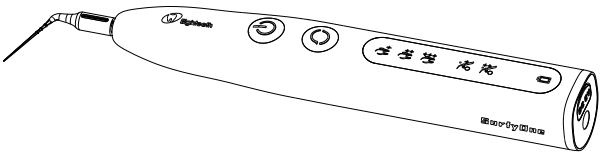
Eighteenth



SurfyOne

USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

P/N: IFU-6235023

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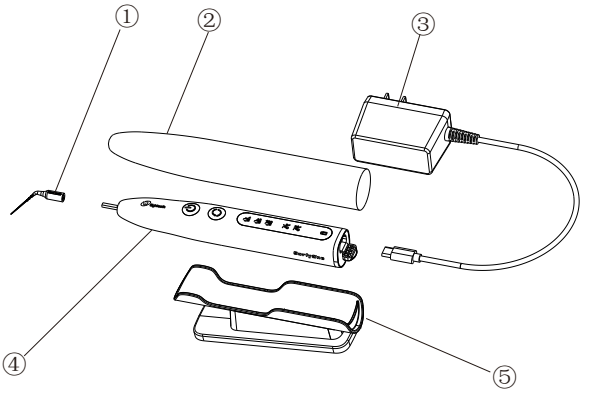
Size: 150mm×95mm

Content

1. Scope of SurfyOne 4
1.1 Parts Identification 4
1.2 Components 5
2. Symbols used 7
3. Before Use 9
3.1 Scope of application 9
3.2 Contraindications 9
4. Install the SurfyOne 11
4.1 Install the Single-use barrier sleeve 11
4.2 Install the Tip 11
4.3 Remove the Tip 11
4.4 Connect/disconnect the Adapter 12
4.5 Use the Main Unit Base 12
5. Use Interface 13
6. Operation 14
6.1 Charge 14
6.2 Operation 16
7. Maintenance 18
7.1 Cleaning, Disinfection and Sterilization 18
7.1.1 Foreword 18
7.1.2 General recommendations 18
7.1.3 Autoclavable accessories 18
7.2 Daily Maintenance 22
8. Troubleshooting 24
9. Technical Data 25
10. EMC Tables 26
11. Warranty 32
12. Statement 33

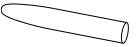
1.Scope of SurfyOne

1.1 Parts Identification



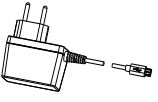
① Sonic Endo Activation Device Tip
② Single-use barrier sleeve
③ Adapter
④ Main Unit
⑤ Main Unit Base

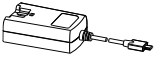
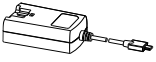
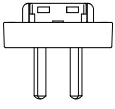
1.2 Components

Main Unit (1 pc) 	Main Unit Base (1 pc) 	Single-use barrier sleeve (100 pcs) 
Sonic Endo Activation Device Tip 17-1502 (5 pcs) 	Sonic Endo Activation Device Tip 17-2504 (5 pcs) 	Sonic Endo Activation Device Tip 21-1502 (5 pcs) 
Sonic Endo Activation Device Tip 21-2504 (20 pcs) 	Sonic Endo Activation Device Tip 25-2504 (5 pcs) 	

Note: Tip stands for Sonic Endo Activation Device Tip.

For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
European standard	**Adapter (1 pc)** 	/

<table>
<tr><td>American standard</td><td>Adapter (1 pc)
  </td><td>American standard power plug (1 pc)
  </td></tr>
<tr><td rowspan="3">Multi-standard</td><td rowspan="3">Adapter (1 pc)
  </td><td>British standard power plug (1 pc)
  </td></tr>
<tr><td>Australian standard power plug (1 pc)
  </td></tr>
<tr><td>Argentina standard power plug (1 pc)
  </td></tr>
</table>

2. Symbols used

	General warning sign
	Caution
	Serial number
	Catalogue number
	Batch code
	Medical device
	Manufacturer
	Country of manufacturer + Date of manufacture
	Class II equipment
	Type B applied part
	Do not reuse
	Washer-disinfector for thermal disinfection
	Direct current
	Alternating current
	Keep dry
	Dispose of in accordance with the WEEE directive
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limit

2 Symbols used

	Humidity limitation
	Atmospheric pressure limitation
	Consult instructions for use
Eighteeth	Manufacturer's Logo

3. Before Use

3.1 Scope of application

The SurfyOne is used in endodontic treatment by application of sonic energy. The SurfyOne can provide the energy for Sonic Endo Activation Device Tip oscillation and vibration.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.

