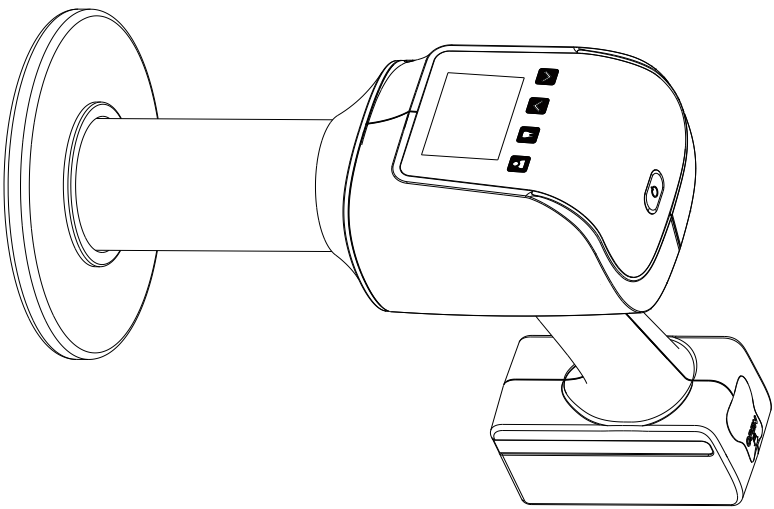
Eighteeth

Rx only

Model: HyperLight



HyperLight Portable X-ray Unit
USER MANUAL

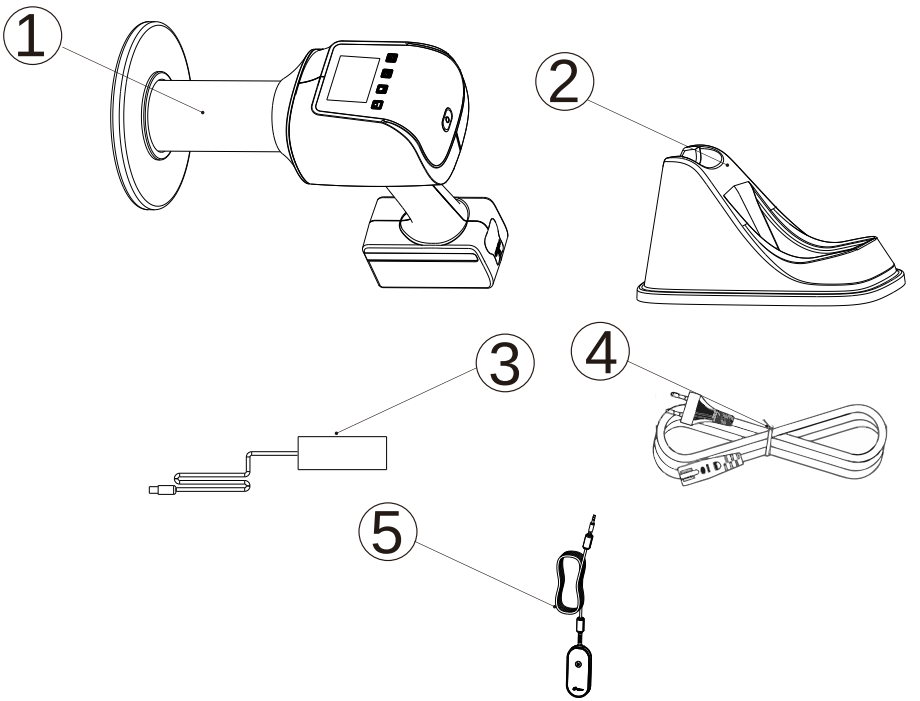
Changzhou Sifary Medical Technology Co., Ltd.

Version: 04
IFU-7035013
Issued: 2024.04.09
Size: 197mmX140mm

Content

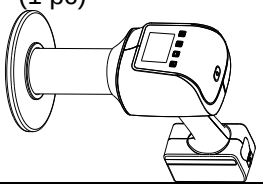
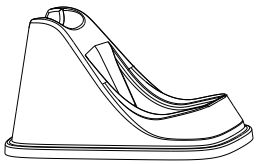
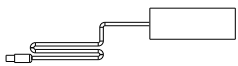
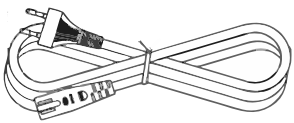
1. Overview

1.1 Content



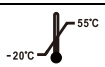
1. HyperLight Main Body with Backscatter Shield
2. Base Holder
3. Power Adapter
4. Power Cord
5. Remote Control Switch (optional)

1.2 Packing list

HyperLight Main Body with Backscatter Shield (1 pc) 	Base Holder (1 pc) 	Power Adapter (1 pc) 
Power Cord (1 pc) 	Remote Control Switch (optional) (1 pc) 	

1.3 Device Label

2. Symbols

	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
	Additional information, explanation of operation and performance.
SN	Serial number
	Type B applied part
~	Alternating current
⎓	Direct current
	Do not dispose this product into the ordinary municipal waste or garbage system
	Keep dry
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
REF	Catalogue number
	Manufacturer
	Date of manufacture
LOT	Batch code
	Manufacturer’s LOGO
	Follow instructions for use
	Warning of ionizing radiation
	Remote control switch

2 Symbols

MD	Medical device
	Dangerous Voltage: Electrical Shock Hazard
Rx only	Federal law restricts the sale of this device by or on the order of a dentist

3. Foreword

3.1 Indication for use

The device is a diagnostic X-ray system, which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic x-ray images using intra-oral receptors. Its use is intended for both adults and pediatric subjects.
This device must only be used in hospital environments, clinics or dental offices where appropriate safeguards are implemented, and not used in the oxygen-rich environment.

