicate what action is required: see the table below.

<table>
<thead>
<tr>
<th>Icon on Flashing Display</th>
<th>Explanation</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery less than 10% charged</td>
<td>Connect the driver to the mains with the supplied charger.</td>
<td></td>
</tr>
</tbody>
</table>
Icon on Flashing Display  | Explanation                                                                 | Action Required                                                                 |
---|---|---|
| ![Battery Icon] | This icon appears for several seconds when the battery becomes less than 5% charged. The UroShield® then shuts down automatically. | Connect the driver to the mains with the supplied charger and then switch ON the UroShield®. |
| ![Actuator Icon] | Actuator malfunction. The actuator is not connected to the driver or is damaged. | Make sure the actuator is properly connected to the driver. If the actuator is properly connected and the malfunction icon is displayed, replace the actuator with a new one. |

### 6.5 Disconnecting the Driver from the Actuator

1. Switch OFF the UroShield® (to prevent the driver from sounding an alarm when it is disconnected from the actuator).

2. Hold the driver cable socket in one hand and the actuator cable plug in the other hand, then pull them apart.

**CAUTION** Never attempt to disconnect the driver from the actuator by holding the driver, actuator, or either of the cables, and pulling on them.
6.6  Showering and Bathing

The UroShield® driver is not waterproof and should not be exposed to water. If the patient wants to shower or bath, do the following:

1. Before entering the bathroom, switch OFF the UroShield®.
2. Disconnect the driver from the actuator.
3. Leave the driver outside the bathroom.

The actuator can remain attached to the catheter while the patient is showering or bathing.
# Frequently Asked Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can the UroShield® be used with catheters made of any type of material?</td>
<td>Yes. It can be used with catheters made of silicone, polyvinyl chloride (PVC), latex rubber, siliconised latex, and all other catheter materials.</td>
</tr>
<tr>
<td>Is there a device similar to UroShield® that can be used with percutaneous nephrostomy catheters?</td>
<td>You can use Z-Shield for percutaneous nephrostomy catheters. For details see Appendix F.</td>
</tr>
<tr>
<td>With which catheter sizes can the UroShield® be used?</td>
<td>The UroShield® can be used with urinary catheter sizes 14, 16, 18, 20, and 22 French.</td>
</tr>
<tr>
<td>Can the actuator be reused after catheter removal?</td>
<td>No. The actuator is for use with a single catheter only and should be disposed of when the catheter is replaced.</td>
</tr>
</tbody>
</table>
8 Product Care

8.1 Storage

Before use, store the UroShield® in its shipment box under the following conditions:

- Temp: 10 °C to 30 °C (50 °F to 86 °F)
- Humidity: 20% to 55%

The driver battery shelf life is 2 years.

The actuator shelf life is 5 years.

8.2 Environmental Operating Conditions

The recommended environmental operating conditions are:

- Temp: 10 °C to 27 °C (50 °F to 80 °F)
- Humidity: 40% to 60%

8.3 The Driver

The life expectancy of the driver is 5 years.

To clean the driver use wipes with 70% alcohol or another disinfecting solution. Do not use solvents (such as acetone) as they may damage the product.

The driver is flame resistant according to UL-94HB. It does not contain toxic, hazardous, or flammable materials and it will not accelerate a fire. Nevertheless, the driver is not intended for use in the presence of flammable liquids.

The driver does not contain recyclable material.

The driver has a 1 year warranty. A faulty unit which is within the warranty period can be sent to NanoVibronix for replacement.
8.4 The Actuator

The actuator is designed for single use only: that is, for use with one catheter only and each actuator will work effectively for 30 days.

If the actuator becomes soiled, it can be cleaned with a damp sponge and then allowed to dry.

