Mamba[e]

OmniSpec

ED-1000

Omnispec™ Model

ED1000

OPERATING MANUAL

REVISION COO

GROUNDBREAKING TECHNOLOGY

Within Reach

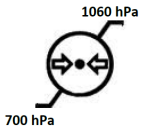
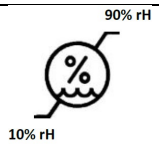
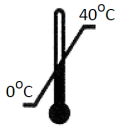

MEDISPEC

The treatment procedures and clinical practices specified in this manual should be considered as recommendations only and must be determined and implemented by the physicians supervising the treatment.

This manual may be amended by the company without prior notice at any time.

Warning: Product liability claims, warranties as well as guarantees made by 3D Medical Technologies Inc. with respect to the product are voided, if it is not used, serviced or maintained in accordance with the instructions in this manual.

LABELS AND SYMBOLS

	Manufacturer
	Manufacturing Date
	This label indicates that the user must refer to the Warnings Section
	Danger Very High Voltage
	Type BF applied part classification
	Equipotential Terminal
	Consult Instructions for Use
	Electrical and Electronic Equipment. Do NOT dispose of in the Municipal Waste Stream
	Keep away from sunlight
	Store in atmospheric pressure range of 700-1060 hPa
	Store in relative humidity range of 10-90%
	Store in temperature range of 0-40°C
	Date of expiry
	Mass of mobile Medical Electrical (ME) equipment (per IEC60601-1)

Note: Images are subjected to change without notice

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1 INTRODUCTION

The MAMBA Omnispec ED1000 is a device designed to deliver non-invasive, extracorporeal, low-intensity shock wave therapy (ESWT).

2 CLINICAL INFORMATION

2.1 Indications for Use

MAMBA Omnispec ED1000 is intended for use as as alternative/complement therapy to relieve vasculogenic erectile dysfunction (ED).

2.2 Contraindications

- Patient with penile tumor
- Patient with prostatic tumor.
- Patient with testicular tumor.
- Patient with local tumor at the treatment area.
- Patient with skin wound at the treatment area.
- Patient with infection at the treatment area.

2.3 Warnings

1. Operators of the MAMBA Omnispec ED1000 should be proficient with the anatomy of the treated area, and skilled in the proper use of the device, in delivering the appropriate number of shocks in the correct energy intensity, to the target area to be treated.
2. Shockwave therapy with the MAMBA Omnispec ED1000 is indicated by and performed under the supervision of a trained physician.
3. Treatment of the following patients shall be subjected to the treating physician discretion, taking into consideration their bleeding tendency. The physician may consider changing anticoagulant regimen prior to shock wave treatment:
    a. Patients having INR > 2.5, prolonged partial thromboplastin time (PTT) or prolonged bleeding time and platelet count less than 100,000 per microliter.
    b. Patients receiving an anticoagulant or antiagregant therapy (e.g., aspirin).
4. The operator should direct the center of applicator membrane (which represents the focal point) towards the center of the treatment area. Mild misdirection will not significantly change the quality of the results, since the MAMBA Omnispec ED1000 maintains a wide focal area, which still has a therapeutic effect.
5. The operator should avoid directing the focal point of the device to areas other then those specified in the treatment procedure.
6. If patient experiences severe pain/discomfort at the shockwave application site during treatment, the system operator should consider interruption or termination of treatment.
7. Shockwave therapy is not recommended in patients under the age of 18.
8. Shockwave therapy should not be used in patients who will undergo surgery or radiotherapy treatment in the pelvic region.
9. Air-filled interfaces in shock wave path: Do not apply shock waves to air-filled areas of the body, i.e., intestines or lungs. Shock waves are rapidly dispersed by passage through an air-filled interface, which can cause bleeding and other harmful side effects.
10. In case of patient's history of allergic reaction to alcohol we recommend using non-alcoholic disinfectants.

2.4 Precautions

1. Do not remove any of the cabinet covers. The high-voltage power supply circuits, utilized by extra corporeal shock wave systems use voltages that are capable of causing serious injury or death from electric shock.

2. If the device malfunctions during treatment or the treatment is discontinued, the therapeutic effects may not be as noticeable.
3. Electromagnetic interference: This device may cause electromagnetic interference to electronic devices.
4. Cross contamination: Patients with skin infection in the treatment area should be taken with precautions in order to avoid cross-contamination.
5. High voltage: The MAMBA Omnispec ED1000 generates high-voltage that can be hazardous and cause serious injury or death from electric shock. The power unit should NEVER be opened, except by properly trained and authorized service personnel.
6. Maintenance: For continuous and safe operation, regular maintenance and inspection by 3D Medical Technologies Inc. authorized technicians is required. For the maintenance procedures and schedule refer to the Maintenance chapter of this manual and to the Service Manual.
7. Fire Hazard: The treatment room must be free of flammable or explosive substances such as volatile solvents, anesthetic gases, etc.
8. Coupling Media: Coupling media should be used to couple between the SWA membrane and patient skin. Regular water-based ultrasound gel can be used.
9. Cleaning and Disinfection: In order to prevent cross-contamination, it is important to follow both cleaning and disinfection procedures. Refer to the "Cleaning and Disinfetion" chapter of this manual.
10. Gloves: To reduce the affect of shock wave energy on the operator hands it is strongly recommended to wear single use gloves during the treatment procedure.

2.5 Recommended Treatment Protocol & Expected Results

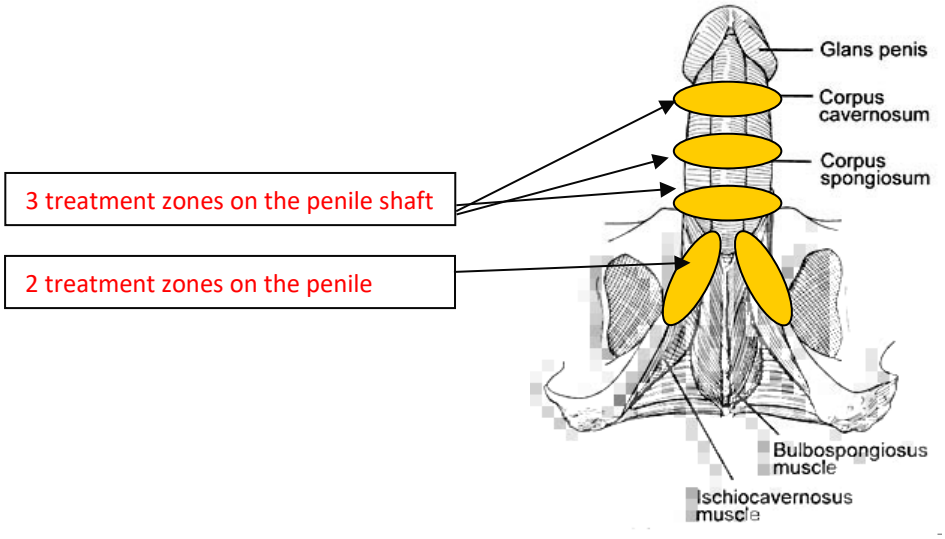
2.5.1 Treatment Design

It is recommended to perform 12 treatment sessions over a period of nine weeks. Each treatment session should last approximately twenty minutes, so that total treatment time is approximately 240 minutes. Treatments should be administered on a bi-weekly basis, on weeks 1, 2, 3, 7, 8 and 9. Weeks 4, 5 and 6 should serve as an interval period, where treatments should not be administered. The table bellow demonstrates treatment schematic:

Week 1						Week 2						Week 3					
	Tr. 1				Tr. 2		Tr. 3				Tr. 4		Tr. 5				Tr. 6	
Week 4, Week 5, Week 6 Interval – No treatments																		
Week 7						Week 8						Week 9					
	Tr. 7				Tr. 8		Tr. 9				Tr. 10		Tr. 11				Tr. 12	

2.5.2 Treatment Zones

Treatment should be applied to a total of five treatment zones at each treatment session. Two zones are treated on the penile crura and three zones are treated on the penile shaft. Treatment of the penile shaft must not include the glans penis. The shaft and the crura will be treated in the same treatment locations throughout treatment period.



2.5.3 Number of Shocks per Treatment

300 shockwaves should be applied to each treatment zone, to a total of 1,500 shocks per treatment session (300 shocks x 5 treatment zones).Treatment parameters will be as follows:

A. Energy intensity: 0.09 mj/mm^2
B. Treatment Frequency: 120 PPM.
C. Number of shockwaves: 300 shocks per treated location, to a total of 1,500 shocks per treatment session (300 shocks x 5 treatment locations).