3.2 Contraindications

The device is designed for use with patients of any overall health status, as solely determined by the practitioner, with the following considerations for specific circumstances:

- The HyperLight is contraindicated in cases where patient/user carries medical implants such as pacemakers or cochlear implants etc.
- Pregnant women. The medical practitioner must weigh the benefits conferred by using the device against the potential hazards to the pregnant woman and fetus resulting from radiation exposure. If the use of the device is considered justified, the practitioner must take appropriate precautions, such as using radiation safety garments, to limit radiation exposure beyond the maxillofacial complex.
- Pediatric. The medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the child resulting from radiation exposure, considering the maturity of the child's physical development. If use of the device is considered justified, the practitioner must take the appropriate precautions, such as use of radiation safety garments, to limit radiation exposure beyond the maxillofacial complex.
- Patients with medical conditions causing involuntary movements. For patients who experience seizures or who have been diagnosed with conditions such as Parkinson's Disease which can cause difficulty in controlling physical movements, the medical practitioner must weigh the benefits conferred by the use of the device against the potential hazard to the patient resulting from additional radiation exposure due to a re-scan in the event that an involuntary movement renders an image unusable for diagnostic purposes.

3.3Intended User Profile

Considerations	Requirement Description
Education	A licensed dentist or dental hygiene, radiologist and graduates of relevant bachelor's degree (national qualifications).
Knowledge	The operator must have understood: 1. Treatment and diagnosis of dental disease; 2. Terms and guidance of diagnostic medical radiation devices; 3. Device connection, installation and operating conditions.
Language understanding	The operator must have understood: The English manuals.
Experience	The operator must have understood: 1. Objectives and effects of treatment and diagnosis of dental disease using diagnostic medical radiation devices; 2. Normal operation of diagnostic medical radiation devices; 3. The contents of the user manual.

WARNING

Read the following warnings before use:

1. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquid.

2. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.

3. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls and do not use this system near the active HF Surgical Equipment in the hospital. 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 HyperLight, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4. Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

5. Gloves are compulsory during the operation.

6. If irregularities occur in the device during treatment, switch it off. Contact the agency.

7. Never open or repair the device yourself, otherwise, void the warranty.

8. Do not use the device while charging.

9. 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.

10. A fall may cause damage to the machine.

11. When battery leakage occurs, handle the leakage according to local laws and regulations to avoid environmental pollution.

12. The HyperLight should not be used in environments where flammable materials are present.

13. Do not spray alcohol on the connection interface.

14. Do not use conductive objects to detect the connection interface.

15. It must be charged before first use.

16. Batteries should be replaced only by trained service personnel, otherwise, the device may be damaged.

17. If the package or equipment is damaged, contact the supplier or manufacturer.

18. The device does not require assembly or installation and can be used directly when fully charged.

19. The type of image receptors must be selected according to local regulations, for example, in New Jersey, the type of Film can only be F-speed.

Disclaimer:

HyperLight is sold with the understanding that the user assumes sole responsibility for radiation safety (as well as any state, provincial, or local regulatory compliance) and that Sifary, its agents or representatives, do not

accept responsibility for:

1) Any injury or danger to personnel from X-ray exposure.

2) Image over/under exposure due to poor operating techniques or procedures.

3) Equipment not properly serviced or maintained in accordance with instructions contained in this publication.

4) Equipment which has been damaged, modified, or tampered with in any way.

5) Changing the focal spot to skin distance without authorization may cause the patient to receive unnecessary radiation.

4. Safety Precautions

4.1 Radiation Safety

The HyperLight was designed to be used in clinical settings (e.g., a dental office) and controlled settings where transportation or use of other X-ray devices might be prohibitive due to the device's size and/or mobility. Because of its portable design, there is a risk that the HyperLight intraoral device could be operated outside the radiation-controlled environment. You must use the HyperLight only within the limits of the radiology department.

This X-ray unit may be dangerous to the patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed.

The HyperLight provides a high degree of protection against unnecessary radiation. However, no practical design can provide complete protection nor prevent operators from exposing themselves or others to unnecessary radiation. There is still residual radiation. It is important to restrict usage and follow all applicable government radiation protection regulations. Pregnant women should not be exposed to X-rays unless necessary. Proper safety precautions should be taken to minimise doses to the fetus.

Operators must be fully acquainted with industry safety recommendations, established maximum permissible doses, and local jurisdiction requirements for use.

This X-ray unit must only be operated by trained personnel in a controlled setting. Within such a setting, ensure that only the patient is in the direct beam of the x-ray, and that any ancillary personnel is a minimum of 6 feet away from the patient. If it is necessary for any ancillary personnel to be closer than 6 feet, these personnel should stay out of the direct beam and wear personal protective equipment, such as protective clothing.

In implementing a radiation protection program, consult all applicable regulations governing radiation protection and the use of X-ray equipment, and ensure full compliance with any such regulations.

Compliance with Applicable Standards

Standard	Title	Edition
IEC 60601-2-65	Complies with X-ray equipment for dental intra-oral radiography IEC 60601-2-65:2017 HyperLight	2017

A list of protective devices and accessories

Name	Remark
Lead sheath	Built into the main body
Beam Limiting Device	Built into the main body
Backscatter Shield	Installed on the main body
Protective clothing, such as protective lead apron and thyroid collar	Recommended for use but not forming part of the equipment.