After use, the actuator must be disposed of together with the catheter and in accordance with the relevant medical facility’s standards for the disposal of used medical equipment.
Appendix A: Electromagnetic Compliance

Table 1: UroShield® Electromagnetic Emission

<table>
<thead>
<tr>
<th>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>UroShield® is intended for use in the electromagnetic environment specified below. The customer or user of the UroShield® should assure that it is used in such an environment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions, CISPR 11</td>
<td>Group 1</td>
<td>The UroShield® uses Radio Frequency (RF) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions, CISPR 11</td>
<td>Class B</td>
<td>The UroShield® may be connected to the Public Mains Network.</td>
</tr>
<tr>
<td>Harmonic emissions, IEC 61000-3-2</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IES 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: UroShield® Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>UroShield® is intended for use in the electromagnetic environment specified below. The customer or user of the UroShield® should assure that it is used in such an environment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601-1-2 Test level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±8 kV air</td>
<td>±8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transfer/burst</td>
<td>±2 kV for power supply</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>±1 kV for input/output</td>
<td>±1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>lines</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Immunity test

### Surge

<table>
<thead>
<tr>
<th>Test level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>±1 kV differential mode</td>
<td>±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>±2 kV common mode</td>
<td>±2 kV common mode</td>
<td></td>
</tr>
</tbody>
</table>

### Voltage dips, short interruptions, and voltage variations on power supply input lines

<table>
<thead>
<tr>
<th>Voltage level</th>
<th>Mains power quality should be that of a typical commercial or hospital environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>±1 kV differential mode</td>
<td></td>
</tr>
<tr>
<td>±2 kV common mode</td>
<td></td>
</tr>
</tbody>
</table>

\[ U_T^* \] is the A/C mains voltage prior to application of the test level.

### Power frequency (50/60 Hz) magnetic field

<table>
<thead>
<tr>
<th>Power frequency magnetic field</th>
<th>3 A/m</th>
<th>3 A/m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 Vrms 150kHz to 80MHz</td>
<td>[V1] V</td>
</tr>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>3 Vrms 80MHz to 2.5GHz</td>
<td>[E1] V/m</td>
</tr>
</tbody>
</table>

### Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

### Recommended separation distance

\[ d = \frac{3.5}{V1} \sqrt{P} \] 80 MHz to 800 MHz

\[ d = \frac{3.5}{E1} \sqrt{P} \] 800 MHz to 2.5 GHz

\[ d = \frac{7}{E1} \sqrt{P} \]
### Immunity test

<table>
<thead>
<tr>
<th>IEC 60601-1-2 Test level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Where ( P ) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ( d ) is the recommended separation distance in meters (m).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by electromagnetic site survey(^a), should be less than the compliance level in each frequency range(^b).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

\(^a\) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the UroShield\(^\circledast\) is used exceeds the applicable RF compliance level above, the UroShield\(^\circledast\) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the UroShield\(^\circledast\).

\(^b\) Over the frequency range 150 kHz to 80 MHz, field strength should be less than [V1] V/m.
Table 3: UroShield® Recommended Separation Distances

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter, W</th>
<th>Separation distance according to frequency of transmitter, m</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>d = \left[ \frac{3.5}{V1} \right] \sqrt{P} \hspace{1cm} d = \left[ \frac{3.5}{E1} \right] \sqrt{P} \hspace{1cm} d = \left[ \frac{7}{E1} \right] \sqrt{P}</td>
</tr>
<tr>
<td>Separation Distance, meters</td>
<td>Separation Distance, meters</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer. V1 is COMPLIANCE LEVEL for the IEC 61000-4-6 test and E1 is the COMPLIANCE LEVEL for the IEC 61000-4-3 test. V1 and E1 are in V/m.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
Appendix B: Specifications

Driver model FD-14B

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>90 kHz ± 0.001 kHz, modulated by 30 Hz</td>
</tr>
<tr>
<td>Voltage output</td>
<td>12 V p-p</td>
</tr>
<tr>
<td>Rechargeable battery</td>
<td>Lithium-Ion, 3.7 V, 1200 mAh (full charging time ~ 2 hours)</td>
</tr>
<tr>
<td>Dimensions</td>
<td>125 mm (L) x 39 mm (W) x 13 mm (H)</td>
</tr>
<tr>
<td>Weight</td>
<td>Approximately 70 g</td>
</tr>
<tr>
<td>Housing</td>
<td>ABS</td>
</tr>
</tbody>
</table>

UroShield Actuator

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>42 mm x 34 mm x 15 mm</td>
</tr>
<tr>
<td>Weight (including cable)</td>
<td>20 g</td>
</tr>
<tr>
<td>Housing</td>
<td>Polypropylene</td>
</tr>
</tbody>
</table>

