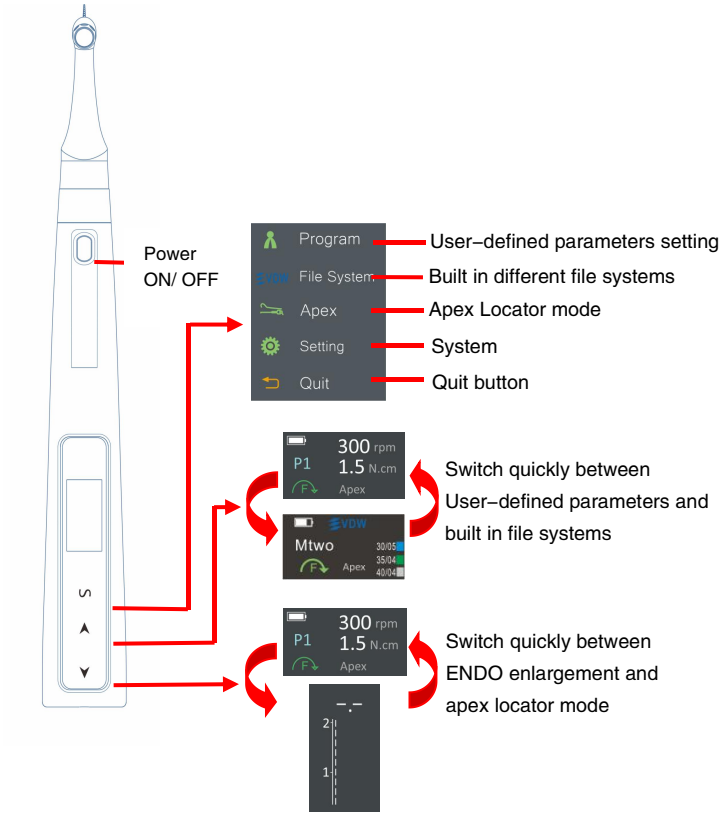
VRN

DM–1

Endo Motor

Operation Manual

Contents



Shortcut keys:

A Press the “➤” key exceeding 2 seconds can switch quickly between ENDO enlargement with apex locator mode.

B Push the “➤” button exceeding 2 seconds can switch quickly between user–defined parameters with built in file systems.

C Push the power button exceeding 2 seconds can access RESET interface directly when the unit is power off.

D Push the power button, the file will quit with rotation clockwise in the reciprocating motion, the file with stop when releasing the button.

1 Introduction

1.1 Description of the device

DM–1 is a supporting device of endodontic treatment, through enlarging root–canal in the process, helping dentists to finish the endodontic treatment. This device with Apex Locator functions also.

1.1.1 Device Features:

1) With Multi–Frequency length measuring technology and the function of root–canal length measuring and enlargement.

2) Colorful OLED screen

3) The Contra–angle can rotate freely.

4) Built in different File systems.

5) Four working modes:

A Forward rotation Symbol: 

Intelligent sensing the surface pressure of a NiTi file, when the torque reaches the setting limit, the motor will auto reverse. Once the surface pressure is removed, the NiTi file will rotate continuously in the original direction.

B Reverse rotation Symbol: 

C Reciprocating motion Symbol: 

The reciprocating motion angle is adjustable, 30º, 60º, 90º, 150º, 180º, 210º, 250º, 370º for clockwise and anticlockwise, can combination freely.

D Automatic torque control Symbol: 

Intelligent sensing the surface pressure of a NiTi file, when the torque reaches the setting limit, the motor will reciprocate rotation instead of the reverse mode until the stress is reduced. Once the surface pressure is below the preset torque value, the NiTi file will rotate continuously in the original direction.

6) Seven functions including Apex Locator, Reciprocating rotary motion, Automatic deceleration in apical zone, Automatic reversion in apical zone with 360º rotation file, Automatic forward rotation in apical zone with reciprocating files, Automatic reversion of torque, Root–canal length measuring and enlargement simultaneously.