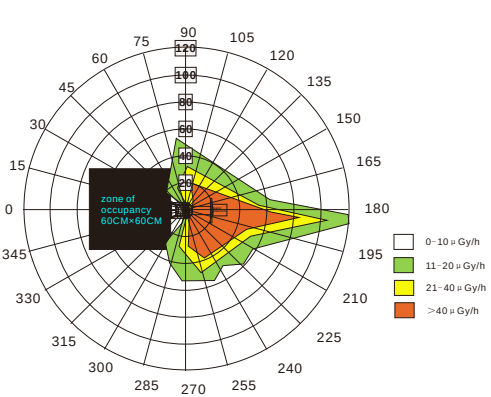
4.2 Leakage Dose

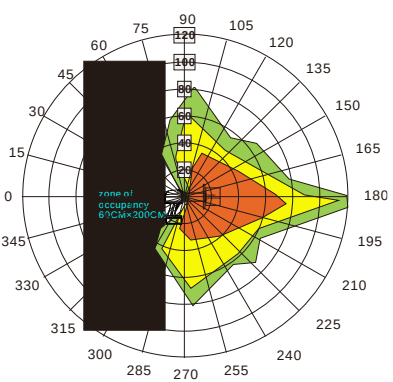
Leakage Dose	Permissive Range
65 kV, 2.5 mA, 0.5 s (Max. Exposure Condition) At 1m from the Focal Spot 1 : 30 Duty Cycle	< 0.25 mGy/h

In order to verify compliance with this leakage requirement, the device is tested for radiation leakage at 1m from the focal spot. The highest measurement out must be lower than 0.25mGy/h in order for the device to successfully pass product release testing.

4.3 Scatter

The significant zone of occupancy for operators has been further verified by internal testing. A HyperLight device was remotely fired into a water phantom(25 X 25 X 10cm)repeatedly, with an ion chamber recording radiation readings in the room, firstly to establish the vertical significant zone of occupancy and then to establish the horizontal significant zone of occupancy. Each exposure was taken for 2 seconds. The dimension of the vertical significant zone of occupancy is 60 cm X 200 cm, while the dimension of the horizontal significant zone of occupancy is 60 cm X 60 cm. A calibrated survey dosimeter can be used to measure scatter radiation.
Data shown in the following diagrams.

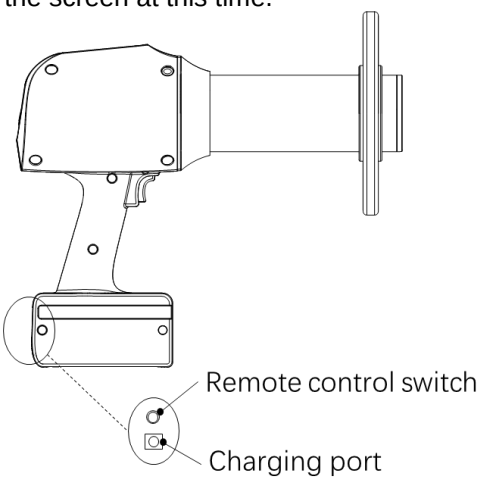




5. Installation

5.1 Plug in the charging cable

First open the silicone cover, then plug one end of the power adapter into the machine, plug the other end into the power cord, and finally plug the other end of the power cord into the power socket. The charging icon will be displayed on the screen at this time.



WARNING

- Do not position the device where it is difficult to operate the disconnection device.
- Only the original adapter can be used.

6 Operation

WARNING

Position operator inside significant zone of occupancy behind the HyperLight, and wear radiation safety apron. Collimator cone and backscatter shield are protective devices provided by manufacturer.

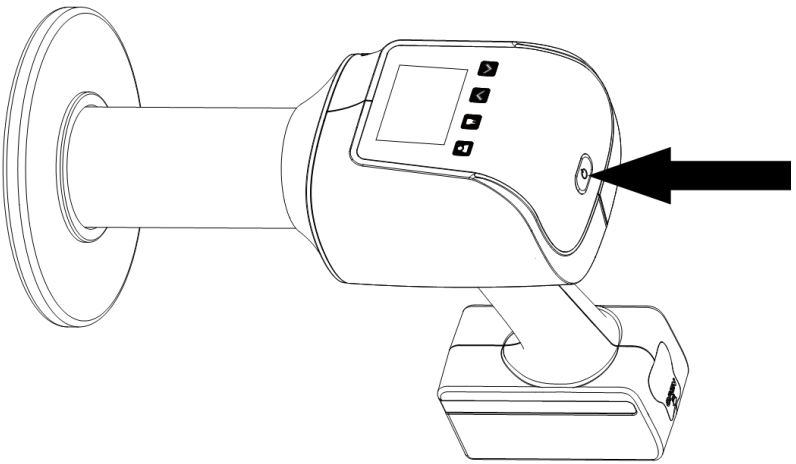
6.1 Operation panel instructions

Symbol	Type
	Choose adult mode or child mode
	Choose tooth type
	Increase exposure time
	Reduce exposure time
	Press two buttons at the same time to lock or unlock the screen.
	Press these two buttons at the same time to enter the setting interface.
	Power Button

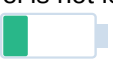
6.2 Power On/Off

6.2.1 Power On

1. First press the power button and then release, then the screen will enter the boot interface.



2. Make sure that the battery level is not lower than the figure below.



Battery level 1

6.2.2 Screen Lock

The screen is automatically locked at startup to prevent unauthorized use.