2.6 Expected Treatment Results

Vardi, Y et al.[1] investigated the effect the MAMBA Omnispec ED1000 treatment modality in subjects diagnosed with Erectile Dysfunction. Data collected in those clinical suggested that treatment with the MAMBA Omnispec ED1000 was both safe and effective in patients diagnosed with Erectile Dysfunction. Results demonstrated a significant improvement in erectile function and treatment satisfaction based sexual questionnaires. Long term follow ups demonstrate that improved scores of sexual questionnaires were maintained at 1, 3, 6 and 12 months post last treatment[2]. Efficacy results suggest high response rate (>70%) to treatment, sometimes as early as second treatment. Table 1 illustrates improvement in sexual questionnaire scores from baseline to 1 month post last treatment in a single-arm investigation.

Questionnaire	Baseline Score ± SD	Score at 1 month FU ± SD	% Change	*p* value
IIEF ED Domain	13.5± 4.1	20.9 ± 5.8	55	< 0.001
Total IIEF	39.3 ± 8.7	54.7 ± 11.7	39	< 0.001
QEQ	32.9 ± 18.2	61.4 ± 25.8	83	< 0.001
RS	1.45 ± 1.0	2.7 ± 1.1	86	< 0.001
SEAR	36.0 ±10.4	46.5 ± 11.3	32	< 0.001

Table 1 - Improvement in sexual questionnaire scores from baseline to 1 month post last treatment.

Results collected from all studies showed no evidence of harmful effects to treated tissues.

2.7 Possible Side Effects

Possible side effects may include:

- Urethral bleeding
- Bruising
- Skin discoloration due to petechiae
- Haematoma
- Pain

1 Vardi, Y., Apple. B., Giris. J., Massarwi. O., Gruenwald. I. Can low-Intensity Extracorporeal Shockwave Therapy Improve Erectile Dysfunction? A 6-months Follow-up Pilot Study in Patients with Organic Erectile Dysfunction. Eur Urol 2010 Press Release.

2 Vardi, Y. Is Low intensity Shockwave Therapy a Curative Treatment for Erectile Dysfunction? 14th World Meeting of the International Society for Sexual Medicine, Seoul. South Korea, September 2010

3 SYSTEM DESCRIPTION

The MAMBA Omnispec ED1000 system (Figure 3-1 and 2-2) consists of the following main parts:

- Power Unit
- User Control Panel
- Foot Switch (optinal)
- Connections Panel
- Shock Wave Applicator (SWA) + holder
- Handles
- Swivel casters with brakes
- Consumables & Accessories

  Note: The user control panel screen has an option of tilt that can be adjusted according to the operator's preference.

Figure 3-1: MAMBA Omnispec ED1000 system – front view

CAUTION: Power Unit contains high voltage generator (HVG). Do not open power unit covers.

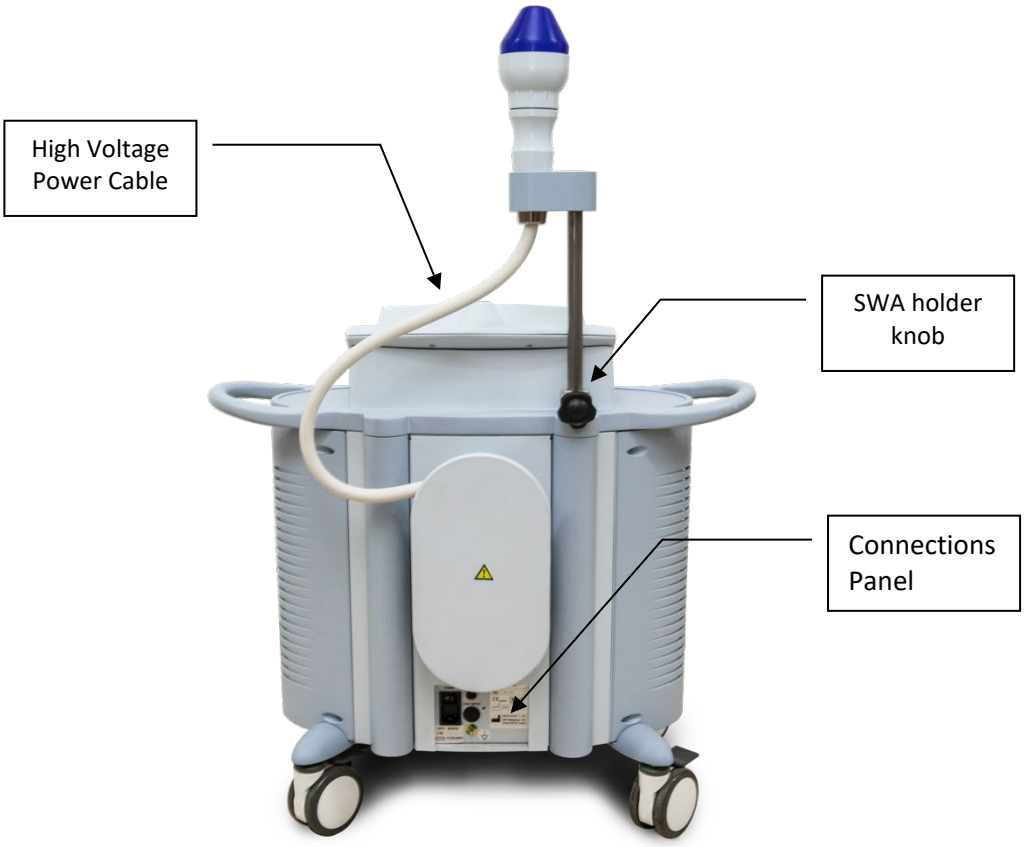


Figure 3-2: MAMBA Omnispec ED1000 system – Rear view

3.1 Power Unit

The Power Unit includes High Voltage Generator and other electronic and mechanical sub-systems of MAMBA Omnispec ED1000™.

The High Voltage Generator should be replaced only by authorized qualified, trained personnel.

Warning:
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth

3.2 User Control Panel

The User Control Panel with its touch screen provides system information and treatment controls (Figure 3-3). It provides access to several screens and supportive windows:

- Main / Treatment screen (Figure 3-3)
- System Information Screen (Figure 3-11)
- Time setting screen (Figure 3-12)
- Technician Screen (password protected for technicians)
- Window for presetting the Countdown Counter (Figure 3-7)

The LCD is coated with delicate film and should be operated with clean fingers. Refrain from pointing on screen with sharp tools.

Figure 3-3: User Control Panel

3.2.1 Main / Treatment Screen

After the system was turned ON, the main screen (Figure 3-4) appears. At this stage, it is in "idle" mode: the operation button is enabled but high voltage is not active.

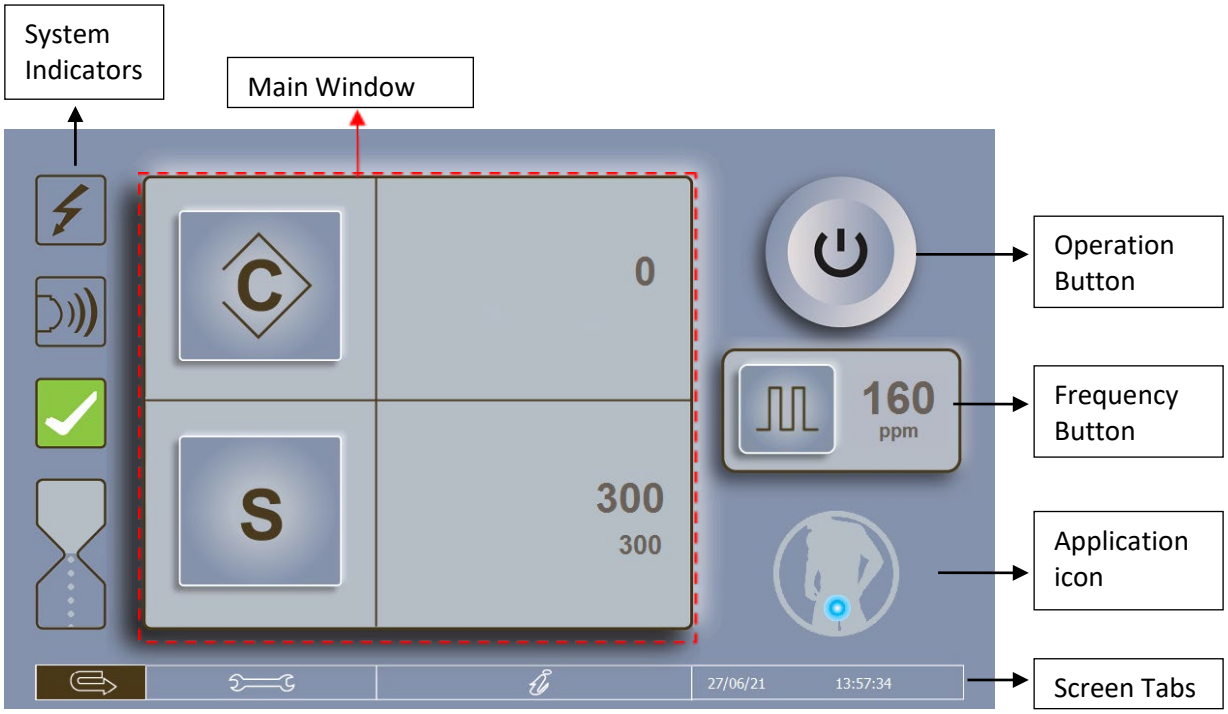


Figure 3-4: Main Screen – Idle mode

To proceed to treatment mode press the operation button. Now the high voltage will become active (voltage indicator turns yellow) and the operation button will turn green. (Figure 3-5).