7) The main accessories (Contra–angle, File Clip, Lip Hook, Touch

Probe and Rubber Case) could be sterilized in high temperature and pressure to avoid cross infection.

1.2 Model, Dimensions and Weight of the main unit

Model：DM–1

Dimensions of Main Unit: Φ28 mm(Biggest Diameter) * 157 mm(Length)

Weight of Main Unit: 100 g

1.3 Structure

DM–1 is composed of main unit, charge base, contra–angle, measuring wire, file clip, lip hook, touch probe, rubber case and charging wire.

1.4 Intended use

DM–1 is an electronic device used for enlarging root canal. This product is only used in hospital environments, clinics or dental offices by qualified dental personnel.

1.5 Contraindications

The DM–1 is not recommended for use:

a) In patients who have a pacemaker or other implanted electrical devices, or have been cautioned by their physicians against the use of small electric appliances such as shavers, hair dryers, etc.

b) In patients allergic to metals.

c) In children.

1.6 Components

1.6.1 The structural figure of the device. (Fig. 1.1)

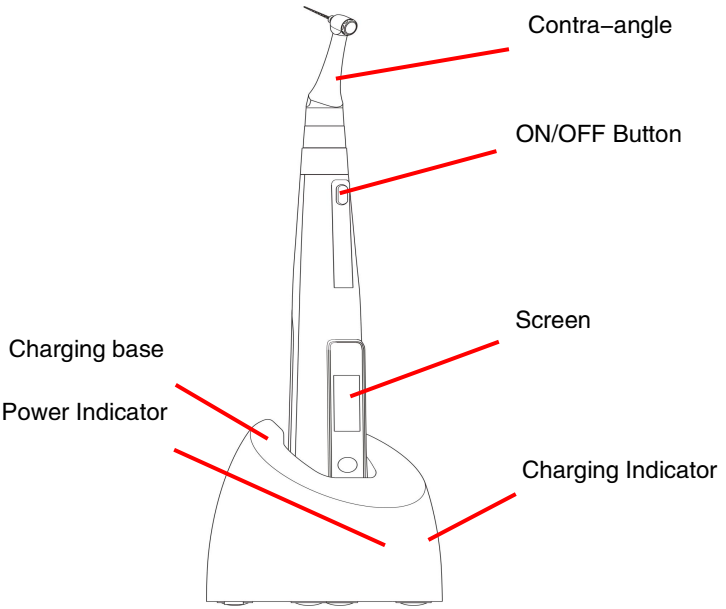
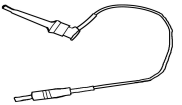