3.2 Contraindications

None known.

Before use, please read the following instructions carefully:

- You should carefully read and understand all the contents of the manual before operating.
- All warnings and instructions on the equipment should be followed during operation.
- Do not place the device in a wet place or where it may come into contact with any liquid.
- Do not expose the device to direct or indirect heat sources. This equipment must be operated and stored in a safe environment.
- Do not use this device in the presence of free oxygen, anesthetic gas, or combustible materials. The equipment must be operated and stored in a safe environment.
- This device may cause radio interference or interfere with the operation of nearby equipment. In this case, the orientation or placement of the equipment should be re-adjusted and shielding should be set in the immediate vicinity of the equipment to minimize the interference effect of the equipment. The electromagnetic radiation issued by the equipment conforms to the relevant regulatory requirements.
- This equipment requires special precautions regarding electromagnetic compatibility (EMC). Do not use this device near strong fluorescent lamps, wireless transmitters, remote control equipment, handheld and mobile high frequency communication equipment.
- Do not charge, use or store the device at high temperatures. Please pay attention to the conditions of use and storage.
- Disposable gloves and rubber barriers must be used during treatment procedures.
- Please do not disassemble and repair the equipment without permission, otherwise it will

automatically lose the warranty qualification.

● If any abnormal phenomena occur during the treatment process, please immediately shut down the device and contact the local dealer for handling.

● Charge the main unit before using it for the first time and use the original adapter when charging. Do not use the device for therapeutic operations during charging.

● Do not spray alcohol on the charging port. Do not use conductive objects to probe the charging interface.

● Do not use accessories other than the company, otherwise it may cause damage to the product. If you use accessories other than our company, any problems occur, the company will not be responsible.

● If liquid flows out of the device, it can be judged as battery leakage. Please stop using it immediately and contact the local dealer for handling.

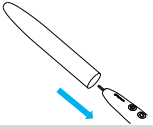
● It is prohibited to modify the equipment without authorization from the manufacturer.

● It is recommended to have the equipment and its accessories inspected at the dealer's location once a year.

4. Install the SurfyOne

4.1 Install the Single-use barrier sleeve

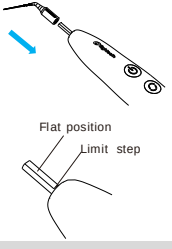
Align the opening of the Single-use barrier sleeve with the head of the main unit, gently put it on, and ensure that the Single-use barrier sleeve fits the main unit.



● The Single-use barrier sleeve must be discarded after use and cannot be reused.

4.2 Install the Tip

Align the flat position on the tip with the flat position of the main unit output shaft and insert the tip on the main unit output shaft all the way to the bottom limit step.



● Use the original tip.

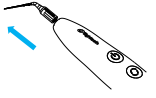
● Before installing the tip, please check the tip and the main unit head, and do not use damaged tip or device.

● After installing the tip to the main unit, pull the tip to ensure that it does not come out and the installation is firm.

● If the connection is not secure it may cause unpredictable rotation or the tip to fall off, or even injure the patient.

4.3 Remove the Tip

Pinch the two sides of the tip with the strip-shaped opening groove at the bottom and pull the tip upward.

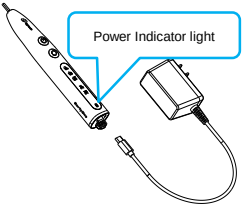


● When installing or removing the work tip, please be careful not to injure your fingers.

● Do not disassemble or assemble the tip while the machine is in operation, otherwise it may damage the machine and even harm the operator or patient.