A lock icon is displayed when screen is locked: 

Press two buttons at the same time to lock or unlock the screen:

NOTE

Automatic screen lock setting: First turn on the device, press the two buttons   5 times at the same time to enter the automatic screen lock setting interface. Short press the button  to switch the function of

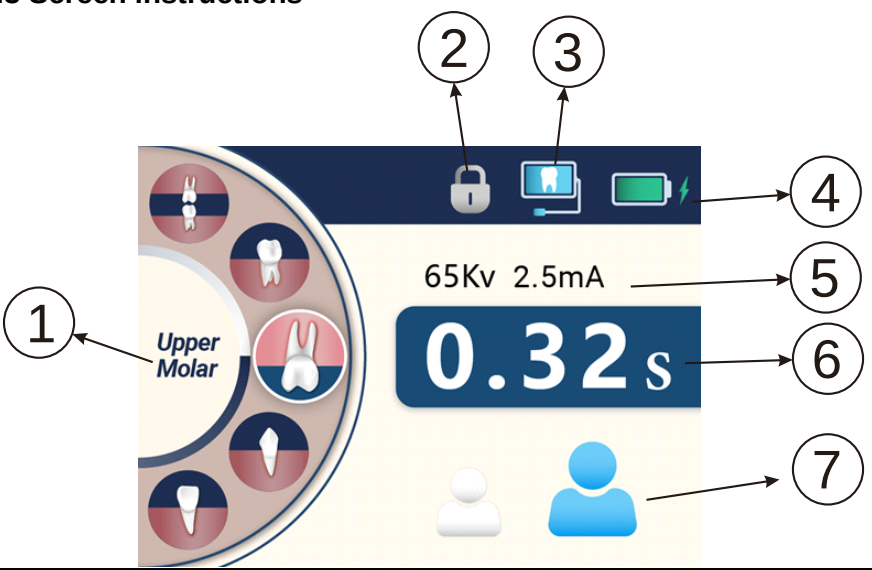
automatic screen lock on or off. Then turn off the device. When it is restarted, the automatic screen lock function defaults to the last setting state.

Please note that only authorized personnel in the medical institutions can close the automatic lock function.

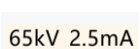
6.2.3 Power Off

Long press the power button to shut down.

6.3 Screen instructions



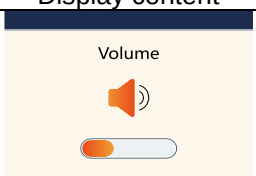
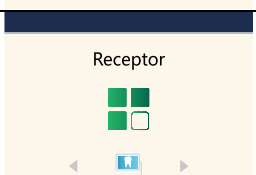
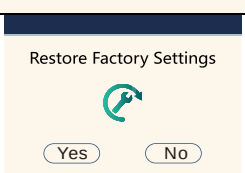
No.	Item		Description
1		Bitewing	Select the tooth type.
		Lower Molar	
		Upper Molar	
		Canine	
		Incisor	

2		Machine lock	The machine is locked and cannot be exposed.
3		Digital Sensor	Use the sensor to receive X-rays.
		Phosphor Plate	Use the Phosphor Plate to receive X-rays.
		Film	Use the Film to receive X-rays.
4		Remaining Battery Indicator	Indicate the remaining battery level. When the indicator light starts flashing red, it means the battery needs to be charged.
		Battery Charging Indicator	Indicate the battery charger is connected to the device.
5		Tube Voltage/Current Indicator	Indicate the tube voltage and tube current of the system.
6		Time Display	Display the X-ray exposure time.
7		Adult/Child Selection	Indicate a patient type (adult or child).

6.4 Settings interface

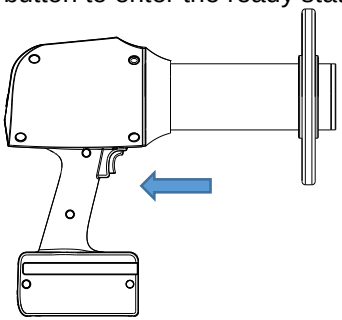
After starting up, you can press the  and  buttons at the same time to enter the setting interface, press the  to turn the page, and press the  and the  to adjust the displayed parameters.

Press the  button to save your changes and exit settings.

Display content	Meaning
	Adjust the volume of the machine.
	Select the type of receptor.
	Choose a language.
	Choose whether to restore factory settings.

6.5 Use of exposure function

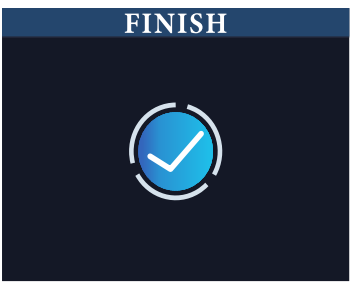
1. After selecting the exposure time, short press the exposure button to enter the ready state.



2. In the ready state, the screen will display the inclination angle of the machine to the ground plane and the 60s countdown.

3. Before the countdown ends, press the exposure button for exposure. At this time, the interface will display "Exposing". HyperLight will also make a "di…" sound until the end of the exposure.

4. When the screen displays “FINISH”, it means that the exposure has completed.



5. After the exposure is complete, the waiting time countdown is displayed, during which no oper ation is allowed until the time el apses. The ratio of waiting time to exposure time is 30:1. (The f igure below shows the longest waiting time.)

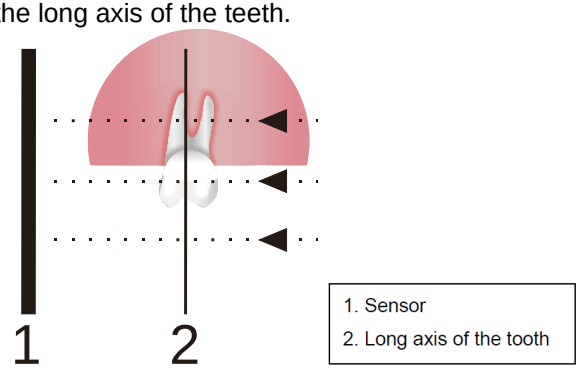
WARNING

- During the exposure, keep pressing the exposure button until the exposure is over. During the exposure, if you release the exposure button, the exposure will stop immediately.
- Do not touch the patient's skin during exposure.

6.6 Positioning Instructions

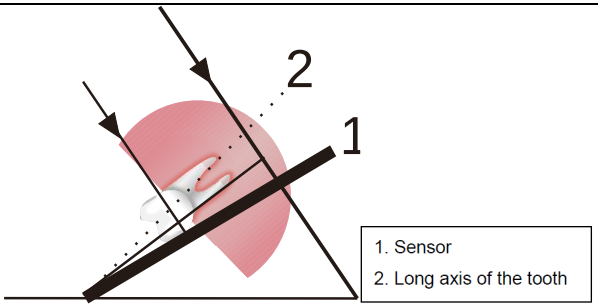
6.6.1 Paralleling technique

The sensor is placed in a holder which is used to align the sensor parallel to the long axis of the teeth.