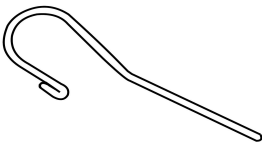
Fig. 1.1 Product appearance structure

1.6.2 The figures of the main accessories. (Fig. 1.2)

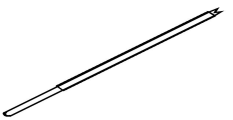
a Contra−angle



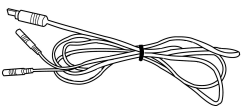
b File clip



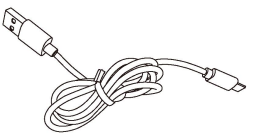
c Lip hook



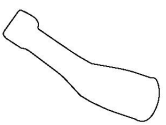
d Touch Probe



e Measuring wire



f Single−head measuring wire



g Rubber case

h Charging wire

Fig. 1.2 The figure of the main accessories

1.7 The classification of the device

1.7.1 Type of protection against electric shock: Class Ⅱ equipment.

1.7.2 Degree of protection against electric shock: Type B applied part.

1.7.3 Ingress protection rating: Ordinary equipment (IPX0).

1.7.4 Device not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.

1.7.5 Operation mode: Continuous operation.

1.8 The main technical specifications

1.8.1 Battery: 3.7 V/1050 mAh

1.8.2 Input Power: DC 5.0 V/1 A

1.8.3 Revolving speed: 150 rpm ~ 800 rpm

1.8.4 Torque: 0.6 N・cm ~ 3.9 N・cm

1.8.5 Buzzer alert: The buzzer will alert when the file is less than 2mm closed to the apex.

1.8.6 Operation condition：

1) Environment temperature: 0 ℃ ~ 40 ℃

2) Relative humidity: 10% ~ 85%

3) Atmosphere pressure: 70 kPa ~ 106 kPa

2 Notice

2.1 Please read the user manual carefully before the operation.

2.2 While being on operation, the scale indication on the MARC III PRO screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the file progression moves toward the apex.

2.3 While being on operation, the following patient’s related factors may influence accurate readings: Blocked root canals, Cracked root canals, Perforated root canals, Root fracture or perforation, Metal crows or bridges contact with the file or the lip file, The inner liquid link to the outer liquid of root canals, Very dry root canals, The file or the file clip contact with other metal or instruments.

2.4 Inaccurate or incorrect readings due to the environment are likely to occur in the following cases:

a) Presence of portable or movable radio frequency transmitters in the surroundings.
b) Electromagnetic interference could cause improper operation of the device.
2.5 This device has electromagnetic interference which is similar to other device, the patient or doctor who with a pacemaker are forbidden to use this device.
2.6 While being on operation, the apical position is located to the place apex locator screen indicates "0.0", as a safety precaution in order to avoid over–instrumentation, it is recommended to subtract 0.5 mm–1.0 mm to determine the working length for shaping.
2.7 Please do not use the file which is broken, crooked and not meeting the ISO standard to avoid any kind of danger.
2.8 Please pay full attention to the device if there is loose, vibration, noise and heat, and pre–test before operation. If any abnormal phenomena, please stop using immediately and contact local agent or manufacturer.
2.9 Do not collide, especially to avoid falling.
2.10 Please clean the collet of file and set aside because the inside parts might be damaged once polluted.
2.11 Please recharge the battery when the battery power is low and indicator flashes.
2.12 Only the original accessories to this device.

3 Installation

3.1 According to the Fig. 3.1, connecting the main unit with accessories

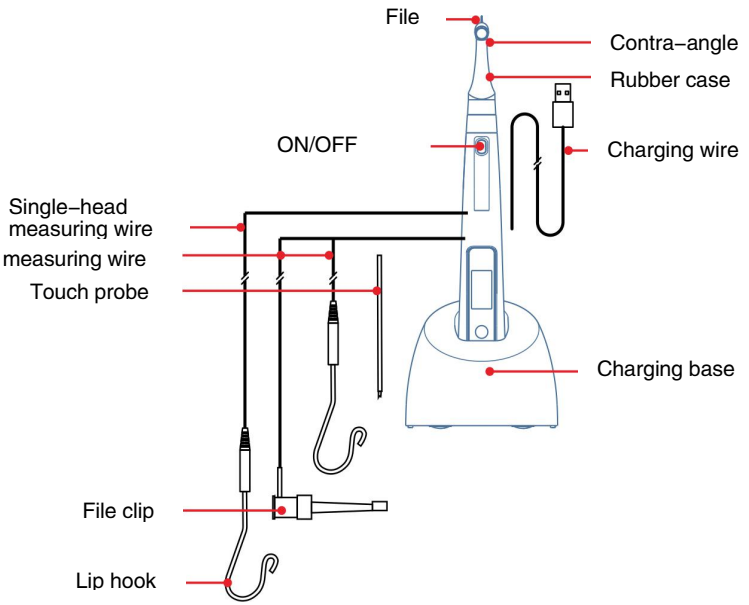


Fig. 3.1 Explanation of connecting the main unit with accessories

1) Before using this instrument, clean all the parts that may contact with patients.
2) Only match the locating points of both contra–angle and main unit, they can connect smoothly.

