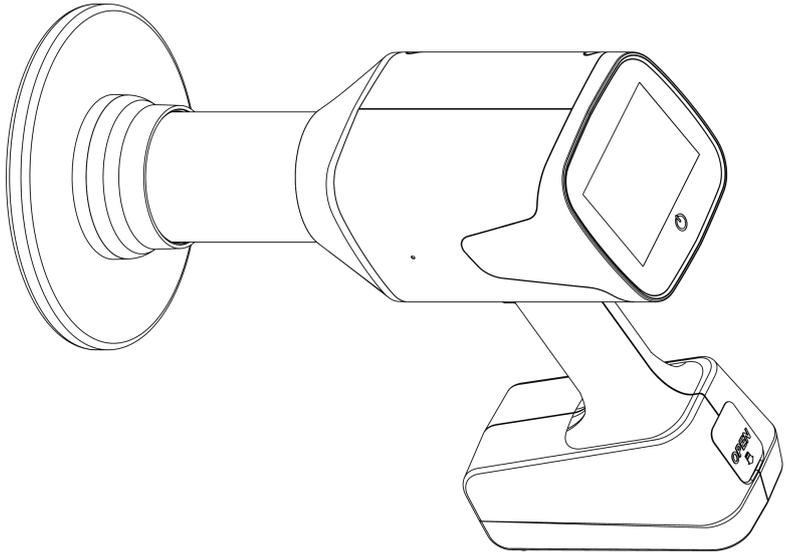




Model: HyperLight-M



**Hand-held Dental X-ray System  
USER MANUAL  
Changzhou Sifary Medical Technology Co., Ltd.**

Version: S01  
IFU-7035301  
Issued: 2024.11.14  
Size:197mmX140mm

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## Content

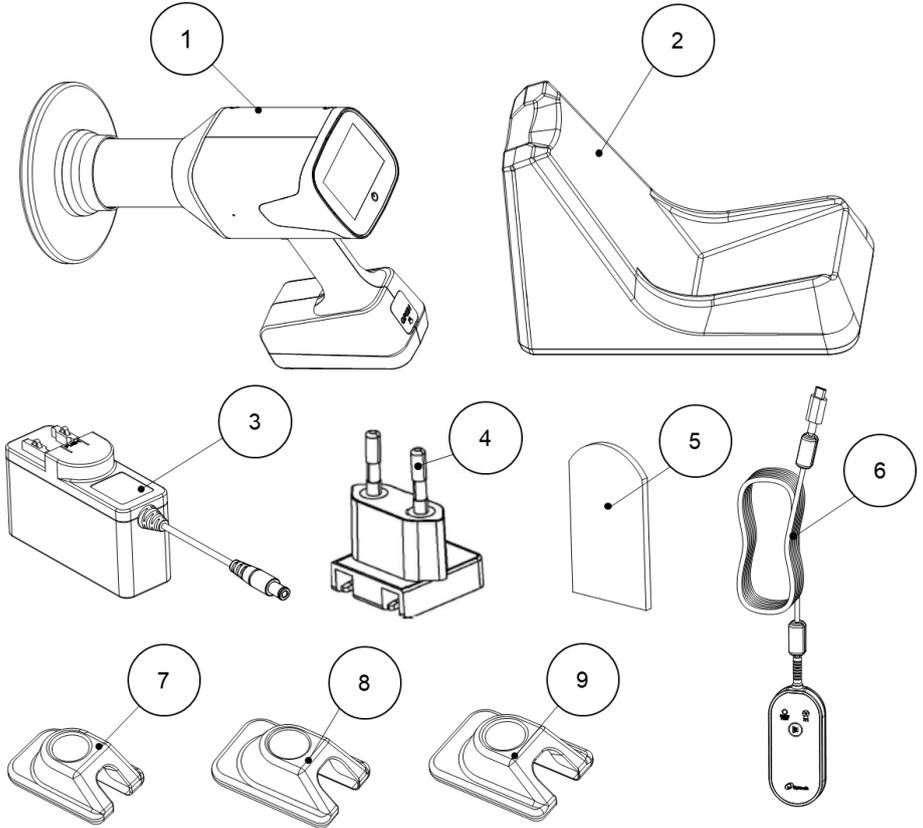
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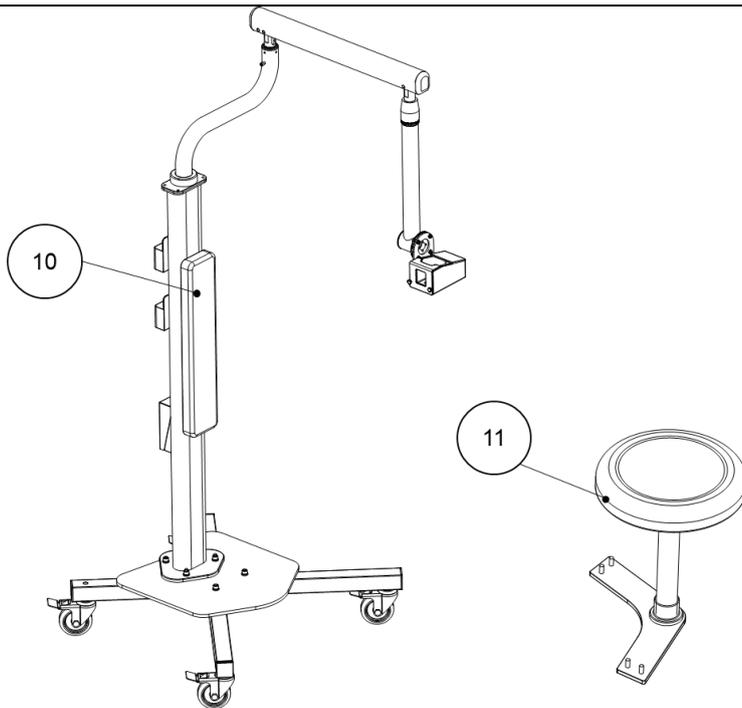
## 1. Overview

### 1.1 Content



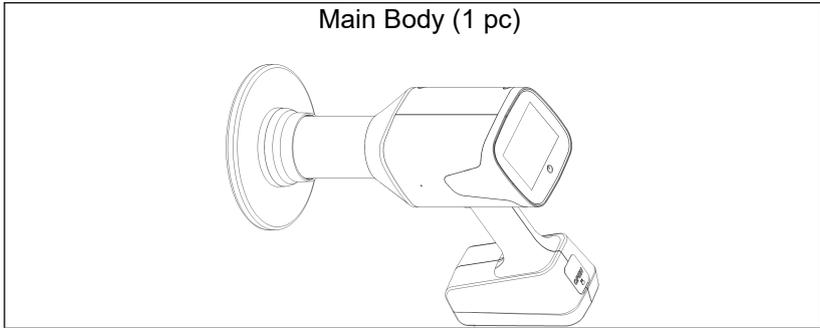
## 1 Overview

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1. Main Body
2. Base Holder
3. Power Adapter
4. Power Plug
5. Disposable Sleeve (optional)
6. Remote Control Switch (optional)
7. 1 Inch Sensor Protective Sleeve (optional)
8. 1.5 Inch Sensor Protective Sleeve (optional)
9. 2 Inch Sensor Protective Sleeve (optional)
10. Bracket (optional)
11. Bracket seat (optional)

**1.2 Component**

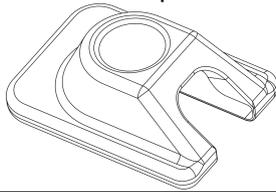


**1.3 Accessory**

<p>Base Holder (1 pc)</p> A line drawing of a base holder, which is a rectangular frame with a curved top edge and a small notch on the right side.	<p>Power Adapter (1 pc)</p> A line drawing of a power adapter, which is a rectangular box with a circular top and a long, thin probe extending from the right side.
<p>Power Plug (1 pc)</p> A line drawing of a power plug, which is a rectangular base with two vertical pins and a small rectangular tab on the left side.	<p>Disposable Sleeve ( optional )</p> A line drawing of a disposable sleeve, which is a simple, rectangular, slightly curved piece.
<p>1 Inch Sensor Protective Sleeve ( optional )</p> A line drawing of a 1-inch sensor protective sleeve, which is a rectangular frame with a circular opening in the center and a small notch on the right side.	<p>1.5 Inch Sensor Protective Sleeve ( optional )</p> A line drawing of a 1.5-inch sensor protective sleeve, which is a rectangular frame with a circular opening in the center and a small notch on the right side.

# 1 Overview

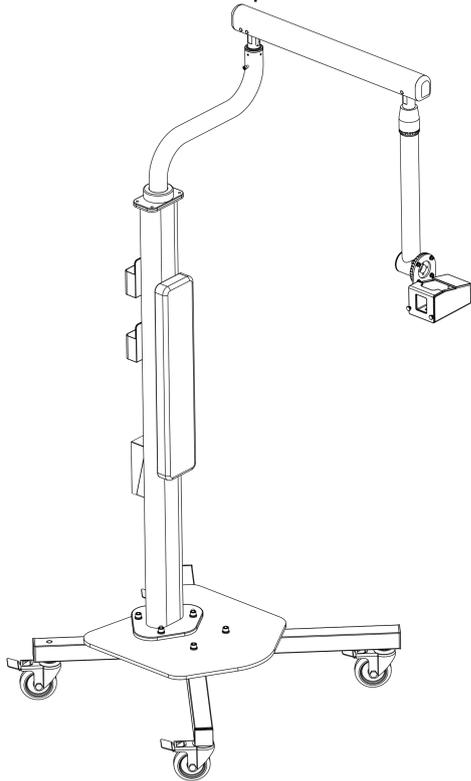
2 Inch Sensor Protective Sleeve (optional)



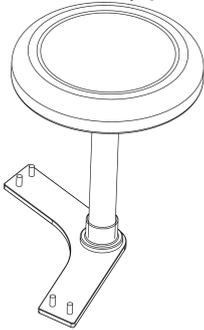
Remote Control Switch (optional)



Bracket (optional)



Bracket Seat (optional)



### 2. Symbol Instruction

 <b>WARNING</b>	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
 <b>NOTE</b>	Additional information, explanation of operation and performance.
	Serial number
	Alternating current
	Direct current
	Dispose of in accordance with the WEEE directive
	Keep dry
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Catalogue number
	Manufacturer
	Date of manufacture
	Lot of manufacture
	Manufacturer's LOGO
	Follow instructions for use
	Warning of ionizing radiation
	Medical device
	Dangerous Voltage: Electrical Shock Hazard

### 3. Foreword

#### 3.1 Scope of application

The Hand-held Dental X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

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-M is contraindicated in cases where patient/user carry medical implants such as pace makers or cochlear implants etc.
- Pregnant women. The medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the pregnant woman and fetus resulting from radiation exposure. 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.
- 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 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.

### 3.3 Intended 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 liquids.
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 Hand-held Dental X-ray System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment

### 3 Foreword

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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 device 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. Replacing batteries by untrained service personnel can lead to hazards (over-temperature, fire or explosion).
18. If the package or equipment is damaged, contact the supplier or manufacturer.
19. No modification of this equipment is allowed.
20. Under normal use, the Beam Limiting Device must not be removed. Including intended use, inspection, maintenance, transportation, cleaning and disinfection, adjustment.
21. No parts can be maintained or serviced while in use with the patient.



### 3 Foreword

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#### Disclaimer:

The device 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 focal spot to skin distance without authorization may cause the patient to receive unnecessary radiation.