6.6.2 Bisected angle technique

The patient holds the sensor in place with a holder. The X-ray beam is directed perpendicularly towards an imaginary line, which bisects the angle between the sensor plane and the long axis of the tooth.



Position the tube head to the patient according to the accepted standard positioning procedures.

6.6.3 Recommended angle and default exposure time for each tooth type

The parameters built into the tooth position are applicable for people of average size. Individuals may vary based on a number of factors, including image density preferences, different imaging sensors or film speeds and brands available, patient size, and physician techniques and preferences.
The use of devices designed for medium sized adults and exposure settings can lead to excessive radiation exposure in small patients, especially children. Pediatric patients may be more sensitive to radiation than adults (i.e., higher cancer risk per unit dose of ionizing radiation), so unnecessary radiation exposure is potentially hazardous to pediatric patients. When using HyperLight, consider the patient's age, body size, physical habits, and clinical indications when confirming the exposure time settings.

Receptor		Patient	Teeth		Angle of inclination (The patient sits in a chair vertically.)	Exposure time(s)
	Digital Sensor	Adult		Bitewing	+5˚~ +8˚	0.4
				Lower Molar	-5˚	0.2
				Upper Molar	+30˚	0.32
				Canine	Maxilla: +45˚ Mandible: -20˚	0.25
				Incisor	Maxilla: +45˚ Mandible: -25 ˚	0.16
		Child		Bitewing	+5˚~ +8˚	0.32
				Lower Molar	-5˚	0.13
				Upper Molar	+30˚	0.2

				Canine	Maxilla: +45˚ Mandible: -20˚	0.1
				Incisor	Maxilla: +45˚ Mandible: -25˚	0.08
	Phosph or Plate	Adult		Bitewing	+5˚~ +8˚	0.5
				Lower Molar	-5˚	0.25
				Upper Molar	+30˚	0.4
				Canine	Maxilla: +45˚ Mandible: -20˚	0.32
				Incisor	Maxilla: +45˚ Mandible: -25˚	0.2
		Child		Bitewing	+5˚~ +8˚	0.4
				Lower Molar	-5˚	0.16
				Upper Molar	+30˚	0.25
				Canine	Maxilla: +45˚ Mandible: -20˚	0.13
				Incisor	Maxilla: +45˚ Mandible: -25˚	0.1
	Film	Adult		Bitewing	+5˚~ +8˚	0.8
				Lower Molar	-5˚	0.4
				Upper Molar	+30˚	0.63
				Canine	Maxilla: +45˚ Mandible: -20˚	0.5
				Incisor	Maxilla: +45˚ Mandible: -25˚	0.32
		Child		Bitewing	+5˚~ +8˚	0.63
				Lower Molar	-5˚	0.25

				Upper Molar	+30˚	0.4
				Canine	Maxilla: +45˚ Mandible: -20˚	0.2
				Incisor	Maxilla: +45˚ Mandible: -25˚	0.16

6.7 Ensuring Image Quality

The following HyperLight features contribute to high image quality:

• DC voltage X-ray generator is efficient in delivering energy at the level optimized for diagnostics, with shorter exposure time required.

• The smaller the focal spot is, the higher the resolution can achieve. The HyperLight has a small focal spot of 0.4 value.

• As with the suspended tubehead of a conventional wall-mounted X-ray system, some motion of the tubehead during actual exposures is possible. Use both hands to hold the HyperLight during the exposure and keep steady. The pistol-grip style is ideal for keeping hands behind the backscatter shield, positioning and aiming (with line of sight through the clear shield) in order to achieve a quality image and avoid cone-cutting or retakes.

The motion of the handheld X-ray source will not result in image degradation and blurriness.

6.8 Dose Area Product (DAP)

Turn on the machine and place the MagicMax in the position of the outlet, then adjust the loading time and enable the exposure function, and then observe the measurement value of different loading time on the computer.

Test condition	Exposure time(s)	Air Kerma (mGy)	Dose Area Product (mGy*cm^2)
65kV, 2.5mA	0.02	0.035	0.89
	0.03	0.06	1.53
	0.04	0.085	2.17
	0.05	0.112	2.86
	0.06	0.137	3.49
	0.08	0.187	4.77
	0.1	0.245	6.25
	0.13	0.326	8.31
	0.16	0.41	10.46
	0.2	0.513	13.08
	0.25	0.665	16.96

	0.32	0.84	21.42
	0.4	1.06	27.03
	0.5	1.34	34.18
	0.63	1.7	43.36
	0.8	2.18	55.60
	1	2.69	68.61
	1.25	3.31	84.42
	1.6	4.38	111.71
	2	5.48	139.77

Overall deviation of the air kerma from the values shown does not exceed 40%. The exit field size at the end of the collimator cone (20 cm from the focal spot) is 5.7 cm. Therefore.

DAP=mGy×π (5.7CM/2)^2

WARNING

- A duty cycle of 1:30 is required after each X-ray discharge to prevent over-heating damage to the X-ray tube.
- Cautions should be exercised when selecting exposure time more than 1.25s. Please use the recommended exposure time as a reference.

6.9 Essential performance

Accuracy of loading factors (see below):

X-ray tube voltage: 65kV±10%

X-ray tube current: 2.5mA±20%

Exposure time: 0.02~2s, ±5% or ±20ms, whichever is larger.

Reproducibility of the radiation output: The coefficient of variation of measured values of Air Kerma shall be not greater than 0.05 for any combination of loading factors.