3.2 Charge the battery

When the power indicator turns red, please stop using the device and recharge the battery.

a) Connect the Charging wire USB plug with the back side socket of the charging base properly, and insert the charging wire plug to the power socket.

b) The right side green indicator is lighted when the device is charging, and it means charging has finished when the green indictor turns down. It may spend 4 hours for charging.

3.3 Automatic shutdown

When not used for 3 minutes, this device will automatically shut down and all of the display and function are stopped.

4 Operation

4.1 Symbol Instructions

A Forward rotation Symbol： 

Intelligent sensing the surface pressure of a NiTi file, when the torque reaches the setting limit, the motor will auto reverse. Once the surface pressure is removed, the NiTi file will rotate continuously in the original direction.

B Reverse rotation Symbol： 

C Reciprocating motion Symbol： 

The reciprocating motion angle is adjustable, 30º, 60º, 90º, 150º, 180º, 210º, 250º, 370º for clockwise and anticlockwise, can combination freely.

D Automatic torque control Symbol： 

Intelligent sensing the surface pressure of a NiTi file, when the torque reaches the setting limit, the motor will reciprocate rotation instead of the reverse mode until the stress is reduced. Once the surface pressure is below the preset torque value, the NiTi file will rotate continuously in the original direction.

4.2 Screen Instructions

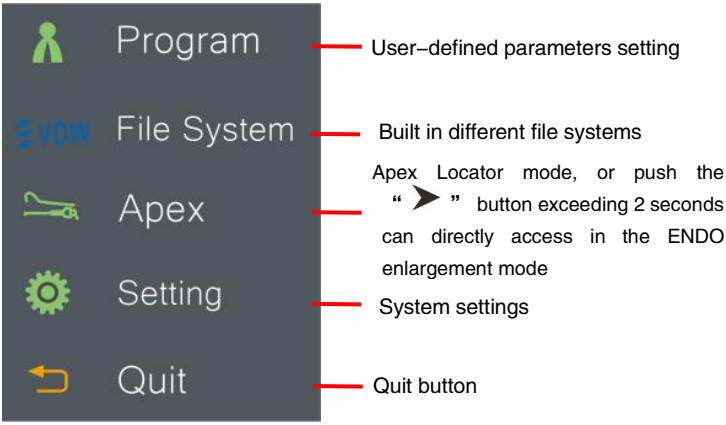
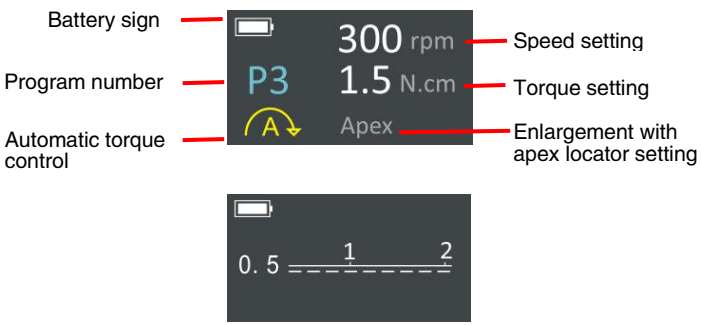


Fig. 4.1 The main interface of screen



Enlargement with apex locator mode, setting the reverse rotation position

Push the "➤" button exceeding 2 seconds can switch quickly between user–defined parameters and built in file systems

