



User Manual

URO**SHIELD[®]**

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NANO **VIBRONIX**[®]
Therapeutic Waves in Motion

URO **S** **HIELD**[®]

CE **1282**

1.0 INTRODUCTION	5
1.1 Biofilm Formation and Urinary Tract Infections	
1.2 Contents	
1.3 Pain, Discomfort, and Spasm	
1.4 General Safety	
1.5 Essential Performance	
2.0 INDICATIONS FOR USE	7
3.0 SAFETY	8
3.1 Contraindications	
3.2 Warnings	
4.0 THE UROSHIELD® SYSTEM	10
4.1 The UroShield® Actuator	
4.2 The UroShield® Driver	
5.0 PRODUCT FEATURES	12
5.1 Operating Cycle	
5.2 Mains and Battery Operation	
6.0 PRODUCT CARE	13
6.1 The Driver	
6.2 The Actuator	
6.3 Storage	
6.4 Environmental Operating Conditions	
7.0 OPERATION	15
7.1 Charging the UroShield® Driver	
7.2 Connecting the UroShield®	
7.3 Switching the UroShield® ON or OFF	
7.4 Monitoring the UroShield®	
7.5 Alerts and Troubleshooting	
7.6 Disconnecting the Driver from the Actuator	
7.7 Showering and Bathing	
8.0 FREQUENTLY ASKED QUESTIONS	23
9.0 APPENDIX	24
9.1 Electromagnetic Compliance	
9.2 UroShield® Specifications	
9.3 Symbol Index	
9.4 Warranty	

This user manual contains the instructions for operation, application and care of UroShield®. To obtain maximum life and efficiency from UroShield® and to assist in its proper operation, please read and understand this manual thoroughly.

UroShield® is to be used only as directed in this user manual.



BIOFILM FORMATION AND URINARY TRACT INFECTIONS

1.1

Urinary catheters readily acquire biofilms after insertion; and the longer the catheter remains in place, the greater the tendency for the formation of biofilms, resulting in urinary tract infections.

The initial step in biofilm formation is the adhesion of bacteria to the catheter surface. This occurs a few hours after urinary catheter placement. Following attachment, the bacteria begin to secrete an extra-cellular polymeric matrix, which allows them to survive and proliferate. The bacteria and extra-cellular polymeric matrix, now adherent to the catheter surface, is known as biofilm which is highly resistant to antibiotics and to the body's immune system.

The UroShield® is intended to prevent bacterial biofilm formation by generating ultrasound waves on the inner and outer surfaces 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.

CONTENTS

1.2

The UroShield® includes the following items:

- UroShield Driver.
- Clip-on actuator with its connecting cable.
- Lanyard.
- Power supply charger.

1.3 PAIN, DISCOMFORT, AND SPASM

By means of the ultrasound waves that mitigate against biofilm formation, 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.

1.4 GENERAL SAFETY

Thoroughly read and understand the safety and operating instructions before attempting to operate the UroShield®. This user manual should be retained for future reference.

1.5 ESSENTIAL PERFORMANCE

The UroShield® is applied on the urethral or suprapubic catheter and emits ultrasound energy to its surface. The waves interfere with the attachment of bacteria, which is the initial step in biofilm formation, and increase antibiotic efficacy against biofilm bacteria.

UroShield® is a low-energy, battery powered medical device with an actuator accessory designed for application to the extracorporeal segment of siliconized latex, silicone or latex urological (urethral or suprapubic) catheter.

The UroShield® is to be worn continuously and is intended to minimize bacterial adhesion and colonization on the catheter surfaces.

The UroShield® can be used with urinary catheters sized 12, 14, 16, 18, 20, or 22 French.

3.1 CONTRAINDICATIONS

UroShield® is not intended as a treatment for an active urinary tract infection.

WARNINGS

3.2



- Insertion and removal of catheters should be performed only by qualified medical staff and in accordance with the relevant medical facility's care guidelines.
- The UroShield® driver is not waterproof. Do not expose it to water.
- Do not use UroShield® in the presence of flammable materials and liquids. The UroShield® driver is classified as internally powered, intermittently operated, ordinary equipment with a disposable type BF applied part.
- Use UroShield® only as instructed in this manual.
- Do not use the UroShield® driver or accessories if they appear to be damaged.
- Do not modify UroShield® in any way.
- UroShield® has no user serviceable parts. If it is not operating correctly, contact the local representative of NanoVibronix. No part of the UroShield® system should be replaced with components or parts other than those supplied by NanoVibronix.
- Do not connect UroShield® to any device or system other than the parts supplied with it.
- Charge the UroShield® driver only with the supplied charger.
- Do not attempt to open or remove the cover of the UroShield® driver.