4.4 Connect/disconnect the Adapter

Insert the USB port of the adapter into the USB charging port of the main unit. The main unit will emit a "Di" sound and the power indicator light will light on.



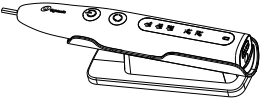
Pull out the USB port of the adapter from the USB charging port of the main unit, and the main unit will emit a "Di" sound and the power indicator light will turn off.

⚠

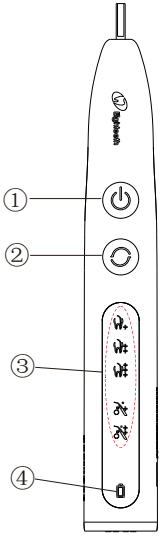
- Use the original adapter for charging.
- Do not place the machine where it is difficult to operate disconnect the machine.

4.5 Use the Main Unit Base

During work breaks, when the machine is not in use, place the machine on the main unit base to protect the tip and the machine.



5. Use Interface



① Power switch button

② Set adjustment button

③ Gear mode indicator light

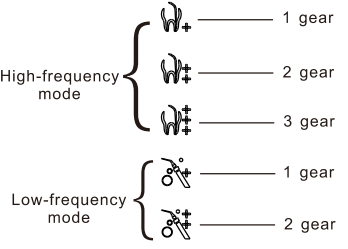
④ Power indicator light

Turn Power On

Press to turn on the device.

Gear mode switching

In standby, press to cycle between the following five gear modes:



In standby mode, long press and at the same time to switch to high-frequency mode 4 gear, and press to exit high-frequency mode 4 gear.

Tip towards angle adjustment

In standby mode, long press , the tip will rotate around the output axis. At this time short press , the tip will reverse. Release , the tip will stop rotating.

Start and stop output

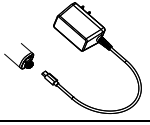
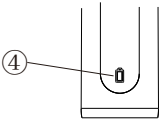
In standby mode, press to start the tip oscillation and vibration. After the machine enters working mode, press again to turn off the output.

Turn Power Off

In standby state, long press to turn off the device.

6. Operation

6.1 Charge

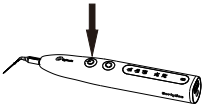
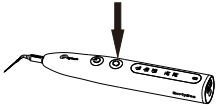
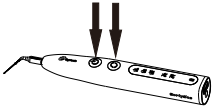
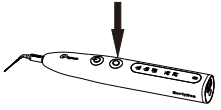
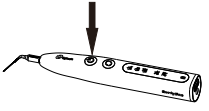
The power indicator light is on green	The remaining battery power is ＞50%, indicating that the battery is fully charged.
The power indicator light is on yellow	The remaining battery power is about 15% ~ 50%, please note.
The power indicator light is on red	The remaining power is ＜ 15%, please charge in time. ⚠ ● If the battery power is less than 15%, it must be recharged within 30 days, otherwise the battery will suffer irreparable damage due to low battery power.
The power indicator light is red and flashing	The remaining power is ＜ 5%, please charge immediately. ⚠ ● If the battery power is lower than 5% to continue to use, the output power may be less than the design value, and the machine will not work. A "DiDi" tone will be heard, and the device will automatically shut down.
Charge 	Connect the adapter according to the diagram.
 	The battery indicator light flashes while charging. When the battery is fully charged or in a nearly fully charged state, the power indicator light remains green. It takes about 4 hours to fully charge the battery. If the remaining battery power is different or the battery status is different (such as aging), the charging time may differ.

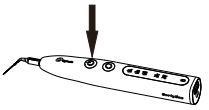
	According to the usage of the device, the battery can be recharged 500 times, and then the battery level will significantly decrease.  ● If the machine is working, connect the main unit to the adapter and it can charge normally, but the machine will automatically stop working, and then enter the charging state. ● If you do not use the machine for a long time, please charge it for at least one month until the power indicator light is constantly green.