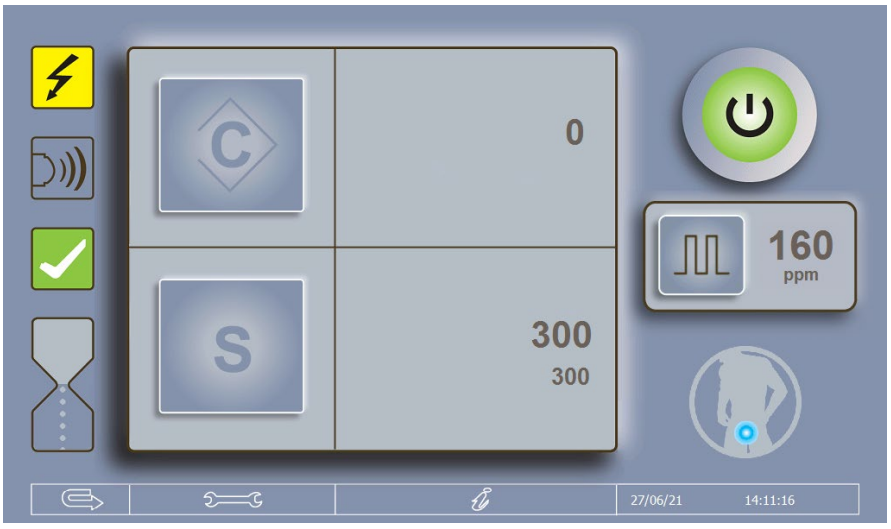


Figure 3-5: Main Screen – Treatment mode

To startshockwaves delivery press on the Operate Button of the Hand Switch. Notice that the trigger indicator turns blue. (Figure 3-6).

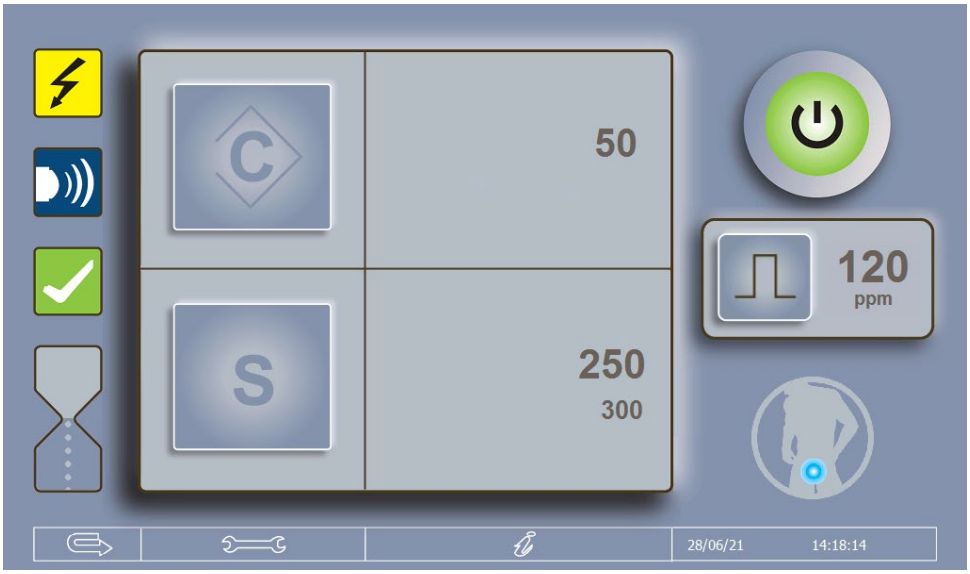


Figure 3-6: Main Screen – Active mode

3.2.1.1 System indicators

	High voltage indicator	high voltage is not active (default)
		high voltage is active
	Trigger indicator	shockwave is not active (default)
		shockwave is active (blinks with every shock applied)
	System Status Indicator	OK status
		System error /warning /failure (touch the indicator and a pop up message will appear)
		system error – operation is disabled (touch the indicator and a pop up message will appear)

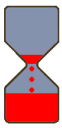
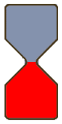
	SWA capacity indicator	SWA with full capacity
		SWA with less than full capacity
		SWA balance is less than 5000 OR SWA is less than 1 month from expiration
		SWA has zero balance and should be replaced.

Table 3-1: System Indicators

3.2.1.2 Main Window

The main window (Figure 3-7) contains buttons for: resetting the treatment total counter and to set Countdown Counter value. It displays the Total Treatment Counter and a Countdown Conunter (when using the Countdown mode).

Figure 3-7: Main window (countdown mode)

3.2.1.2.1 Set Countdown Counter

This button allows to preset the number of shocks in the "Countdown" mode and to change to "Countup" mode. In "Countdown" mode the default value is 300. To change this , touch the Set Countdown Counter button. A new window with numeric pad will appear (Figure 3-8). Type the number and press enter to return to the main screen. To set "Countup" mode leave the numeric field empty or type "0" and then touch Enter to return to the Main Screen.

Figure 3-8: Window for presetting the Countdown

Figure 3-9 (A+B) bellow show the main screen in "countup" and "countdown" modes.

Figure 3-9 (A): Countup mode
50 shocks were applied

Figure 3-9 (B): Countdown mode
50 out of 300 shocks were applied (250 shocks left)

When the preset number of shockwaves was completed, shockwaves delivery will stop and the Set Countdown Counter value button will change to Reload button (Figure 3-10). Touch it to reload the Countdown Counter (or press on the left pedal) and press the right pedal to restart shock delivery.

Figure 3-10: Main screen waits reloading

3.2.1.3 Operation Button

The operation button has three optional statuses which are listed in the following table.

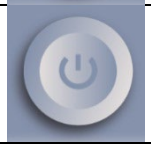
	Enabled for operation. Touch to start shockwaves delivery
	Active during shockwave delivery
	Disabled for operation

Table 3-2: Operation button statuses

3.2.1.4 Frequency Button

The MAMBA Omnispec ED1000 shockwaves can be triggered in two different frequencies: 120 or 160 PPM (pulses per minute).
To change the frequency, touch the frequency button (Figure 3-11).

Figure 3-11: Frequency button

3.2.1.5 Screen tabs

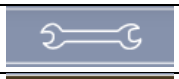
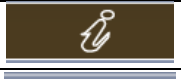
	Return	Main Screen is displayed
		Touch to return to Main Screen
	Technician	Technician screen is displayed
		Touch to access to technician screen
	Information	Information screen is displayed.
		Touch to access to system information screen (Figure 3-10).
	Time / Date Display	Double click to access Time setting screen. (Figure 3-11).

Table 3-3: Screen Tabs

3.2.2 System Information Screen

This screen (Figure 3-12) displays information in two sections:

- System information (upper section)

- Device expiration date
- S/N (System serial number)
- Total number of pulses applied by the system (this number will appear for 5 seconds after you touch the machine icon)

- SWA information (lower section)
  - S/N (SWA serial number)
  - Number of shocks left
  - Expiration date (see appendix)

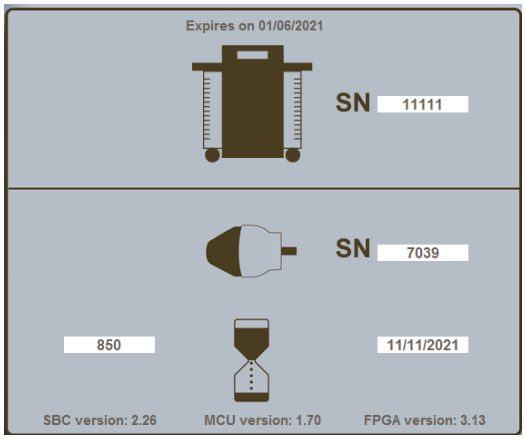


Figure 3-12: System information screen

3.2.3 Time Setting Screen

This screen (Figure 3-13) enables setting the current time. To access this screen, double click the date/time display on the main screen. After setting the time, press "Enter" to save and return to the main screen.