Fig. 4.2 The User–defined parameter setting interface

Fig. 4.3 Built in file systems interface

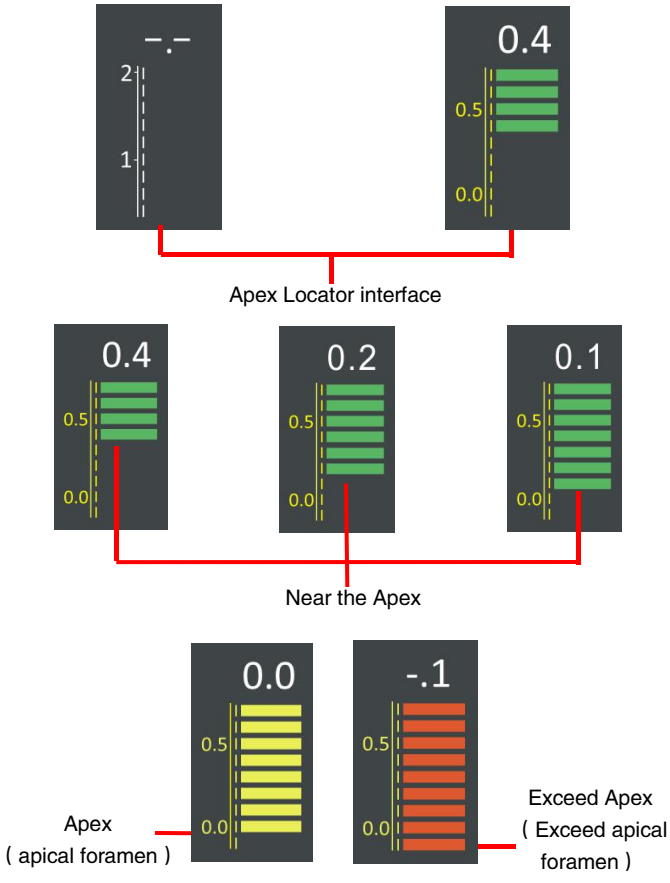


Fig. 4.4 Apex locator interface

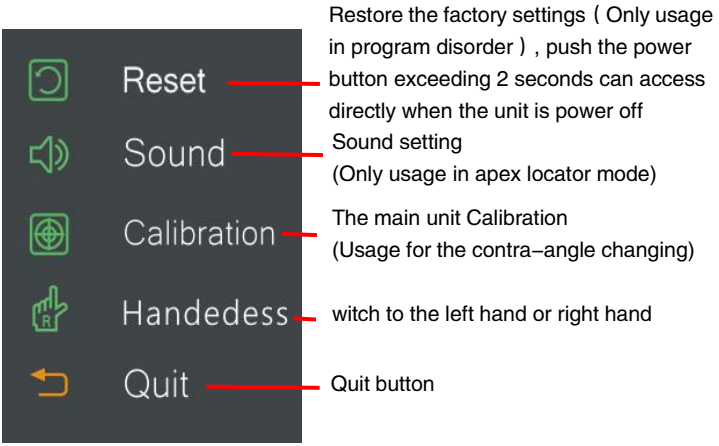


Fig. 4.5 System settings interface

4.3 Operation Instructions

1) Turn on the main unit, the screen shows the file system or parameters last time automatically. Press the ON/OFF button exceeding 2 seconds or the main unit doesn't work exceed 3 minutes, the main unit will turn off.

2) Press the "S" key exceeding 2 seconds, then enter into the main interface. The "S" key is the confirm button, "◀" key and "▶" key are page button.

3) User–defined parameter setting "Program":

The device can save 9 programs, each program can set different parameters according to the user. Press "S" key enter into the user–defined interface, press "S" key switch to the required symbol, press the "◀" key or "▶" key change the settings or parameters. When the "Apex" symbol is gray, this is the function

of ENDO enlargement only, when the “Apex” symbol is blue, this is the function of combination ENDO enlargement with apex locator. Press the “◀” key or “▶” key adjust the “Apex” symbol turns blue and flashes, then press the “S” key, it will enter to the apex locator interface, press the “◀” key or “▶” key can set the auto reverse position in apical zone.

When use the function of combination ENDO enlargement with apex locator, the motor speed will decelerate automatically and the sound will buzz hurried near the apical zone, the motor speed will reverse automatically in the setting auto reverse position of apical zone.

A Speed setting: Speed is from 150 rpm to 800 rpm

B Torque setting: Torque is from 0.6 N・cm to 3.9 N・cm

Notice: If use the function of combination ENDO enlargement with apex locator, the contra–angle must be covered by the rubber case first.