● Non professionals or untrained personnel are prohibited from replacing batteries.

● Do not use non-original batteries. If the wrong batteries are used or incorrectly installed, the electronic components will be damaged.

6.2 Operation

	When the machine is turned off, press ⏻ and the machine will emit a "DiDI" prompt sound, complete the startup, and enter the standby state. The power indicator light will light up.
	In standby mode, short press ◎ to cycle through five gear modes, and the corresponding gear mode indicator light will light up.
	In standby mode, long press ◎ and ⏻ at the same time to switch to high-frequency mode 4 gear. At this time, all 3 gear mode indicator lights of high-frequency mode will light up. Press ◎ again to exit high-frequency mode 4 gear.
	In standby mode, long press ◎ and the tip will rotate around the output shaft. At this time, short press ⏻ and the tip will reverse. When the tip reaches the appropriate position, release ◎ and the tip will stop rotating.
	In standby mode, press ⏻ to start the tip oscillation and vibration. After the machine enters working mode, press ⏻ again to turn off the output. The machine has a timed prompt function, with a prompt sound every 5 seconds during operation. ⚠ ● Do not allow the machine to oscillation and vibration without load for a long time. ● Ensure that the tip is upper 2mm from working

	length when moving the tip up and down.
	In standby state, long press ⏻ and the machine will emit a "DiDi" tone to complete shutdown.

After the machine works continuously for 1 minute, it will automatically turn off the output and stop working, and enter the standby state.

Enter standby mode, and after 5 minutes of standby without any operation, the machine will automatically shut down.

If the machine stops during operation, simply restart it.

- Before use for treatment, please test the device outside the mouth to ensure that there are no issues with its functionality.
- The tip may be damaged suddenly when entering a root canal that is too curved or has a bad shape. If the user feels abnormal, please stop using this device immediately.
- Even with normal use, fatigue and aging of the tip may cause the instrument to separate, so please replace it in time. Do not use the working tip more than the recommended number of times.
- When the tip is subjected to excessive external force, it may deform or break. When using this equipment, do not apply excessive external force to the tip.
- After the operation is completed, please remove the tip in time.
- If any abnormality occurs, please stop using this device. This device is not suitable for all types of root canals.
- Please do not use this device for extremely deformed root canals.

7.Maintenance

7.1 Cleaning, Disinfection and Sterilization

7.1.1 Foreword

For hygiene and sanitary safety purpose, the component (Tip) must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent uses. Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

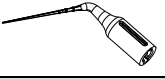
Reprocessing procedures have only limited implications to this dental device. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. The Tip is verified to be able to withstand 10 times reprocessing cycles. The device should no longer be 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.

7.1.2 General recommendations

- The user is responsible for the sterility of the product before the first use and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- Clean the products within two hours after each use.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- The water quality must meet the requirements of EN 13060.
- Thoroughly clean and wash the components before autoclaving.
- Do not use bleach or chloride disinfectant materials.

7.1.3 Autoclavable accessories

Autoclavable accessories
Tip 
⚠ ● Only the above component can undergo high-temperature steam sterilization and can

withstand up to 10 cycles of high-temperature steam sterilization. ● Before first use and after each use, the tip must be sterilized with high-temperature steam.	
Reprocessing instructions	
Preparation at the point of use	Remove gross contaminations from the components with a cloth, which dipped in cold water (＜40°C) immediately after use. Don't use a fixating detergent or hot water (＞40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.  ● Do not wipe the motor components with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in component corrosion and adhesion of the residual medical agents to the components.
Transportation	Safe storage and transportation to the reprocessing area to avoid any damage and contaminate on to the environment.
Preparation for Decontamination	The devices must be reprocessed in a disassembled state.  ● Observe suitable personal protective measures.
Pre-Cleaning	Manually pre clean until the appearance of the components is clean. Immerse the above components in a cleaning solution and rinse with a cold water spray gun for at least 10 seconds. Clean the surface with a soft bristled brush.
Cleaning	**Automated cleaning:** Carefully put the components into the washer-disinfector on a tray and set the parameters as follows, then start the program: 4 min pre-washing with cold water (＜40°C); Emptying