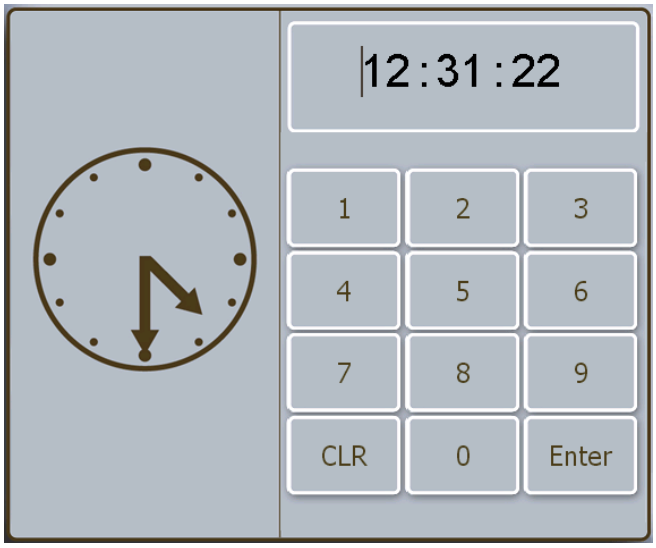


Figure 3-13: Time setting screen

3.2.4 Error Messages

For Error messages screens refer to the troubleshooting chapter of this manual.

3.3 Hand Switch

Shockwaves delivery is controlled by the Operation Button together with the Hand Switch. The Hand Switch is integrated in the High Voltage Power Cable (Figure 3-14A) and contains two buttons:

Operate and Reload. To start delivery of shockwaves, touch the Operation button in the Main Screen and then press on the Operate Button. If the Hand Switch Operate button is pressed before the Operation Button of the Main Screen, an error message appears.
To stop shockwaves delivery, release the Operate Button of the Hand Switch.
The Reload Button is used to reload the countdown counter when working in the Countdown mode.

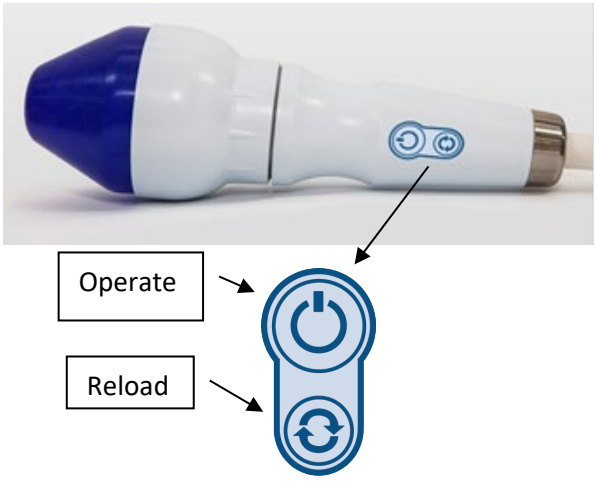


Figure 3-14A: Hand Switch and its connection port.

3.4 Foot Switch (Optional)

In similar to the Hand Switch Operate Button, shockwaves delivery can be controlled by a Foot Switch. The Foot Switch (Figure 3-14B) is connected to the Connections Panel (Figure 3-15) of the MAMBA Omnispec ED1000™.
To start delivery of shockwaves, press on the right pedal of the Foot Switch. If it is pressed before the Operation Button of the Main Screen, an error message appears.
To stop shockwaves delivery, release the Foot Switch pedal.
The Reload pedal is used to reload the countdown counter when working in the Countdown mode.

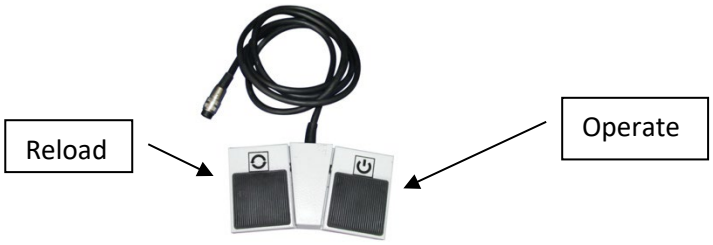


Figure 3-14B: Hand Switch and its connection port

3.5 Connections Panel

The Connections Panel (Figure 3-15) is located at the bottom of the rear side of MAMBA Omnispec ED1000™. It allows operating and servicing the system. It includes the following:

- Main Power Switch – for turning the system ON/OFF
- Fuses housing – Main fuses location (220V-5A or 110V-10A)
- Power Cable Socket - for connecting the power cable
- Foot switch connection port - for connecting the Foot switch
- Equipotential Terminal – for connecting the MAMBA Omnispec ED1000™ ground to external ground.

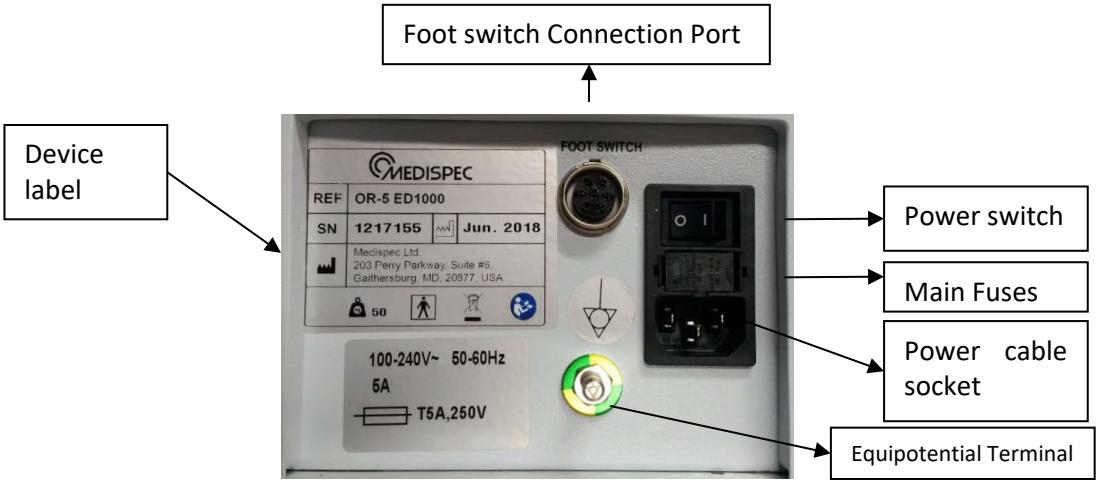


Figure 3-15: Connections Panel

Attention!
Fuse replacement shall be done only by an authorized technician. The fuse must comply with the specifications indicated on the device label.

Warning:
To avoid risk of electric shock, disconnect the Mains Power Cable from the device and from the mains outlet before replacing a fuse.

3.6 Shockwave Applicator (SWA)

The Shockwave Applicator (SWA) is the essential part of the system that generates the shockwaves and delivers them to the targeted area (Figure 3-16, 2-16). It is covered by a silicone membrane that provides close contact with the patient's skin and contains 3D Medical Technologies Inc. supplied applicator solution.
The solution is inserted to the SWA through the water port with a designated tool.
Between procedures, the SWA can be placed in the SWA holder (Figure 3-1).

The membrane is not made with natural rubber latex

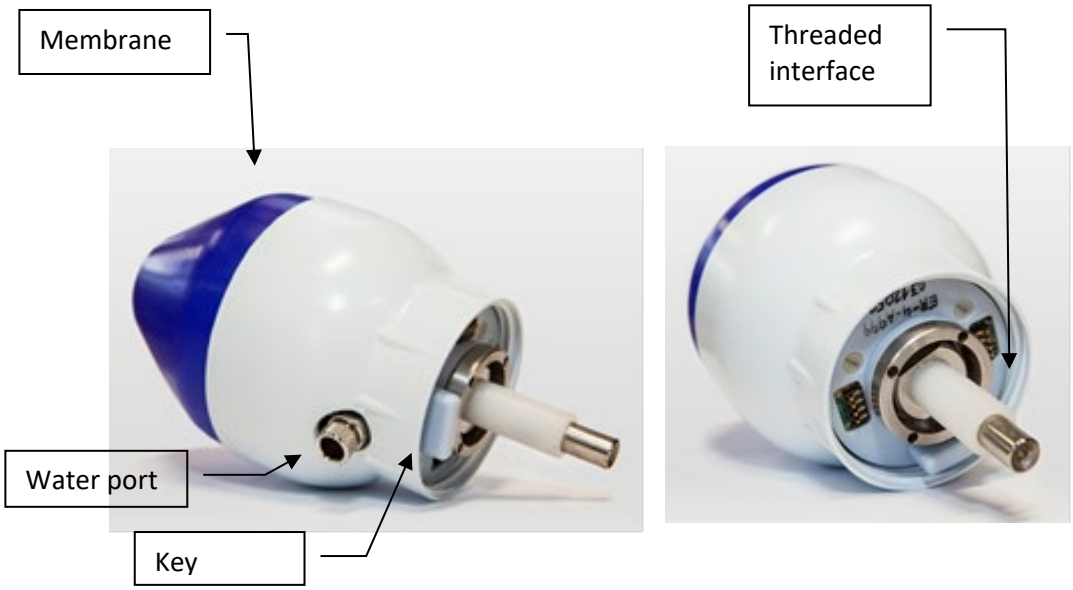


Figure 3-16 – Shock Wave Applicator

In order to connect the SWA to the High Voltage Power Cable, align the keyway of the High Voltage Connector (Figure 3-17) with the key of the SWA (Figure 3-16) and turn clockwise.
To disconnect the SWA, turn the power OFF and **wait 5 minutes**. Then, turn counterclockwise. The connection steps are shown in Figure 3-18.