4) Built in different file system “File System”:

Press “S” key enter into the file system interface, press the “◀” key or “▶” key to select different files, then the “Apex” symbol will flash after pressing “S” key. When the “Apex” symbol is gray, it presents the function of ENDO enlargement only, when the “Apex” symbol is blue, it presents the function of combination ENDO enlargement with apex locator.

Press the “◀” key or “▶” key adjust the “Apex” symbol turns blue and flashes, then press the “S” key, this device will enter to the apex locator interface, press the “◀” key or “▶” key can set the auto reverse position in apical zone.

5) Apex locator mode “Apex”: Press “S” key enter into the apex locator mode, connecting the accessories with the main unit correctly.

Notice: The apex locator calibration, connecting the accessories with the main unit correctly, touch the file clip with lip hook, if the screen turns red and displays “–0.1”, this means the device works very well.

Notice: Press the “>” key exceeding 2 seconds, it can enter or exit the apex locator mode quickly in the ENDO enlargement mode.
Notice: If use the function of combination ENDO enlargement with apex locator, the contra–angle must be covered by the rubber case first.

6) System settings “Setting”:
A Sound setting “Sound”: Pressing the “S” key to turn on the sound or mute, this setting is valid only in apex locator mode.
B Calibration automatically “Calibration”: Pressing the “S” key to calibrate the device automatically, calibration only used when the Contra–angle changed.
7) Restore the factory settings “Reset”: Only usage in program disorder, push the power button exceed 2 seconds can access directly when the unit is power off.
8) Quit button “Quit”: Quit the interface when the setting finished.
9) Shortcut keys
A Press the “➤” key exceeding 2 seconds can switch quickly between ENDO enlargement with apex locator mode.
B Push the “➤” button exceeding 2 seconds can switch quickly between user–defined parameters with built in file systems.
C Push the power button exceeding 2 seconds can access directly when the unit is power off.

5 Troubleshooting

NO.	Problems	Possible causes	Solutions
1	No displays on the screen after turning on	1 The incorrect battery installation 2 The lower power	1 Install the battery correctly 2 Recharge the battery
2	File is not working	1 Resistance is too large	1 Set a higher torque
3	Endo file stops	1 Resistance is too large 2 Root canal in a bad situation	1 Set a higher torque 2Change to non–root–canal measuring mode
4	Root canal measurement values are inaccurate	1 Root canal in a bad situation 2 Electromagnetic interference	1 Removal of liquid and residual pulp 2 Please check the equipment used nearby, and be away from interference sources
5	Endo file does not reverse rotate	1 The mode with automatic positive / reverse rotation function is not selected 2 A too large torque value was set 3 Endo file does not reach the root top region	1 Select automatic positive/reverse rotation model 2 Set a lower torque value 3 Endo file will automatically rotate when reaching root top
6	Endo file doesn’t work in combination enlargement with	1 Root canal is too dry 2 A poor connection of file clip or measuring	1 Drip into proper saline 2 Remove contamination or replace

NO.	Problems	Possible causes	Solutions
	apex locator mode	wire 3 Oral mucosa is too dry 4 The double–head measuring wire inserts into main unit 5 Electromagnetic interference	spare part 3 Wet oral mucosa 4 Replace to a single–head measuring wire 5 Please check the equipment used nearby, away from interference sources
7	File reversed too frequently	1 Resistance is too large 2 Root canal in a bad situation 3 Root top setting point is too high 4 Root canal is narrow 5 Endo file is oversized 6 Electromagnetic interference	1 Set a higher torque 2 Removal of liquid and residual pulp or Change to non–root–canal measuring model 3 Reset root top region 4 Root–canal enlarge 5 Replace a smaller size file 6 Please check the equipment used nearby, away from interference sources

Notice: If the problem can’t be solved yet, please contact the local distributors or us.

