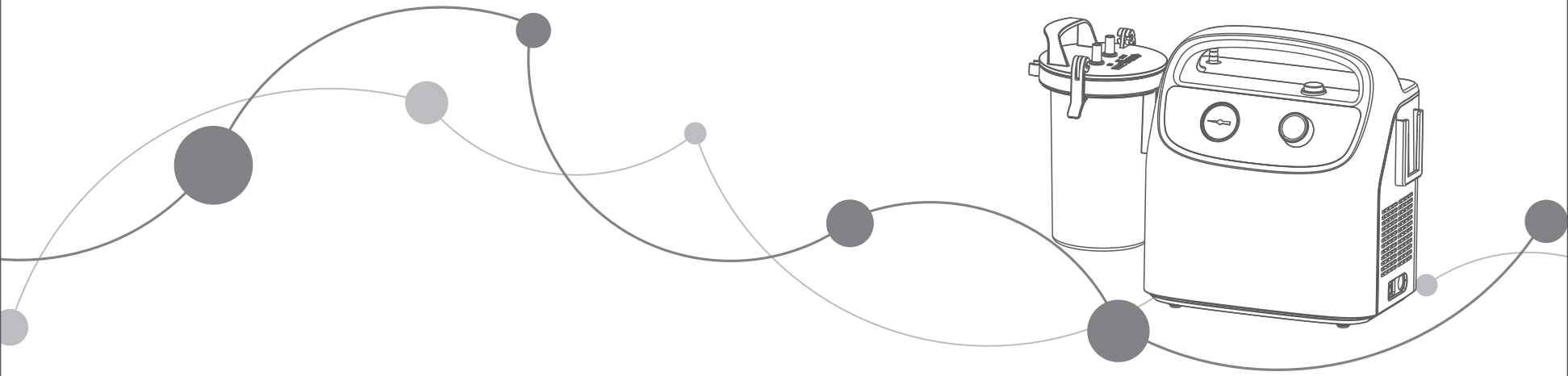

7E-H1

Portable Phlegm Suction Unit

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JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD.
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EC REP
Metrax GmbH
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CE 0123

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YY-ATT1008C-01(A/0)

Please read the user's manual closely before using!

Contents

I. Important Safety Rules

⚠**Warning:** This product is precision manufactured,finely assembled and wired,so do not disassemble or attempt to repair.All repairs must be carried out by qualified personnel at authorized repair centers.

⚠**Danger:** Reduces the risk of electric shock.

1.Cut off the power immediately after each use.

2.Immediately cut off the power when the machine falls into water rather than reach for it.

3.Do not place or store the machine where water or other liquid is easy to drip.

4.Do not touch the machine when it is wet.

5.Do not disassemble the machine.Services shall be performed by qualified service personnel.

6.Regularly check the electrical safety index of the machine.

7.If the power cord of the machine needs to be replaced, the service should be carried out by the Yuyue or the maintenance point designated by the Yuyue.(Refer to Electric Systematic Diagram if necessary).

8.The materials of applied parts in contact with patients meet the requirements of ISO10993 and will not lead to unacceptable risks.

9.This product is expected to be used in the home. Considering the actual operation, the legibility of the label was evaluated at a 0.5m distance.

⚠**Waring:** Reduce the risk of burs,electric shocks, fire or personal injury.

1.When the machine is powered on,it shall not be left unattended.

2.Timely monitor the products when they are used by children or individuals，keep cables away from children or pets as cables can be a choking hazard.

3.This manual only describes the usage of the product. Do not use accessories other than the manufacturer，s recommendation.This will reduce the performance of the machine.

4.Please do not use the machine and return it to the service center for inspection and repair when the following situations occur: The power cord or plug is damaged,the machine can't work properly,the machine has

been dropped or destroyed,the machine falls into the water and so on.
5.Keep the power cord away from the surface of heating or heating equipment.
6.Do not block the air vent of the product. Avoid soft cloth,nap and other similar things in the vent.
7.Do not drop or insert any substance at the orifice of the machine.
8.It should be noted that excessive negative pressure may cause harm to human body.
9.The compressor pump of this equipment has an air outlet, which is inside the machine. Please avoid blocking the vent when using the machine.
10.The suction equipment should only be used by personnel who fully understand the instructions for using these equipment.
11.When patients use, all parts should not be maintained, and all parts should be used and maintained by professionals.
12.The patient cannot use the equipment as the intended operator.
13.The power supply plug with a flexible cord is used to isolate ME EQUIPMENT from the SUPPLY MAINS.
14. Keep away from children and pets during use.