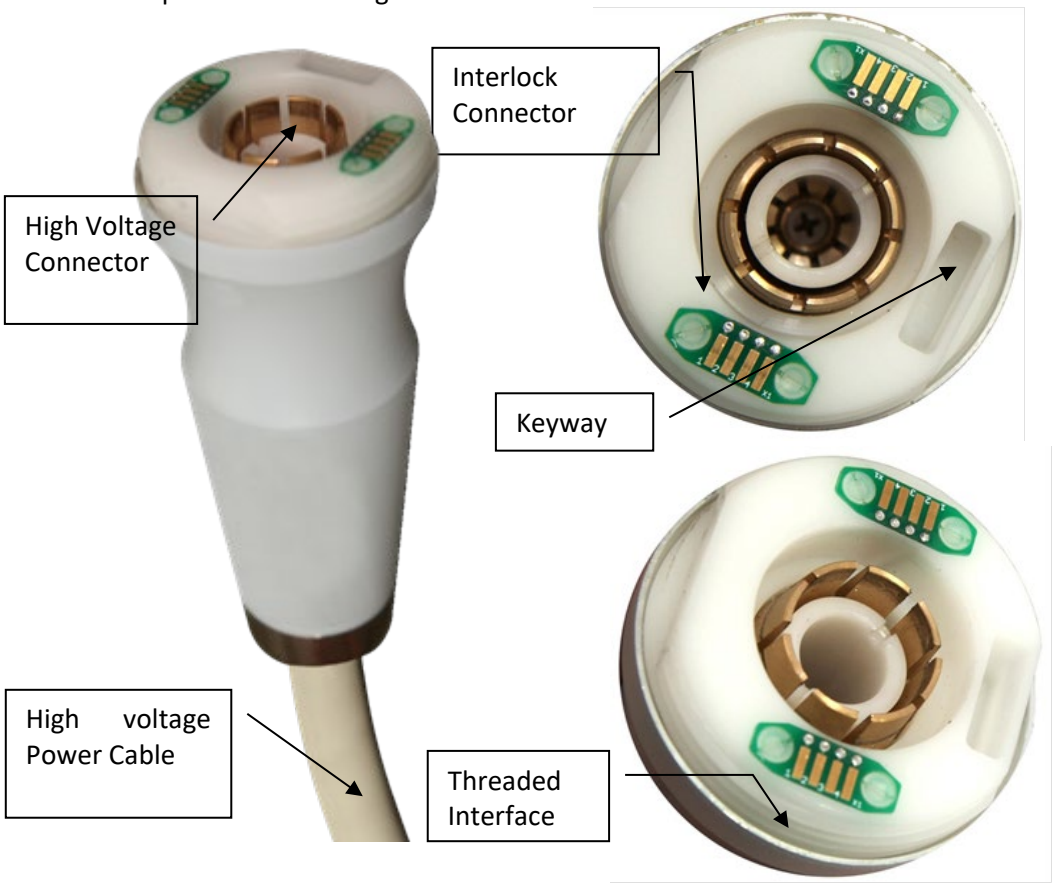


Figure 3-17: High Voltage Power Cable and Connector

Important note: Do not hold the membrane to connect / disconnect the SWA. Always hold the plastic cover.

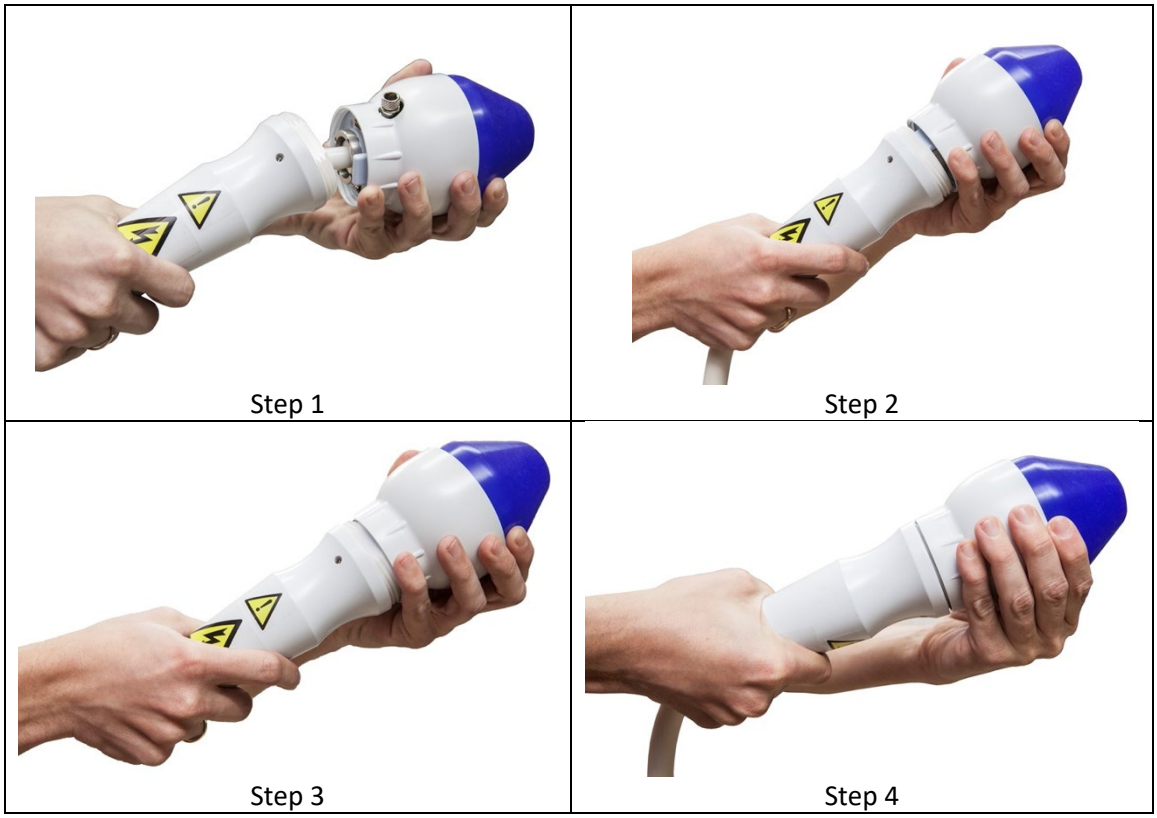


Figure 3-18 – SWA connection

WARNING! High Voltage
Before disconnecting SWA from the High Voltage Power Cable, always turn off the system AND wait 5 min after the last shockwave was delivered.

3.6.1 Shockwave Applicator Use-Life

The SWA is a disposable component of MAMBA Omnispec ED1000™system and must be replaced once its shockwaves balance is 0 or when expired (by date) whichever comes first. The user will be notified by the system when the SWA shockwaves balance decreased below 5000 shocks or 1 month before its expiry date by changing color of the SWA capacity indicator (refer to the Main Screen description in the User Control Panel chapter).
Both expiration date and shockwaves balance are displayed in the System information screen (Figure 3-11). See also "shelf life" in the appendix.

NOTE: To avoid interruption of the treatment process it is recommended to order a new SWA once the icon turns red.

3.6.2 Shockwave Applicator Carrying Case (optional)

The shockwave applicators (2 units) are supplied in a cardboard box together with: 3D Medical Technologies Inc. applicator solution container, 100 cc syringe for filling, Air Removal Tool and a measuring ring.

As an option, they can be supplied in a plastic carrying case (Figure 3-19).

Figure 3-19: SWA Carrying Case

WARNING!
Operating the SWA Applicator with water content other than specified may result in inefficient treatment.

4 SYSTEM OPERATION

4.1 System Setup

4.1.1 Shockwave Applicator (SWA) set-up

1. Attach the SWA to the High Voltage Power Cable (Figure 3-17).
2. Check for air bubbles (∅ >3mm) inside the SWA membrane and remove if necessary (refer to the Maintenance chapter).
3. Follow disinfection instructions.
4. Place the SWA in its holder (Figure 3-1).

Recommendation: Do not disconnect the SWA from the High Voltage Power Cable if not necessary.

4.1.2 MAMBA Omnispec ED1000™ system set-up

1. Position the system on a flat surface and lock the casters.
2. When using a Foot Switch - Connect the it to the Connections Panel (Figure 3-14).
3. Plug in the system to the electric outlet.
4. Turn the Power Switch ON (Figure 3-14).
5. Set the Countdown Counter to the desired value (for countdown mode) or "0" for countup mode.
6. Press Enter to return to Main Screen.

Operating the SWA Applicator with air inside may result in inefficient treatment.