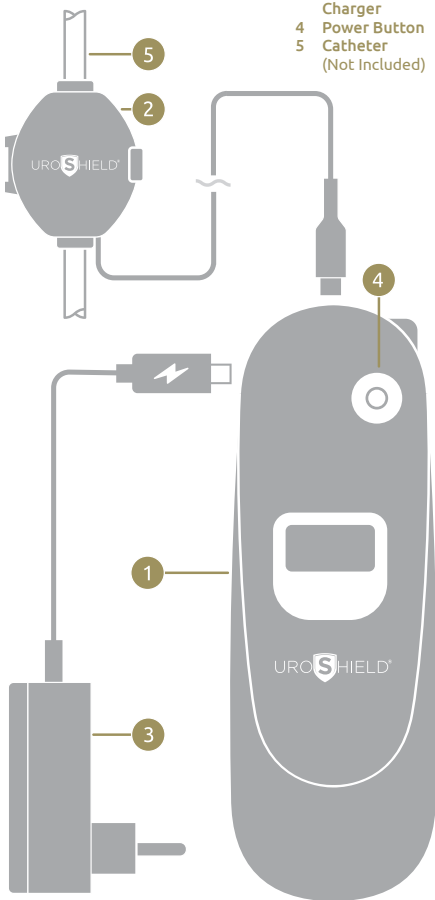
- The lithium-ion rechargeable battery in the UroShield® driver must not be disassembled, heated above 100 degrees Celsius, incinerated, or exposed to water.
- Be aware of the actuator cable which can get caught or wrapped around a person's body and lead to potential injury or restrict blood flow.
- Use of UroShield® adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, observe the UroShield® system to verify it is operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by NanoVibronix could result in increased electromagnetic emissions or decreased electromagnetic immunity of this medical device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be no closer than 30 cm (12 inches) to any part of the UroShield® system during operation. The performance of UroShield® may be affected.
- Refer to Appendix A for information on maintaining basic safety and essential performance with regard to electromagnetic disturbances of UroShield®.
- The UroShield® is not MRI compatible and therefore, should be removed from the catheter before entering the MRI suite.

UroShield® has two components:

A Driver ① and an Actuator ②

A Mains Adapter/Charger ③ is also included

- 1 Driver
- 2 Actuator
- 3 Mains Adapter/Charger
- 4 Power Button
- 5 Catheter (Not Included)



The UroShield® System 4

THE UROSHIELD® ACTUATOR

4.1

The actuator is attached onto the urinary catheter after the catheter's insertion into the patient's urethra. When the UroShield® driver is active, the actuator generates ultrasound waves on the surface of the catheter. The actuator is intended for single use only, should be worn continually and changed every 30 days or when the catheter is changed.

First time users of the UroShield® system should ensure that it is used on a new catheter.

THE UROSHIELD® DRIVER

4.2

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

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

The driver is small and lightweight and can be attached using a lanyard (*fig. 1*), or placed on the patient's bed. When the patient needs to be mobile, the UroShield® driver can be placed in a pocket, attached to a belt or attached to a walker or wheelchair using a lanyard.

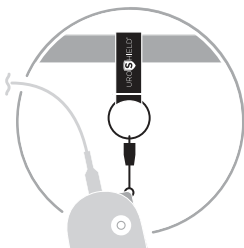


fig.1

5.1 OPERATING CYCLE

UroShield® is preconfigured to provide intermittent ultrasound output at a pre-set frequency which cannot be modified by the user.

When in ON mode, UroShield® alternates between 2 phases:

- **Active phase**

UroShield® delivers 15 minutes of ultrasound waves on the surface of the catheter. A low audible sound may be heard.

- **Idle phase**

UroShield® is idle for 5 minutes.

5.2 MAINS AND BATTERY OPERATION

The UroShield® can be powered by mains or by its internal rechargeable battery. To provide patient mobility it can be powered by the internal battery for up to 6 hours when fully charged. The internal battery can be fully charged in approximately 2 hours.