II . Product Features

I. Intended purpose

Portable Phlegm Suction Unit is intended for negative pressure supply,and is used in combination with suction tubing and suction catheters to remove fluids and debris from the surgical field during surgical procedures.

II . Intended users

The suction equipment should only be used by personnel who fully understand the instructions for using these equipment.

III. Intended patient population

It is suitable for patients who need to aspirate purulent and viscous fluids.

- The portable phlegm suction unit is not intended to be used in hazardous areas/in the MRI environment.
- The portable phlegm suction unit is not intended for field and transport use.
- No contraindications.

IV. Structure&working principle

1.Oil free lubrication pump to keep the environment from being polluted by the oil mist.

2.Low noise.

3.Round negative pressure meter, and plastic cover.

4.No any positive pressure to be generated during running, to ensure reliable and safe operation.

5.Negative pressure regulating system can be adjusted steplessly. Small in size, light in weight and portable.

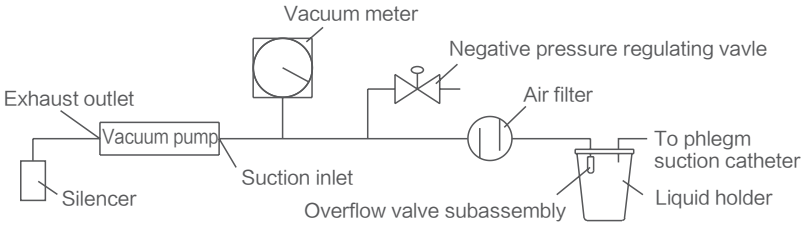


Fig. 1 Operating principle diagram

V. Main technical performances

1	Category	High vacuum / high flow
2	Power supply	AC 230V, 50Hz
3	Input power	120VA
4	*Maximum vacuum	(85 ± 5) kPa
5	Vacuum regulating range	20kPa ~ Maximum vacuum
6	*Free air flow	(28 ± 4)l/min **
7	Collection container	1000ml/pc,1pc
8	Noise	≤65dB(A)
9	Weight	Approx 3.9kg
10	Dimension(approx)	480mm(L) × 165mm(W) × 285mm(H)
11	Service life	5 years (except for fragile and consumable parts)
12	Mode of operation	non−continuous operation 30 minutes on, 30minutes off
13	Electric shock protection degree: BF type applied parts Applied part(Suction catheter) The suction unit is not suitable for use in the place with inflammable & explosive gas. Air filter service life: two weeks, Fuse and Power cord service life: 5 years. Detachable components of Portable Phlegm Suction Unit shelf−life: See inner packing bag. Fuse: F1.6AL 250V, Φ5 × 20	
*Test conditions: 760mmHg (at one atmosphere pressure)		
** Measuring point at the device inlet, cold machine status		

VI. Normal operating condition

Ambient temperature: +5℃~+35℃

Relative humidity: 30%~80%

Atmosphere pressure: 86kPa~106kpa

ⓘ **NOTE:** When storage temperature is below 5℃ or above 35℃, please keep the equipment in normal working condition for at least 4 hours before using.

ⓘ **NOTE:** Not intended to be used in an MRI environment.

III.Installing and Commissioning

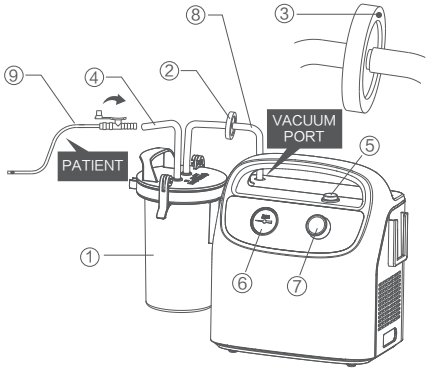
I. Open package inspection

The customer shall carefully inspect if the appearance of product is good, and the varieties & quantities of the attachments are in conformity with those as indicated in the attachments are in conformity with those as indicated in the attached list before installing and commissioning. Also, the customer shall timely notify the supplier or manufacturer of damage(s) if any.

II. Connecting(See Figure 2)

(with phlegm suction catheter temporarily not connected.)

ⓘ **NOTE:** Apply small amount of distilled water around the part (pressed into the holder mouth) of holder plug during installing, which is good for tightly pressing the holder plug and enhancing its sealing.