6.10 Calibration Checks

The HyperLight is factory calibrated and tested prior to release.

The following is a detail of the testing equipment used at the factory, to check conformance of the HyperLight. Using other test instruments may yield differing results.

Finally, we will perform performance tests on each machine. MagicMax will be used for performance testing. Compare the results with the factory release parameters (indicated in the chart below). For results outside these parameters, discontinue use and contact your dealer/distributor or Sifary.

Test Description	Acceptance Limits	Timer Settings and Corresponding Acceptable Ranges				
		0.05s	0.1s	0.5s	1s	2s
Tube voltage	65kV±10%	58.5-71.5 kV	58.5-71.5 kV	58.5-71.5 kV	58.5-71.5 kV	58.5-71.5 kV
Timer Accuracy	0.02-2s(± 5% or 20ms)	0.03-0.07s	0.08-0.12s	0.475-0.525s	0.95-1.05s	1.9-2.1s
Tube Current	2.5mA (±20%)	2-3mA	2-3mA	2-3mA	2-3mA	2-3 mA
Dose rate	2-3.2 mGy/s	2-3.2 mGy/s	2-3.2 mGy/s	2-3.2 mGy/s	2-3.2 mGy/s	2-3.2 mGy/s

Technical Parameters Measurement Description:

Tube voltage: The tube voltage shall be measured 5ms after its onset or after the tube current has exceeded 75 % of its final value, whichever occurs later.

Tube current: The exposure time is set to 0.5s, the tube voltage is fixed to 65kv, and the tube current is calculated by measuring the voltage across the sampling resistor of the tube current.

Exposure time: Duration from the tube current first reaches 75% of the final value to the tube current drops to 75% of the final value.

7 Cleaning and disinfection

7.1 Foreword

The parts for clinical application contamination are the outer surfaces of the HyperLight main body with backscatter shield and base holder. For hygiene and sanitary safety purpose, these components must be cleaned and disinfected between different patients 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 and disinfection. Reprocessing procedures have only limited implications to these parts. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.
In case of damage, the device should be reprocessed before sending back to the manufacturer for repair.

7.2 General recommendations

- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
- Do not use bleach or chloride disinfectant materials.

7.3 Reprocessing Instructions

Preparation before processing:	Before cleaning and disinfecting, make sure the power is off.
Cleaning:	Wipe all the exterior surfaces of HyperLight main body with backscatter shield and base holder thoroughly with a cloth lightly moistened with Ethanol (Ethanol 70 to 80 vol%) at least 3 min, repeat for 5 times. (Visual inspection for cleanliness of the device and its accessories. If necessary, perform reprocessing process again until the component is visibly clean.)
Disinfection:	Wipe all the exterior surfaces of HyperLight main body with backscatter shield and base holder thoroughly with a cloth lightly moistened with Ethanol (Ethanol 70 to 80 vol%) at least 3 min, repeat for 5

	times.
Drying:	Use a lint free cloth to wipe the surfaces.
Inspection and maintenance:	Perform functional testing according to the user manual. Before packaging, make sure that the components have been maintained according to the manufacturer's instruction.
Storage:	Storage of the processed device in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

NOTE

- Make sure the power is off before cleaning and disinfecting.
- Do not use cleaners other than ethanol (Ethanol 70 to 80 vol%), since certain chemical combinations may deteriorate the HyperLight plastic prematurely.
- Never apply sprays or liquids directly on the surfaces of the device.
- The HyperLight main body with backscatter shield, base holder, the power adapter and power cord are not designed to be subjected to any kind of sterilization procedure.

WARNING

- Use any anti-contamination bag that can cover the HyperLight for each patient use to prevent cross-contamination.

8 Maintenance

Incorrect operation or failure to maintain the device in accordance with the maintenance schedule relieves the manufacturer or his agent from all the responsibilities for subsequent non-compliance, damage, injury, defect and/or other malfunction. Only authorized Service Representatives, trained specifically on the HyperLight device, can maintain the device.

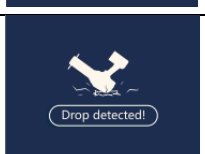
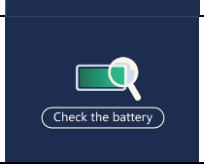
Annual Maintenance: Observe the following steps for annual maintenance of the HyperLight.

1. Verify that the Power button is working properly. When the device is powered on, the display should illuminate and an indicator alarm should sound.
2. Verify that the Panel key is working properly.
3. Check whether all interfaces on the screen are normal.
4. Enter the Settings screen to check whether the Settings function is normal.
5. Use the exposure function to test whether the machine can be exposed properly.
6. Check whether the battery is abnormal. If you do not use the machine for a long time, you need to charge the machine every 6 months.

Maintenance Test	Year 1	Year 2	Year 3	Year 4	Year 5
Power Button					
Panel key					
Screen					
Setting interface.					
The exposure function					
Battery					

9 Troubleshooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

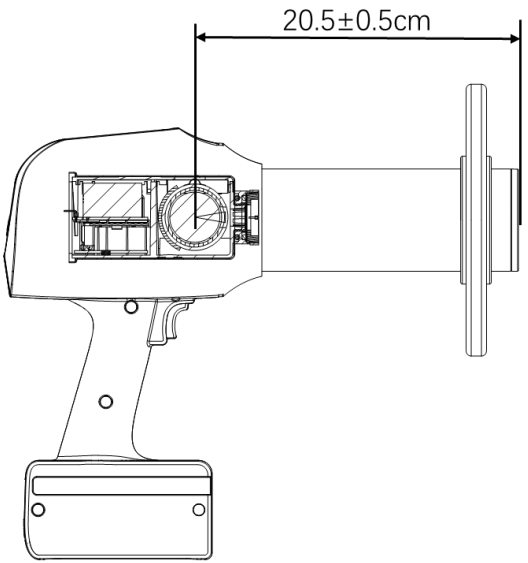
Malfunction	Causes	Methods
	Insufficient charge	Use the charger to charge the machine.
	The machine temperature is too high.	Let stand for more than half an hour.
	Abnormal exposure time	During the exposure process, the finger released the exposure button, causing the exposure to be forcibly terminated.
	Drop detected	A fall of the machine is detected, which may cause damage to the machine.
	Check the battery	Frequent use of the machine for a long time causes the battery temperature to be too high.