### 4. Safety Precautions

#### 4.1 Radiation Safety

The HyperLight-M 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.



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

The HyperLight-M provides a high degree of protection from 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 use 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 minimize dose to the fetus.

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



Operator exposure to radiation will increase due to proximity.

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 are 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.

## 4 Safety Precautions

### Compliance with Applicable Standards

<b>Standard</b>	<b>Title</b>
IEC 60601-2-65:2012+A1 :2017+A2:2021	Medical electrical equipment-Part 2-65:Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 60601-1-3:2008+A1: 2013+A2:2021	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

### A list of protective devices and accessories

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

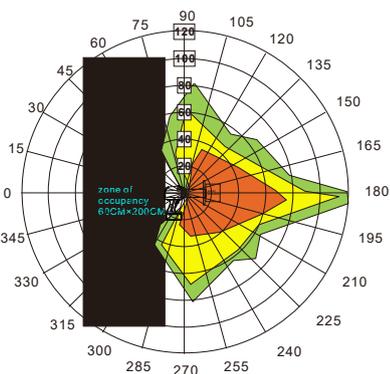
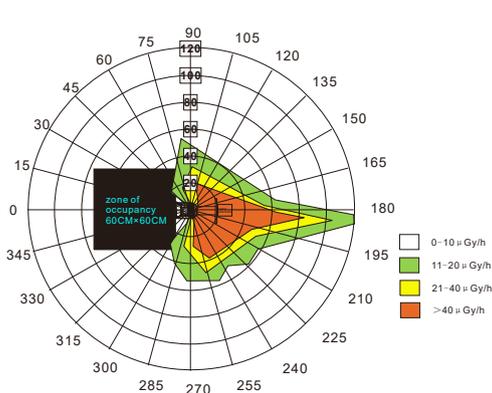
### 4.2 Leakage Dose

Leakage Dose	Permissive Range
70 kV, 3 mA, 2s (Max. Exposure Condition) At any point on the outer surface of HyperLight-M 1 : 30 Duty Cycle	$\leq 0.05$ mGy/h

In order to verify compliance with this leakage requirement, device is tested for radiation leakage at any point on the outer surface of HyperLight-M. The highest measurement out must be lower than 0.05mGy/h in order for the device to successfully pass product release testing.

### 4.3 Scatter

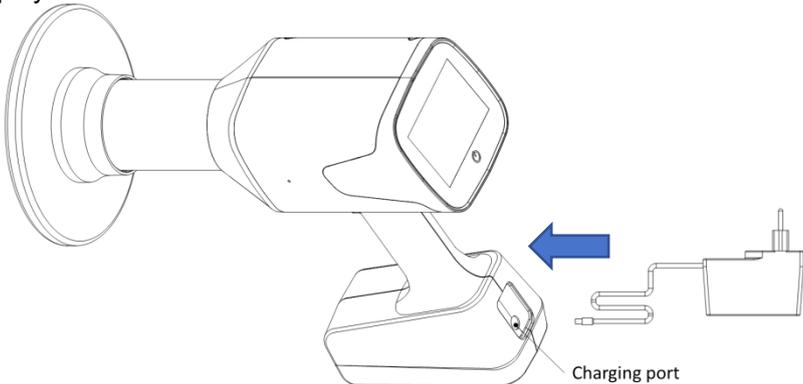
The significant zone of occupancy for operators has been further verified by internal testing. A HyperLight-M device was remotely fired into a water phantom ( 25 X 25 X 10cm ) repeatedly, with an ion chamber recording radiation readings in the room, first to establish the vertical significant zone of occupancy and then to establish the horizontal significant zone of occupancy. Each exposure was taken at 2 seconds. The vertical significant zone of occupancy measures 60 cm X 200 cm, while the horizontal significant zone of occupancy is 60 cm X 60 cm. A calibrated survey dosimeter can be used in order to confirm 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 charger into the machine and the other end into the socket. The charging icon will be displayed on the screen at this time.



If plug the charger in the off state, the following interface will be displayed



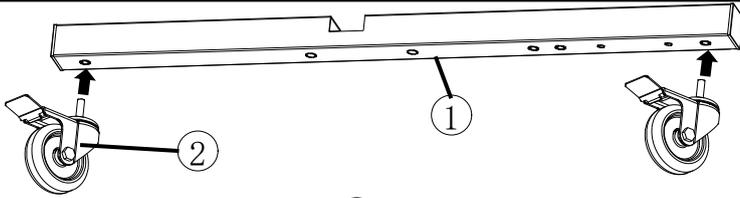
#### **WARNING**

- Don't position the device where it is difficult to operate the disconnection device.
- Only original adapter can be used.

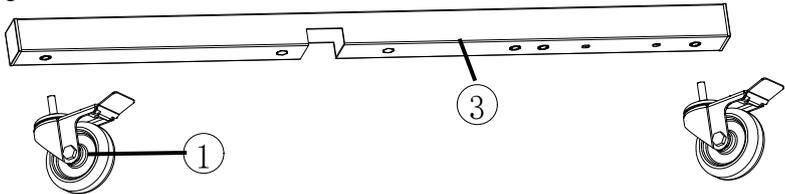
#### 5.2 Install Bracket

1. Rotate the casters ① clockwise into the threaded holes at both ends of the below base pipe ② as shown in the figure and tighten them;

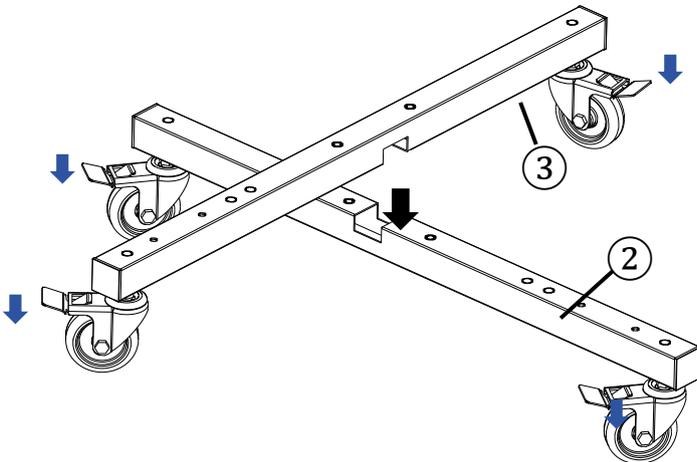
## 5 Installation



2. Similarly Rotate the casters ① clockwise into the threaded holes at both ends of the upper base pipe ③ as shown in the figure and tighten them;



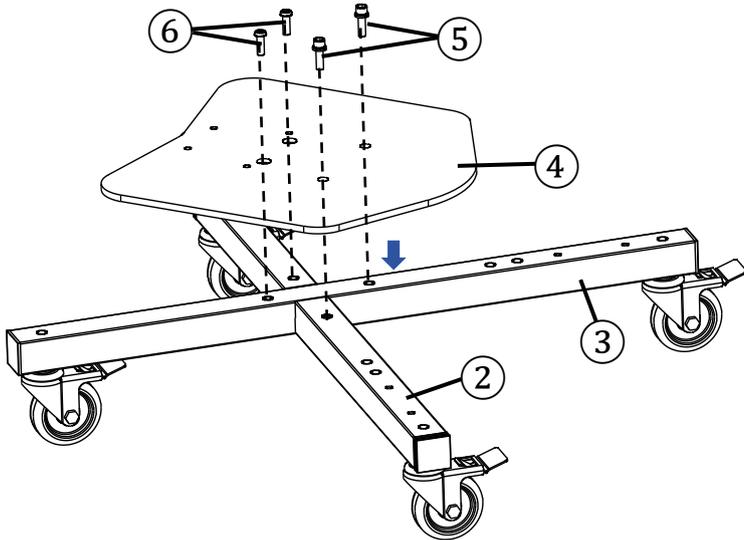
3. Insert the upper base pipe ③ into the corresponding slot of the below base pipe ② as shown in the figure, and press the four casters locking switch as shown in the figure to lock the four casters. The base is installed.



4. Place the bottom plate ④ at the cross position of the base pipe ③ and the below base pipe ② in the direction indicated in the figure. Align the four installation holes with dotted lines as shown in the figure.

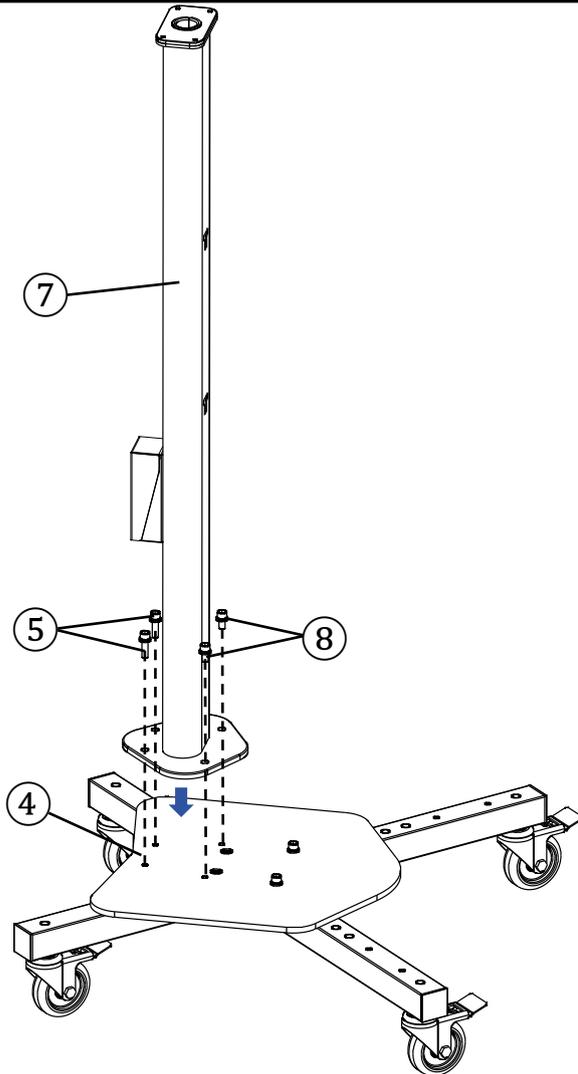
## 5 Installation

Secure the bottom plate (4) to the base pipe (3) and the below base pipe (2) using two M10\*35 hexagon assembly bolts (5) in the two through holes and two M10\*30 round head hexagon bolts (6) in the two countersunk holes.



5. Place the support column (7) at the bottom plate (4) in the direction shown in the figure, align the four mounting holes as shown in the figure, and use two M10\*35 hexagon assembly bolts (5) and two M10\*20 hexagon assembly bolts (8) to lock the support column with the bottom plate.