1、Collection container
2、Air filter
3、 “IN” Mark
4、Suction tubing
5、Switch
6、Vacuum level indicator
7、Vacuum regulator
8、Intermediate tubing
9、Suction catheter

ⓘ **NOTE:** size and type of tubing and connection to the collection container.

1. Suction tubing Spec: Length: 2M Spec: Inner Diameter 7 × Outer Diameter 11.

2.intermediate tubing: Spec: Inner Diameter 7 × Outer Diameter 11.

III. Power line connection

Connect the plug with the power source. Turn on the power supply, and the power indicator will illuminate.

Note: Power plug is used as the isolation from supply mains and shall position the ME EQUIPMENT so that it is convenient and easy to operate the disconnection device(refer to Important Safety Rules 13).

IV. Connector inspection

1. Turn tightly the negative pressure regulating valve clockwise, and block the air suction inlet with the finger or the rubber head of dropper, or fold up

and hold the suction tubing.

2. Start the aspirator for running with no strange sound; the pointer of the vacuum meter will quickly reach up to the limit negative pressure. Release the air suction inlet, the pointer will return below 20kPa. If so, the connector can be regarded as being in good connection.

3. Attach the phlegm suction catheter. The negative pressure in the negative pressure system shall be less than 70kPa when attaching F8 suction catheter, less than 30kPa when attaching F12 suction catheter. If so, the phlegm aspirator is considered as being in normal condition.

ⓘ**NOTE:** Dredge the suction catheter if blocked as per the following method: Bend the suction conductor in "V" form (with no liquid in the holder), and release it to the original status when the negative pressure reaches up to the maximum value. Repeat this procedure several times till the catheter is not blocked.

V. Negative pressure regulating

1.Block the suction inlet, open the phlegm suction unit switch, adjust the negative pressure regulating valve, the reading on the vacuum gauge should not be within the range of 20kPa ~ the limit negative pressure value.

2.During clinical practice, the negative pressure regulating valve is used to control the negative pressure value required by phlegm suction.

3.Keeping turning the negative pressure control valve clockwise and the negative pressure increases.

4.Reduce the negative pressure below 20kPa prior to power shut-off.

5.Adjust the required negative pressure according to the actual situation of the patient, notice that excessive negative pressure may cause personal injury.

VI. Inspection&test on the overfill protection device

1. Open the holder plug; clean up the valve mouth, and leveling the rubber valve clack on the float. The valve clack shall not be warped, bent and

broken, but well connected with the float. The float shall be able to move freely in its support without any blockage, lift the holder plug with hand to make the float contact the water surface perpendicularly gradually lower the holder cover to let the float rise.

2. Tighten the hold plug, attach the suction tubing conductor at the inlet, and screw firmly the regulating valve, then, actuate the aspirator.

3. Put the suction conductor into one clean water pail or attempt to simulate actual application to suction the liquid into the holder of the overfill protection device. As a result, the float will rise as the liquid level ascends until the valve is closed and suction stops automatically. The final position of liquid level depends on the suction process adopted.

4. Release the regulating valve, set the aspirator switch off, open the holder plug and empty the liquid in the holder. The float shall be at the bottom of the support and the valve is in open status in case of rescrewing firmly the hold plug.

5. If so, the overfill protection device is considered as being in normal condition, which can be used for clinical practice.

ⓘ **NOTE:**

1. The liquid level still continuously ascends after the overfill protection device has been shut off, possibly due to:

(1) Residual negative pressure still in the holder.

(2) Valve mouth not fully closed.

For Item (1), the liquid level in the holder will not ascend when the suction tubing conductor is placed again into the liquid as suctioned, and for Item (2), the liquid level still ascends. Thus, it is required to observe carefully, and lift immediately the conductor out of the suctioned liquid when the holder is close to full, then, switch off the aspirator to stop suction, and examine the possible reason of the valve fault.

2. The float is still adhered on the valve mouth as already closed by the float, possibly due to the negative pressure in the line. At this moment, release the regulating valve or shut off the aspirator (to release the negative pressure in the line), the float will descends from the valve mouth under the action of gravity. (It is forbidden to pull the float with hand, in

order to avoid the rubber valve clack being separated from the float).
After shut-off, release the negative pressure, then, open the holder plug;
Never use the aspirator under the condition of the overfill protection device & the conductor dismantled.
3.Once overfill protection activate, the suction catheter should be immediately put forward from the aspirated fluid, close the suction device, stop the suction, and reexamine ,check and test the anti-overflow device and contact the manufacturer if necessary.