4.2 SWA Disinfection

In order to prevent cross-contamination between patients, the shockwave applicator and its connector must be disinfected prior to the start of each treatment session. Disinfection procedure is as follows:

1. Be sure to use new single-use gloves.
2. Remove the shockwave applicator with its connector (handle) from its holder and hold it steadily with one hand.
3. Disinfect the following SWA sections (Figure 4-1):
    A. Silicone membrane
    B. SWA plastic cover
    C. SWA connector (handle)
4. Use sterile, single-use, disposable alcohol 70% prep wipes.
5. Wipe each section in stripes directed one-way from the top part (membrane side) of the SWA.
6. Use 1 new alcohol wipe for each wiping stripe.
7. Use several wipes to cover the whole disinfected section.
8. Do not touch disinfected areas with bare hands.

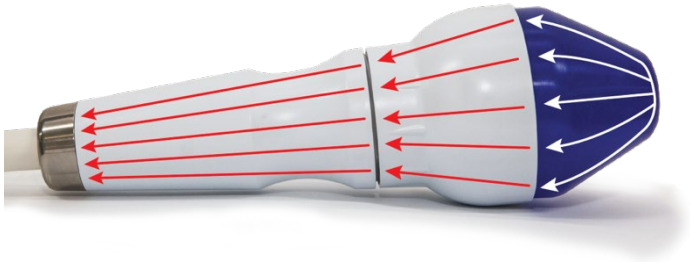


Figure 4-1: Wiping stripes direction

To avoid cross contamination, clean the SWA at the end of each treatment **and** disinfect it prior to the start of each treatment.

4.3 Treatment procedure

1. Disinfect the SWA according to disinfection procedure above.
2. Let the patient lie on a bed in a convenient position for treatment. Ask the patient not to move during the treatment.
3. Locate the treatment area.
4. Apply generous amount of ultrasound gel (2-3mm) to the treatment area.
5. Apply generous amount of ultrasound gel to the membrane for good coupling between the skin and the SWA.
6. Check for good contact between the membrane and patient's skin. Make sure there are no air pockets or wrinkles in between.
7. Press Counter reset button to clear previous counts.
8. Press Operation button.
9. Press on the Operate Button of the Hand Switch.
10. Keep the center of the membrane perpendicular to the treatment zone.
11. Apply shocks per recommended protocol for each of the treatment zones.
12. Use the reload button to apply treatment to the next treatment zone (in countdown mode).
13. Clean the SWA immediately after completing the treatment. Follow cleaning instructions below.
14. Place the SWA in its holder.
15. Use soft tissue to clean the patient treated area.

To avoid infection -
While non-sterile, multi-dose containers can be used on intact skin, they should be sealed when not in use.
Multi-dose containers should be discarded and replaced, not refilled, when empty.

4.4 SWA Cleaning (post treatment)

Do not omit post-treatment cleaning procedure. It is necessary for avoiding cross contamination between patients.

In order to prevent cross-contamination between patients, the shockwave applicator and its connector must be cleaned immediately after the end of each treatment session. Cleaning procedure is as follows:

1. Be sure to use new single-use gloves.
2. Remove the shockwave applicator with its connector (handle) from its holder and hold it steadily with one hand.
3. Use sterile, single-use, disposable alcohol 70% prep wipes.
4. Clean the Silicone membrane with several wipes until all visible foreign materials are removed.
5. Clean the SWA plastic cover with several wipes until all visible foreign materials are removed.
6. Clean the SWA connector (handle) with several wipes until all visible foreign materials are removed.
7. Do not touch already cleaned areas with bare hands.

If any foreign material has enetered the applicator cable connectors (interlock) use soft cloth to gently clean and dry it.

4.5 Shut-Down Procedure

- Press Operation button to disable high voltage.
- Turn OFF the MAMBA Omnispec ED1000™ system.
- Turn OFF the device.

5 MAINTENANCE

To maintain proper functioning of the device, several maintenance procedures are required:

- Device check-up
- SWA check up
- SWA replacement
- Device expiry date extension
- Applicator expiry date extension
- Filling applicator solution
- Adding applicator solution
- Cleaning the touch panel

5.1 Device Check-Up

Every treatment day a visual inspection of the device components should be performed. This should include:

- High Voltage Power Cable – check for any visual damage and verify proper connection to the device and to the mains.

5.2 SWA Check-up

To ensure therapeutic effect it is recommended to perform visual check-up of the SWA before each treatment session. Check for the following:

- Visual damage to the plastic cover
- Leakage from the SWA membrane
- Presence of air bubbles inside the SWA membrane – if necessary follow the procedure in "Removing Air from the SWA" section.
- If there is damage to the plastic cover, the SWA must be replaced. If there is a leakage from the membrane, the SWA must be replaced.
- Applicator cable connectors (data/interlock) - check it is dry and free of any foreign material (due to leaks or coupling media). If necessary, use soft cloth to gently clean and dry it.

5.3 SWA Preparing Procedure

5.3.1 Applicator solution

Shock waves are initiated and applied through a liquid medium.
Required liquid for refilling the SWA in water solution mixed with 5% NaCl.
The user may prepare this solution using the ingredients supplied with the:
Prepare 1 liter of Water Solution from the accessory kit:
1 x 50 gr. of NaCl (small bag), dissolved in 1 liter of distilled water.
Once prepared, the solution could be stored for future use up to 3 months.
Note:
Another option is to use the solution that supply by 3D Medical Technologies Inc. and ready for use.

CAUTION: Do no over inflate the SWA. It can damage the membrane.

5.3.2 Filling / Adding Applicator Solution

To fill the SWA with applicator solution, follow the instructions below.
Note: for adding a small amount of solution you may use the 10cc syringe that is used for removing air from the SWA (see next paragraph).

1. Take the supplied 100cc syringe and a tip-tube.

Figure 5-1: 100 cc syringe + tip tube

2. Connect the tip-tube to the SWA.

Figure 5-2: Tip tube

3. Fill the 100 cc syringe with 3D Medical Technologies Inc. supplied applicator solution.

Figure 5-3: Applicator solution

4. Remove air bubbles from the syringe if any.
5. Attach the syringe to the tip tube (on the SWA water port).

Figure 5-4: Attaching the syringe to the SWA

6. Turn the water port counter clockwise to open it.
7. Fill the SWA. Make sure no air is inserted during the procedure.

Figure 5-5: Filling the SWA

8. Turn the water port clockwise to close it.
9. Disconnect the syringe from the tip tube leaving the tip tube connected to the SWA.
10. Repeat steps 3 to 9 above until the SWA is sufficiently filled without any wrinkles in the membrane (~280 cc).
11. Disconnect the tip tube from the SWA.
12. Check for air presence inside the SWA membrane. If necessary, remove the air from the SWA (see next).

If any applicator solution has leaked on the applicator/cable connectors (data/interlock) or on the water port, use soft cloth (preferably with Alcohol) and gently absorb them.

5.3.3 Removing Air from the SWA

Presence of air in the SWA membrane will diminish the therapeutic effect of the treatment. There are two ways to detect air bubbles inside the membrane:

1. Air changes the sound of shockwaves (while membrane facing down) to a more metallic sound.

2. When turning the SWA with its membrane facing up, air bubbles will be visualized at the top of the membrane (Figure 5-6).

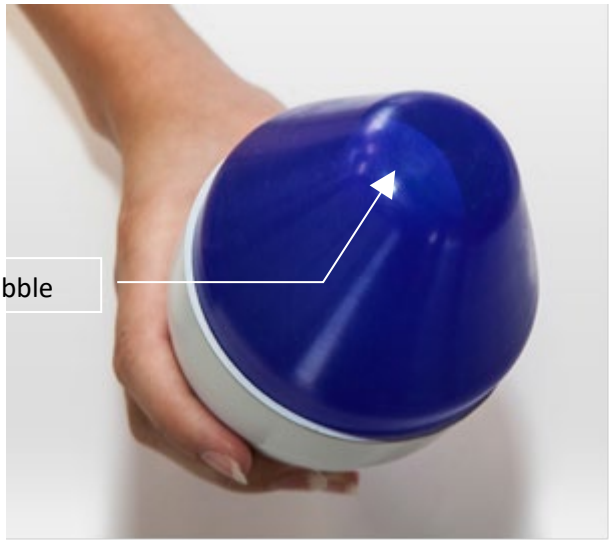


Figure 5-6: Air bubbles inside membrane

In order to remove the air bubbles use the Air Removal Tool (Figure 5-7) and follow the instructions below:

- Turn the main power OFF and wait 5 minutes.
- Disconnect the SWA from the device.
- Hold the SWA at an angle such that the water port faces upwards (Figure 5-8).

Figure 5-7: Air Removal Tool

Figure 5-8: Holding SWA at an angle + Swivel direction

- Connect the Air Removal Tool to the SWA water port. Verify it is well fitted insode the water port.