The internal battery can undergo greater than 500 full charge cycles. The operational time may decrease over time when running on the battery. Mains power use is unaffected.

THE DRIVER

6.1

- The life of the driver is dependent on the battery use, refer to section 5.2. To clean the driver, use 70/30 Iso Propyl Alcohol or disinfectant medical wipes.
- Do not use solvents such as acetone as they may damage the product. Do not immerse the UroShield® driver in water or any other liquid.
- The driver is flame resistant according to UL-94HB. It does not contain flammable materials and will not accelerate a fire. The driver is not intended for use in the presence of flammable liquids.
- A faulty unit which is still under warranty, can be sent to NanoVibronix for replacement. Refer to Appendix D for conditions of warranty.
- The driver does not contain recyclable material.



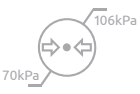
THE ACTUATOR

6.2

- The actuator is designed for single use only and should be changed every 30 days or when the catheter is changed.
- 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 in accordance with the local authority requirements for the disposal of used medical equipment.




6.3 STORAGE CONDITIONS

UroShield® storage conditions:

	<p>5 - 40°C</p>
	<p>10 - 80%</p>
	<p>70 - 106 kPa</p>

6.4 ENVIRONMENTAL OPERATING CONDITIONS

The recommended environmental operating conditions are:

	<p>5 - 35°C</p>
	<p>10 - 80%</p>
	<p>70 - 106 kPa</p>

CHARGING THE UROSHIELD® DRIVER

7.1

When the battery is fully charged, the UroShield® can be used without mains power for a duration of 6 hours.

Charge the driver in accordance with the following guidelines:

- Charge the driver with the supplied charger only.
- Before first use, remove the driver from its packaging and verify that it is fully charged.

To charge the driver:

- Connect the USB-C plug of the supplied charger to the driver's charging port.
- Plug the charger into a mains power outlet.

When the driver begins to charge, the screen lights up brightly and displays the battery icon:

After approximately 3 minutes, the screen dims. To refresh the display, briefly press the ON/OFF button.

During charging the battery icon fills gradually.

Charging takes about 2 hours. When the battery is fully charged, the battery icon appears full.

The UroShield® should be recharged from mains power when the internal battery capacity is less than 10%.

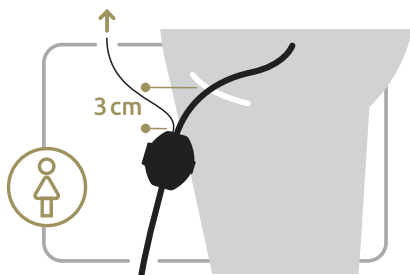
7.2 CONNECTING THE UROSHIELD®

- 1 UroShield® application should occur after catheter insertion into the bladder.
- 2 Remove the actuator from its packaging.
- 3 Remove the two protective strips from the inside of the actuator. (fig.2)



fig.2

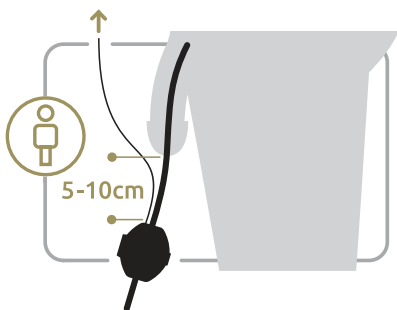
- 4 Place the actuator on the catheter in accordance with the following:



Operation

7

For women, make sure that there is 2 to 3 cm of space between the actuator and the point where the catheter exits the body.



For men, make sure that there is 5 to 10 cm of space 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.

- 5** 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 into the driver, ensuring that the plug is correctly orientated in relation to the socket, and that the plug is fully inserted and secured.
(fig.3)

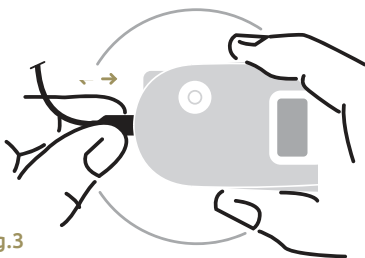


fig.3

- 9 Connect the supplied charger to the driver charging port. (fig.4)

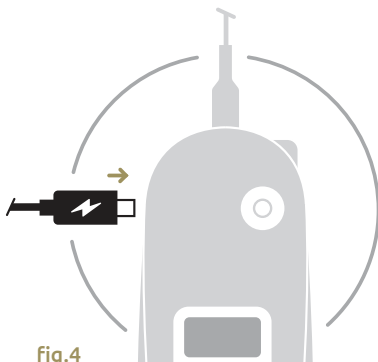


fig.4

- 10 Plug the charger into the mains power.
- 11 The UroShield® driver will automatically turn on, showing the following screens sequence.