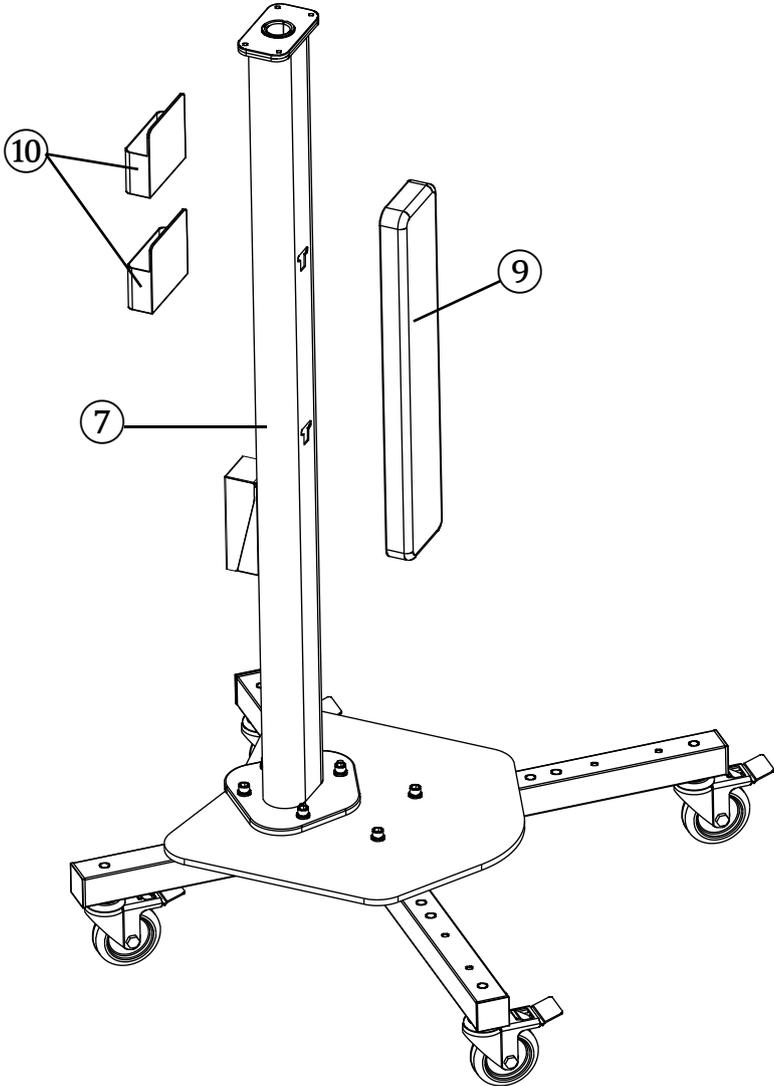
## 5 Installation



6. Hang the buckle on the wooden side of the column back (9) into the corresponding slot of the support column (7), and then press it in the direction shown in the figure.

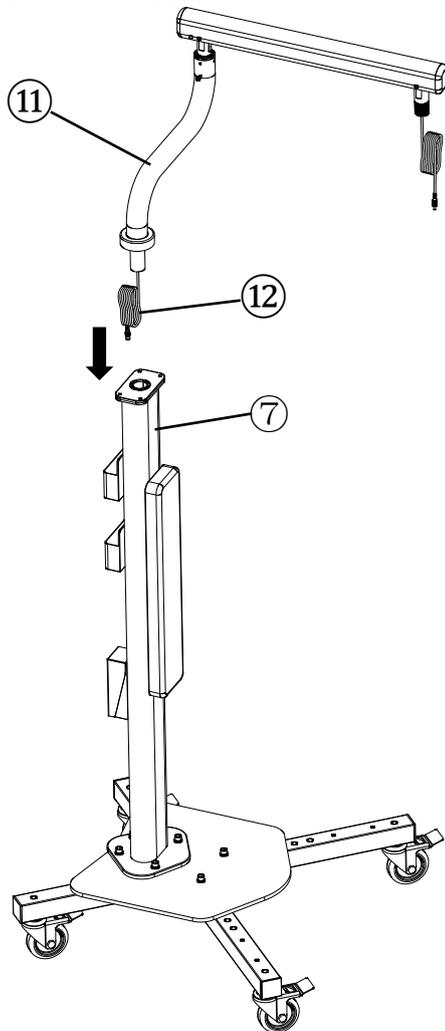
## 5 Installation

7. Attach two magnetic absorption nanoboxes (10) to the other side of the support column, and adjust the height according to personal habits.



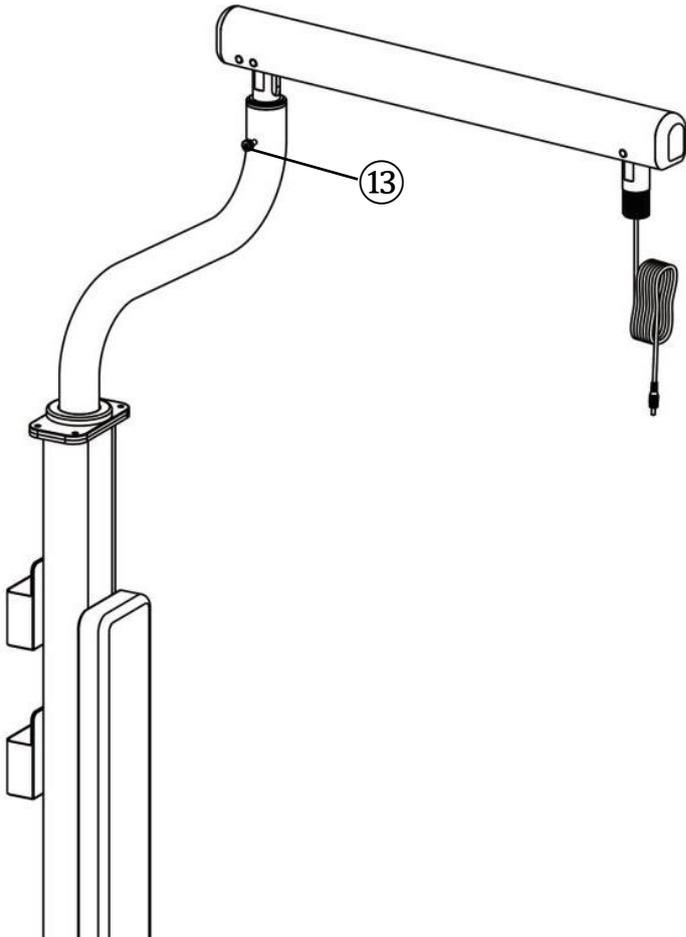
## 5 Installation

8. Straighten the input part of the power extension cable (12) and put it into the support column (7). Insert the balance arm assembly (11) into the hole at the top of the support column (7) in the direction shown in the figure and press it to the bottom.



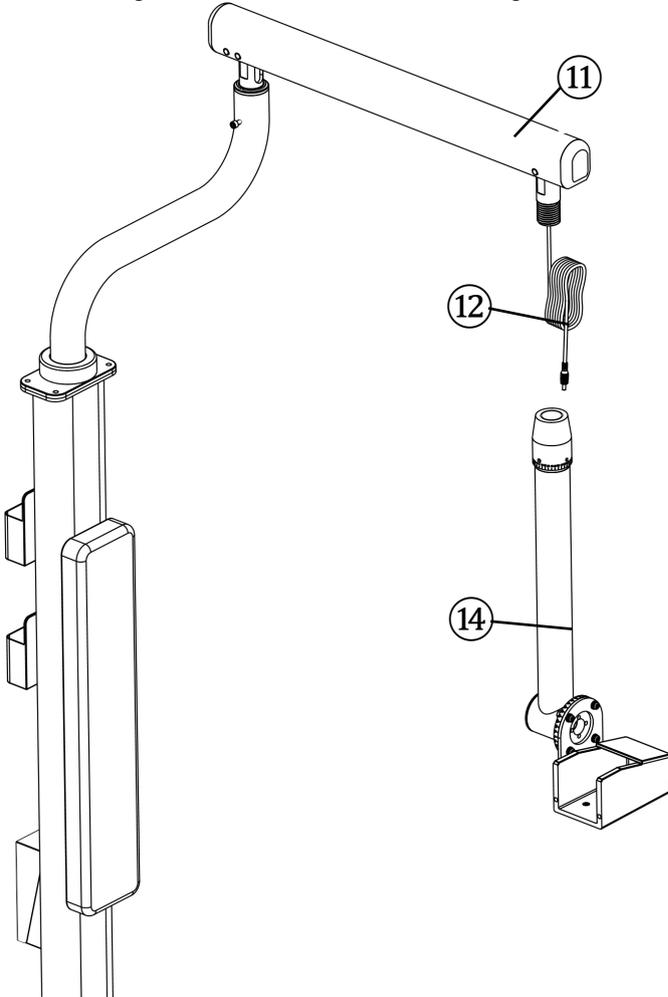
## 5 Installation

9. After the balance arm assembly ⑪ is installed into the hole and pressed to the bottom, cut the binding band of the balance arm assembly ⑪, and then the balance arm will spring up. Please pay attention to safety.
10. Turn the balance arm assembly to the position as shown in the figure, and then tighten the screw ⑬ on the rotating arm as shown in the figure.



## 5 Installation

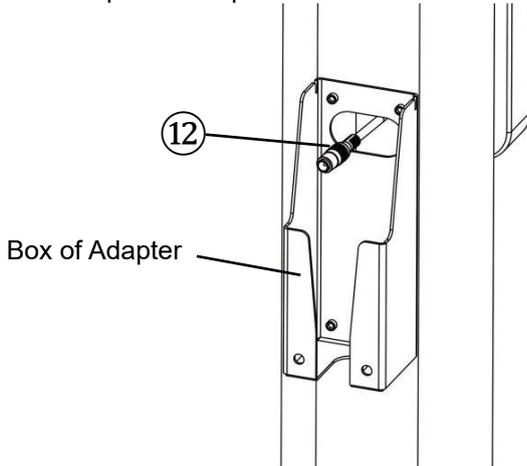
11. Straighten the output port of the power extension cable (12) and put it into the main arm assembly (14). Screw the main arm assembly (14) anti-clockwise into the thread of the balance arm assembly (11) and tighten it according to the direction shown in the figure.



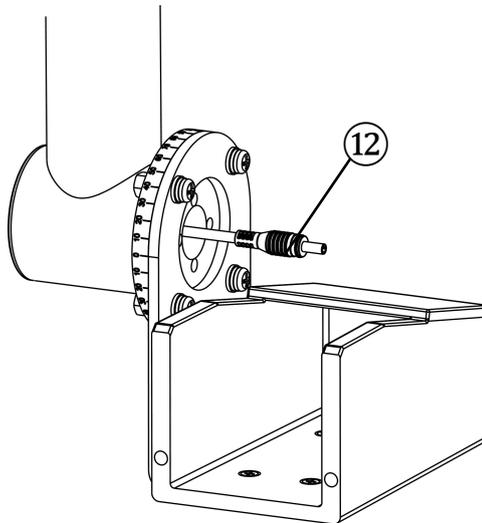
12. Pull out the input port of the power extension cable (12) from the waist hole shown in the adapter box (for placing the power adapter) to

## 5 Installation

connect the power adapter.



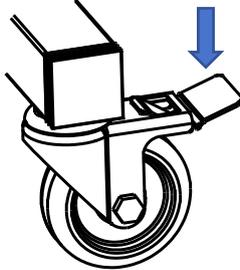
13. Pull out the output port of the power extension cable ⑫ from the round hole shown in the main arm assembly to connect the mainbody charging port.