Figure 5-9: Connecting the Air Removal Tool

- Open the water port by turning it clockwise

Figure 5-10: Opening the Water Port

- Eject the air from the SWA.

Figure 5-11: Ejecting air

- Close the water port by turning it counterclockwise
- Disconnect the Air Removal Tool.
- Turn the SWA upside down and check if any air bubbles left inside the membrane.
- Repeat procedure if necessary.

5.4 SWA Replacement Procedure

- Turn off the device.
- Wait 5 minutes.
- Disconnect the SWA from the High Voltage Power Cable (Figure 5-12).

Figure 5-12: Disconnecting the SWA from the power cord

- Take a new applicator and inspect it for visual damage.
- Connect the SWA to the High Voltage Power Cable (Figure 5-13).

Figure 5-13: Connecting the SWA to the High Voltage Power Cable

5.5 Cleaning the Touch Panel

Use dry cloth or soft cloth with alcohol, neutral detergent or ethanol for clearing the touch panel in case of dirt on it. Do not use any organic solvents except alcohol.

5.6 Applicator expiry date extension

- Notice that this section refers to expiry by date only and not expiry by a number of shocks.
- When reaching expiry date of the applicator, Error #1001 (Applicator Expired) with Expiration Date will appear.
- System will show Info button in addition to the error message on the screen (See figure 5-14).
- When user presses on the "info" button:

The system will open a sub screen with the message (See figure 5-15) :
"The applicator has reached end of life, it is highly recommended to use a new applicator for optimal treatment results.
For more details, please check the system operating manual.
Continue with current applicator? "

- In the subscreen, press "Cancel" button to replace the applicator **or** "Confirm" button to continue with the current applicator.

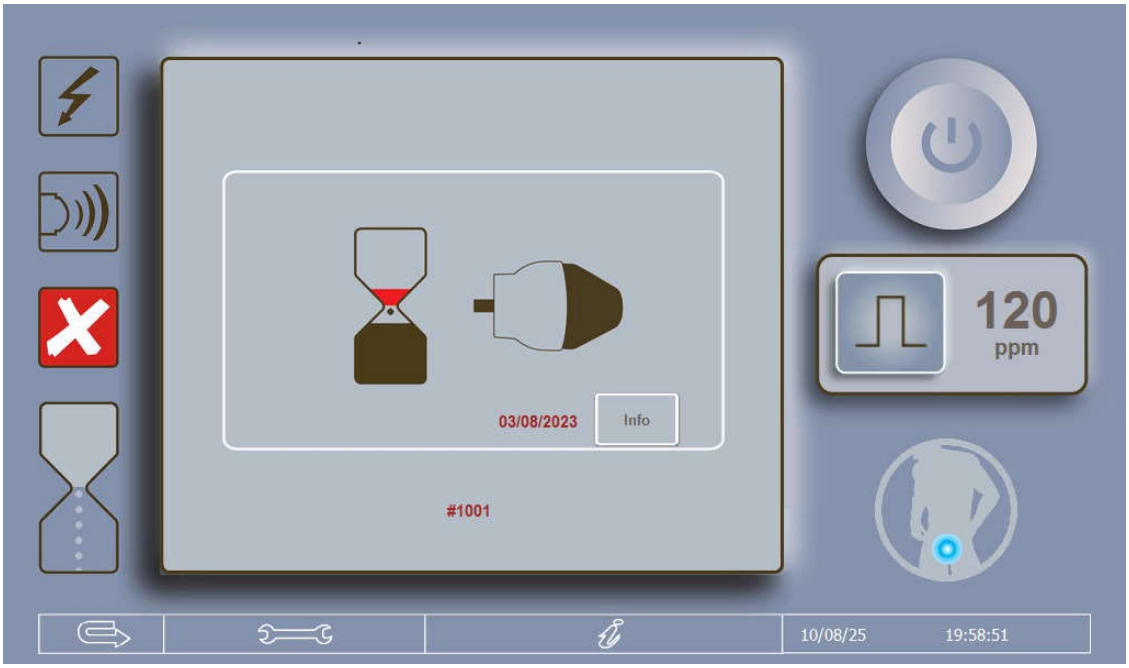


Figure 5-14: Error #1001 with expiration date

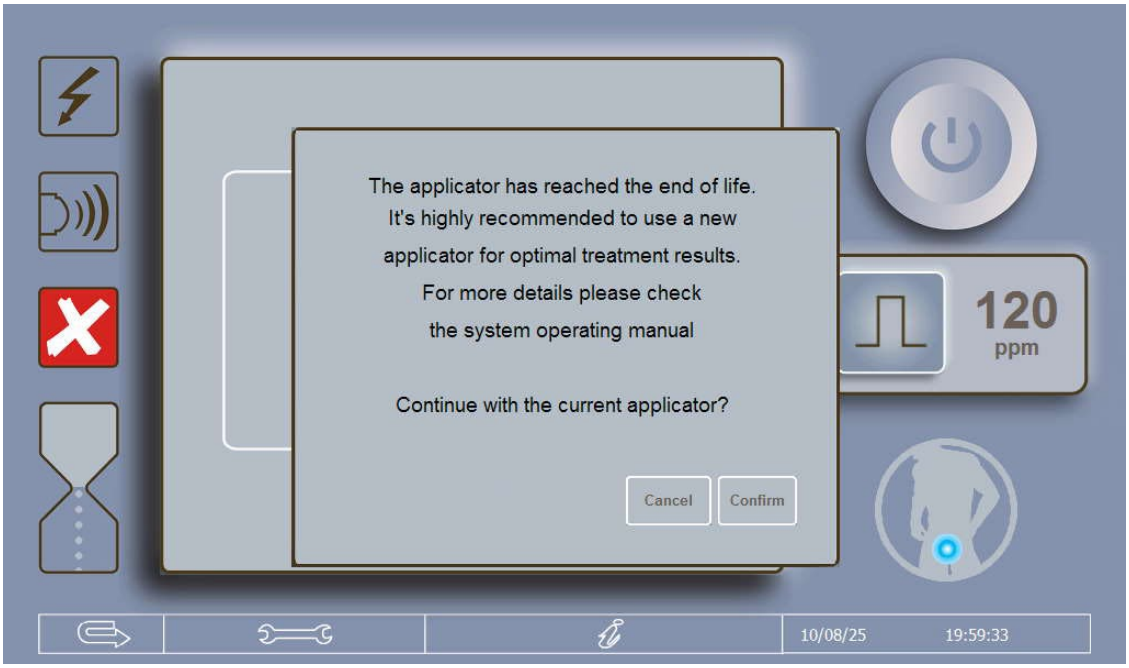


Figure 5-15: Message for applicator expiry date extension

- Before pressing confirm button, examine the applicator visually to verify that there is no physical damage or degradation of the applicator materials, and then allow extension for another month.
- After pressing the "Confirm" button the system will ignore applicator expiration by date only and extend the expiration date in one month.
- The system can allow applicator extension to one applicator only at a time.
- The extension is for one month, every month the user need to allow extension again if needed.

Optimal usage of applicator is 12 months from first use and no more than 24 months from manufacturing date.

5.7 Maintenance Schedule

Action	Frequency
Visual inspection of the device components for damage or disconnection.	Every treatment day.
Visual inspection of SWA for: • Visual damage to the SWA cover • Leakage from the SWA membrane • Presence of air bubbles with ∅ > 3mm inside the SWA membrane	Every treatment day.
SWA replacement	When its shockwaves balance is 0 or when expired (by date), whichever comes first.
Device expiry date- Entering a password code to extend the expiry date	When the device expiry date is about to arrive (By date on the information screen)
Applicator expiry date extension: If decided to extend, examine the applicator visually to verify that there is no physical damage or degradation of the applicator materials	After reaching end of life the message will appear every month
Applicator solution adding	When the amount of applicator solution becomes insufficient to fill the SWA as necessary
Cleaning the touch panel	As required

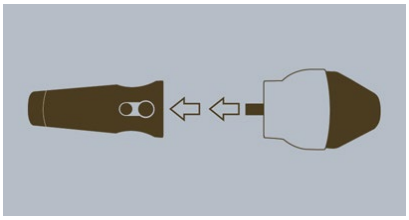
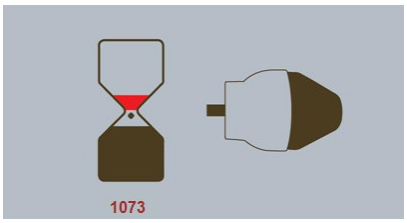
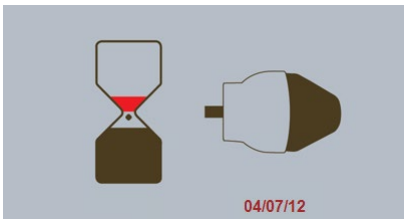
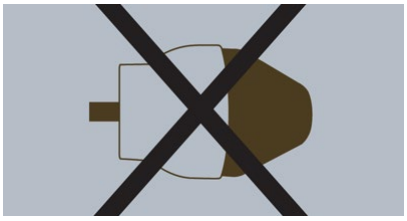
Table 4-1: Maintenance Schedule