VII. Stop Running

Turn off the aspirator switch, and pull the power plug out of the socket to shut off the power supply.

VIII. Symbols

Symbol	Description	Symbol	Description
	FRAGILE		KEEP DRY
	Recyclable		KEEP UP
	OFF(power, disconnection from the mains)		ON(power, connection to the mains)
	Refer to instructions manual		Caution
	Alternating current		Type BF applied part
	Class II Equipment		Batch code
	Manufacturer		Date of manufacture
	Use-by date		Humidity limitation
	Atmospheric pressure limitation		Temperature limit

SN	Serial number		Consult the manual
UDI	Unique identification of medical devices		Do not dispose of in domestic refuse
EC REP	Authorized representative in the European Community		
IP21	Protected against solid foreign objects of 12.5 mm ϕ and greater. Protection against vertically falling water drops.		
MR	MR Unsafe: An item which poses unacceptable risks to the patient, medical staff or other persons with in the MR environment.		
CE 0123	CE marking and notify body number		
MD	Medical device		
5	Safety and environmentental protection use period for 5 years.		

IV. Application and Maintenance

I. Application and Maintenance

1.Check the aspirator before using as per the installing and commissioning sequence to ensure its good performances, afterwards, start operation by connecting the suction conductor and the phlegm suction catheter already sterilized.

Note: Please refer to the instructions before attempting to use the suction catheter supplied with the aspirator.

2.Regulate the negative pressure as required for suction through the regulating valve, open/close the switch based on the situation, and observe frequently the liquid level in the holder in the process of operation. Stop suction if the liquid level in the holder ascends to the rated capacity (still applicable if slanting the aspirator 10 degree), and re-use it after empty and clean-up. Otherwise, the float will rise as the liquid level ascends till the valve is closed and suction stops automatically.

Note: Adopt the procedures mentioned in "Inspection & test on the overfill protection device", if the liquid level still ascends after the overfill protection device has been shut off.

3.Emergency measures in the process of application

(1) Quickly loosen the negative pressure regulating knob to release the negative pressure if the suction catheter is blocked by strong phlegm and mucus, and start suction again after changing the suction tubing.

(2) Adopting the above method to loosen the egative pressure regulating knob if it is not easy to take out the suction catheter after completion of knob if it is not easy to take out the suction catheter after completion of suction or the tube is adhered to human body tissue.

ⓘ **Note 1:** Bend the tube in "V" form prior to starting suction, insert the suction catheter into the location of existing phlegm on the patient when the negative pressure reaches the desired range after start-up, then, recover the tube to its original status. This will lead to quicker suction effect.

ⓘ **Note 2:** The medical personnel shall select the proper suction catheter according to the clinical requirement.

ⓘ **Note 3:** The aspirator shall be operated under the medical personnel's instructions strictly according to the scope of application and the operating sequence listed in the instruction manual. Please contact the supplier or manufacturer if there is any question.

II. Changing air filter

It is required to change air filter with the one produced by us in case of foam or dusts fully accumulated in the air filter, which leads to gradually darkening of the color of filter diaphragm and obviously reducing or even disappearing of suction force at the inlet of tube while the negative pressure indicated on the vacuum meter climbs up to 40kPa or more.

Replacement method: remove the intermediate tubing at both ends of the air filter, replace it with a new air filter, and reinsert it into the intermediate tubing at both ends.

Note 1: The suction force will diminish or disappear, and the negative pressure ascend if the overfill protection device is closed, and the tube blocked in the process of application. Please refer to "trouble Shooting".

Note 2: Necessary to frequently change air filter and destroy it centrally.

Note 3: Air filter must be replaced for each new patient .When used exclusively for one patient, replace the external bacterial filter no less than every two weeks,if it is used frequently , wipe the surface with 75% alcohol before each use。

III. Replace Fuse Tube

Fuse tube is fixed at the back of the pedestal. Cut off power supply first before changing. Unscrew fuse box counterclockwise, then change the fuse tube. (Type: F1.6AL250V, Φ5×20).

IV. Maintenance

1.It is recommended to have the suction tubing suctioned small amount of clean water for cleaning up the inner wall before switching off the aspirator.

2.After use, empty the holder, clean up dirt on the holder and plug with soft brush or rag, flush it with water and conduct sterilization. (including the overfill protection device, the seal ring and various tubes. Unscrew the overfill protection device, and separate the float from its support for completely cleaning up, if necessary. (Note: The rubber valve clack shall not be separated from the float.)