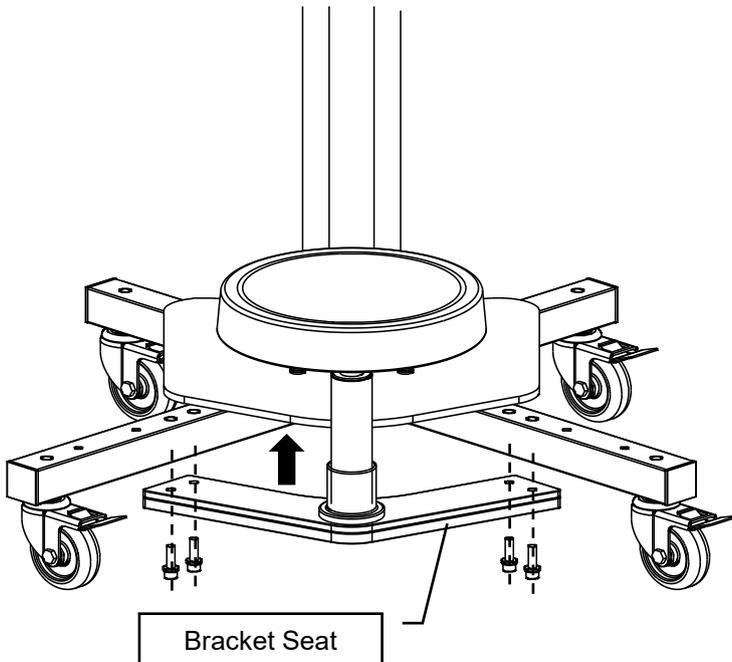
## 5 Installation

### 5.3 Install Bracket Seat

1. Before installing the bracket seat or using the bracket, be sure to press the locking switch as shown in the figure to ensure that the four casters are locked. When the bracket needs to be moved, move the locking switch upward to unlock it.

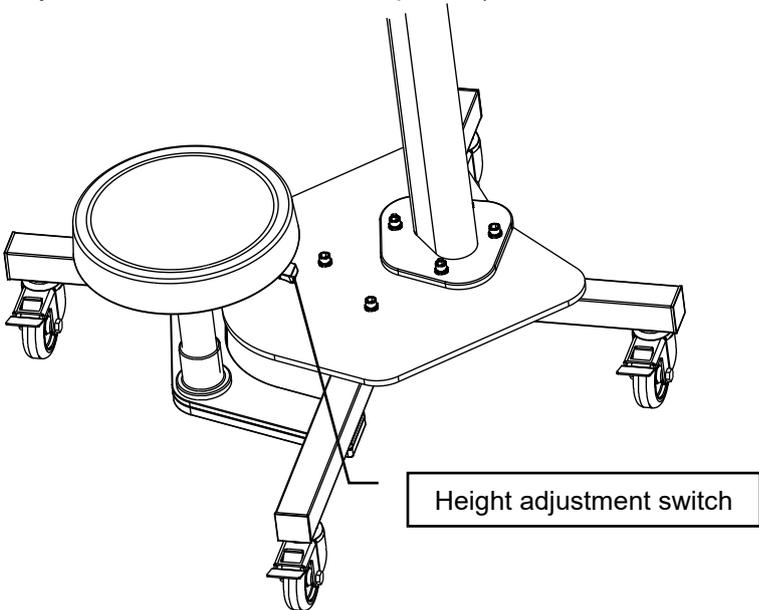


2. Use four bolts to secure the Bracket Seat assembly to the bottom of the bracket as shown



## 5 Installation

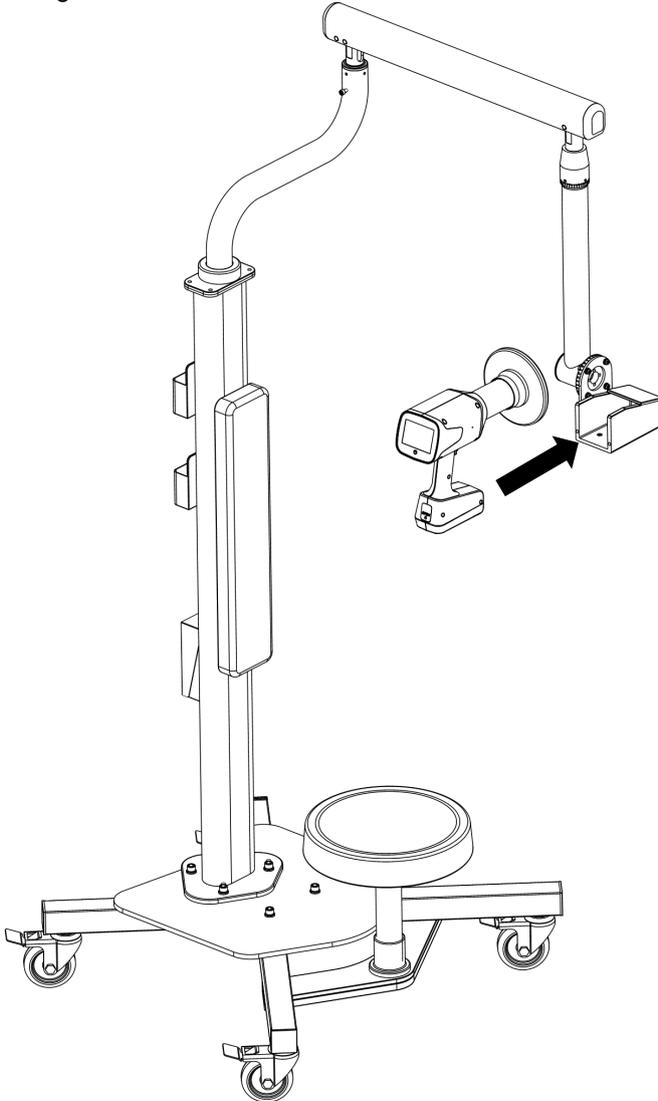
3. After installation, the seat can be rotated freely and the height can be adjusted according to individual needs. (The Bracket Seat is optional and only needs to be installed if it is optional.)



## 5 Installation

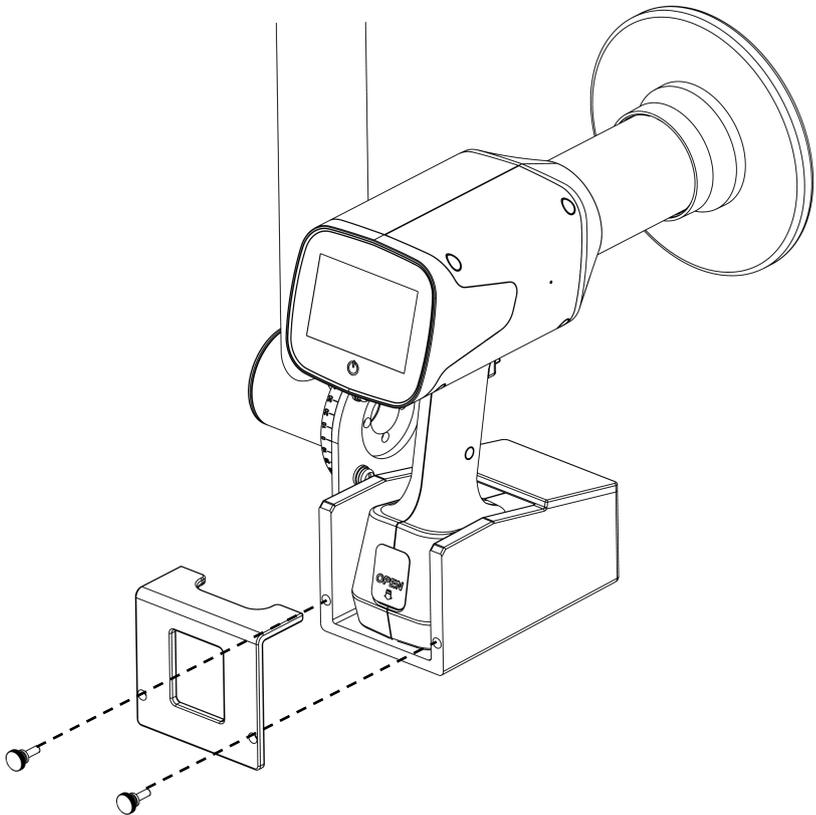
### 5.4 Install main body to Bracket

Push HyperLight-M into the holder of Bracket in the direction shown.



## 5 Installation

2. Use the screws to lock the rear cover into mounting holes of the holder.

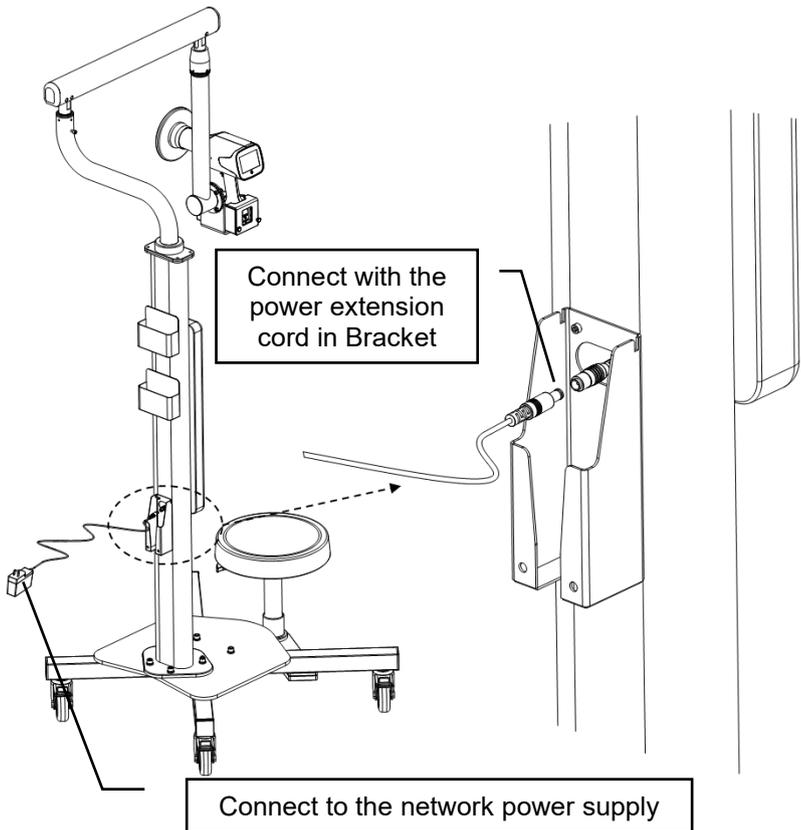


(The bracket is optional and only needs to be installed if it is optional.)

## 5 Installation

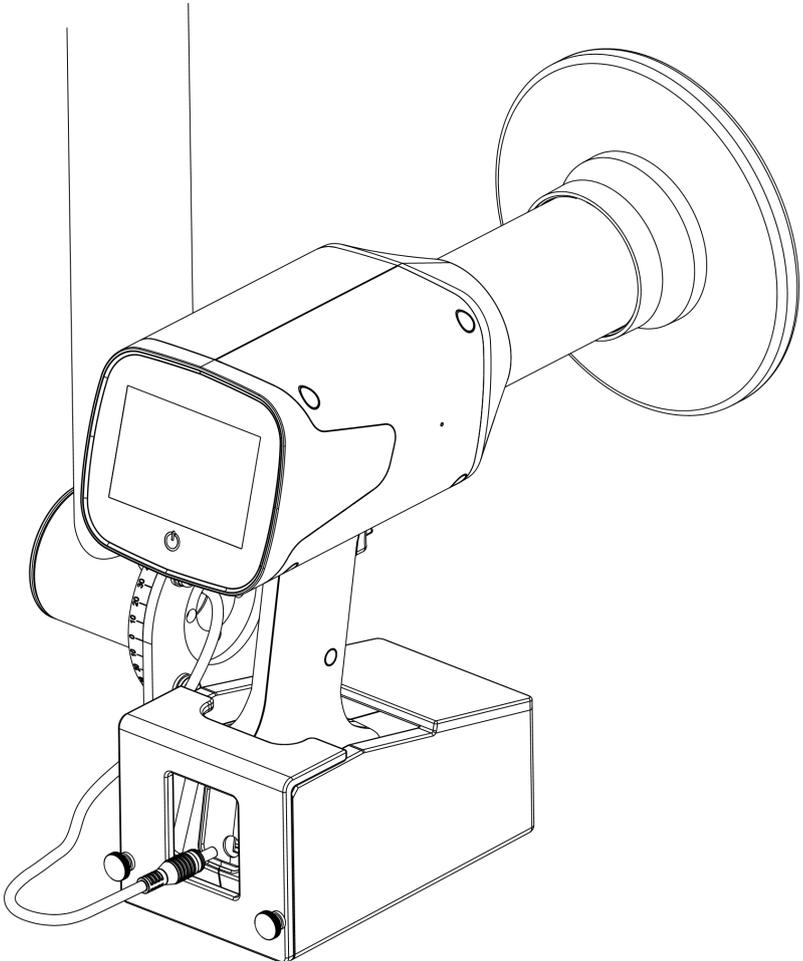
### 5.5 Charging with Bracket

1. Connect the power adapter output plug of HyperLight-M to the power extension cord plug drawn out from the bracket.
2. Connect the power adapter input plug of HyperLight-M to the network power supply.