10 Technical Data

10.1 Main Body Technical Data

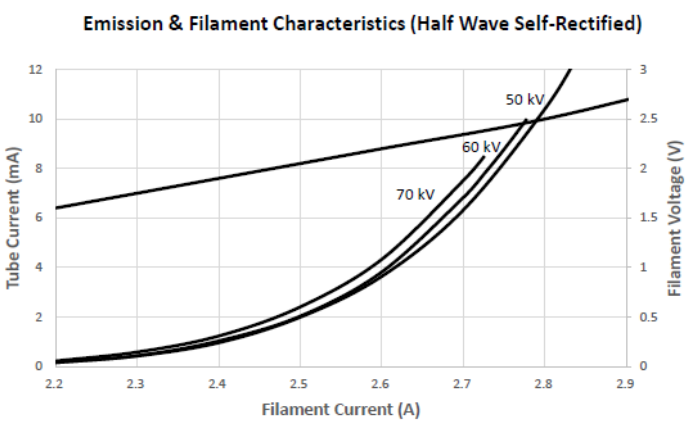
Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	HyperLight
Software version	HL 1
Package Dimensions	489mm×367.5mm×219mm (±10%)
Total Weight	4kg±20%
Charger power supply	~100-240V 50/60Hz
Power supply	Lithium ion battery: 14.8V, 2500mAh ±10%
Input AC Current	1.2A max
Charger power output	24V ⎓ 1.5A
Charging overcurrent protection	1.8A
Discharge overcurrent protection	50A
Ray type	X Ray
X-ray tube model	KL11-0.4-70
Tube voltage	65kV (±10%)
Tube Current	2.5mA (±20%)
Fuse	F 15AL 65V Size:6.1mm×2.69mm×2.69mm
Exposure time adjustment range	0.02-2s(±5% or ±20ms whichever is larger)
Nominal power	162.5W nominal at 65kV, 2.5mA
Inherent Filtration	0.8mm Al/75kV
Added filter	1mm Al (1mm Al)
Total Filtration	≥1.8mm Al (0.8mm glass, 1mm Al)
Duty Cycle	1:30
Source to skin distance	20.5cm±0.5cm (from focal spot to cone tip)
X-ray exit field size and configuration	57mm diameter circle
Applied part	B(The handheld part on the main body is as applied part)
Electrical safety class	Class II
IPX specification	IPX0; do not operate under wet conditions

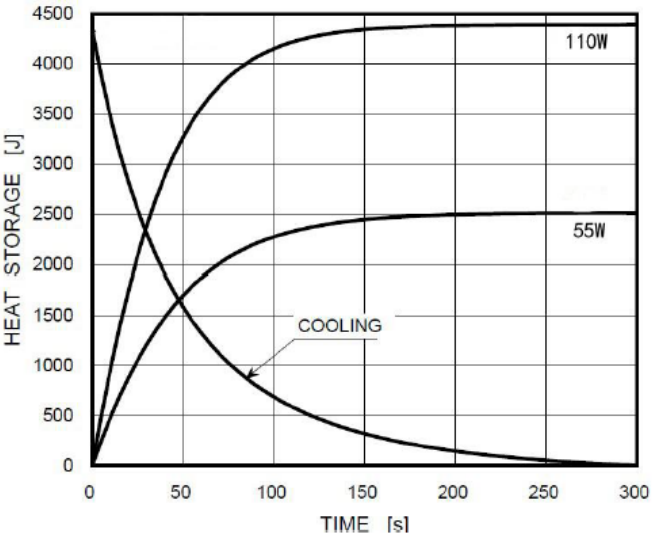
Apparent resistance of supply main	≤2Ω
Mode of operation	Intermittent operation 2s ON/60s OFF
Ambient conditions	Use: in enclosed spaces Ambient temperature: 10°C ~ 40°C Relative humidity: 30%-75% Atmospheric pressure: 70 kPa - 106 kPa
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% - 80 % Atmospheric pressure: 70 kPa - 106 kPa