3.Use the physiological saline to clean out the residual strong phlegm and mucus in the tube after used. Replace the suction catheter if not smooth. It is recommended to adopt single use suction catheter and suction tubing.

Place the holder, cover and all tubes into the disinfectant compounded with the disinfector tablets (0.5 g per tablet) in 1:500 concentration for 1 hour.

ⓘ **NOTE:**

Keep the holder away from any sharp utensils to avoid drop in the process of cleaning and application.

ⓘ Wipe the case outer surface with lightly wet rag already soaked in the disinfectant, and prevent any liquid seeping into the pump. Never wipe the places marked with letters and patterns.

Place the machine in dry and clean places,We recommend the user to maintain the machine every half a year and confirm according to the above start-up operation process. If there is any problem with the machine performance, please contact the manufacturer or dealer.

ⓘ **Note1:** Performance confirmation shall be carried out after each cleaning and disinfection according to the operation method recommended by the manufacturer .

ⓘ **Note2:** Parts of the suction equipment intended for re-use shall meet 30 cycles of cleaning and disinfection .

ⓘ **Note3:** Install the overfill protection device, conductor and other tubes as per the connecting mode before reuse.

ⓘ **Note4:** Portable Phlegm Suction Unit host and accessories does not require professional hygienic maintenance prior to reuse.

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Precautions and warnings listed here are for the proper and safe use of the product so as to prevent any harm or damage to the user or other people.

The contents of warnings and precautions are as follows:

Symbol	Content
⚠Warning	Indicates that there is a risk of personal injury or property damage when misused
ⓘ	ⓘ The mark indicates mandatory (things that must be observed). Specific compulsory contents are in or around ⓘ, in words or pictures. Left symbol means "general compulsory".
⃠	⃠ The mark indicates prohibition (things that are not allowed). Specific forbidden contents are in or around ⃠, in words or pictures. Left symbol means "general prohibition"

IV. Trouble Shooting

Problem	Probable reasons	Solution	Remark
Maximum vacuum < 80kPa	1)Holder mouth leakage 2)Leakage on connecting points 3)Regulating valve loose or released 4)Surrounding atmosphere is not as required.	1)Remove dirt,tighten or change the holder cover, seal ring, and connector 2)Re-tighten each connection point 3)Turn tightly the regulating valve 4)Move the machine to the required atmosphere	Change the broken suction tubing
vacuum > 40kPa,with distinct reduction or disappear-ing of suction force at tube outlet	1)overfill protection device shut-off 2)Tube blockage 3)Air filter blockage	1) After shut-off,turn the regulating valve loose counterclock-wise to release negative pressure in tube,then re-screw 2) Dredge,clean or replace the tube 3) Replace it with air filter produced by us.	1) Empty cleaning the container
Normal power voltage, but the indicator doesn't illuminatethe indicator 3) Change new fuse	1)The socket is loose 2)Indicator damaged 3)Fuse damaged	1) Repair or change the socket 2) Replace the indicator 3) Change new fuse	By the specialized mainte-nance worker(Re-fer to Electric Systematic Diagram)

ⓘ **NOTE:** The dismantling & repair on the pump body if fault (example: Not work or liquid or solid has been drawn into the vacuum pump) shall be conducted by the specialized worker. Please contact the manufacturer if required.

V. Precautions

I. Transportation and storage conditions

Environment Temperature: −40℃~+55℃

Relative Humidity: 10%~93%

Atmospheric Pressure: 70kPa ~106kPa

ⓘ **NOTE:** It is required to store the portable phlegm suction unit in the well−ventilated room without corrosive gas, and avoid any violent shock while handling.

II. Electric systematic diagram(See Figure 3)

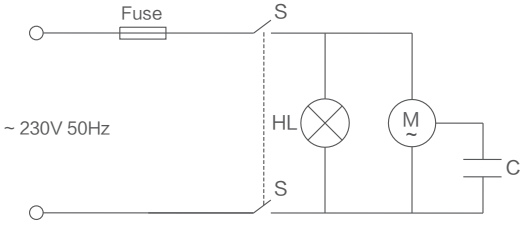


Fig. 3. Electrical schematic diagram

Electrical maintenance should be operated by professionals.