## 5 Installation

3. Connect the power extension cord plug drawn out from the Bracket to the charging port of HyperLight-M.

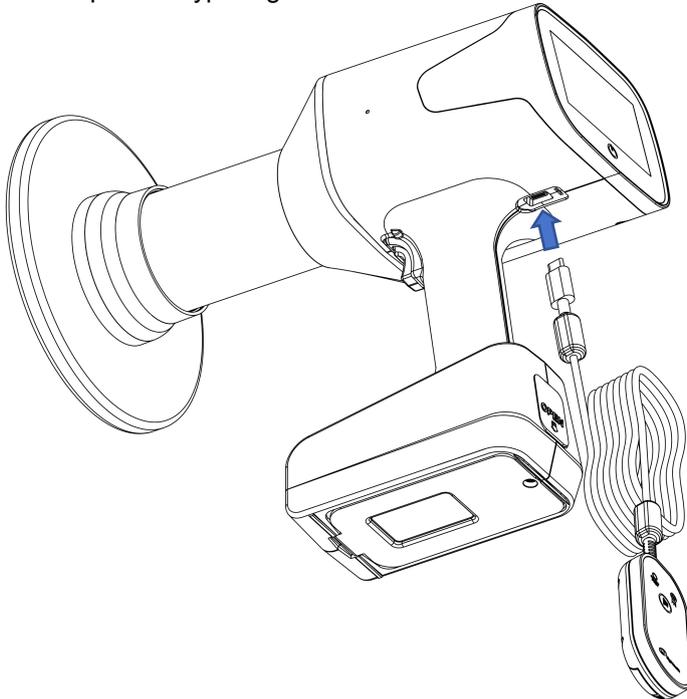


(The bracket is optional and only needs to be installed if it is optional.)

## 5 Installation

### 5.6 Plug in the Remote Control Switch

When using Remote Control Switch, connect its plug to the Remote Control Switch port of HyperLight-M.



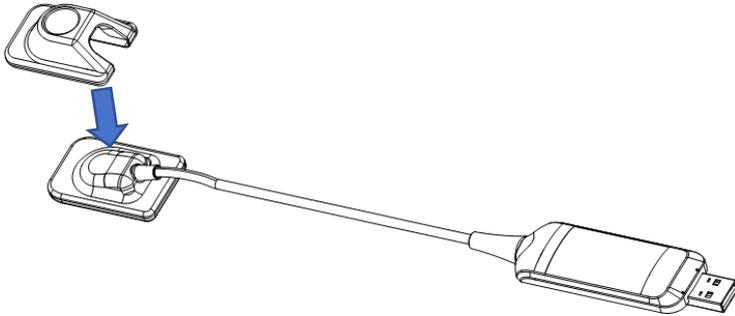
(The Remote Control Switch is optional and only needs to be installed if it is optional.)

### 5.7 Install Sensor Protective Sleeve

When using our sensor products NanoPix to achieve the M-TECH function of HyperLight-M, please follow the instructions below to install the Sensor Protective Sleeve on NanoPix first, then wrap it with the Disposable Sleeve before use. The detailed correspondence is shown in the table below. The corresponding Sensor Protective Sleeve must be used for installation.

(1 Inch Sensor Protective Sleeve, 1.5 Inch Sensor Protective Sleeve, 2 Inch Sensor Protective Sleeve, Disposable Sleeve are optional and only needs to be installed if it is optional.)

## 5 Installation



NO.	Sensor Protective Sleeve	Corresponding sensor model
1	1 Inch Sensor Protective Sleeve	NanoPix1
2	1.5 Inch Sensor Protective Sleeve	NanoPix1.5
3	1 Inch Sensor Protective Sleeve	NanoPix2



### **WARNING**

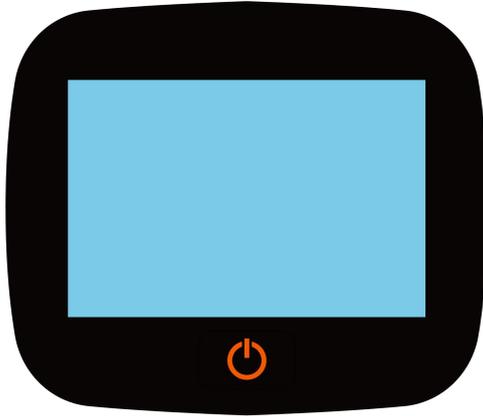
- Please make sure that the backscatter shield is securely installed on the machine before use.
- Do not remove the backscatter shield and do not operate if the backscatter shield is broken.
- The optional Bracket and Bracket Seat are heavy. Please pay attention to safety during installation and handling.
- The optional Bracket must be placed in the right direction when using. It is prohibited to put it on the side or upside down.
- When using the optional Bracket, be careful to place it stably, otherwise it may hurt people or equipment.
- Pay attention to the direction and height of the cantilever when using the optional Bracket, otherwise people or equipment may be injured.
- When the optional Bracket is used with HyperLight-M, all casters must be placed in a fully braked state to avoid involuntary movement during use.
- Make sure that used disposable sleeves are disposed of as infected

## 5 Installation

waste which is potentially biologically hazardous.

## 6 Operation

### 6.1 Operation panel instructions

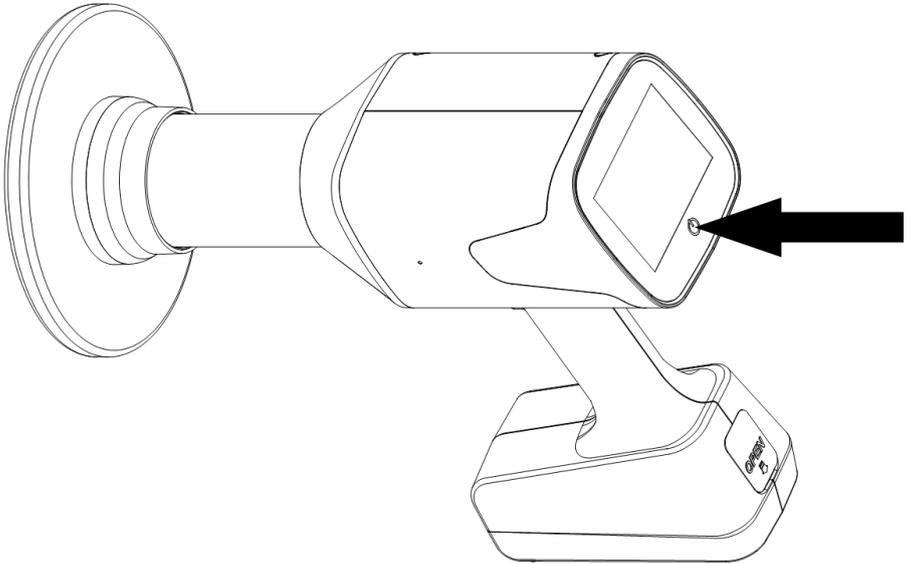


Symbol	Type
	Power Button

### 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.

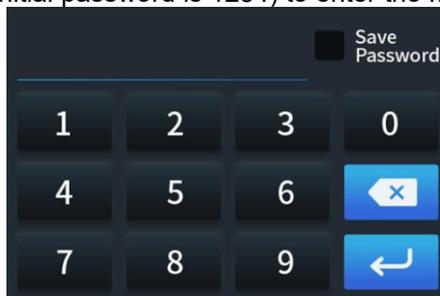


2. Make sure that the battery level is not lower than the figure below.



Battery level 1

3. After the Logo animation is over, the password screen is displayed. Enter the password (the initial password is 1234) to enter the main screen.

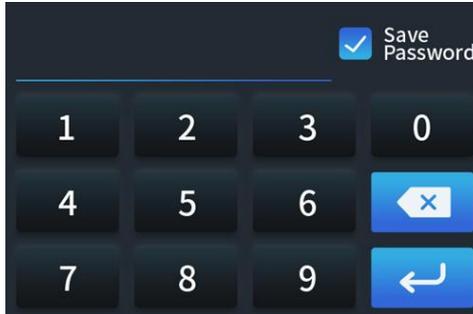


## 6 Operation

---

It's not necessary to enter the password next boot after choosing the Save

Password in top right corner of screen, just just press  to enter the boot interface.



4. Please ensure that there are no magnetic objects around the machine before starting. Otherwise, the machine will enter the following interface.



Remove the magnetic object and click Yes to enter the boot interface.

### 6.2.2 Power Off

Long press the power button to shut down.

6.3 Screen instructions



No.	Item	Description
1		Remaining Battery Indicator  Indicates remaining battery level. When the indicator light starts to red glow, it means the battery needs to be charged.
		Battery Charging Indicator  Indicates the battery charger is connected to the device.

## 6 Operation

2		Tube Voltage/Curre nt Indicator	Indicates the tube voltage and tube current of the system.
3	 <b>Adult</b>	Adult/Child Selection	Indicates a patient type (adult or child).
	 <b>Child</b>		
4		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
5		Time Display	Displays the X-ray exposure time.
6		Bitewing	Selects the tooth type.
		Lower Molar	
		Upper Molar	
		Canine	
		Incisor	

## 6 Operation

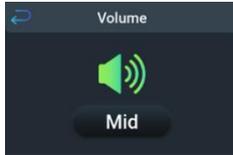
7		M-TECH switch	Close M-TECH function
			Open M-TECH function
8		Machine lock	The machine is locked and cannot be exposed.
			The machine is unlocked and can be exposed.

## 6.4 Set interface

After starting up, you can swipe down the  to enter the setting interface, Press the six options on the screen to enter the corresponding Settings page.

Display content	Meaning
	<p>Press  to enter The receptor selection page;</p> <p>Press  to enter The Volume adjustment page;</p> <p>Press  to enter The Light adjustment page;</p> <p>Press  to enter The Language selection page;</p> <p>Press  to enter The password setting page; Press</p> <p> to enter The restore factory setting page;</p>

## 6 Operation



Adjust the volume of the machine.



Adjust the light of the machine.