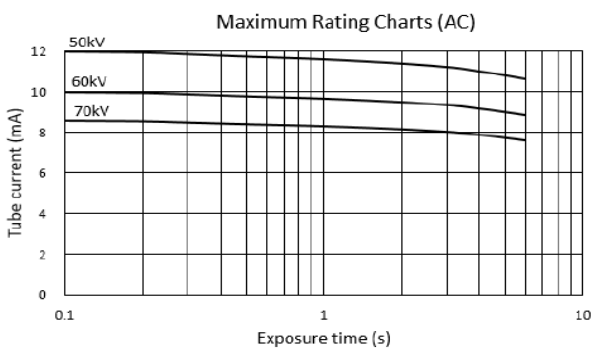


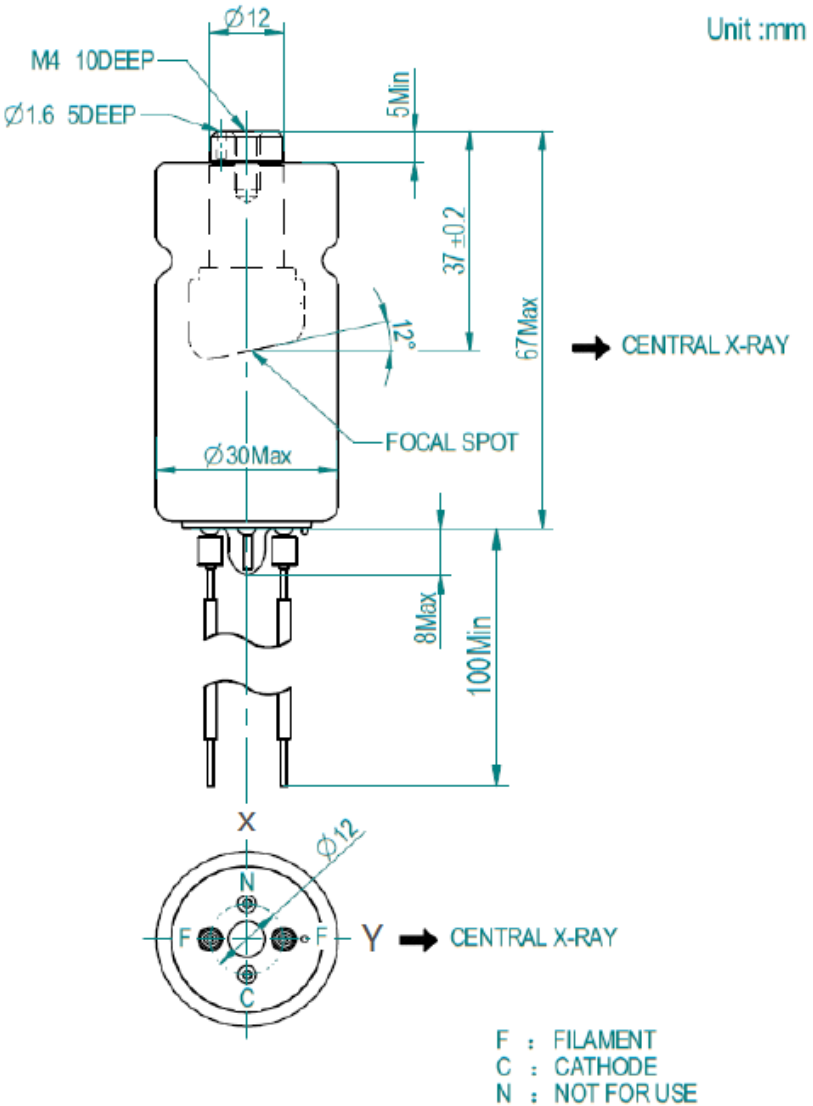
10.2 X-ray Tube Assembly Specifications and Characteristics

Filament voltage	2.8-3.4V
Maximum filament current	3A
Nominal tube voltage	70kV
X-ray source assembly maximum heat content	4500J
Maximum anode cooling rate	110W
Nominal anode input power	600W
Target material	Tungsten
Minimum target angle	12°
Filament voltage (at maximum filament current 2.9A)	2.4~ 3.0V
Minimum permanent filtration (IEC 60522:1999)	0.8mm/75kV
Nominal focal spot (IEC 60336:1993)	0.4




4500
4000
3500
3000
2500
2000
1500
1000
500
0
HEAT STORAGE [J]
110W
55W
COOLING
0
50
100
150
200
250
300
TIME [s]


Maximum Rating Charts (AC)
50kV
60kV
70kV
12
10
8
6
4
2
0
Tube current (mA)
0.1
1
10
Exposure time (s)


Unit :mm
Ø12
M4 10DEEP
Ø1.6 5DEEP
5Min
37 ±0.2
67Max
12°
CENTRAL X-RAY
FOCAL SPOT
Ø30Max
8Max
100Min
X
Ø12
N
F
F
Y
CENTRAL X-RAY
C
F : FILAMENT
C : CATHODE
N : NOT FOR USE

11 EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The HyperLight is intended for use in the electromagnetic environment specified below. The customer or the user of the HyperLight should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The HyperLight uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The HyperLight is suitable for use in all establishments other than domestic establishments, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Provided the following warning is heeded: Warning: This HyperLight is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the HyperLight or shielding the location.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The HyperLight is intended for use in the electromagnetic environment specified below. The customer or the user of the HyperLight 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 +/-15kV air	+/-2, 4, 6 & 8kV contact +/-2, 4, 8, & 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	+/-2 kV for power supply lines +/-1 kV for input/ output lines	+/-0.5, 1 & 2 kV for power supply lines +/-0.5 & 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV differential mode +/-2 kV common mode	+/-0.5 & 1 kV differential mode +/-0.5, 1 & 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	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 cycle	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 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HyperLight requires continued operation during power mains interruptions, it is recommended that the HyperLight be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	3 & 30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The HyperLight is intended for use in the electromagnetic environment specified below. The customer or user of the HyperLight should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)=3Vrms	Portable and mobile communications equipment should be separated from the HyperLight by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
	6Vrms in ISM bands between 0,15 MHz and 80 MHz	(E1)= 6Vrms in ISM bands	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	(E1)=3V/m	D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter. Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (m).

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
The HyperLight is intended for use in the electromagnetic environment specified below. The customer or user of the HyperLight should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

1. 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 Model 005 is used exceeds the applicable RF compliance level above, the Model 005 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 005.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.
3. The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

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 HyperLight has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the HyperLight as recommended below.

11 EMC Tables

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	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

WARNING

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

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Power Adapter	1.2	NO	/
Power Cord	1.4	NO	/
Remote control switch	2	NO	/

2. Use of HyperLight adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, HyperLight and the other equipment should be observed to verify that they are operating normally.
3. 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.

12 Service Life

Service Life

The service life of HyperLight series products is 5 years.

Maintenance

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

Disposal

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Please deal with them according to the local environmental protection laws and regulation.

Rights

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NOTICE

Any serious incident should be reported to manufacturer and competent authority.