Potenza™

OPERATOR MANUAL

CYNOSURE®

JMUM_PTZ_03, Rev. 1, 10/2020

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1.1 Purpose and Scope

This Operator Manual provides information on configuration, components, intended use, features, caution and instructions about how to operate the Potenza.

CAUTION	
✗	All Personnel involved with the operation or maintenance of Potenza must be thoroughly trained and understand this operator manual prior to the use of the Potenza machine.
✗	Potenza should only be used by physicians and staff who have been appropriately trained.

1.2 Potenza Overview

This Potenza is used for coagulation using high frequency current. This device consists of the main body, two types of handpieces, a handpiece (HP) holster, disposable electrodes, neutral electrodes, neutral electrode cable, footswitch and power cord. It is controlled by software. The electrosurgical unit uses separately authorised products, which operate under the principle that the coagulation of skin tissue occurs with the heat introduced by the load or contact resistance when high frequency (RF) energy is transmitted into the tissue.

1.3 Intended Use of the Potenza

Fractional RF Microneedle Electrosurgical Unit is intended for use in dermatologic and electronic surgical procedures for electrocoagulation and hemostasis.

1.4 Component List

The Potenza consists of the following components (illustrations and chart):

Main Body

Tip

Footswitch

Handpiece

Neutral electrode

TABLE 1: DEVICE LIST					
No.	Name		Quantity		Remarks
1	Main Body		1 unit		-
2	Handpiece	Motor handpiece	1 ea.		
		AC Handpiece	1 ea.		
4	Tip	I-49	5 ea.	Starter kit	Optional (Specified Parts) Applied Part
		S-49	10 ea.		
		I-25	10 ea.		
		S-25	20 ea.		
		CP-21	10 ea.		
		One needle: A1-15	5 ea.		
5		I-16	5 ea.	Optional	
		S-16	5 ea.		
		C21-2	5 ea.		
		C21-1	5 ea.		
		C9	5 ea.		
		One needle: P1-08	5 ea.		
		One needle: A1-12	5 ea.		
6	Neutral Electrode Pad		5 ea.		Applied part
7	Neutral Electrode Pad Cable		1 ea.		-
8	Footswitch		1 ea.		-
9	Powercord		1 ea.		-
10	Handpiece Stand		1 ea.		-
11	Operation Manual		1 ea.		-

2.1 General Safety

- Do not operate the Potenza before thoroughly reading and understanding this manual.
- The Potenza device should only be used by physicians and staff who have been appropriately trained.
- If a problem occurs when using the Potenza, please contact the Cynosure Customer Service.
- Do not attempt to repair and modify the Potenza.
- Unauthorised or improper repairs, changes or modification performed by unauthorised personnel may be hazardous.

2.2 Medical Safety

- There is no limit in the application of this Potenza on clients in terms of age or gender; but the physician should determine whether to use this product on a client after checking the client's health status.
- This product can be used for both men and women.
- This product can be used for both men and women without physical problems such as cardiovascular disorders.

2.3 Contraindications

Do not use this product on clients listed below:

- Clients with a pacemaker.
- Clients who have previously had a gold-thread skin-rejuvenation treatment.
- Clients with keloid formation propensity.
- Clients with skin infections.

2.4 Warnings

- Do not use the Potenza on a client with electronic implants, such as a cardiac defibrillator, without consulting with a qualified professional (i.e. cardiologist). It may interfere with the operation of electronic implants or damage the implants, causing risks.
- Since there is a risk of fire or explosion, do not use this product near flammable materials (i.e., flammable gas or anesthetic, etc.) or volatile materials (i.e., ether or alcohol, etc.).
- Store the unplugged Potenza device and equipment in a clean, dry and secure location when not in use. Incidental contact with the equipment may result in a burn.
- Check the electrical cords, equipment, accessories and cables for cracks or exposed wires, etc., before every use. Using the device with damaged cables, cords, accessories, etc., may result in a burn or other injury to clients or users.
- When RF current is not activated for a moment during operation, be careful because the surface of the active electrode may be hot enough to burn a client.
- Since injury or electric shock may occur on clients or users, connect adapters or accessories to the equipment only when the power is off.
- The treating physician is responsible for selecting appropriate and safe treatment parameters at all times.
- The power inlet must be easily accessible.

- The entire area of the neutral electrode pad should be securely attached to the client's body as close to the treatment site as possible.
- The client must not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (i.e., operating table supports, etc.).
- Skin-to-skin contact (i.e., between the arms and the body of the client) should be avoided. Place dry gauze between the parts with skin-to-skin contact.
- The cables to the electrodes should be positioned in such a way that contact with the client or other leads is avoided.
- Temporarily unused active electrodes should be stored securely in the holster and out of reach of and contact with the client.
- For surgical procedures where the high frequency (HF) current could flow through parts of the body that have a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted tissue damage.
- The output power selected should be as low as possible for the intended purpose. Certain equipment or accessories may present a safety hazard even at low power settings.
- Apparent low output or failure of the HF surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral electrode pad or poor contact in its connections.
- Before selecting a higher output power, the application of the neutral electrode pad and its connections must first be checked.
- Non-flammable agents for cleaning and disinfection are recommended wherever possible.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of the flammable solutions underneath the client or in body depressions such as the umbilicus or in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF surgical equipment is used.
- For a client with a cardiac pacemaker or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur–or the pacemaker may be damaged. When in doubt, approved qualified advice should be obtained.
- Interference of HF surgical equipment may adversely influence operation of other electronic equipment.
- For situations where the maximum output voltage is less than or equal to 1600 V, associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than the maximum output voltage.
- Failure of HF surgical equipment could result in an unintended increase in output power.
- With modes which produce electrical arcs between the active electrode and tissue, risks resulting from neuromuscular stimulation may occur.
- The following precautions are necessary to prevent burns at the neutral electrode pad (return pad) site:
    - Do not cut or modify the neutral electrode pad or its connector in any way.
    - Select an area that is free of hair and tattoos, has minimal curvature, and is appropriately distanced from the treatment area.
    - Inspect the cable and connector for any signs of damage or wear that may have produced exposed wiring or other defects.

    - Regularly check that the neutral electrode pad cable connections are intact.
    - Poor neutral electrode pad contact may lead to low RF delivery and/or a system error condition.
- When setting HF output, the maximum output voltage should not exceed the rated accessory voltage.
- Peak rated accessory voltage is 400 V.
- Unauthorised cables and accessories may have an adverse effect on electromagnetic compatibility (EMC) performance and safe operation.
- An accessory that is not manufactured by the manufacturer for use with the Potenza must not be attached to the system to prevent potential injury and/or equipment damage. Rated voltage accessories must be used.
- It is recommended that monitoring electrodes are placed as far as possible from surgical electrodes when HF surgical equipment and physiological monitoring equipment are used simultaneously on the same client.
- Operators must take care to avoid simultaneously touching any part where the current flows (i.e., fuse holder, earth, power cord, rear connector, handpiece output section, etc.).
- The essential performance of medical electrical (ME) equipment and a description of what the operator can expect if the essential performance is lost or degraded due to EM disturbances are below:
    - Monitor flicker
    - Touchscreen error
    - A warning that other cables and accessories may negatively affect EMC performance
    - A statement that portable RF communications equipment including antennas, can affect medical electrical equipment. The warning includes a use distance such as "... be used no closer than 30 cm (12 in) to any part of the ME equipment, including cables specified by manufacturer".
- For ME equipment and ME SYSTEMS that are classified as class A according to CISPR 11, the instructions for use (IFU) include the following 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."
- Strong static (15kV) electricity between the handpiece and the tip may cause some equipment to stop functioning.
- Please refer to the spec sheet provided by the manufacturer, as the output may be different from the displayed watt at the impedance that is out of the rated load (200Ω).

2.5 Caution

- For Potenza tips, check the packaging for damage and a valid expiration date before use; never use the product if the sterilised package is open or damaged or if it is past the printed expiration date.
- If the sterile package has been opened or damaged, discard the contents.
- Clients should be advised to be careful not to expose the treatment area to external stimulation for two days post treatment.
- Clients should be advised to refrain from intense exercise, hot baths or saunas, which may cause an increase in skin temperature, for five days post treatment.

- If a burn occurs on skin's surface during treatment, the operator should stop treatment immediately and care for the burn first.
- If skin swells up severely during treatment, the operator should stop treatment immediately.
- If a patient complains of severe pain during treatment, the operator should stop treatment immediately and consult with a physician.
- If a problem occurs with the equipment or on a patient during treatment, the operator should take suitable actions by ceasing treatment and transferring the patient to a safe place.
- Be advised that the surface of the treatment tips is hot enough to cause a burn after RF current has been flowing through it.
- The physician should administer treatment only after considering the status of the patient.
- A light cold pack with ice may be applied on the area of treatment if it is hot after treatment.
- Clients should be advised to refrain from drinking alcohol or taking medicine that interferes with blood coagulation, such as aspirin, for two weeks post treatment.
- Change to this product must not be made without the approval of the manufacturer. If product is changed, suitable inspection and testing should be conducted for continuous safe use of the product.
- The container, which is attached to the handpiece stand, can accommodate up to 3 kg.
- The lithium battery should be replaced by Cynosure service personnel only.
- Non-continuous mode: Activation time: Max 30min / Deactivation time: Min 10min

2.6 Precautions

If the client presents with the following, do not use this product and obtain physician's prescription before use:

- Herpes simplex
- Autoimmune disease
- Diabetes
- Epilepsy
- Pregnant and breast-feeding women
- Acute disease
- Hypertension
- Dermatitis

2.7 Potential Side Effects

- Temporary erythema: area of treatment may turn red right after treatment, but this symptom disappears within 48 hours after treatment.
- Temporary tingling: slight edema may occur right after treatment, but this symptom disappears within 48 hours after treatment.
- Burning sensation: patients may feel uncomfortable temporarily while receiving treatment.
- Mild pain while the treatment
- Post therapy bleeding
- All side effects are resolved in two days after the treatment.

2.8 Electrical Safety

POWER SAFETY

Check whether power cord is securely plugged into the outlet. Connect to a power dl source that meets device and electrical specifications. Otherwise, the equipment may malfunction.

Do not use if the electric wire is damaged in any way. It may result in a fire due to electric leakage.

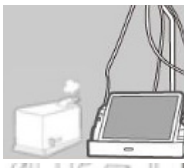
Do not plug in with wet hands. It may result in electric shock.

Do not overload electrical outlets with power cords. It may result in a fire.

INSTALLATION SAFETY

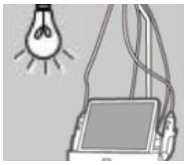
Do not place the device near an open flame.

Do not place electric wire near a heating device. Electric wires may melt and electricity may leak from exposed wires.



To prevent risk of fire, do not position or store the device near any combustible agents including oil.

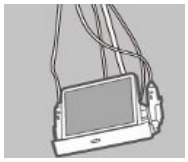
Keep the device out of direct sunlight and areas with high heat and humidity, as well as areas with high levels of dust or salty air. Store device in a well-ventilated location



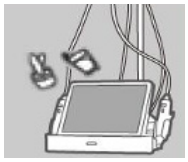
Ensure that adequate lighting is available where the device will be located and operated.

TRANSPORTATION SAFETY

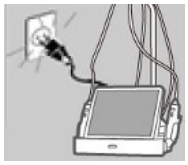
Be careful not to drop the handpiece. Lens embedded in the device may be broken.



Do not tilt the device.



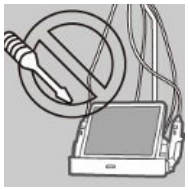
Do not pour water over the device nor place heavy things on it.



When not in use, turn the device off and unplug the power cord from the electrical outlet.

HANDLING RELATED

Do not use the device near combustible items or objects. Always have a working fire extinguisher nearby in case of an emergency



If unit is not functioning correctly, stop treatment and call customer service. Do not repair or dissemble. Service should be performed by a designated technician. Only regulated parts should be used.

Do not use unnecessary force to remove the power cord.

- Only the power cord provided by the manufacturer should be used to prevent risk of electric shock. Do not operate the equipment if the power cord is damaged or shows signs of wear.
- Use only Cynosure-supplied components and accessories.
- Since it may cause electric shock, be careful not to allow ingress of any liquid to this product
- Rated voltage of this product is AC 100-240V. Directly connect the power cord of main body into an outlet. Overloading several plugs in one socket may result in a fire.

- To avoid the risk of electric shock, the Potenza must only be connected to a supply main with protective earth.
- If disassembled or external cover opened by persons other than authorised service personnel, it may result in exposure to high voltage or high current. Never remove the cover of the handpiece or the main body.
- The Potenza meets IEC60601-1-2 for electromagnetic compatibility and is not likely to cause interference in nearby electronic equipment. However, in order to avoid any possible risk, other electronic equipment should not be stacked under or placed immediately adjacent to the Potenza.

2.9 Cautions for Installation and Transportation

- Be careful not to drop handpiece during transport.
- Do not tilt the equipment during transport.
- Keep the fire extinguisher near the product to manage a fire that may occur due to electric leakage.
- Do not keep the electric wire near any heating devices, since electric wire may be fused or short-circuited.

2.10 Preventive Check or Maintenance Repair Parts

- Motor Handpiece/AC Handpiece
- Neutral Electrode Pad Cable

3.1 Overview

The Potenza is a microneedling device which generates RF frequency of 1 or 2MHz that cause soft tissue coagulation through tissue heating. A total of 13 microneedle tips that attach to one of two of handpieces are available for treatments and should be used in accordance with the clinical reference guide (CRG). Changes to the treatment parameters can be made by adjusting the settings on the LCD user interface. Once settings are confirmed and verified by the qualified clinician, the device is placed in treatment mode and is ready for use. The microneedle tip is placed on the desired treatment site and the foot pedal is depressed to transmit RF energy to the tissue at multiple depths. The RF energy causes the molecules within the tissue to vibrate, resulting in a rapid increase in temperature; this causes coagulation of the proteins within the tissue.

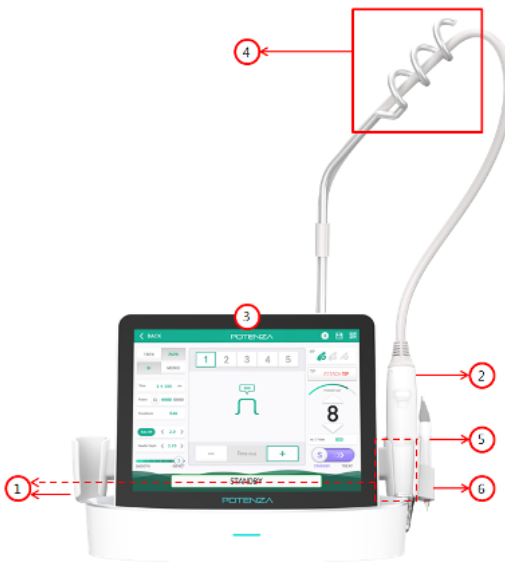
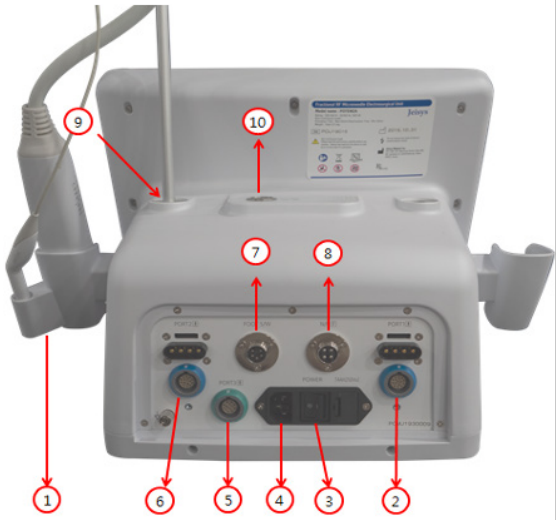
The monopolar mode requires that a neutral electrode pad be securely attached to the skin at an area adjacent to the intended treatment site, i.e. the upper back for facial treatments.

Safely power off the device by depressing the switch on the top surface of the device when not in use.

Appearance of Product

3.2 Main Body

3.2.1 Front and Rear

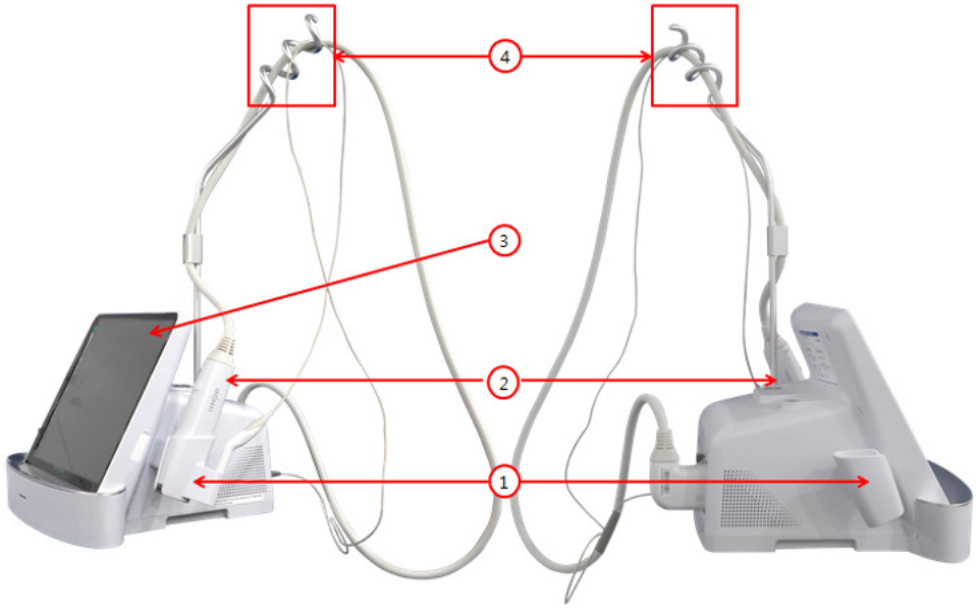
FRONT	REAR
	

FRONT		
No.	Name	Function
1	Motor Handpiece Holster	Receptacle that securely holds the motor handpiece
2	Motor Handpiece	Delivery method for the electrosurgical device, which includes mounted electrodes that coagulate the tissue using high-frequency current
3	Operation Panel (LCD)	Touchscreen user interface and display where adjustments to treatment settings can be made
4	Cable Stand	Vertical stand for the handpiece cable
5	AC Handpiece	Delivery method for the electrosurgical device, which includes a electrode that coagulate the tissue using high-frequency current
6	AC Handpiece Holster	Receptacle that securely holds the AC handpiece

REAR		
No.	Name	Function
1	Handpiece Holster	Receptacle that securely holds the handpiece
2	Motor Handpiece Port	Port connecting the main body of the device to the handpiece via a cable (motor handpiece position compatible)
3	Mains Power Switch	Mains power on and off switch for the device
4	Power Cable Socket	Socket for connecting the power cable
5	AC Handpiece Port	Port connecting the main body and the AC Handpiece Cable
6	Motor Handpiece Port	Port connecting the main body of the device to the handpiece via a cable (motor handpiece position compatible)
7	Footswitch Connection Socket	Socket for connecting the footswitch
8	Neutral Electrode Pad Socket	Socket for connecting the neutral electrode pad
9	Cable Stand	Vertical stand for the handpiece cable
10	Device Power Switch	Switch for turning the device on or off

3.2.2 Side

SIDE



NO.	NAME	FUNCTION
1	Handpiece Holsters	Receptacles that securely hold the handpieces
2	Handpiece	Delivery method for the electrosurgical device, which includes mounted electrodes that coagulate the tissue using high-frequency current
3	Operation Panel (LCD)	Operation Panel (LCD) Touchscreen user interface and display where adjustments to treatment settings can be made
4	Cable Stand	Vertical stand for the handpiece cable

3.3 Handpiece (Applied Part)

There are two types of handpieces available for use with the Potenza: the motor handpiece and the AC handpiece. One or the other will be used depending on the treatment type.

3.3.1 Motor Handpiece

The motor handpiece automatically inserts the needles into the skin using a stepping motor. Because the needles are quickly inserted into and retracted out of the skin, it reduces the pain of the treatment.

- Depth: Maximum of 4.0mm
- Two treatment modes: bipolar and monopolar
- Available tips:

S-49 TIP, I-49 TIP	S-25 TIP, I-25 TIP	S-16 TIP, I-16 TIP
C21-2 TIP,C21-1 TIP,C9- TIP	CP-21 TIP	

1 Overall Appearance

2 Description

NO.	NAME	FUNCTION
1	Connection Port to Main Body	A connection terminal used to connect the handpiece to the main body
2	Handpiece Cable	A cable for connecting the handpiece to the main body
3	Handpiece	Delivery method for the electrosurgical device, which includes mounted electrodes that coagulate the tissue using high-frequency current
4	Tip Connection Port	Where the disposable needle tips are connected

3.3.2 AC Handpiece

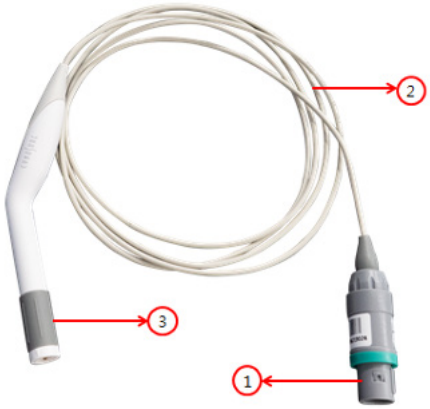
The AC handpiece is used with a disposable one-needle tip while in monopolar mode.

Type of disposable tips: 0.8mm, 1.2mm and 1.5mm tip; depth is adjustable by installing a new tip.

P1-08 (0.8mm)	A1-12 (1.2mm)	A1-15 (1.5mm)

1. Overall AC Handpiece Appearance

2. AC Handpiece: Image and Description



NO.	PART	DESCRIPTION
1	Handpiece Connector	A connection terminal used to connect the handpiece to the main body
2	Handpiece Cable	A cable for connecting the handpiece to the main body
3	Tip Connection Port	Where the disposable needle tips are connected

3.4 Electrode (Tip)

The tips for Potenza are sterilised and are one-time use disposable tips. There are 13 types of tips with various numbers and types of needles relative to the handpiece being used and the tissue being treated.

3.5 Motor handpiece Tip (Applied Part)

1. Relevant tip:

Appearance

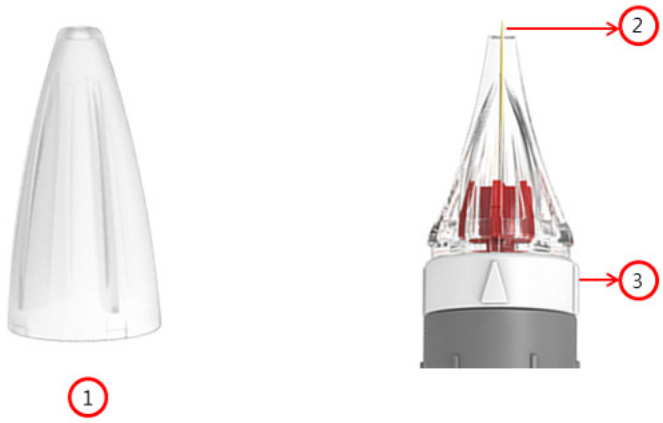
NO.	PART	DESCRIPTION
1	Needle Case	Protects the needles from damage
2	Needle	Inserted into skin or tissue of client, delivering high-frequency energy. Insertion depth is adjustable depending upon the treatment parameters set via the touchscreen

2. Specifications per Tip

TYPE OF TIP	NUMBER OF NEEDLES	STERILISATION	HANDPIECE FOR INSTALLATION	MAXIMUM NUMBER OF PULSE
S-49 TIP	49	EO Sterilisation	Motor Handpiece	1,000 pulses per tip
I-49 TIP	49			
S-25 TIP	25			
I-25 TIP	25			
S-16 TIP	16			
I-16 TIP	16			
C21-2 TIP	21			
C21-1 TIP	21			

3.6 AC Handpiece Tip (Applied Part)

- The tip that connects to the AC Handpiece that has only one needle.



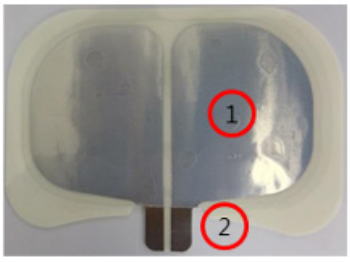
NO.	PART	DESCRIPTION
1	Tip Protection Cap	Protects needle during storage
2	One-Needle Tip	Inserted into skin or tissue of client, delivering high-frequency energy
3	Tip Connection Port	Where the disposable needle tips are connected

The following table shows the tips available for use with the AC Handpiece.

MODEL NAME	NEEDLE LENGTH	STERILISATION	HANDPIECE FOR INSTALLATION	MAXIMUM NUMBER OF PULSE
P1-08	0.8mm	EO Sterilisation	AC Handpiece	No shot tracking
A1-12	1.2mm			
A1-15	1.5mm			

3.7 Neutral Electrode (Return Pad) (Applied Part)

The neutral electrode (return pad) is an accessory that must be attached to the client's body during treatment while in monopolar mode. High-frequency current introduced to the body through the needle tip is returned via the return pad. The product itself is sterile and disposable.



NO.	PART	DESCRIPTION
1	Neutral Electrode	Attaches to the client to return the high-frequency current
2	Neutral Electrode Terminal	Connection terminal to connect the neutral electrode to the body of the device via the neutral electrode connection clip
3	Neutral Electrode Connection Clip	Connection socket from the neutral electrode to the electrode cable
4	Neutral Electrode Connection Plug	Plug which connects the neutral electrode cable to the body of the device

3.8 Footswitch

The footswitch activates RF energy in the treatment tips.

NO.	PART	DESCRIPTION
1	Plug	Part which connects to the main body
2	Safety Cover	Safety cover to protect the switch and to prevent unintended output
3	Switch	Pressed with the foot to control the device's energy output

3.9 Other Accessories

3.9.1 POWER CORD	3.9.2 HANDPIECE STAND
	

4.1 Operating environment

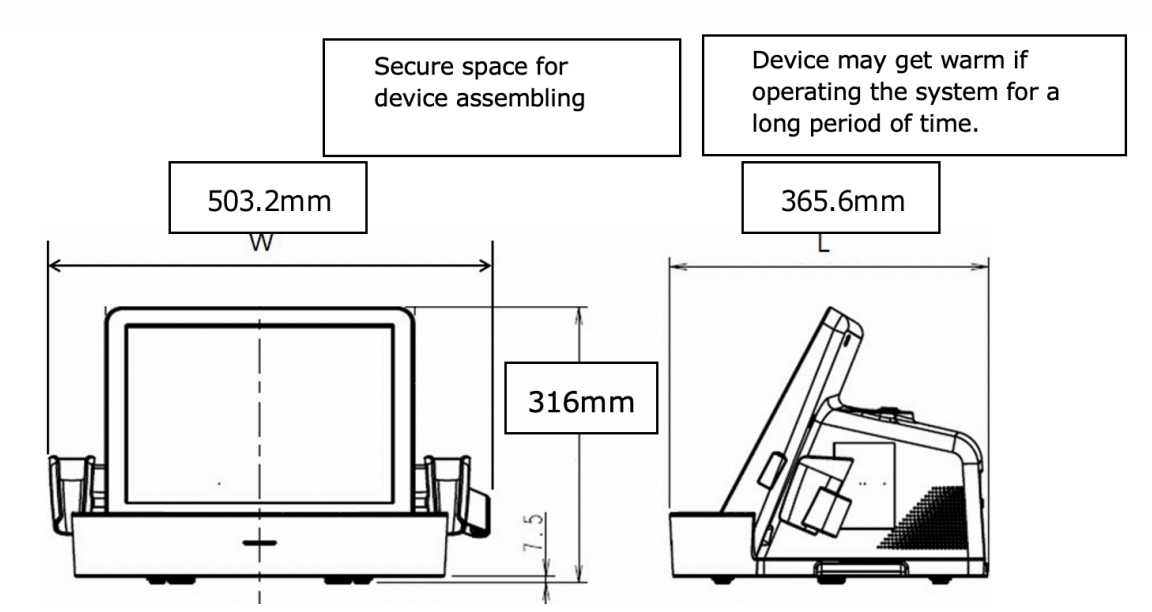
- Operating temperature: +10°C to +35°C
- Humidity: 0% to 75%
- Atmospheric Pressure: 700hPa~1060hPa (use at altitudes < 3000m)

4.2 Unpacking

Unpack the product and remove the transparent film attached to the LCD touchscreen.

CAUTION	
✗	If the transparent film is not removed, the touch function of the LCD monitor may not work properly.

4.3 Conditions for Device Installation



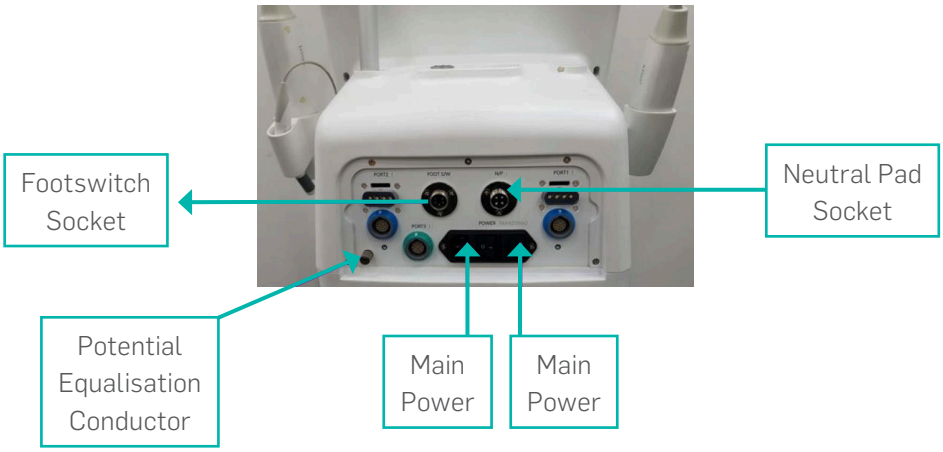
Check the overall size of the intended treatment space before installation to ensure adequate room for the device. Advance planning will lead to more a more efficient installation.

4.4 Installation of Main Body

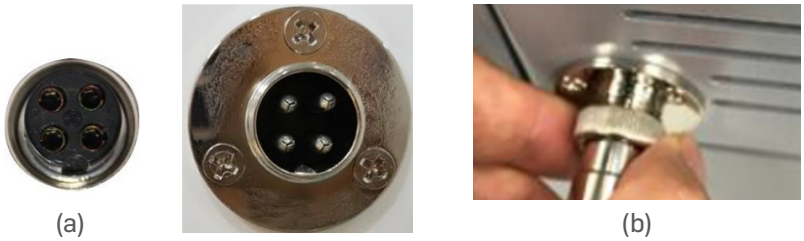
NOTE

Handpiece cannot be repaired directly by the user; it can only be repaired by Cynosure service technicians. (See contact information on page 2.)

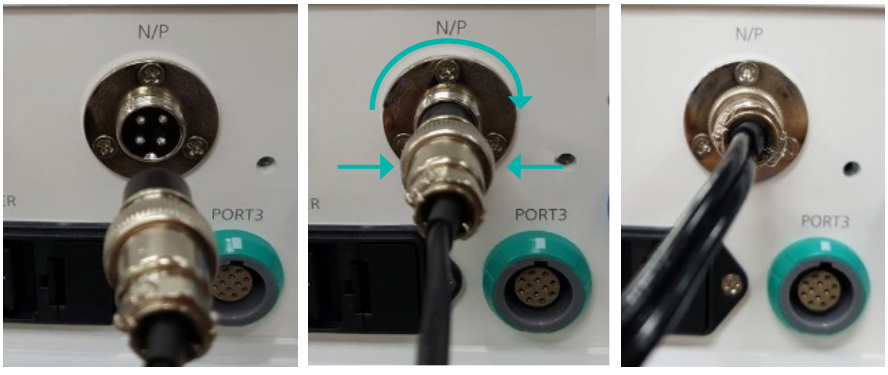
Connect the Power Cord, Footswitch and Return Pad, Locate the ports for the power cord, footswitch and return pad on the rear part of the device and connect the proper cables to them.



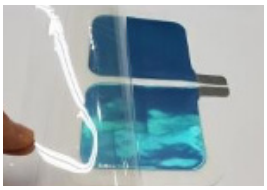
1. How to Connect the Neutral Pad Cable to the Device Socket



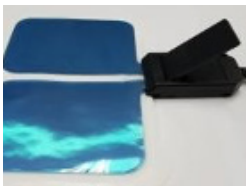
- Line up the cable receptacles **(a)** with the neutral pad socket pins on the device and push the cable in.
- Turn the screw **(b)** to the right to fasten it tight.



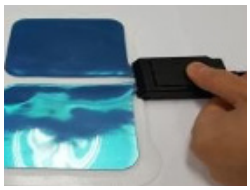
2. How to Connect the Neutral Electrode (Return Pad) Cable



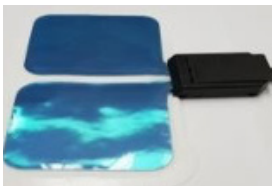
Peel off coating on pad.



Insert the tab on the return pad into the connector.



Press the connector lever all the way down.



Check the LCD screen for the Connection Complete status

3. Potential Equalisation Conductor

a. Function: Contact voltage reduction and zeroing to prevent electric shock and reduce loop impedance.

b. How to use: connect to building wall ground.

4.5 Installation of Tips

4.5.1 Installation of Motorised Needle Tip

CAUTION	
✗	Since the tips are sterilised products, wearing medical-grade gloves during installation is recommended.

1. Insert the tip into handpiece 20 degrees counterclockwise from the center.
2. Turn the tip clockwise until it clicks to fasten.

4.5.2 How to disassemble the motorised tip (reverse order of installation)

1. Turn the tip 20 degrees counterclockwise.
2. Pull it out to separate it from the handpiece.

4.5.3 Installation of One-Needle Tip

1. Set the protruded part of AC (one-needle) tip into the groove of the handpiece and apply pressure.
2. Turn it clockwise to fasten the tip to the handpiece.
3. Remove the protective cap before use.

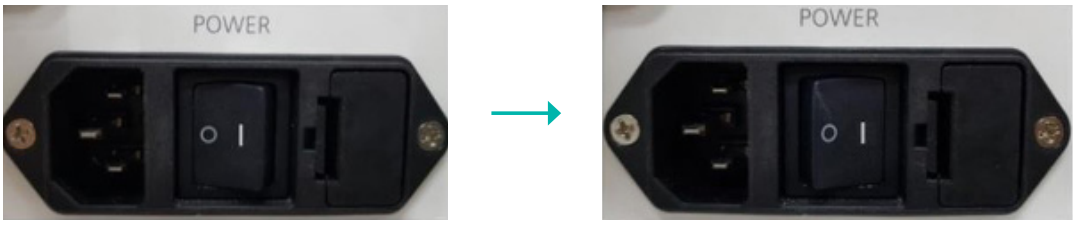
4.5.4 How to Disassemble the One-Needle Tip (reverse order of installation)

1. Turn the tip to the left with protection cap when removing the tip.

2. Remove it from handpiece.

5.1 Preparation for Use

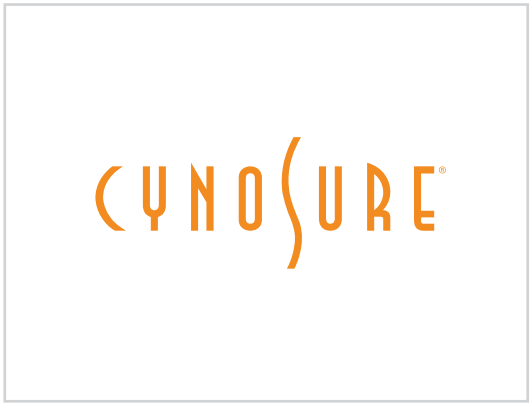
1. Turn on the main power switch on the rear part of the device.



2. Press the Power switch on the rear of monitor on the upper part of the device.

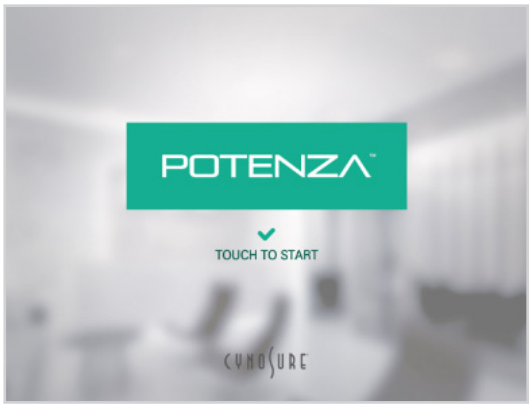
3. When a password window appears on the screen, enter the password. When the Potenza voice and logo come together, touch anywhere to operate the device. After the system check, a mode selection screen appears.

1



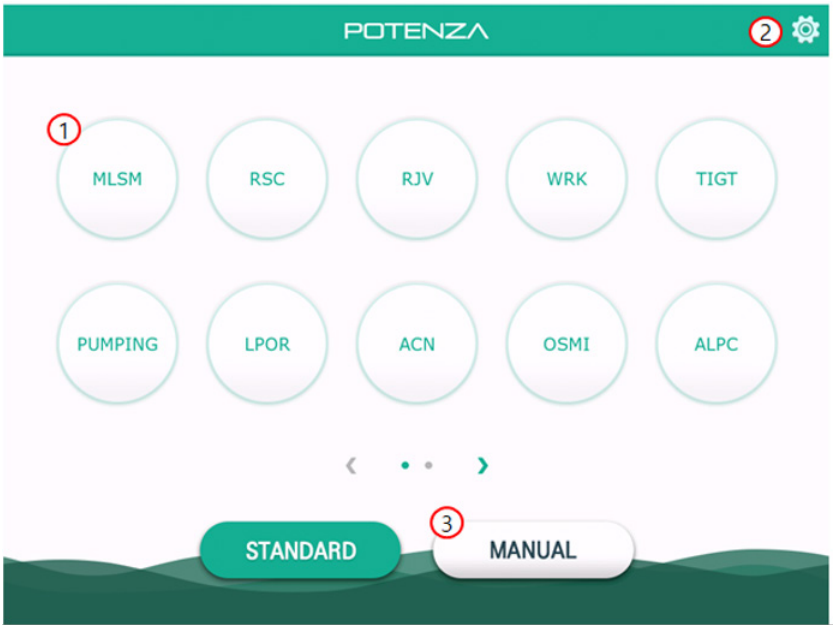
2

3

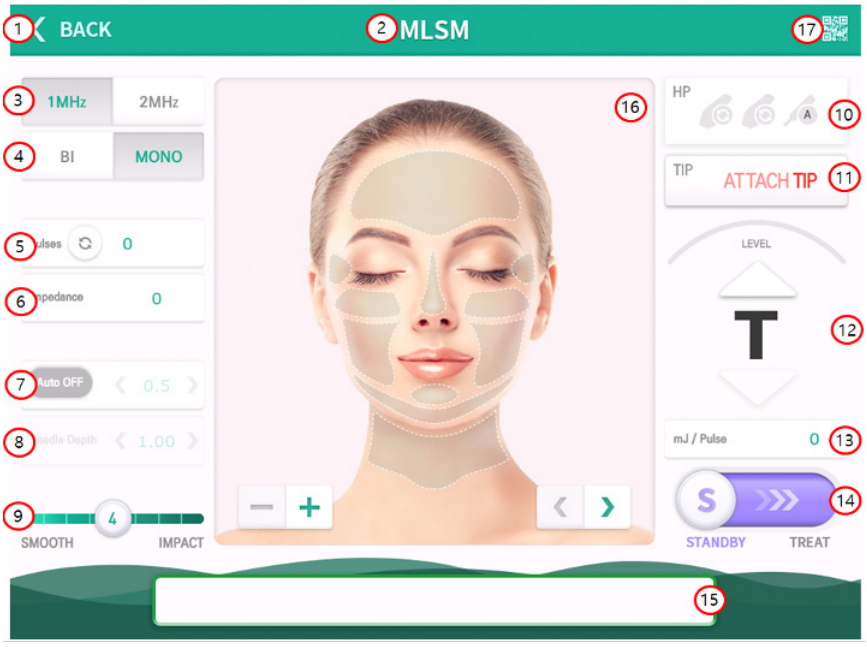


4

4. 1. Press the lesion you want to go to the Standard mode procedure screen.
   2. Press the System Preferences icon to go to service screen.
   3. Press the Manual icon to go to manual mode procedure screen.
   4. Press '>' icon to move to the 2nd page of the screen.
      Press '<' icon to move to the 1st page of the screen.



5. STANDARD Mode Screen:

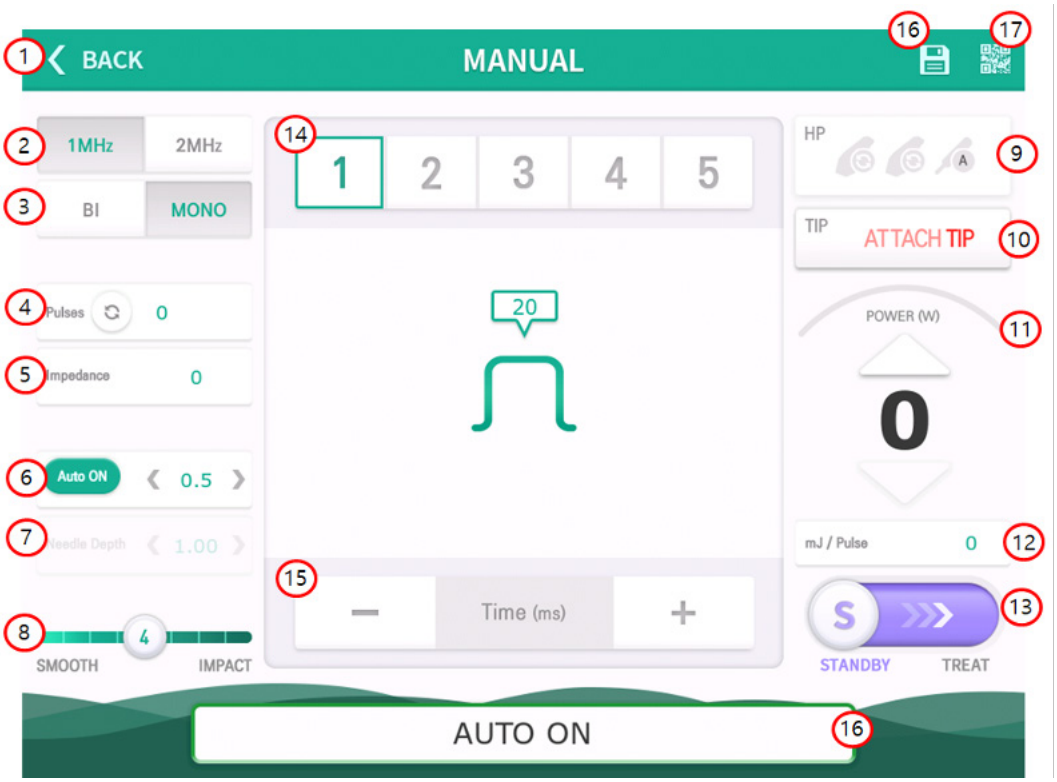


Operation

Pick up the desired handpiece and connect the desired tip. The tip will automatically be displayed on the screen.

1	BACK	Previous screen navigator
2	Lesion Name	The lesion selected identifier on the Standard mode screen
3	1Mhz/2Mhz	Frequency selection
4	BI/MONO	Bipolar or monopolar selection
5	Pulses	Pulse count display (current pulses/remaining pulses): resets the current pulse count to 0 when the reset button is pressed; when fewer than 10% of the shots remain, they are displayed in red
6	Impedance	Impedance value of the tissue being treated
7	Auto ON/OFF	Auto Mode selection; when set to Auto ON, it allows the device to continuously treat at a user-selected interval while holding down the footswitch
8	Needle Depth	Needle depth selection for the motor handpiece
9	Handpiece Speed Controller	Handpiece speed selection from slow (SMOOTH) to quick (IMPACT); seven settings are available
10	HP	Handpiece selection: indicates the user-selected, currently connected handpiece
11	Tip Display Window	Tip selection: displays the tip of the currently connected handpiece; pressing the button allows the user to view other tips available for the device
12	Level	Displays the level used for the procedure; pressing the button allows the user to adjust level from T~10.
13	mJ/Pulse	Display a calculation of (Power x Time)/pulse in mJ
14	STANDBY/TREAT	Device mode selection: device must be set to “Treat” mode to perform a treatment
15	Guide Message	Device message display
16	Treatment Area	Pressing the each area and it will automatically change to the level properly for the corresponding area; Zoom in/out with ‘+’ icon, and move the front and side face with ‘<>’ icon
17	QR CODE	QR Code Pop-up image. user interface (UI) version, F/W version, and device serial number. Pop-up disappears when touching anywhere on screen * If the protective film is not removed, it may not be recognised.

6. Manual Mode Screen



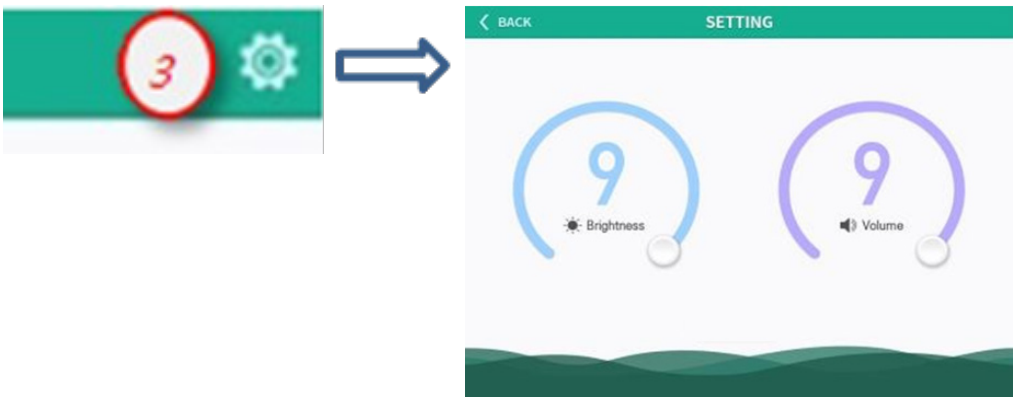
Operation

Pick up the desired handpiece and connect the desired tip. The tip will automatically be displayed on the screen.

1	BACK	Previous screen navigator
2	1Mhz/2Mhz	Frequency selection
3	BI/MONO	Bipolar or monopolar selection
4	Pulses	Pulse count display (current pulses/remaining pulses): resets the current pulse count to 0 when the reset button is pressed; when fewer than 10% of the shots remain, they are displayed in red
5	Impedance	Impedance value of the tissue being treated
6	Auto ON/OFF	Auto Mode selection; when set to Auto ON, it allows the device to continuously treat at a user-selected interval while holding down the footswitch
7	Needle Depth	Needle depth selection for the motor handpiece
8	Handpiece Speed Controller	Handpiece speed selection from slow (SMOOTH) to quick (IMPACT); seven settings are available
9	HP	Handpiece selection: indicates the user-selected, currently connected handpiece

10	Tip Display Window	Tip selection: displays the tip of the currently connected handpiece; pressing the button allows the user to view other tips available for the device
11	POWER(W)	Treatment power level selection; can adjust from 0-50W by pressing the up or down arrow
12	mJ/Pulse	Display a calculation of (Power x Time)/pulse in mJ
13	STANDBY/TREAT	Device mode selection: device must be set to “Treat” mode to perform a treatment
14	Pulse Type Selection	Pulse type selection: can divide RF emission from 1 to 5 per each pulse by pressing the digital button.
15	Time(ms)	Treatment pulse width selection; can adjust from 10(bipolar)/20(monopolar) – 500ms including on time and off time by pressing the plus or minus button.
16	Save Button	Save present parameter as default for each treatment area.
17	QR CODE	QR Code Pop-up image. UI version, F/W version, and device serial number. Pop-up disappears when touching anywhere on screen * If the protective film is not removed, it may not be recognised. Remove the protective film.

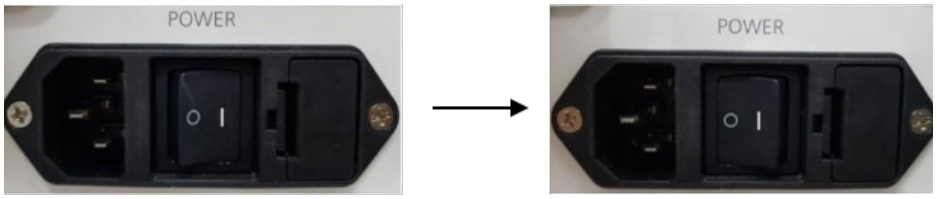
7. Press the gear icon in the right corner to move to the setting screen for adjusting the brightness of the LCD screen and the device volume.



5.2 Turning Off Device

1. Press the POWER switch.

2. After the LCD touchscreen has powered off, turn off the main switch on the rear of the device.



5.3 Disposal

Used Tips cannot be reused, reprocessed or re-sterilised. Therefore, they must be processed according to the sharps protocol of the medical facility to prevent possible cross-contamination or infection.

6.1 Storage and Transportation Conditions

Device

- Temperature: -10°C to +60°C
- Humidity: 0 to 95%
- Atmospheric Pressure: 700hPa to 1060hPa (altitude < 3000m)

Electrode

- Temperature: 0°C to +20°C
- Humidity: 30 to 80%

6.2 Storage

1. Corrosion may occur in the electric cord or electric parts in an acidic and/or corrosive atmosphere.
2. The device and tips should be stored in a safe place accessible only by authorised personnel.
3. Avoid storing the device or the tips in a location with these conditions:

- Wet or damp
- Direct sunlight
- Dust
- High humidity
- Salty air
- Poor ventilation
- With chemicals or gases nearby

4. Since the tips are sterilised disposable products, do not store used tips; they must be discarded.

6.3 Transportation

1. Only personnel who have received education and training on the device should move it around in the treatment room.
2. To move the device safely, see 4.4 Installation menu and perform the steps in reverse order.
3. Hold the handle of device and transport it to a place that complies with 4.3 Conditions for Device Installation and then install again according to 4.4 Installation.
4. To transport further than within your local office, contact Cynosure Customer Service (page 2) for assistance.

CAUTION	
✗	Do not hold the LCD monitor during transportation; it may result in damage to it.
✗	More than one person is required to transport the equipment.

7.1 Cleaning

Main Body and Handpiece

- At the end of the treatment day, clean the contaminated area before storing the device.
- Wet a soft pad with a noncorrosive cleaning agent such as isopropyl alcohol or 99% ethanol, and softly wipe screen, main body and outer area of handpiece.

NOTE

Use a clean and dry cloth or pad to wipe the main body and the handpiece again. Be sure to turn the power off and remove the power cord from the electrical outlet before any cleaning and maintenance procedures. Never clean, maintain or repair the main body or handpiece while the power is on. It may cause fatal damage to the user or ruin the equipment.

Tips

- Since the tips are sterilised and disposable, they cannot be used again.

7.2 Maintenance

Inspection

- After use, always check for any dust and other contamination on the device and the handpieces.
- Inspect all parts of the device regularly for any problems or issues (cracks, damage, etc.). Do not use if problems are detected. Contact Cynosure Customer Service immediately (see page 2).

Maintenance and Repair

- Unauthorised modification of hardware, software or specifications of the Potenza voids all warranties, expressed and implied. Cynosure LLC takes no responsibility for the service or operation of such equipment.
- Every part must be repaired and maintained exclusively by Cynosure Service technicians.
- After cleaning the device, move to a secure and clean location.
- To purchase additional accessories and parts (such as disposable tips), please contact your local Cynosure representative or contact Customer Service (see page 2).

8.1 Main Body and Handpieces

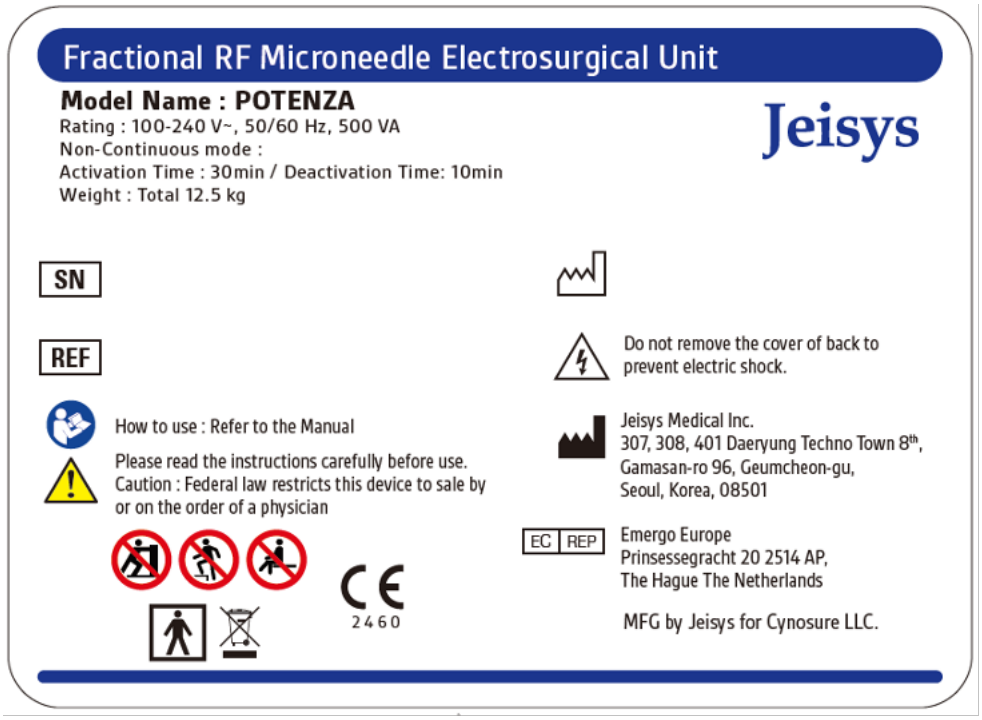
8.2 Disposable Products

FRACTIONAL MICRONEEDLE TIP	ONE-NEEDLE TIP

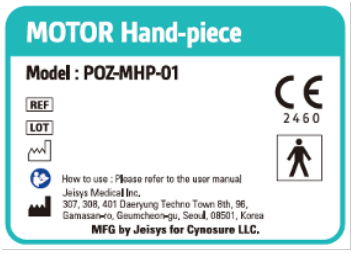
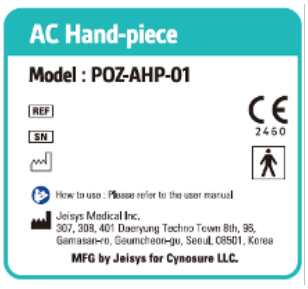
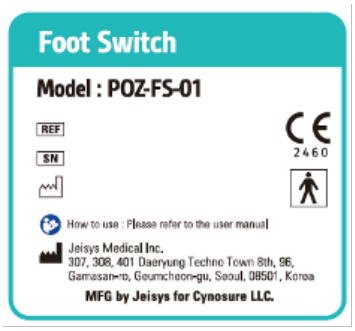
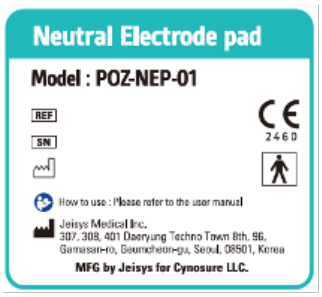
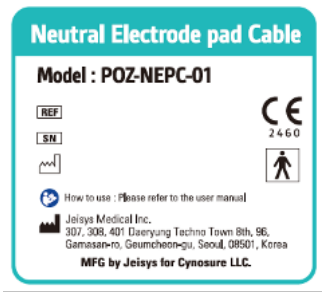
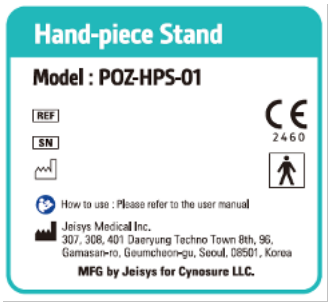
8.3 Labels

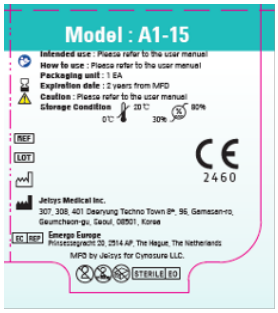
8.3.1 Main Body

Device Label

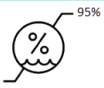
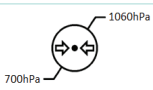


8.3.2 Accessories

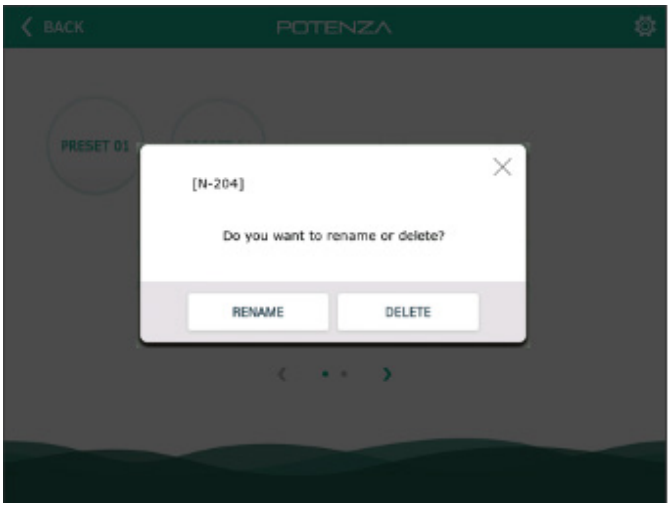
HANDPIECE		FOOT SWITCH
Motor handpiece	AC handpiece	
		
Neutral Electrode Pad	Neutral Electrode Pad Cable	Hand-piece Stand
		

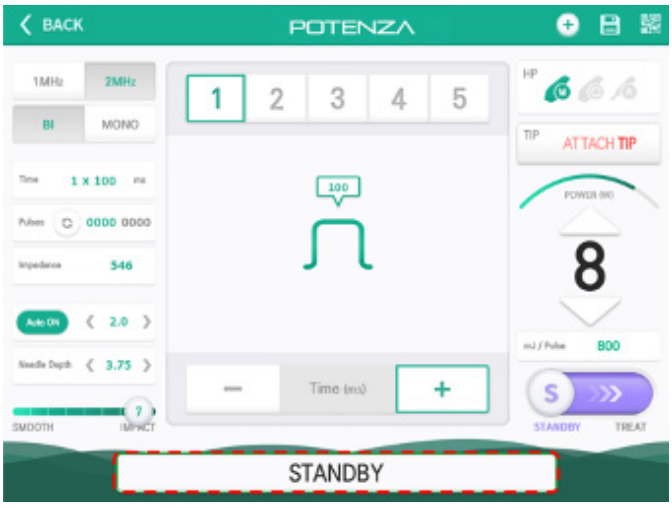
TIP (STARTER KIT INCLUDED)			
Fractional Microneedle Tip (S-25, I-25, S-16, I-16)			
			
Fractional Microneedle Tip (CP-21)		One Microneedle Tip (A1-15)	
			

8.3.3 Symbols

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Type BF Applied Part		Keep electrical waste separate from municipal waste
	Equipotentiality		Refer to instruction manual
	Earth-referenced patient circuit		Dangerous voltage
	ON (power)		No pushing
	OFF (power)		No sitting
PN	Part number		No stepping on surface
	Date of Manufacture		Caution
	Manufacturer		General warning sign
SN	Serial Number		Do not reuse
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner		DO NOT RESTERILISE
	NRTL certification mark _ Certified to US and Canada Standards		DO NOT USE IF PACKAGE IS DAMAGED (This symbol may also mean “Do not use if the product sterile barrier system or its packaging is compromised.”)
	Sterilised using ethylene oxide		This way up
	Expiration date		Storage conditions (Upper - Lower limit of temperature)
IPX8	Degrees of protection provided by enclosures (IP Code)		Humidity limitation (0 to 95%)
	Keep away from rain		Upper and lower limits of atmospheric pressure for transport and storage
	Fragile: handle with care		Use no hooks

The Potenza continuously monitors the status of the equipment. If an error occurs, an error message appears as shown below, either on the bottom part of the screen or in a pop-up window.





9.1 Kinds of Pop-Up Messages

NO.	MESSAGE	POSSIBLE CAUSE	RECOMMENDED ACTIONS
1	No connected handpieces	A handpiece is not connected before entering treatment screen	Connect a handpiece.
2	Communication port is not responding	Faulty mainboard communication port or faulty UI board communication port or faulty mainboard to UI board cable connection	Contact Cynosure Customer Service to check the device setting.
3	Incorrect AC Power Hz	AC Power Hz differs from setting value	Contact Cynosure Customer Service to check the device setting.
4	Error: [Number]	Faulty board status	Note RF error number and contact Cynosure Customer Service.
5	Unidentified tip	An unrecognisable tip has been connected to the handpiece	Contact Cynosure Customer Service after checking the UI version.
6	Mainboard is not responding	No response when sending communication from UI board to mainboard	Contact Cynosure Customer Service to check the device setting.
7	Data error [No.].	Data in SD card is unrecognisable	Contact Cynosure Customer Service to check the device setting.
8	Load fail.	Data load has failed	Reboot the device. If problem is not solved, please contact Cynosure Customer Service to check the device setting.

9	Reset shot count?	Pressing the shot-count rest button triggers this message	
10	Replace with “Overwrite existing settings and replace with current parameters?”	Pressing save button in treatment screen of either quick start or preset mode triggers this message	
11	No return pad detected.	Impedance value is reached more than 750 in monopolar mode during procedure	Check the return pad connection and if it is perfectly attached to patient. If problem is not solved, contact Cynosure Customer Service to check the device setting
12	High energy may cause side effect. Do you still want to proceed?	Pressing ready button when the set energy is higher than 2J. (Number of pulse x Power (Watt) x pulse duration (ms))	Check the energy setting and decrease the energy if needed.
13	The lifetime of the tip is over. Please replace the tip.	Connecting the treatment tip having time limit reached	Replace treatment tip.
14	A used tip connected.	When the used tip is connected to motor handpiece	Replace with a new tip.
15	Do you want to rename or delete?	Pressing the icon that user produced for more than 2 seconds.	

9.2 Kinds of Guide Messages

NO	MESSAGE	POSSIBLE CAUSES	RECOMMENDED ACTIONS
1	SELECT HANDPIECE	More than two HPs are connected and HP is not selected (recommended HP blinks)	Select a handpiece.
2	MONO DEDICATED TIP	Connecting the monopolar-exclusive tip in bipolar mode or pressing bipolar mode after inserting the monopolar-exclusive	To use bipolar mode, insert the bipolar-available tip.
3	CONNECT A	Connecting the tip not recommended for the lesion selected.	Connect a recommended tip as tip popup.
4	CONNECT HP	Pressing the Ready button without connecting a handpiece	Connect a handpiece.
5	CONNECT TIP	Pressing the Ready button without connecting tip	Connect a tip.
6	CONNECT RETURN PAD	Pressing the Ready button	Connect the neutral pad.
7	RETURN PAD CONNECTED	Connecting the return pad cable in monopolar mode	
8	FOOTSWITCH CONNECTED	Connecting Footswitch cable to main body	
9	CONNECT FOOTSWITCH	Pressing the Ready button without connecting the footswitch	Connect the foot switch.
10	MIN AUTO TIME / MAX AUTO TIME	Adjusting the Auto time to minimum/ maximum	
11	MIN NEEDLE DEPTH / MAX NEEDLE DEPTH	Adjusting motor depth to minimum/ maximum	
12	MIN LEVEL / MAX LEVEL	Adjusting the level (general mode energy) to minimum/maximum	
13	MIN ENERGY / MAX ENERGY	Adjusting the energy to minimum/ maximum	
14	MIN TREAT TIME / MAX TREAT TIME	Adjusting pro mode time to minimum/ maximum	
15	SET THE DEPTH ON HP TO '2MM/1.5MM'	Touching 'Standby-Treat' button after connecting. Cushion TIP (21pin:2mm/1.5mm, 9pin:2mm) and selecting needle depth impossible to use.	Manually adjust the motor HP depth to recommended Depth (1.5/2mm).
16	CONNECT A CUSHION / CP-21 TIP	Connecting the tip impossible to use for the lesion selected.	Connect a Cushion TIP

17	1MHZ SELECTED / 2MHZ SELECTED	Selecting 1Mhz / 2Mhz	
18	BIPOLAR SELECTED / MONOPOLAR SELECTED	Selecting Bipolar / Monopolar	
19	AUTO ON/ AUTO OFF	Selecting Auto On / Auto Off	
20	PORT'1/2/3' 'MOTOR/ ACN' HP SELECTED	Selecting handpiece, display port	
21	STAND BY SELECTED / TREAT SELECTED	Selecting STAND BY / TREAT	
22	STANDBY	Main board receiving a standby signal	
23	READY FOR TREATMENT	Main board receiving treatment signal	
24	HP DISCONNECTED	Separating handpiece during treatment	
25	TIP DISCONNECTED	Separating tip during treatment	
26	NO STORAGE SPACE IS AVAILABLE	Pressing Save, but maximum storage space will be exceeded	At preset selection screen, press Delete preset user to make storage space available.
27	EXCEED MAX DURATION 500 ms	Setting time of total pulse duration exceed 500 ms	Adjust pulse duration ≤ 500
28	MIN PULSE ON TIME / MAX PULSE ON TIME	Adjusting 'on time' to maximum/minimum	
29	MIN PULSE OFF TIME / MAX PULSE OFF TIME	Adjusting 'off time' to maximum/minimum	
30	'XXX' TIP CONNECTED	Connecting 'XXX' tip to motor handpiece.	

10.1 RF Type

Bipolar, Monopolar

10.2 Power

Max 50 watts

10.3 Frequency

1Mhz, 2Mhz

10.4 Repetition Rate

0.5-3.0 sec (0.1 sec step)

10.5 Handpieces

100-7043-001: Motorised Handpiece 100-7043-002: AC Handpiece

10.6 Tips

MOTORISED HANDPIECE	AC HANDPIECE
100-7043-051: S-16	100-7043-060: P1-08
100-7043-052: S-25	100-7043-061: A1-12
100-7043-053: S-49	100-7043-062: A1-15
100-7043-054: I-16	
100-7043-055: I-25	
100-7043-056: I-49	

10.7 Needle Thickness

0.25

10.8 Treatment Duration

5-500ms (5ms.step)

10.9 Electrical Power

100-240V, 50/60Hz, 500VA

10.10 Dimensions

503.2mm (W) x 365.6mm (L) x 316mm (H)
(Incl. cable stand: 550.16mm (W) x 701mm (L) x 366mm (H))

10.11 Weight

12.5kg

10.12 Cart

478mm (W) x 482.1mm (L) x 967.2mm (H), 32.26kg

10.13 Footswitch Specification

Footswitch button: IPX8

10.14 Sterilisation

Motor Handpiece tip and AC Handpiece tip were sterilised by ethylene oxide.

10.15 EMC

Electromagnetic Field Information According to IEC 60601-1-2

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The Potenza is intended for use in the electromagnetic environment specified below. The customer or the user of the Potenza should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 2	The Potenza must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Potenza 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 Potenza 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 Potenza or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The Potenza is intended for use in the electromagnetic environment specified below. The customer or the user of the Potenza should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test 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 61000-4-4	±2 kV for power supply lines ±1 kV for input/output Lines	±2 kV for power supply lines Not applicable ±2 kV line(s) to earth	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	±1 kV line(s) to line(s)	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	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle 40 % U_T (60 % dip in U_T) for 5 or 6 cycle 70 % U_T (30 % dip in U_T) for 25 or 30 cycle <5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle 40 % U_T (60 % dip in U_T) for 5 or 6 cycle 70 % U_T (30 % dip in U_T) for 25 or 30 cycle <5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Potenza image intensifier requires continued operation during power mains interruptions, it is recommended that the Potenza image intensifier be powered from an uninterruptible power supply.
Power frequency (50 Hz and 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the A.C. mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The Potenza is intended for use in the electromagnetic environment specified below. The customer or the user of the Potenza should assure that it is used in such an environment.			
Immunity Test	Test Level IEC 60601	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC61000-4-6 Radiated RF IEC 61000-4-3	3Vms 150kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vms 3 V/m	Portable mobile RF communications equipment should be used no closer to any part of the POTENZA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800MHz to 2.5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE

1. At 80 MHz and 800 MHz, the higher frequency range applies
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 by 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 ULTRAcel is used exceeds the applicable RF compliance level above, the POTENZA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the POTENZA.

B) Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances

BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE POTENZA			
The POTENZA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer of the user of the POTENZA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the POTENZA as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1{,}2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10.11 Lifetime

Potenza has a minimum 5 years of device life, while conforming to the maintenance policy.

Warranty Conditions

Warranty will be provided for a one-year period, for functional and operational problems on the machine used under reasonable, normal conditions.

Warranty Exceptions

- Problems caused by user's intention or negligence (Broken monitor, damage on body, broken handpiece & etc.)
- Expired warranty period
- Life spans of parts have expired
- Problems caused by a natural disaster

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