## 6 Operation

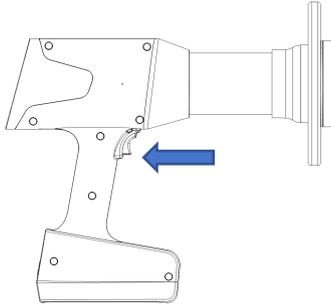
	<p>Select the type of receptor.</p>
	<p>Choose a language.</p>
	<p>Choose whether to restore factory settings.</p>

## 6 Operation

	
	<p>Choose whether to enable password.</p>

### 6.5 Use of exposure function

1. After starting up, press M-TECH switch to follow state , Close the M-TECH function.
2. After selecting the exposure time, short press the exposure button to enter the ready state.

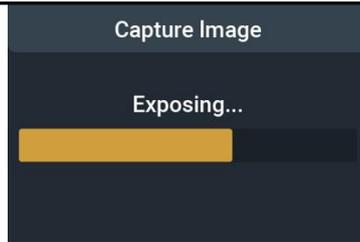


3. In the ready state, the screen will display the inclination angle of the machine to the ground plane and the 60S countdown.

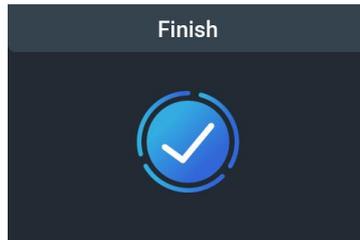


4. Before the countdown ends, press the exposure button for exposure. At this time, the interface will display "Exposing", HyperLight-M will also make a "beep" sound until the end of the exposure.

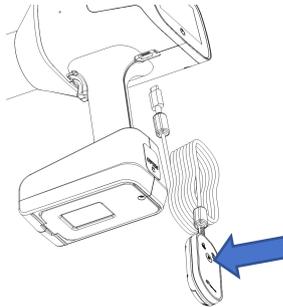
## 6 Operation



5. When the screen displays "Finish", it means that the exposure has completed.



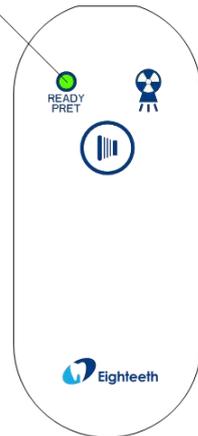
6. When using Remote Control Switch, connect its plug to Remote Control Switch port of HyperLight-M. After selecting the exposure time, short press the exposure button on Remote Control Switch to enter the ready state.



7. In the ready state, the screen will display the inclination angle of the machine to the ground plane and the 60s countdown, and the green light of the Remote Control Switch will be on. (In the ready state, press the switch button to exit the ready state)

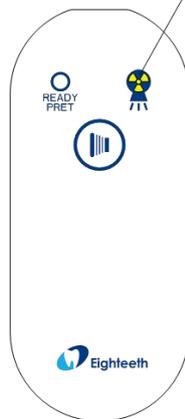
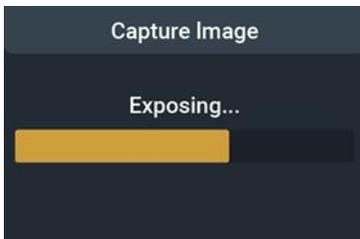
## 6 Operation

Green Light



8. Before the countdown ends, press and hold the exposure button for exposure. At this time, the interface will display "Exposing", the yellow light of the Remote Control Switch will turn on, and HyperLight-M will also make a "beep" sound.

Yellow Light



9. When the screen displays "Finish", it means that the exposure has completed.

## 6 Operation

Finish

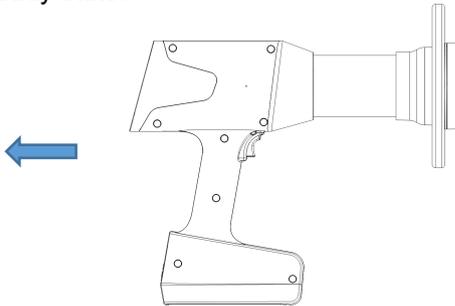


### **WARNING**

- 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 Use of M-TECH function

1. After starting up, press M-TECH switch to follow state , open the M-TECH exposure function.
2. After selecting the exposure time, short press the exposure button to enter the ready state.



3. In the ready state, the horizontal relative position of the tube head and the receiver will be displayed in the center of the screen, the vertical relative distance between the tube head and the receiver will be displayed in the upper right corner of the screen, and the Angle and countdown of 60s will be displayed on the right side of the screen (In the ready state, press the switch button to exit the ready state)

## 6 Operation



4. Observe the relative position of the blue circular cross cursor and the gray sensor icon which is in the center of the screen. If they don't overlap, move the tube head in the opposite direction until they overlap. For example, if the blue circular cross cursor is on the right of the gray sensor icon, move the tube head to the left until they overlap. And the device will make a "beep" sound when they overlap. It means the horizontal relative distance between the tube head and sensor is suitable. And so on in other directions .



5. The approximate distance between the tube head and the sensor will be displayed on the right side of the screen  
In this interface, observe the icon indicating the distance between the



tube head and the sensor in the upper right corner. indicates that the distance between the tube head and the sensor is too far. Move the tube head closer to the sensor, the icon will change to



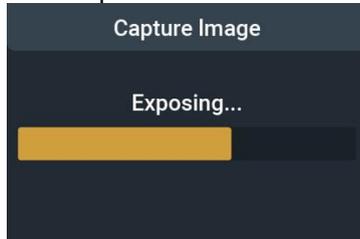
, it means the distance is closer. Till the icon changes to



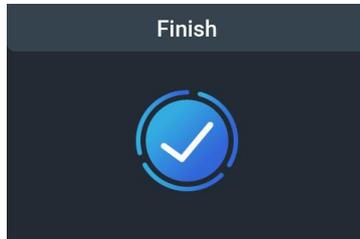
, it means the vertical distance is close.

## 6 Operation

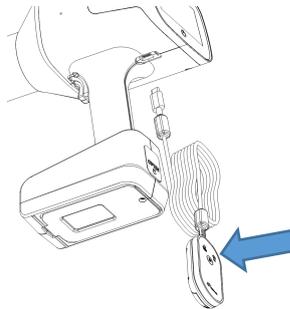
6. After moving the tube head to suitable position to the sensor, Before the countdown ends, press the exposure button for exposure. At this time, the interface will display "Exposing", device will also make a "di..." sound until the end of the exposure.



7. When the screen displays "Finish", it means that the exposure has completed.



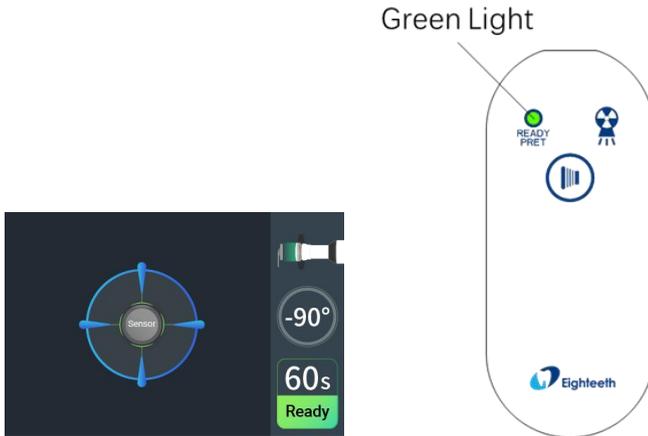
8. When using Remote Control Switch, connect its plug to Remote Control Switch port of HyperLight-M. After selecting the exposure time, short press the exposure button on Remote Control Switch to enter the ready state.



9. Then adjust tube head to suitable position with the same method in Article 4/5 of this table.

## 6 Operation

10. In the ready state, the screen will display the inclination angle of the machine to the ground plane and the 60s countdown, and the green light of the Remote Control Switch will be on. (In the ready state, press the switch button to exit the ready state)

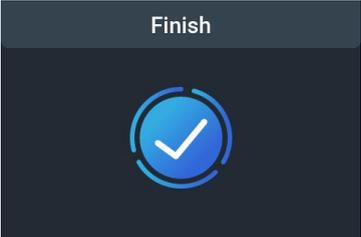


11. After moving the tube head to suitable position to the sensor, Before the countdown ends, press and hold the exposure button for exposure. At this time, the interface will display "Exposing", the yellow light of the Remote Control Switch will turn on, and HyperLight-M will also make a "beep" sound.

## 6 Operation



12. When the screen displays “Finish”, it means that the exposure has completed.



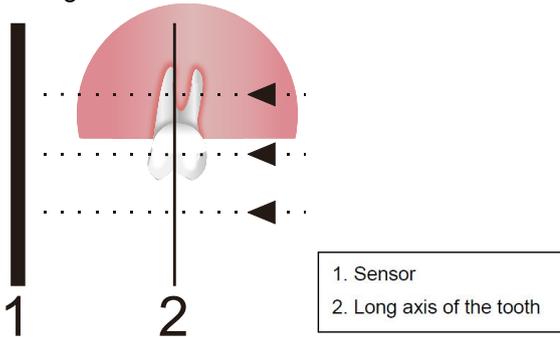
**WARNING**

- 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.

## 6.7 Positioning Instructions

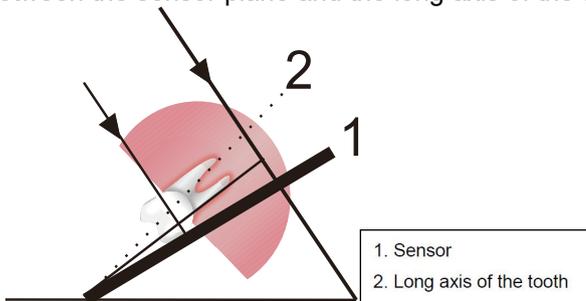
### 6.7.1 Paralleling technique

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



### 6.7.2 Bisected angle technique

The patient holds the sensor in place with his/her finger. 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.

### 6.7.3 Recommended angle and default exposure time for each tooth type

The parameters built into the tooth position are set for people of average size. Individual results 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 particularly important for pediatric patients. When using HyperLight-M, consider the patient's age, body size, physical habits, and clinical indications when validating 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°	0.32
				Lower Molar	-5°	0.16
				Upper Molar	+30°	0.25
				Canine	Maxilla: +45° Mandible: -20°	0.2
				Incisor	Maxilla: +45° Mandible: -25°	0.13

## 6 Operation

<b>P</b>	Phosphor Plate	Child		Bitewing	+5° ~ +8°	0.25	
				Lower Molar	-5°	0.1	
				Upper Molar	+30°	0.16	
				Canine	Maxilla: +45° Mandible: -20°	0.08	
				Incisor	Maxilla: +45° Mandible: -25°	0.06	
		Adult		Bitewing	+5° ~ +8°	0.63	
				Lower Molar	-5°	0.32	
				Upper Molar	+30°	0.5	
				Canine	Maxilla: +45° Mandible: -20°	0.4	
				Incisor	Maxilla: +45° Mandible: -25°	0.25	
			Child		Bitewing	+5° ~ +8°	0.5
					Lower Molar	-5°	0.2
					Upper Molar	+30°	0.32
					Canine	Maxilla: +45° Mandible: -20°	0.16

## 6 Operation

				Incisor	Maxilla: +45° Mandible: -25°	0.13
	Film	Adult		Bitewing	+5° ~ +8°	1.0
				Lower Molar	-5°	0.5
				Upper Molar	+30°	0.8
				Canine	Maxilla: +45° Mandible: -20°	0.63
				Incisor	Maxilla: +45° Mandible: -25°	0.4
				Bitewing	+5° ~ +8°	0.8
		Child		Lower Molar	-5°	0.32
				Upper Molar	+30°	0.5
				Canine	Maxilla: +45° Mandible: -20°	0.25
				Incisor	Maxilla: +45° Mandible: -25°	0.2

### 6.8 Ensuring Image Quality

The following HyperLight-M features contribute to high image quality:

- DC voltage X-ray generation is efficient in delivering energy at the level optimized for diagnostics, with shorter exposure times required.
- The smaller the focal spot, the better the resolution. The HyperLight-M has a small 0.4mm focal spot.