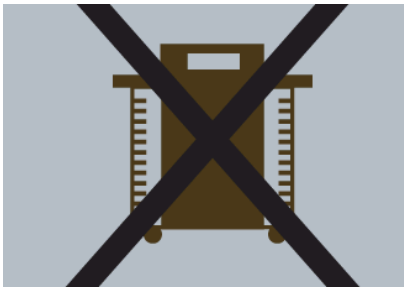
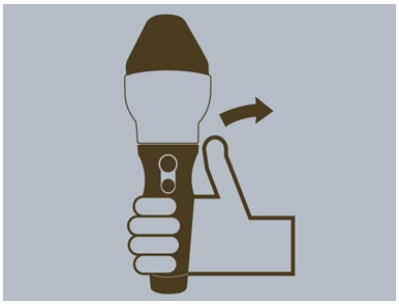
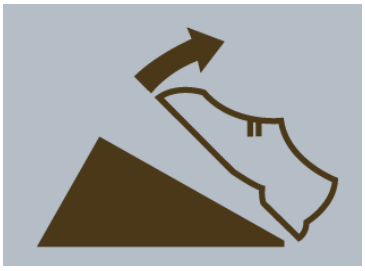
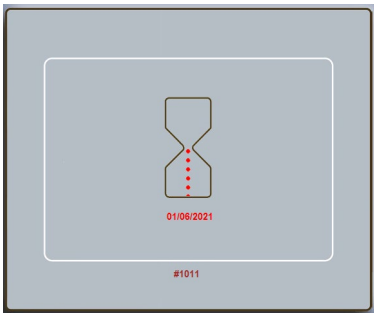
5.8 Expected Service Life

The expected service life of the MAMBA Omnispec ED1000 main unit is 7 years.

6 TROUBLESHOOTING

The following table presents some common troubles and the way to solve them. If these procedures were not found helpful or the problem persists call 3D Medical Technologies Inc. authorized technician.

Problem Observed	Solution / Suggested actions
System cannot be turned on	1. Verify that the power cable is plugged into a suitable **and live** electrical outlet and well fitted inside its socket on the Connections Panel. 2. Verify that the Main Power Switch is turned on. 3. Check the fuses and call for authorized technician to replace if necessary.
	SWA is disconnected or connected improperly. Reconnect it.
	SWA shockwaves balance is less than 5000 (balance is displayed below the icon) It is recommended to order a new SWA.
	SWA is about to expire (Expiry date is displayed below the icon) It is recommended to order a new SWA.
	SWA cannot be identified or is not properly connected Replace SWA.

Problem Observed	Solution / Suggested actions
	Hardware or operational software failure. Call service.
	The Hand Switch is pressed - Release it.
	The Foot Switch is pressed - Release it.
	The device expiry date is less than 30 days It is recommended to contact Service for a new password code.
	The device date is expired Contact Service for a new password code.

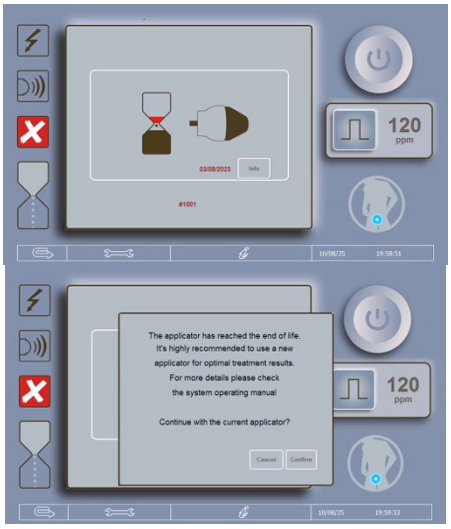
Problem Observed	Solution / Suggested actions
	The applicator has reached end of life, it's highly recommended to use a new applicator to achieve optimal treatment results. **Optimal usage of applicator is 12 months from first use and no more than 24 months from manufacturing date.** If you are still interested in applicator expiry date extension, examine the applicator visually to verify that there is no physical damage or degradation of the applicator materials, and then allow extension for another month.
Errors during operation	One of possible causes can be an electrostatic discharge. Avoid using carpets and take precautions to avoid generating electric charges on the operator/user.
Device turns off and on several times	One of the possible cause is the quality of electrical supply. Check other devices for similar behavior and contact your electricity provider.

Table 6-1: Troubleshooting table

7 PRODUCT CONTACT INFORMATION

If an adverse event occurs, such as a malfunctioning of the device, a mistake in using the device, or an injury relating to the use of the device, report the occurrence immediately. Alert the physician of any patient health issues that occur while using the MAMBA Omnispec ED1000™. For troubleshooting assistance, complaints or additional questions regarding the MAMBA Omnispec ED1000™ device, contact the Service Department:

3D Medical Technologies Inc.
Maple Ridge, BC, V4R 1P9, Canada
Email: ops@3dmedicaltech.com
Site: www.3dmedicaltech.com

Phone: 647-477-9216

APPENDIX 1: TECHNICAL SPECIFICATIONS

General	
Shockwave Source	Electro-hydraulic
Spark Voltage	13 – 24 KV
Frequency	120, 160 Pulse/minute (PPM)
Dimensions	Height: 740 mm Width: 775 mm Depth: 410 mm
Weight (without SWA)	~50 kg
Shockwave Applicator	
Dimensions	Diameter: 90 mm Length: 172 mm
Weight	1 kg
Shelf Life	Wet: 12 months after the first shockwave was delivered Dry: 24 months

Electrical Supply*	
Voltage (Volts AC)	Single Phase, 100-240
Line Frequency (Hz)	60/50
Current (Amps)	5

(*) factory set – refer to the label on your device

Compliance with Standards	
ISO 13485	
MDD (93/42/EEC) (CE)	
IEC 60601-1	
IEC 60601-1-2	
IEC 60601-2-36	
ISO 10993-1	
ISO 14971	
Electrical safety classification	 Type BF Applied Part

APPENDIX 2: ENVIRONMENTAL AND TRANSPORT REQUIREMENTS

Temperature	
Operating Ambient	10°C to 30°C (50 to 86°F)
Extended Term Storage and Transportation	0°C to 40°C (32°F – 104°F)
Short Term Storage and Transportation	-10°C – 55°C (14°F – 131°F)
Humidity	
Operating	20 to 80% relative humidity, non-condensing
Transport	20 to 80% relative humidity, non-condensing
Stability	
	Positive stability on grades up to 10 degrees when in transport position, and on grades up to 5 degrees in any position of normal use.
Altitude / Pressure	
Operating Altitude	3000 m
Operating / Transport pressure	700-1060hPa

APPENDIX 3: ACOUSTIC SPECIFICATIONS

Description	Minimum	Typical	Maximum
Peak-positive acoustic pressure (MPa)	13.3	19.6	41.7
Peak-negative acoustic pressure (MPa)	2.8	2.0	3.8
Rise time (ns)	108	39	40
Compressional pulse duration (ns)	120	136	128
Maximum focal width (mm) -6 dB	2	3	3
Maximum focal width (mm) 5 MPa	3	5.4	40.5
Orthogonal focal width (mm) -6 dB	2	3	3
Orthogonal focal width (mm) 5 MPa	3	5.4	40.5
Focal extent (mm) -6 dB	120	130	108
Focal extent (mm) 5 MPa	130	160	200
Focal volume (cm^3) -6 dB	0.25	0.61	1.69
Focal volume (cm^3) 5 MPa	0.61	1.69	164.8
Distance between the focus and target location (mm)	70	65	0
Derived focal acoustic pulse energy (mJ)	0.93	1.03	1.737
Total temporal integration limits T_T (µSec)	1.25	1.05	0.70

APPENDIX 4: INFORMATION REGARDING EMC

Do not expose Device to the EM disturbances beyond specified in EMC declarations and guidance sections. Exposure to such disturbances can cause degradation in performance of the device and lead to hazardous situation. The device is not suitable to work with HF surgical equipment, RFID tags and readers, MRI and other sources of extreme EM disturbances."

Declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group1 Class A	The OR-5 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.
Harmonic emissions IEC 61000-3-2	Class A	The OR-5 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the OR-5 or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV 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 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OR-5 requires continued operation during power mains interruptions, it is recommended that the OR-5

	Single phase at 0° 0% UT; 250/300 cycle	0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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 a.c. mains voltage prior to application of the test level.			

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the OR-5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz	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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	

			D Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between portable and mobile RF communications equipment and the OR-5				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test Friquency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ±5kHz deviation 1KHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, DECT, LTE band 1,3,4,25 UMTS	Pulse modulation 217 Hz	2	0.3	28

2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	2	0.3	9

Warning:
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning:
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OR-5, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment