Bondent

CE 0197 MD EN

Ultrasonic Endo Activation Devices

User Manual

Read this Operation carefully before use.

Keep this User Manual for future reference.

Thank you very much for choosing the Ultrasonic Endo Activation Device Bomedent

- To give full play to the function of this device, and operate and maintain it correctly and safely, please read this User Manual carefully before using it, and keep this User Manual properly for reference at any time

Classification of device safety level:

- Classification of electric shock protection type: Class II
- Classification of electric shock protection level: Class B
- Classification of liquid entry prevention level: IPX0（Device），IPX6（Wireless pedal）
- Sterilization or disinfection method: refer to sterilization part in the manual
- Classified by the safety level in the case of using the product with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: not to be used in the case of using the product with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide
- Operation mode: continuous operation
- Software release version: 1.0

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1. Product Introduction

1.1 Brief Introduction

Ultrasonic Endo Activation Device (hereinafter referred to as "Actor I pro" or "device") is an auxiliary device for dentists to perform root canal treatment. It is mainly used to effectively clean the root canal with the help of ultrasonic cavitation, so as to assist dentists to complete root canal treatment.

The features of this device are as follows:

a) The working process of this device is under full automatic control of microchip, which is convenient and simple to operate;

b) The vibration amplitude of the Working tip can be adjusted so as not to harm the root canal, and its frequency can be dynamically adjusted to ensure cleaning efficiency;

c) The Working tip, Silicone case and wrench can be sterilized by high temperature and high pressure.

d) This device can be illuminated to make it clearer.

1.2 Model

Actor Ⅰ pro

1.3 Intended use, user, patient

1.3.1 Intended use: It is used for cleaning of the root canal area of teeth.

1.3.2 Intended user: This device is only allowed to be used in hospital environments, clinics or dental offices by qualified dentists and other legally licensed professionals. Do not use this device for anything other than its specified dental purpose.

13.3 Intended patient: People who need root canal shaping and cleaning, and root canal shape is good. Age 12 or older.

1.3.4 Use place: Hospital or dental clinic.

1.4 Contraindications

None

1.5 Precaution and warning

Please read this User Manual carefully before use.

- It is contraindicated by hemophiliacs, patients with cardiac pacemaker or cochlear implant and doctors;
- It should be used with caution on patients with heart disease, pregnant women and young children;

- This device may not work properly due to the following environmental factors:

1) Portable or movable radio frequency transmitters are present nearby.

2) Electromagnetic interference may cause abnormal operation of this device.

- As with all electronic devices, this device has electromagnetic interference and should not be used on patients with cardiac pacemaker.
- During operation and cleaning, be sure to pay attention to the direction and position of the Working tip, so as not to hurt the patient and the operator.
- Please fully check whether there is looseness, noise or heating on the Working tip. For any abnormal phenomenon, please stop using it and contact the local distributor or manufacturer.
- Please beware of collision, especially falling.
- When the Working tip and Silicone case need to be removed, please turn off the power first. So as not to accidentally touch the switch on the handle, thus leading to its accidental starting and causing injury to human body.
- When the battery on the screen displays flashing, please timely charge it. When charging, please use the original Power Adapter.
- Please use the original accessories. Accessories from other manufacturers may make this device unusable or damaged.
- Please do not disassemble and repair this device without permission, otherwise it may automatically lose the warranty qualification.
- Please do not place this device in a damp place or where it may come into contact with any liquid.
- Please do not expose this device to direct or indirect heat sources. This device must be operated and stored in a safe environment.
- When the operator is in use (including charging), do not place it in a location where it is difficult to disconnect the power, when it is dangerous.

1.6 Performance characteristics

1.6.1 Appearance and structure:

The outer surface of Ultrasonic Endo Activation Device should be smooth and neat, and there should be no obvious bump, cracks, edge, the outline of the transition should be clear, and there should be no obvious scratches.

1.7 Clinical benefit

The performance of Ultrasonic Endo Activation Device has been fully identified and evaluated, the product can meet the clinical intended use, and the related risks have been fully evaluated, and the residual risks are acceptable.

1.8 Contact information

Tel.: 86 0519-88991980

Website:www.bome-dent.com

After launch of European Database on Medical Devices/EUDAMED, the summary of safety and clinical performance will be made available to the public at https://ec.europa.eu/tools/eudamed.

Basic UDI-DI: 697107537Actor proVK

For a patient/user/third party in the European Union and in countries with identical regulatory regime(Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

a) name of manufacturer or distributor;

b) type of instruments, product identification;

c) product size;

Complete Contraindications, Warnings and Precautions will be available and kept up to date on the IFU.

For additional information, contact your United Dental Changzhou Sales Representative or ChangZhou BoMedent Medical Technology Co., LTD. Customer Service. No electronic version of the IFU provided.

2. Product Configuration

2.1 External Structure of Main frame of Product

2.2 Main Accessories of Product

Working tip

Wrench

Silicone case

Power adapter

Charging base

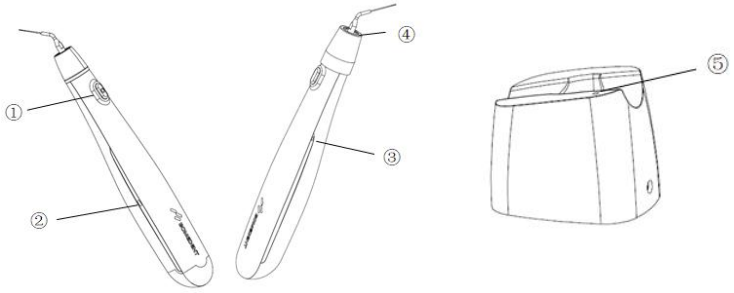
Wireless pedal (optional)

2.3 Accessories List

Components	Type	No.
Main frame	Actor I pro	1
Working tip	BMWT0001 (2002/21)	3
	BMWT0002 (2502/18)	3
Wrench	BMWH0001	1
Silicone case	BMSC0002	3
Power adaptor	UES06WNCP-050100SPA	1
Charging base	BMCB0002	1
Wireless pedal (optional)	iPedal	1

Please see the packing list for the device configuration.

3. User Interface



① : switch button with built-in power indicator light
② : battery power indicator light and charging indicator light
③ : bluetooth button with built-in bluetooth indicator light
④ : illuminating light
⑤ : Charging indicator light on Charging base

Switch button ①:

- Power on: when the device is off, press and hold the switch button for 1 second, and the device will enter the standby state with the ring tone;
- Power off: in standby state, press and hold the switch button for 1 second, and the device will be turned off with the ring tone.
- Operation and stop: in standby state, press the switch button for 0.1 seconds, and the device will enter the working state and start vibrating. Press the switch button again to stop working.
- Power setting: press and hold the switch button for 1 second in the working state to switch between "high" power and "low" power
- Power indicator light:
  - Under "high" power: the power indicator light is always green;
  - Under "low" power: the power indicator light flashes in green

Battery power indicator light ②

- Blue: it means that the battery power is above 50%;
- Yellow: it means that the battery power is between 10% and 50%;
- Flashes in yellow: it means that the battery power is less than 10%, and the battery should be charged in time;
- Green: when the green light is always on, it indicates that the device is being charged. When the device is fully charged, the green light will turn off automatically.

Bluetooth button ③

- Turn on bluetooth: when both the Wireless pedal and the device are in standby state, press any button of the Wireless pedal first, and then press the bluetooth button ③ to open the bluetooth;
- Turn off bluetooth: when the bluetooth is on, press the bluetooth button ③ to turn off the bluetooth;
- Bluetooth indicator light:
  - The indicator light is always on in blue: it means that the bluetooth has been turned on, but the device is not connected with the Wireless pedal;
  - The indicator light flashes in blue: it means that the device has been connected with the Wireless pedal, and they can communicate normally;
  - The indicator light is off: the bluetooth is not turned on.

Illuminating light ④

- This indicator light is always on when the device is working

Charging indicator light on the Charging base ⑤

- When the Charging base is powered on, the charging indicator light on the Charging base is always on in green;
- When the Main frame is placed on the Charging base to charge: the charging indicator light on the Charging base is always on in blue.

4. Product Installation

4.1 Installation of Silicone case

Align the Silicone case with the head and gently put it on.

4.2 Installation of Working tip

Align the thread on the Working tip with the stud on the Main frame, insert them together to make sure the thread matches correctly, and rotate gently clockwise.

Align the wrench with the slot of the Working tip, rotate the wrench

clockwise, and slowly apply force until the Working tip is tightened.

After the Working tip is tightened, deviation within 10° is normal.

Warning:

- When installing the Working tip, please ensure that the Main frame is powered off;
- When the Working tip is installed on the Main frame, it will not become loose or fall off to ensure that the Working tip is firmly installed;
- Before inserting the Working tip, check the assembly interface between the Working tip and the Main frame. Please do not use the damaged Working tip or device;
- If the Working tip is not firmly installed, it may lead to unpredictable rotation or the Working tip may fall off, and even hurt the patient.
- Please use the original Working tip;
- The Working tip has not been disinfected and sterilized before leaving the factory. Please use it after sterilization;
- After each treatment, the Working tip should be cleaned, disinfected and sterilized.

4.3 Removal of Working tip

Align the wrench with the slot of the Working tip, rotate the wrench counterclockwise to loosen the Working tip, and continue to rotate the wrench until the Working tip comes out.

Caution:

The number of use of the Working tip should not exceed 20 operations, with the number of 2 root canals per operation as the reference.

Warning:

- When installing or removing the Working tip, please be careful not to injure your finger;
- When installing or removing the Working tip, please make sure the Main frame stops working.

5. Product Use

5.1 Operation

Start the device: press and hold the switch button for 1 second, the device

starts up and enters the standby state.

Run the device: in standby state, press the switch button to run the device, the power indicator light is on, the illuminating light opens, and the Working tip begins to vibrate.

Warning:

- Once the device is started, please do not touch the Working tip to avoid scalding;
- Please do not operate the device without flushing fluid in the root canal. Make sure there is enough flushing fluid in the root canal for cooling during the use of the device;

Caution:

- Hold for 30 to 60 seconds at a time for a better cleaning effect.

Switch between "high/low" power working states: in the working state of the device, press and hold the switch button for 1 second to switch between high and low power working states. In the "high" power working state, the power indicator light is always on in green; in the "low" power working state, the power indicator light flashes in green.

Stop working: when pressing the switch button in the working state, the Working tip will stop vibration, and the device will enter the standby state. The device will be powered off automatically after standby for 1 minute. Be sure to remove the Working tip after the use of the device.

After 3 minutes of continuous working, the device will automatically turn off the output and enter the standby state; in the course of operation, if the device stops suddenly, restart the device. In addition, the device has the function of timing prompt, and there is a prompt tone every 5s in the working process.

Warning:

- Before using the device for treatment, try it out of the mouth to make sure the device is functional;
- The Working tip may be damaged suddenly when it enters the root canal which is too curved or not in good shape. If the user feels uncomfortable, please stop using the device immediately.
- Even in normal use, the Working tip may be separated from the Main frame due to metal fatigue and wear. Please replace it in time. Please do not use the Working tip more than its recommended times of use.
- When the Working tip suffers excessive external force, it may break.

When using this device, please do not apply excessive external force to the Working tip.

- Please do not disassemble the Working tip during the treatment, because it may scratch the operator or the patient.

Caution:

- Please stop using this device when any abnormalities occur. This device is not suitable for all types of root canals. Please do not use this device for extremely deformed root canals.
- Please use disposable gloves and rubber dam during treatment;
- Be sure to remove the Working tip after each treatment.

5.2 Charging

Please use the Charging base corresponding to this device for charging:

- Insert the USB cable into the Charging base (Figure a);
- Connect the USB cable to the Charging base and turn on the power. Then put the Main frame of Actor I pro into the Charging base for charging. When the Main frame is placed in the Charging base for charging, the Main frame will be powered off automatically. The charging indicator light of the Main frame will always be on in green. If it goes off, the charging is completed. When the Charging base is powered on, the charging indicator light on the Charging base is always on in green, and when the Main frame is placed on the Charging base, the charging indicator light on the Charging base turns to be on in blue. It is expected that the time for the device to be fully charged is about 4 hours, which can guarantee the operation of the device in the state of maximum power consumption for about 3 hours.

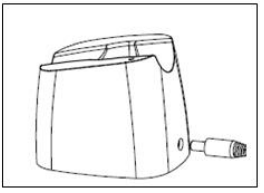


Figure a

Caution:

- When the battery power indicator light flashes in yellow, accompanied

by the prompt tone, the battery power is low, and the device should be charged in time;

- The battery used in this product lacks of memory property and can be charged at any time;
- Please charge the device for at least 4 hours before the first charge;
- When the Main frame is inserted into the Charging base, but it does not enter the charging state, please stop charging it immediately and then contact the local distributor;
- When charging with the Charging base, please place the Charging base or the Main frame in a dry and safe place where they are not easily knocked over;
- The Power Adapter should meet the requirements of the IEC 60601-1 standard. Please use the Power Adapter and cable provided by the manufacturer for charging;
- After the battery is discharged completely, the battery may not be recharged, thus causing it to be damaged. When the device is not used for a long time, it should be fully charged every one to two months;
- Do not place the Charging base or Main frame in dust, or especially in the environment with metal debris. Please pay special attention to the protection of charging port;
- Please pull out the Main frame vertically upward after full charge.

5.3 Wireless Connection Control

We always design the product from the perspective of the doctor's use to make its operation easier. Actor I pro is a safe, accurate, compact and convenient product. When a doctor performs root canal treatment on the molar teeth, they need to go deep into the mouth, so it is inconvenient to press the buttons on the device. In order to provide doctors with more convenient operation experience, we also provide an optional wireless control solution. You can choose our Wireless pedal to achieve this function.

Actor I pro can be connected wirelessly with our Wireless pedal through bluetooth. After successful connection, the operation of Actor I pro can be controlled within 5 meters.

Bluetooth connection setting of Actor I pro:

- Step on any button of the foot switch to open the power supply of the foot switch;
- Turn on the power of Actor I pro, press the bluetooth button ③, turn on the bluetooth, and the indicator light is always on in blue; Actor I pro will automatically search, pair and connect to the Wireless pedal.
- After the connection is successful, the bluetooth indicator light flashes. After pressing and holding any button of the foot switch, Actor I pro starts to run; release the button to stop its operation;

⚠ Caution:

- Only when the Wireless pedal is in standby state, the bluetooth can be turned on by pressing the bluetooth button of Actor I pro;
- When multiple devices are searching and pairing at the same time, the target device may not be connected, so please pair it with one to one separately;
- In order to avoid the unrecognized risks to patients, operators or third parties, the equipment can not be connected to other IT networks (including other equipment);
- When turning on the bluetooth function, please stay away from other bluetooth, WiFi and other 2.4G wireless products;
- After successful bluetooth connection, the device information of the Wireless pedal will be automatically saved in the internal storage space of Actor I pro. This function is turned off by default.

6. Troubleshooting

When a trouble is found, check the following points before contacting your dealer,If none of these are applicable, Or if the trouble is not resolved even aft er taking actions, Please contact your distributor.

Fault phenomenon	Check items	Fault analysis and handling method	Reference chapter or section
The device does not work after starting up	The battery power is low.	Charge it in time.	5.2
	The time to press the switch button is too short	Please press and hold the switch button	5.1
The device is not charged	The wrong Power Adapter is used	Please use the original Power Adapter	1.5

properly	The Charging base is not powered on	Please check the connection	5.2
	The Main frame is not inserted into the Charging base properly	Please check whether there is any foreign body in the Main frame	5.2
The Working tip fails to vibrate	1. The Working tip is not tightened; 2. The Working tip is damaged. 3. The Main frame is damaged	1. Tighten the Working tip with a wrench; 2. Replace the Working tip with a new one. 3. Please contact the distributor	4.2
The indicator light on the Main frame is not on	The Main frame is damaged	Please contact the distributor	3
The Main frame has not sound	The main-board is damaged	Please contact the distributor	5.1
The Main frame gives an alarm and the battery power indicator light is on	The battery power is low	Please charge it in time	5.2

7. Cleaning, Disinfection and Sterilization

Caution:

- No part of Actor I pro is sterilized before leaving the factory

Warning:

- Do not immerse the Main frame in the ultrasonic cleaner.
- Do not use liquid or spray cleaner directly, especially on the screen.
- Except the Working tip, wrench and Silicone case, all other parts for the device can't be sterilized by high temperature and pressure. See the following table for the cleaning methods of other parts
- Do not use any heat, radiation, formaldehyde, ethylene oxide or plasma for sterilization.

Advice:

- Reprocessing procedures have only limited implications to this dental instruments. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable

reprocessing. The device should no longer be reused in case of signs of material degradation.

- In case of damage the device should be reprocessed before sending back to the manufacturer for repair.

Reprocessing Instructions

Step	Parameter
Preparation at the Point of Use:	Remove gross soiling of the instrument with cold water (<40 ℃) immediately after use. Don't use a fixating detergent or hot water (>40℃) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding, if required.
Transportation :	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state, as far as possible. Only Working tip, wrench and Silicone case can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the Main frame, Power Adapter, Charging base and Wireless pedal! The Main frame, Power Adapter, Charging base and Wireless pedal cannot be cleaned and disinfected in a washer/disinfector! For these parts, only a general wipe decontamination is possible!
Decontamination of other parts than Working tip, wrench and Silicone case:	After operation, take the Main frame, Power Adapter, Charging base and Wireless pedal on the workbench. Soak a soft cloth completely with distilled water or deionized water, and wipe all the surfaces of these components, until the surface of the components is visually clean. For decontamination, soak a dry soft cloth with 75% alcohol or other disinfects which are approved for its efficacy by VAH/DGHM-listing, CE marking, FDA and Health Canada Approval. Wipe all surfaces of the Main frame, Power Adapter, Charging base and other components with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectants. Wipe the surface of the component with a dry soft lint-free cloth.
Following instructions are only relevant for Working tip, wrench and Silicone case!	
Pre-Cleaning of Working tip, wrench and Silicone case:	Not use automated cleaning, disinfection and sterilization for other parts than Working tip, wrench and Silicone case in this system! Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumen with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.

Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program: ● 4 min pre-washing with cold water (<40℃); ● emptying ● 5 min washing with a mild alkaline cleaner at 55℃ ● emptying ● 3 min neutralising with warm water (>40℃); ● emptying ● 5 min intermediate rinsing with warm water (>40℃) ● Emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert). Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.
Disinfection:	Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection at 90℃ has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93 ℃.
Drying:	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling, if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Before packaging and autoclaving, make sure that these devices have been maintained acc. to manufacturer’s instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134℃ (in EU: 5 min at 134℃) Maximum sterilization temperature: 137℃ Drying time: For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave’s instructions for use. After sterilization: a. Remove the product from the autoclave. b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged. Flash sterilization is not allowed on lumen instruments!
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

8. Storage, Maintenance and Transportation

8.1 Storage

a. This product should be handled with care, kept away from earthquake source, and stored in a dry and ventilated place.
b. This product should not be placed together with toxic, corrosive, flammable and explosive items.
c. The relative humidity of the storage environment should be 10%~80%, the atmospheric pressure should be 500-1060hPa, and the temperature should be -10℃~ +50℃.

8.2 Maintenance

a. This product does not contain self-repair spare and accessory parts. Repair of this product should only be carried out by specialized maintenance personnel or special repair shops.
b. Please keep this product dry. Rainwater, moisture and liquids may contain minerals that can corrode the electronic circuit of this product.
c. Do not throw, knock or vibrate this product. Rough handling of this

product may damage its internal circuit board and wires.

d. Do not apply paint to this product, as it will leave debris in the removable parts, thus affecting its normal operation.
e. The battery of this device is not replaceable.

8.3 Transportation

a. During the transportation, excessive impact and vibration should be prevented. Handle it with care. placing it upside down should be avoided.
b. This product should not be transported together with dangerous goods.
c. This product should not be exposed to the sun, rain or snow during transportation.

9. Technical Parameters

Manufacturer	Changzhou Bomedent Medical Technology Co., Ltd.
Product name	Ultrasonic Endo Activation Device
Model	Actor Ⅰ pro
Dimensions	Main frame: 169*26*28mm Charging base: 82*64*73 mm
Packing weight	780g
Power supply mode	Lithium battery, DC 3.7V, 1600mAh
Charging base	Input: DC5V/1A Output: DC 5V, 0.5A max
Power Adapter	Input: AC100-240V, 50/60Hz Output: DC5V/1A
Liquid permeation protection	IPX0（Device） IPX6（Wireless pedal）
Classification of electric shock protection type	Class II, Internal power unit
Classification of electric shock protection level	Class B
Main vibration offset of Working tip	≤120μm

Vibration frequency of Working tip	45kHz ± 5kHz
Effective connection range of bluetooth	⩽5m
Power consumption	<3W
Use environment	Temperature: 10-40℃ Humidity: 10-70% Atmospheric pressure: 700-1060hPa
Storage/transportation environment:	Temperature: -10-50℃ Humidity: 10-80% Atmospheric pressure: 500-1060hPa
Expected service life	4 years

10. Symbol instruction

	General warning sign		Refer to the Operation Manual
	Type B applied part		Class II equipment
	Direct current		Serial number
	Manufacturer		Date of manufacture
	For indoor use only		This way up
	Keep dry		Fragile, handle with care
	Washer-disinfector for thermal disinfection		Sterilizable in a steam sterilizer(autoclave) at the temperature specified

	Temperature limitation		Humidity limitation
	Atmospheric pressure limitation		Follow the waste of electric and electronic equipment (WEEE) Directive
CE 0197	This conforms to CE European Directive of “ Medical equipment directive 93/42/EEC”.	EC REP	Authorized representative in the European Community
UDI	Unique Device Identifier	MD	Medical device

11. Environmental Protection

This product does not contain harmful ingredients and can be disposed and destroyed according to the relevant local regulations.

12. After-sales Service

The manufacturer provides quality assurance to the purchaser of the product due to quality problems caused by the product's own materials and workmanship during normal installation and use. The host and reducer are guaranteed for 1 year free of charge, and consumables such as accessories are not covered by the warranty. If the accessories are damaged, please use the accessories provided by the manufacturer. The maintenance of the components needs to be repaired by professional personnel. Please refer to "Warranty Card" for the warranty period and manufacturer details.

If the maintenance personnel need to use the circuit diagram, our company will provide it.

13. EMC Statement

Guidance and Manufacturer’s Declaration

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
DC Power Line (USB Cable)	1.8m	Unshielded	1 Set	DC Power

Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; the equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

The equipment with no ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

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" .

The 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

WARNING: If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

EMI Compliance Table (Table 1)

Table 1 – Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment

Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

EMS Compliance Table (Table 2-5)

Table 2 – Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ± 5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		

5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T, 250/300 cycles

Table 5 – Signal input/output parts Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz

Warranty Card

Dear user:

For the warranty:

1. We offer 1 year warranty for the product Actor I pro (excluding the battery and accessories).
2. The following circumstance does not belong to the scope of free warranty:
   a) Using the product did not follow the matters needing attentions in user`s manual;
   b) Disassembling the product by yourself;
   c) Altering the invoice or without the invoice.
3. Fill up the following information, then send it back to us with our products.

User’s Name: _____

Telephone Number: _____

Address:_____

_____

_____

Trouble Description:

_____

_____

_____

_____

(The information such as: When, Where and How it happened. How many times)

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