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UroShield
Ver: XX.05

Operation 7

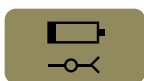
The UroShield® is now working and charging at the same time. The UroShield® is supplied with a small amount of charge, to fully charge the battery it takes approximately 2 hours.

SWITCHING THE UROSHIELD® ON OR OFF

7.3

To switch the UroShield® ON, when the driver is turned off and not connected to the mains, press and hold the ON/OFF button for 2–3 seconds.

After the intro sequence, the driver display shows the status of the battery and actuator connection as shown in the following screen:



If another screen appears instead of the above, see section 7.5 Alerts and Troubleshooting.

After another 3 minutes, the display shows the screensaver:



Note: when the screensaver is shown, you can return to the battery/actuator status by pressing the ON/OFF button briefly for less than 2 seconds.



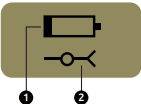


Instruct the patient as follows:

- The actuator should not be pulled.
- The actuator should not be disconnected from the driver, except for bathing.
- The ON/OFF button should not be pressed unless the patient or clinician needs to turn the device on or off.

7.4 MONITORING THE UROSHIELD®

The following information explains the symbols and text that may be displayed on the driver display during normal functioning of the UroShield® at various times.

Driver Display Glossary

	<p>Manufacturer name</p> <p>Displayed briefly when you switch ON the driver.</p>
	<p>Product name Software version number</p> <p>Displayed briefly in the interval before the information display appears.</p>
	<p>Battery</p> <ul style="list-style-type: none"> ① Battery charge indicator ② Actuator status = correctly connected and correctly working. <p>The UroShield® is ON.</p>
	<p>Battery charge indicator</p> <p>The battery is charging. The UroShield® is OFF.</p> <p>The battery icon fills gradually to show charging progress.</p> <p>If the screen has dimmed, you can brighten it by pressing the ON/OFF button briefly (that is, for less than 2 seconds).</p>
	<p>Screensaver</p> <p>The UroShield® is ON. You can show the battery charge indicator and actuator status by pressing the ON/OFF button briefly (that is, for less than 2 seconds).</p>

ALERTS AND TROUBLESHOOTING

7.5

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:

**Explanation**

The battery has less than 10% capacity.

Action Required

Connect the driver to the mains power supply with the supplied AC charger.

**Explanation**

This icon appears for several seconds when the battery has less than 5% capacity left. The UroShield® then shuts down automatically.

Action Required

Connect the driver to the mains power supply with the supplied AC charger.

**Explanation**

Actuator malfunction. The actuator is not connected to the driver or is damaged.

Action Required

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.

7.6 DISCONNECTING THE UROSHIELD®

- 1 Switch OFF the UroShield® to prevent the driver from sounding an alert when it is disconnected from the actuator.
- 2 Hold the driver in one hand and the actuator cable plug in the other hand, then pull them apart. (fig.5)

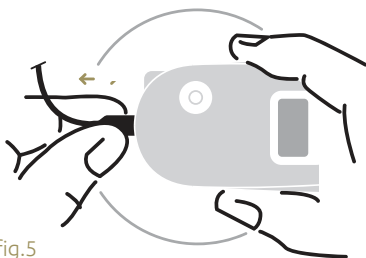


fig.5

7.7 SHOWERING AND BATHING

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

- 1 Before entering the bathroom, switch OFF the UroShield® driver.
- 2 Disconnect the UroShield® 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. Prior to reconnecting the actuator back to the driver, wipe off any water from the connector on the actuator cable. After reconnecting the driver, turn on the driver to make sure the display shows the actuator being properly connected the actuator is functioning normally.

**Question**

Can the UroShield® be used with catheters made of any type of material?

Answer

The UroShield® can be used with catheters made of uncoated silicone, polyvinyl chloride (PVC), latex rubber, siliconized latex, and all other catheter materials.

Question

What catheter sizes can the UroShield® be used with?