As with the suspended tubehead of a conventional wall-mounted X-ray system, some motion of the tubehead during actual exposures is possible.

## 6 Operation

Use both hands to hold the HyperLight-M 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) so as to achieve a quality image and avoid cone-cutting or retakes.

Image degradation or blurriness does not result due to motion of the handheld X-ray source.

### 6.9 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 <sup>2</sup> )
70kV, 3mA	0.02	0.06	1.53
	0.03	0.09	2.30
	0.04	0.12	3.06
	0.05	0.15	3.83
	0.06	0.18	4.59
	0.08	0.24	6.12
	0.1	0.30	7.66
	0.13	0.39	9.95
	0.16	0.48	12.25
	0.2	0.60	15.31
	0.25	0.75	19.41
	0.32	0.96	24.50
	0.4	1.20	30.62
	0.5	1.50	38.28
	0.63	1.89	48.23
	0.8	2.40	61.24
	1	3.00	76.55
	1.25	3.75	95.69
1.6	4.80	122.48	
2	6.00	153.11	

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,  $DAP = mGy \times \pi (5.7CM/2)^2$



## 6 Operation

- 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.

### 6.10 Essential performance

Accuracy of loading factors (see below):

X-ray tube voltage: 70kV $\pm$ 10%

X-ray tube current: 3mA $\pm$ 20%

Exposure time: 0.02~2s,  $\pm$ 5% or  $\pm$ 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

### 6.11 Calibration Checks

The HyperLight-M 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-M. 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	70kV $\pm$ 10%	63-77 kV	63-77 kV	63-77 kV	63-77 kV	63-77 kV
Timer Accuracy	0.02-2s ( $\pm$ 5% or $\pm$ 20ms, whichever is larger)	0.03-0.07s	0.08-0.12s	0.475-0.525s	0.95-1.05s	1.9-2.1s
Tube Current	3mA ( $\pm$ 20%)	2.4-3.6 mA	2.4-3.6 mA	2.4-3.6 mA	2.4-3.6 mA	2.4-3.6 mA
Dose rate	2.5-3.5mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s

## 7 Cleaning and disinfection

### 7.1 Foreword

The parts for clinical application contamination are the outer surfaces of the main body 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.

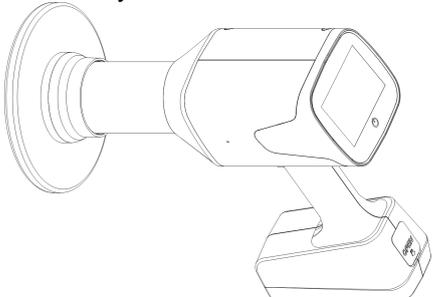
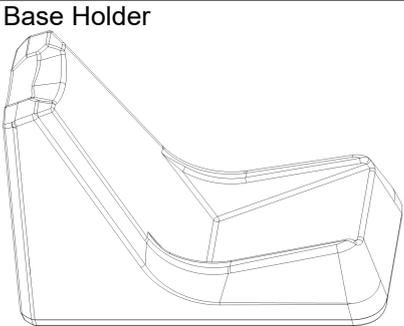
Reprocessing procedures have only limited implications to these parts. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused 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

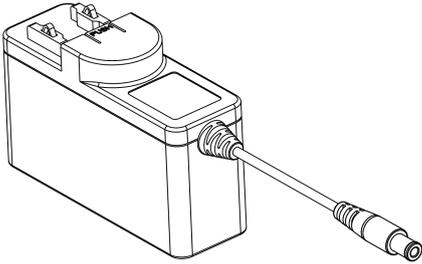
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
- Do not use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

### 7.3 Reprocessing Instructions

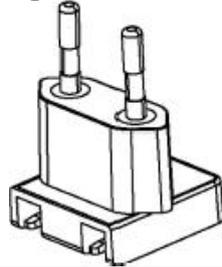
Disinfection devices	
Main Body 	Base Holder 

## 7 Cleaning

Power Adapter



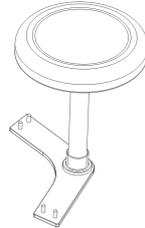
Power Plug



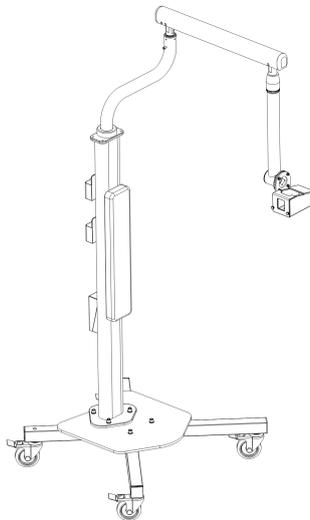
Remote Control Switch



Bracket Seat



Bracket



**WARNING**

## 7 Cleaning

Before first use, after each use and whenever there is a risk of contamination, disinfect the above devices.

Do not sterilize the Main Body, Base Holder, Power Adapter, Power Plug, Remote Control Switch, Bracket, Bracket Seat by heating, autoclaving or UV.

### Reprocessing Instructions

#### Preparation before cleaning:

Before cleaning and disinfecting, make sure the power is off.



#### **WARNING**

Make sure that used Disposable Sleeves are disposed of as infected waste which is potentially biologically hazardous.

#### Cleaning:

Wipe all the exterior surfaces of Main Body, Base Holder, Power Adapter, Power Plug, Remote Control Switch, Bracket, Bracket Seat 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 Main Body, Base Holder, Power Adapter, Power Plug, Remote Control Switch, Bracket, Bracket Seat thoroughly with a cloth lightly moistened with Ethanol (Ethanol 70 to 80 vol%) at least 3 min, repeat for 5 times.

#### Drying:

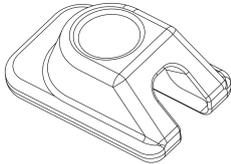
Use a lint free cloth to wipe the surfaces.

#### Storage:

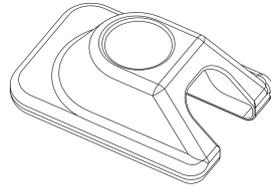
Storage of the processed device in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

**7.4 Autoclavable accessories**

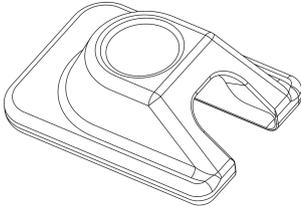
1 Inch Sensor Protective Sleeve (optional)



1.5 Inch Sensor Protective Sleeve (optional)



2 Inch Sensor Protective Sleeve (optional)



**WARNING**

1. Only the above devices can be automated cleaning, disinfection and sterilization.
2. The Sensor Protective Sleeve should be cleaned, disinfected and sterilized for the first use and whenever they are used between patients. The Sensor Protective Sleeve are verified to be able to withstand 250 times reprocessing cycles. Please contact the local distributor to request for repair or exchange in case of damage of the two parts during the claimed service life.
3. Before first use and after each use, clean, disinfect and sterilize the above devices.

**Reprocessing Instructions**

**Preparation at the Point of Use:**

1. Disconnect the Sensor Protective Sleeve before cleaning. Remove

## 7 Cleaning

gross contaminations from the devices with 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.

2. Store the devices in a humid surrounding.



### **WARNING**

Do not submerge the devices or wipe them 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 metal corrosion and adhesion of the residual medical agents to the devices.

### **Preparation for Decontamination:**

The devices must be reprocessed in a disassembled state.



### **WARNING**

Observe suitable personal protective measures.

### **Pre-Cleaning:**

Do a manual pre-cleaning, until the devices are visually clean. Submerge the devices in a clean water. Clean the surfaces with a soft bristol brush.

### **Cleaning:**

Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.

#### Automated Cleaning:

Carefully put the devices 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);

## 7 Cleaning

- emptying
- 5 min washing with a mild alkaline cleaner at 55°C;
- emptying
- 3 min neutralising with warm water ( $\geq 40^{\circ}\text{C}$ );
- emptying
- 5 min intermediate rinsing with warm water ( $\geq 40^{\circ}\text{C}$ );
- emptying

Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.



### **WARNING**

1. Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly.
2. Follow instructions and observe concentrations given by the manufacturer (see general recommendations).

### **Disinfection:**

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see 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.

### **Drying:**

Automated Drying:

Dry the devices according to the drying program of the washer/disinfector by setting parameter to 120 °C, 15 min.

If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of devices by using sterile compressed air.

### **Packaging:**

Pack the devices in an appropriate packaging material for sterilization.



### **WARNING**

## 7 Cleaning

1 Check the validity period of pouch given by the manufacturer to determine the shelf life.

2 Use pouches which resist to a temperature up to 141°C and in accordance with EN ISO 11607.

### **Sterilization:**

Sterilization of devices 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.

Sterilization parameters: 134°C, 5 minutes, dry 8 minutes.



### **WARNING**

1 Use only approved autoclave devices according to EN 13060 or EN 285.

2 Use a validated sterilization procedure according to EN ISO 17665.

3 Respect the maintenance procedure of the autoclave device given by the manufacturer.

4 Use only this recommended sterilization procedure.

5 Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycle parameters).

6 Wait for cooling before touching.

### **Functional Testing, Maintenance:**

Visual inspection for cleanliness of the devices and reassembling.

Functional testing according to instructions of use. If necessary, perform reprocessing process again until device is visibly clean.

### **Packaging:**

Pack the devices in an appropriate packaging material for storage.

### **Storage:**

Storage of sterilized devices in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

## 7 Cleaning

### **Reprocessing validation study information:**

The above-mentioned reprocessing process (cleaning, disinfection and sterilization) has been successfully validated.



#### **NOTE**

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. 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.



#### **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-M plastic prematurely.
- Do not remove the Beam Limiting Device when cleaning, disinfecting and maintaining.
- Never apply sprays or liquids directly on the surfaces of the device.
- The main body, base holder, the power adapter and power cord are not designed to be subjected to any kind of sterilization procedure.



#### **WARNING**

- The external surface of the Hand-held Dental X-ray System must be protected by recognized isolation film to avoid cross-contamination.

### 8 Maintenance

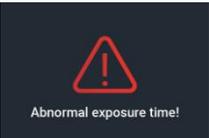
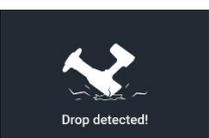
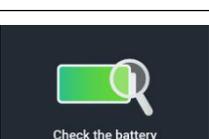
Incorrect operation or failure to maintain the device in accordance with the maintenance schedule relieves the manufacturer or his agent from all the responsibilities for subsequent non-compliance, damage, injury, defect and/or other malfunction. Only authorized Service Representatives, trained specifically on the HyperLight-M device, maintain and service the device. Annual Maintenance: Observe the following steps for annual maintenance of the HyperLight-M.

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 protective panel is damaged.
7. 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.