6 Cleaning and Sterilization

6.1 After use, all parts that have contacted with the patients should be wiped by sterilized towel. (no bacteria, no fungi and no aldehyde liquid)
6.2 Cleaning with chemical reagents may cause damage to the instrument.
6.3 Contra angle, file clip, lip hook, touch probe and rubber case must be autoclaved before use.
6.4 Main unit, charging base, measuring wire and charging wire can’t be autoclaved with high temperature and pressure.

7 Storage, maintenance and transportation

7.1 Storage

7.1.1 Handle with care, far away from vibration source. Install or store in a cool, dry, well–ventilated area.
7.1.2 Do not store with toxic, corrosive, flammable, explosive items.
7.1.3 Store in environment of relative humidity no more than 90%, atmospheric pressure 70 kPa ~ 106 kPa, temperature –20 ℃ ~ 55 ℃.

7.2 Maintenance

7.2.1 The product does not contain any user–serviceable accessories. Instrument maintenance should only be operated by the professional trained maintenance personnel.
7.2.2 If the battery is fully charged but does not allow the instrument to function for at least one day, the battery must be replaced as soon as possible. Please use the original accessories, so as not to cause damage to the instrument.

7.3 Transportation

Avoid excessive shock and vibration during transport, handle with care, keep away from dangerous goods and avoid sun and rain.

8 Standard symbols

Symbol	Description
	Manufacturer's logo
	Caution,consult accompanying documents
	Refer to instruction manual/ booklet
ON/OFF	Switching on (ON) / Switching off (OFF)
POWER	Charging indicator
DC 5 V / 1 A	USB charging socket
	Do not dispose of the product into the ordinary municipal waste or garbage system
	Manufacturer
	Date of manufacture
	Use by date
	Temperature limitation

Symbol	Description
	Atmospheric pressure limitation
	Humidity limitation
	Serial number
	This way up
	Fragile, handle with care
	Keep away from rain
	Type B applied part
	Sterilizable at up to 135 ℃ in the steam sterilizer (autoclave) attemperature specified
	Medical Device

9 Environmental Protection

Name	Toxic and harmful substances or elements					
	Pb	Hg	Cd	Cr（Ⅵ）	PBB	PBDE
Plastic shell	O	O	O	O	O	O
Circuit board	O	O	O	O	O	O
Stamping parts	O	O	O	O	O	O
Tips	O	O	O	O	O	O
Silicone sleeve	O	O	O	O	O	O

The table is compiled in accordance with the provisions of SJ/T 11364.

O：It means that the content of this toxic and hazardous substance in all homogeneous materials of this part is below the limit requirement of GB/T 26572.

X：It It means that the content of the toxic and hazardous substance in at least one of the homogeneous materials of the part exceeds the limit requirement of GB/T 26572.

(This product complies with the requirements of EU RoHS environmental protection: currently there is no mature technology in the world that can replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys)

In accordance with *Administrative Measures on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products*, *Regulations on the Management of the Recycling and Disposal of Waste Electrical and Electronic Products* and related standards, please observe the safety and use precautions of the product, and recycling or disposal of this product please apply appropriate measures in accordance with local laws and regulations after the product is used.

10 Manufacturer's rights

The company reserves the right to modify the design, technology, accessories, user manual content and packing list content of the product at any time without notice. In case of discrepancies, the actual product shall prevail.

11 Electromagnetic compatibility

NOTICE：

1）Without the express consent of URIT, unauthorized changes or modifications to the device may cause electromagnetic compatibility(EMC) problems of the device or other device.

2）The design and test of device comply with the operating regulations related to EMC.

3）WARNING：Even if other devices meet the launch requirements of the corresponding national standards,the device or system may interfere with other electronic devices.

11.1 Cable length

Cable name	Type	Length
Power Cord	Unshielded parallel line	1.5 m

11.2 Key components of EMC

The product key components of EMC are the scaler's main board chip and adapter. The use or replacement of accessories, cables, transducers, etc. that are not designed to match will cause the electromagnetic emissions and immunity performance to be significantly reduced. Do not replace device parts without authorization.