Charger

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage input</td>
<td>100-240 VAC, ~ 300 mA, 50/60 Hz</td>
</tr>
<tr>
<td>Output</td>
<td>5 VDC, 1 A</td>
</tr>
<tr>
<td>Note</td>
<td>Use an appropriate adaptor for local mains.</td>
</tr>
</tbody>
</table>

**Product classification**

Low risk device classification:

CE mark – Class II a

**Compliance with standards**

EN 60601-1; EN 60601-1-2
Appendix C: Labels

Figures 1–4 show the UroShield® labels.

Figure 1: Driver Label

Figure 2: Actuator Label

Figure 3: Actuator Pouch Label

Figure 4: Kit Label
## Appendix D: Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="CE mark" /></td>
<td>CE mark</td>
</tr>
<tr>
<td><img src="image" alt="Refer to instruction manual/booklet" /></td>
<td>Refer to instruction manual/booklet</td>
</tr>
<tr>
<td><img src="image" alt="Type BF applied part" /></td>
<td>Type BF applied part</td>
</tr>
<tr>
<td><img src="image" alt="Rated frequency or rated frequency range(s) (Hz)" /></td>
<td>Rated frequency or rated frequency range(s) (Hz)</td>
</tr>
<tr>
<td><img src="image" alt="Separate collection for electrical and electronic equipment" /></td>
<td>Separate collection for electrical and electronic equipment</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Authorized representative in the European Community" /></td>
<td>Authorized representative in the European Community</td>
</tr>
<tr>
<td><img src="image" alt="Lot" /></td>
<td>Lot</td>
</tr>
<tr>
<td><img src="image" alt="Do not reuse" /></td>
<td>Do not reuse</td>
</tr>
<tr>
<td><img src="image" alt="Use by YYYY-MM" /></td>
<td>Use by YYYY-MM</td>
</tr>
<tr>
<td><img src="image" alt="S/N" /></td>
<td>Serial number</td>
</tr>
<tr>
<td><img src="image" alt="W" /></td>
<td>Watt (1W = 1000mW)</td>
</tr>
<tr>
<td><img src="image" alt="0.4W" /></td>
<td>Power output 0.4 watts</td>
</tr>
<tr>
<td><img src="image" alt="kHz" /></td>
<td>Kilohertz (1 kHz = 1000 Hz)</td>
</tr>
</tbody>
</table>
Appendix E: Warranty

NanoVibronix warrants that the UroShield® driver shall be defect-free for a period of one year from the product date of shipment.

The liability of NanoVibronix under this warranty is limited to the repair or replacement (at NanoVibronix’s choice) of any allegedly defective part or parts under warranty by NanoVibronix at its expense. The defective driver shall be returned to NanoVibronix accompanied by a notice that describes the nature of the problem.

This warranty shall not apply to a product which has been subject to misuse, unauthorised use, negligence, accident, (including but not limited to fire, water, explosion, smoke, or vandalism) or which has not been operated in compliance with NanoVibronix instructions of use.

Without derogating from the above, this warranty is void, if at any time anyone other than NanoVibronix authorised personnel removes the product casing and/or attempts to make any internal changes, removals, attachments or additions to the product or its components.
Appendix F: Z-Shield for Percutaneous Nephrostomy Catheters

A sister product, Z-Shield, is intended for use with percutaneous nephrostomy catheters. Instead of the UroShield® actuator, the Z-Shield has an acoustically-active stabilization patch. The patch does the following:

- Stabilises the catheter
- Decreases the pain and discomfort associated with percutaneous nephrostomy catheters by applying low-frequency ultrasound to the puncture site
- Maintains catheter patency by applying low-frequency ultrasound to it, thus mitigating the need for urgent medical attention to maintain patency or replace the catheter with a new one
- Prevents bacterial biofilm formation by applying low-frequency ultrasound to the catheter

The patch requires replacement after 30 days use, or sooner if determined by the supervising physician.

The Z-shield is not suitable in the following cases:

- If the patient has damaged or diseased skin in the area where the patch needs to be placed
- If the patient is sensitive to medical grade adhesive