	5 min washing with a mild alkaline cleaner (pH value between 7.5 and 8.5) at 55°C; Emptying 3 min neutralising with warm water (min ne Emptying 5 min intermediate rinsing with warm water (min in Emptying Note: The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert) and Rapid-A520 Washer-disinfector from Shandong Xinhua Medical Device Co., Ltd.  ● Use only approved wash-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. ● Please strictly follow the concentration of cleaning agent provided by the manufacturer for cleaning.
Disinfection	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements with regard to A0 value (refer to EN ISO 15883). A disinfection cycle of 5 min disinfection at 93 °C has been validated for the device to achieve an A0 value of 3000. After cleaning, the parts should be automated disinfected or sterilized immediately. A manual disinfection is not recommended.
Drying	**Automated Drying:** Drying the devices according to drying program of washer/disinfector by setting parameter 120 °C, 15min. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of devices by using sterile compressed air.

Functional Testing, Maintenance	Visual inspect the cleanliness of the components and reassemble them. Conduct functional testing according to instructions of use. If necessary, perform reprocessing process again until the components are visibly clean. Before packaging and autoclaving, make sure that the components have been maintained according to the manufacturer's instruction.
Packaging	The devices that require sterilization can be packaged together in one pounch, but it is necessary to ensure that the packaging pounch is large enough and will not be damaged due to excessive volume.  ● Check the validity period of pouch given by the manufacturer to determine the shelf life. ● Use pouches which resist to a temperature up to 141℃ and in accordance with 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: 5 min at 134°C Drying time: at least 8min  ● Use only approved autoclave devices according to EN 13060 or EN 285. ● Use a validated sterilization procedure according to EN ISO 17665. ● Respect the maintenance procedure of the autoclave device given by the manufacturer. ● Use only this recommended sterilization procedure.

	● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycle parameters). ● Wait for cooling before touching.
Storage	Store the sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and User Manual.  ● Sterility cannot be guaranteed if packaging is open, damaged or wet.

● The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

● Please comply with relevant regulations for cleaning, disinfection, and sterilization.

● Please be careful during maintenance to avoid cross infection.

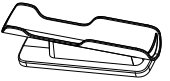
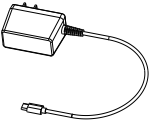
● The next patient should replace the cleaned, disinfected, and sterilized the tip.

● The tip is easily damaged by external forces, so be careful when maintaining them.

● Be careful when cleaning, disinfecting, and sterilizing, and wear disposable sterile gloves to avoid cross infection.

7.2 Daily Maintenance

Daily maintenance

Main Unit	Main Unit Base	Adapter
		

When necessary, wipe the outer surface of the machine with a soft cloth soaked in Ethanol (70-80 vol% Ethanol).

⚠

- Do not use disinfectants other than ethanol for disinfection (Ethanol 70 to 80 vol%).
- Do not use excessive ethanol to prevent ethanol from seeping into the parts and damaging the internal parts.
- The above components must be disinfected before first use and after each use.
- When used by patients, the equipment should not be maintained or serviced.

8.Troubleshooting

When a problem or malfunction occurs, please check according to the table below before contacting the dealer to quickly eliminate common problems or malfunctions. If the problem or malfunction persists, please contact the dealer.

Problem	Cause	Solution	Ref. chap
The power is not turned on.	The battery power is too low.	Charge the main unit.	6.1
The power indicator light of the main unit does not light up when charging.	Use the wrong adapter.	Use the original adapter.	4.4
	The adapter is not plugged into the outlet	Check the connection.	/
	There is no electricity in the outlet.	Check the connection.	/
The indicator light on main unit do not light up.	The main unit is damaged.	Press the power switch button to turn on the machine, check whether the sound is normal, and then contact the dealer	6.2
Tip does not work.	Tip is not installed in place.	Check the installation.	4.2
	Tip is broken.	Replace a new tip.	/
	The main board is broken.	Contact your dealer.	/
There is no beep.	The main board is broken.	Contact your distributor.	/

9. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd.
Model	SurfyOne
Battery	Lithium ion battery: 3.7V, 1400mAh, ±10%
Adapter input	100-240V～, ±10%
Adapter output	5V ⎓ 1A
Adapter fuse	T2.0 AL250V
Input	0.2A
Frequency	50/60Hz, ±1Hz
Type of protection against electrical shock	Class Ⅱ, internal power supply equipment
Waterproof protection strength	IPX0
AP/APG type equipment	Non AP/APG equipment
Anti defibrillation application part	None
Application part	Type B (Tip)
Operation mode	Intermittent operation 1min. ON / 1 min. OFF
Operating conditions	Ambient temperature: 10℃~40℃ Relative humidity: 30%~75% Atmospheric pressure: 70kPa-106kPa
Transport and storage conditions	Ambient temperature:-20℃~ +55℃ Relative humidity:20% ~ 80% Atmospheric pressure:70kPa~ 106 kPa

10. EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The **SurfyOne** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SurfyOne** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Professional healthcare facility environment and Home healthcare environment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC61000-3-2	Class A	Professional healthcare facility environment.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliances	

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.

Guidance and manufacturer's declaration – electromagnetic immunity
The **SurfyOne** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SurfyOne** 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 +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 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 transients/bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV	Line to line: ±0.5kV, ±1kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles single phase at 0°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles single phase at 0° 0% UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery

	0% UT; 250/300 cycles		
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			

Guidance and manufacturer's declaration – electromagnetic immunity			
The **SurfyOne** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SurfyOne** should assure that it is used in such an environment.			
Proximity magnetic fields	**IEC 61000-4-39 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Proximity magnetic fields	134.2kHz Pulse modulation 2.1kHz	65A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	13.56MHz Pulse modulation 50kHz	7.5A/m	

Guidance and manufacturer's declaration – electromagnetic immunity

The **SurfyOne** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SurfyOne** should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands and amateur radio bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the **SurfyOne**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended minimum separation distances See the RF wireless communication equipment table in "Recommended minimum separation distances"
Radiated RF EM fields IEC 61000-4-3 Proximity fields from RF wireless communication equipment IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz See the RF wireless communication equipment table in "Recommended minimum separation distances"	3V/m Complies	

Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **SurfyOne** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the **SurfyOne** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900;	Pulse modulation 217Hz	2	0.3	28

		DECT; LTE Band 1, 3, 4, 25; UMTS				
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

1. Use of accessories and cables other than those specified or provided by the manufacturer of SurfyOne could result in increased electromagnetic emissions or decreased electromagnetic immunity of SurfyOne and result in improper operation.

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter Cable	1.2	No	/

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

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

4. 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.

11.Warranty

1. SurfyOne is warranted against manufacturing errors and defects in materials, and the warranty period is 12 months starting from the day of delivery to the customer.

2. SurfyOne should be repaired by the equipment technology department of Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partners authorized by Changzhou Sifary Medical Technology Co., Ltd. Do not provide circuit diagram, bill of material, legends, calibration rules, and other maintenance materials to other organizations.

3. Should the quality assurance complaint be reasonable, Changzhou Sifary Medical Technology Co., Ltd. or maintenance service partner authorized by Changzhou Sifary Medical Technology Co., Ltd shall provide repairing service as soon as possible.

4. Should the damage be proved to be caused by the user's negligence in daily maintenance, warranty is then voided.

5. Changzhou Sifary Medical Technology Co., Ltd reserves the right to analyze and determine the cause of any problems.

12. Statement

Service Life

The service life of SurfyOne series products is 3 years.

Maintenance

MANUFACTURE will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Those parts of the equipment that shall not be serviced or maintained while in use with a PATIENT:

- Main Unit
- Tip

Disposal

Comply with your national regulations, guidelines and requirements for the disposal of waste electrical equipment and medical devices.

Make sure the device is not mixed with other types of waste when it is being disposed of.

Rights

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