11.3 Electromagnetic emissions

<table>
<tr><td colspan="3">GUIDANCE AND MANUFACTURER’S DECLARATION– ELECTROMAGNETIC EMISSIONS</td></tr>
<tr><td colspan="3">DM–1 is designed for use in the electromagnetic environment described in the table below. The user or purchaser must ensure that the medical device is used in the environment described below.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions
GB 4824</td><td>Group 1</td><td>DM–1 uses radiofrequency energy for its internal operation. Consequently, its radiofrequency emissions are very low and are not likely to create any interference with other nearby equipment.</td></tr>
<tr><td>RF emissions
GB 4824</td><td>Class B</td><td rowspan="3">DM–1 is suitable for use in all establishments, including domestic and those directly connected to the low voltage energy supply public network supplying buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
GB 17625.1</td><td>N/A</td></tr>
<tr><td>Voltage fluctuation and flickers GB 17625.2</td><td>Conforming</td></tr>
</table>

11.4 Electromagnetic immunity

GUIDANCE AND MANUFACTURER'S DECLARATION– ELECTROMAGNETIC IMMUNITY			
DM–1 is designed for use in the electromagnetic environment described in the table below. The user or purchaser must ensure that the medical device is used in the environment described below.			
Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) GB/T 17626.2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst GB/T 17626.4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for link cable	Main power quality should be that of a typical commercial or hospital environment.
Surge GB/T 17626.5	± 1 kV differential mode ± 2 kVcommon mode	± 1 kV differential mode	Main power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines. GB/T 17626.11	< 5%U_T (>95% dip in U_T) for 0.5 Cycle 40%U_T (60% dip in U_T) for 5 Cycles 70%U_T (30% dip in U_T) for 25 Cycles < 5%U_T (>95% dip in U_T) for 5 seconds	< 5%U_T (>95% dip in U_T) for 0.5 Cycle 40%U_T (60% dip in U_T) for 5 Cycles 70%U_T (30% dip in U_T) for 25 Cycles < 5%U_T (>95% dip in U_T) for 5 seconds	Main power quality should be that of a typical commercial or hospital environment. If the user of DM–1 requires continued operation during power main interruptions, it is recommended that the DM–1 be powered from an UPS or battery supply.
Power frequency (50 Hz–60 Hz) magnetic field GB/T 17626.8	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 applications of the test level.			

11.5 Electromagnetic immunity

GUIDANCE AND MANUFACTURER’S DECLARATION– ELECTROMAGNETIC IMMUNITY			
DM–1 is designed for use in the electromagnetic environment described in the table below. The user or purchaser must ensure that the medical device is used in the environment described below.			
Immunity test	IEC 60601 test level	Conformity level	Electromagnetic environment – guidance

Conducted RF GB/T 17626.6 Radiated RF GB/T 17626.3	3 Vrms 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of DM–1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V1}\right]\sqrt{p}$ $d = \left[\frac{3.5}{E1}\right]\sqrt{p} 80MHz \sim 80MHz$ $d = \left[\frac{7}{E1}\right]\sqrt{p} 800MHz \sim 2.5GHz$ Where P is the maxi mum 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] 

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

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which theDM–1 is used exceeds the applicable RF compliance level above, DM–1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating DM–1.

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

11.6RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF

COMMUNICATIONS EQUIPMENT AND DM–1

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND DM–1			
DM–1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of DM–1 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DM–1 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 ~ 80 MHz $d=\left[\frac{3.5}{V1}\right]\sqrt{p}$	80M Hz ~ 800 MHz $d=\left[\frac{3.5}{E1}\right]\sqrt{p}$	800 MHz ~ 2.5 GHz $d=\left[\frac{7}{E1}\right]\sqrt{p}$
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 distance d 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 higher frequency range applies.

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

DM–1 has passed test according to the standard IEC 60601–1–2：2014, but it cannot guarantee in any way that it is not affected by electromagnetic interference. DM–1 should be avoided using in high electromagnetic environments.

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