Answer

The UroShield® can be used with urinary catheter sizes 12, 14, 16, 18, 20, and 22 French.

Question

Can the actuator be reused after catheter removal?

Answer

No. The actuator is for use with a single catheter only and should be disposed of when the catheter is replaced. A physician or healthcare provider should be consulted prior to disconnecting UroShield® actuator for reasons other than routine catheter replacements.

9.1 UROSHIELD® ELECTROMAGNETIC EMISSION

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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.

Emissions test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR-11	Group 1	The UroShield® uses 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.
RF emissions CISPR-11	Class B	The UroShield® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

UROSHIELD® ELECTROMAGNETIC IMMUNITY

9.1

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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.

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment Guidance
Electrostatic discharge (ESD), IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 6100-4-4	2 kV for power supply lines 1 kV for SIP/SOP lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line (Class II ME equipment)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	0 % UT for 0.5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. During system charging, it is recommended that the UroShield® is powered from an uninterruptible power supply.
Power frequency magnetic field, IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the AC mains voltage prior to application of the test level.

9.1 UROSHIELD® ELECTROMAGNETIC IMMUNITY

Table 3

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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.

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6	<p>3 Vrms</p> <p>150 kHz to 80 MHz</p> <p>6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz) and amateur bands (1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz)</p>	<p>[V] = 3 Vrms</p> <p>[V] = 6 Vrms</p>

UROSHIELD® ELECTROMAGNETIC IMMUNITY

9.1

Table 4

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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.

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-3 Radiated RF	10 V/m 80 MHz to 2.7 GHz	[E] = 10 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
5785 MHz		

9.2 UROSHIELD® DRIVER & ACTUATOR SPECIFICATIONS

UroShield® Driver



Frequency	91 kHz \pm 5 kHz, modulated by 30 Hz
Voltage output	12 V p-p
Rechargeable battery	Lithium-Ion, 3.7 V, 1250 mAh (full charging time ~ 2 hours)
Dimensions	137 mm (L) x 47 mm (W) x 21 mm (D)
Weight	Approximately 85 g
Housing	ABS

UroShield® Actuator

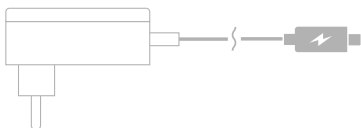


Dimensions	42 mm (L) x 34 mm (W) x 15 mm (D)
Weight	20 g
Housing	Polypropylene

UROSHIELD® CHARGER SPECIFICATIONS

9.2

UroShield® Charger



Voltage input	100-240 VAC, 0.4-0.2 A, 50/60 Hz
Output	5 VDC, 2.4 A

Note: Use an appropriate adaptor for local mains.

UROSHIELD® PRODUCT CLASSIFICATIONS

9.2

Classification & Compliance

Product classification

Low risk device classification: CE mark – Class II a

Compliance with standards

EN 60601-1; EN 60601-1-2

9.3 UROSHIELD® SYMBOL INDEX

	Refer to instruction manual/booklet
	Type BF applied part
	Rated frequency or rated frequency range(s) (Hz)
	The product must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substance, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner. Consult your municipal authority or your dealer for information about disposal.
	Manufacturer
	Authorized representative in the European Community
	LOT
	Serial Number
	Do not reuse
	Date of Manufacture: YYYY-MM-DD
	Use by YYYY-MM
W	Watt (1W = 1000mW)
0.4W	Power output 0.4 watts
kHz	Kilohertz (1 kHz = 1000 Hz)
	Keep dry
IP22	IP rating per IEC 60529

UROSHIELD® WARRANTY

9.4

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

The liability of NanoVibronix under this warranty is limited to the replacement (at NanoVibronix's choice) of any allegedly defective part or parts under warranty by NanoVibronix at its expense. The defective driver must 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, unauthorized use, negligence or accident (including but not limited to fire, water, explosion, smoke, or vandalism), or which has not been operated in compliance with NanoVibronix instructions for use.

Without derogating from the above, this warranty is void, if at any time anyone other than NanoVibronix authorized personnel removes the product casing and/or attempts to make any internal changes, removals, attachments or additions to the product or its components.

Cat. # 20-100-0006

Ver. 08



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www.nanovibronix.com

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NANO*VIBRONIX*[®]
Therapeutic Waves in Motion

URO**S**HIELD[®]