III. Attachments (User replaceable)

Problem	Spec	QTY	Code
Air filter	/	2	10008984
Fuse	F1.6AL250V, ϕ5×20	2	10044215
User's manual	/	1	/
Certificate of inspection	/	1	/
Warranty card	/	1	/
Air filter(including intermediate tubing)	/	1	20022286

⚠It is recommended to use the Portable Phlegm Suction Unit with Suction tubing and Suction catheter.

Device name	Size	Manufacturer
Disposable Suction Connecting Tubes(Suction tubing)	32FR-2m	JiangSu Weikang Jiejing Medical Apparatus Co., Ltd.
Disposable Suction Catheters (Suction catheter)	8FR、12FR	JiangSu Weikang Jiejing Medical Apparatus Co., Ltd.

ⓘ **NOTE:** The material used in this product will not cause skin irritation.

IV. To dispose the castoff

The castoff should be disposed in accordance with all applicable government regulations.

VI. EMC instruction

Instructions for use

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

2. 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.

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

4. If the essential performance is lost or degraded due to EM disturbanc-es, the operator can inform customer service staff to overhaul.

5. In order to maintain basic safety and essential performance in regards to EMC, the user should regularly check the equipment lines and compo-nents to avoid line aging, component failure,etc.

6. Before using this device, please read the user manual to prevent adverse events to protect patient and operator due to electromagnetic disturbances .

Electric and magnetic environment guidance in use

1.Portable and mobile RF communications equipment may affect the product.

2.You can prevent electromagnetic interference by maintaining a minimum.

⚠**Warning:**

Far away from HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging in hospitals.

⚠**Warning:**

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is

necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠**Warning:**

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

Electric and magnetic environment guidance in use

Table 1 For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture s declaration– electromagnetic emission	
The 7E-H1 is expected to be used in the electromagnetic environment specified below. Purchaser or user should ensure that it is used in this electromagnetic environment.	
Emission test	Compliance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1, Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuation/flicker emissions IEC 61000-3-3	Complies

Table 2 For all ME EQUIPMENT and ME SYSTEMS

7E-H1 is intended for use in the electromagnetic environment specified below. The customer or the user of the 7E-H1 should assure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air
Electrical fasttransient /burst IEC 61000-4-4	± 2 kV 100kHz repetition frequency	± 2 kV 100kHz repetition frequency
Surge IEC 61000-4-5	± 1 kV line(s)to line(s) ± 2 kV line(s)to earth	± 1 kV line(s)to line(s)
Voltage dips IEC 61000-4-11	0 % U_T; 0,5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 0,5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions IEC 61000-4-11	0% U_T ; 250/300 cycles	0% U_T ; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz
NOTE1: U_T is the a.c. mains voltage prior to application of the test level. NOTE2: When the device voltage drops, there may be a brief period of low flow. Once the interference is removed, the machine returns to normal operation.		

Table 3 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture' s declaration–electromagnetic immunity		
The 7E-H1 is intended for use in the electromagnetic environment specified below. The customer or the user of the 7E-H1 should assure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz–80 MHz 6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % Am at 1 kHz	3 Vrms 0,15 MHz–80 MHz 6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % Am at 1 kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot 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 the 7E-H1 is used exceeds the applicable RF compliance level above, the 7E-H1 should be observed to verify normal operation. If abnormal performance is observed, additional 7E-H1. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

Table 4 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13,17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900,TETRA 800, iDEN 820,CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800;CDMA 1900; GSM 1900;DECT; LTE Band 1,3,4,25;UMTS	Pulse modulation [b] 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth,W−LAN, 802.11 b/g/n,RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28

5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	9

If necessary to achieve the IMMUNITY TEST LEVEL,the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m.The 1m test distance is permitted by IEC 61000−4−3.

[a)]For some services,only the uplink frequencies are included.

[b)]The carrier shall be modulated using a 50%duty cycle square wave signal.

[c)]As an alternative to FM modulation,the carrier may be pulse modulated using a 50%duty cycle square wave

signal at 18 Hz.Whileit does not represent actual modulation,it would be worst case.

Table 5 –Test specifications for EnCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL(A/m)
30 kHz[a)]	CW	8
134,2 kHz	Pulse modulation[b)] 2,1 kHz	65[c)]
13,56 MHz	Pulse modulation[b)] 50 kHz	7,5[c)]
[a)]This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. [b)]The carrier shall be modulated using a 50% duty cycle square wave signal. [c)]r.m.s.,before modulation is applied.		

Notes:

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