<b>Maintenance Test</b>	Year 1	Year 2	Year 3	Year 4	Year 5
Power Button					
Screen					
Setting interface.					
The exposure function					
Backscatter Shield					
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
 <p>Low power!</p>	Insufficient charge	Use the charger to charge the machine.
 <p>Overheating!</p>	The machine temperature is too high.	Let stand for more than half an hour.
 <p>Abnormal exposure time!</p>	Abnormal exposure time	During the exposure process, the finger released the exposure button, causing the exposure to be forcibly terminated.
 <p>Drop detected!</p>	Drop detected	A fall of the machine is detected, which may cause damage to the machine.
 <p>Check the battery</p>	Check the battery	Frequent use of the machine for a long time causes the battery temperature to be too high.

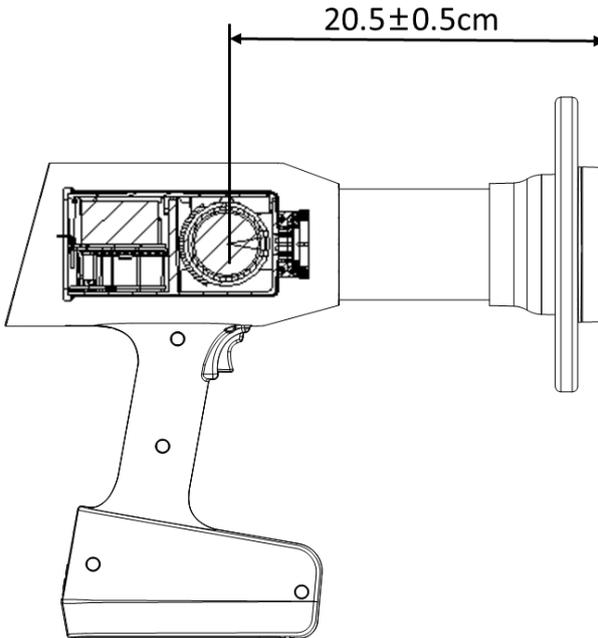
## 10 Technical Data

### 10.1 Main Body Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	HyperLight-M
Software version	HLM 1
Charger power supply	~100-240V 50/60Hz
Power supply	Lithium ion battery: L1-18650 4S1P 14.8V, 2500mAh $\pm 10\%$
Input AC Current	0.5A max
Charger power output	20V $\overline{\sim}$ 0.9A
Charging overcurrent protection	0.9A
Discharge overcurrent protection	50A
Ray type	X Ray
X-ray tube model	KL11-0.4-70
Tube voltage	70kV( $\pm 10\%$ )
Tube Current	3mA ( $\pm 20\%$ )
Fuse	F 20AL 65V Size:6.1mm $\times$ 2.69mm $\times$ 2.69mm
Exposure time adjustment range	0.02-2s( $\pm 5\%$ or $\pm 20\text{ms}$ whichever is larger)
Nominal power	210W nominal at 70kV, 3mA
Inherent Filtration	0.8mm Al
Added filter	1mm Al (1mm Al)
Total Filtration	$\geq 1.8\text{mm Al}$ (0.8mm glass, 1mm Al)
Duty Cycle	1:30
Minimum source to skin distance	20cm (from focal spot to cone tip)
X-ray exit field size and configuration	57mm diameter circle
Electrical safety class	Class II
IPX specification	IPX0; do not operate under wet conditions
Apparent resistance of supply main	$\leq 2\Omega$
Mode of operation	Intermittent operation 20s ON/600s OFF
Ambient conditions	Use: in enclosed spaces

## 10 Technical Data

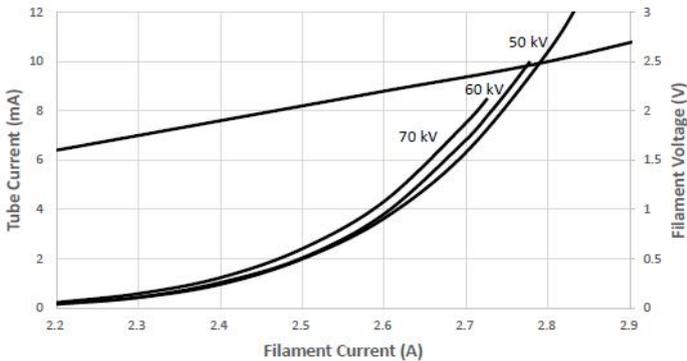
	Ambient temperature: 10°C ~ 40°C Relative humidity: 30%-75% Atmospheric pressure: 70 kPa - 106 kPa
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% - 80 % Atmospheric pressure: 70 kPa - 106 kPa



**10.2 X-ray Tube Assembly Specifications and Characteristics**

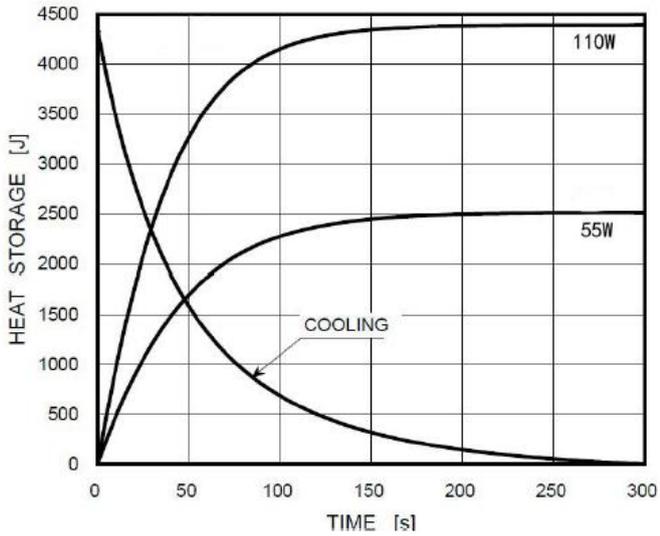
Filament voltage	2.8-3.4V
Maximum filament current	3A
Nominal tube voltage	70kV
X-ray source assembly maximum heat content	4500J
Maximum anode cooling rate	110W
Nominal anode input power	600W
Target material	Tungsten
Minimum target angle	12°
Filament voltage (at maximum filament current 2.9A)	2.4~ 3.0V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

**Emission & Filament Characteristics (Half Wave Self-Rectified)**

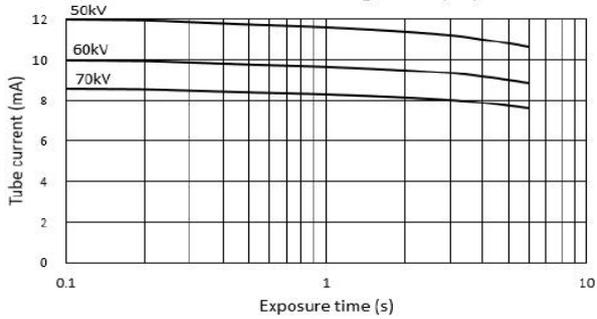


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## 10 Technical Data

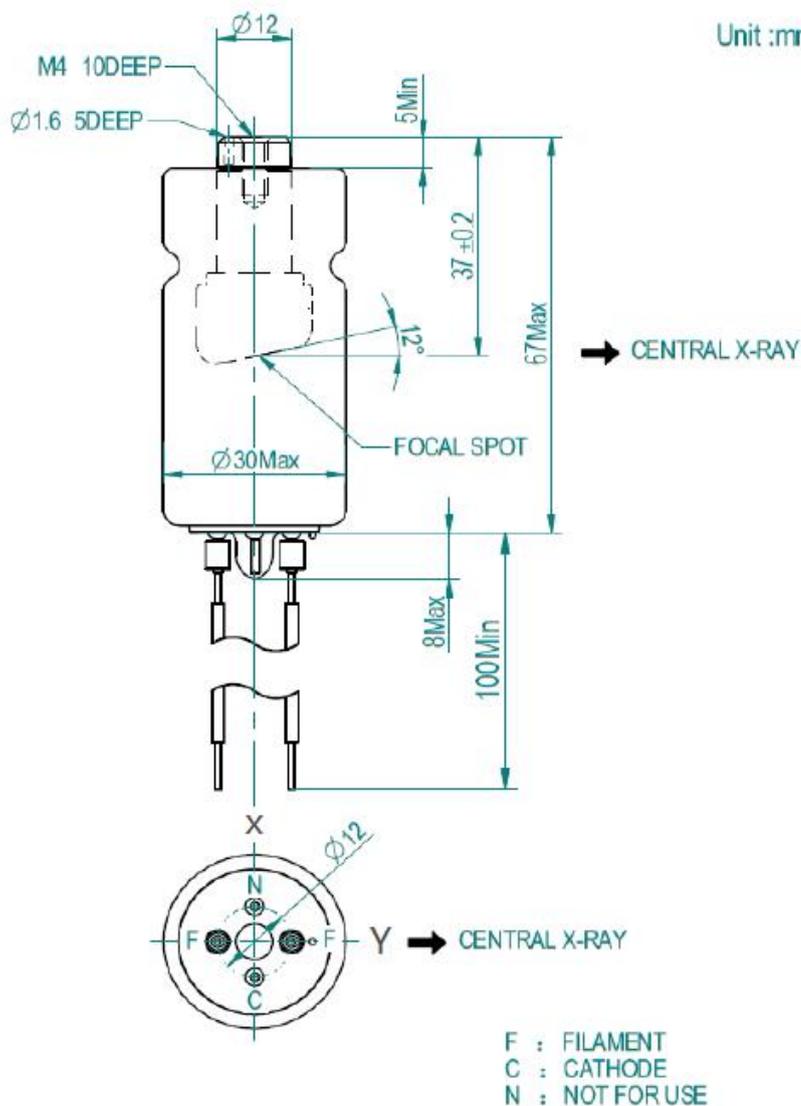


Maximum Rating Charts (AC)



# 10 Technical Data

Unit :mm



## 11 EMC Tables

<b>Guidance and manufacturer’s declaration – electromagnetic emissions</b>		
<p>The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or the user of the HyperLight-M should assure that it is used in such an environment.</p>		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The HyperLight-M 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	<p>The HyperLight-M 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:</p> <p>Warning: This HyperLight-M 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-M or shielding the location.</p>
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

<b>Guidance and manufacturer’s declaration – electromagnetic immunity</b>			
<p>The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or the user of the HyperLight-M should assure that it is used in such an environment.</p>			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>

## 11 EMC Tables

<p>Electrostatic Discharge (ESD) IEC 61000-4-2</p>	<p>+/-8 kV contact +/-15kV air</p>	<p>+/-2, 4, 6 &amp; 8kV contact +/-2, 4, 8, &amp; 15 kV air</p>	<p>Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%</p>
<p>Electrical fast Transient/burst IEC 61000-4-4</p>	<p>+/-2 kV for power supply lines +/-1 kV for input/output lines</p>	<p>+/-0.5, 1 &amp; 2 kV for power supply lines +/-0.5 &amp; 1 kV for input/output lines</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Surge IEC 61000-4-5</p>	<p>+/-1 kV differential mode +/-2 kV common mode</p>	<p>+/-0.5 &amp; 1 kV differential mode +/-0.5, 1 &amp; 2 kV</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>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</p>	<p>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</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the <b>HyperLight-M</b> requires continued operation during power mains interruptions, it is recommended that the <b>HyperLight-M</b> be powered from an uninterruptible power supply or battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>30A/m</p>	<p>3 &amp; 30A/m</p>	<p>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</p>

## 11 EMC Tables

<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>			
The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or user of the HyperLight-M should ensure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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-M by no less than the distances calculated/listed below:  $D=(3.5/V1)(\text{Sqrt } P)$ 150kHz to 80MHz
Radiated RF IEC 61000-4-3	6Vrms in ISM bands between 0,15 MHz and 80 MHz  3 V/m 80 MHz to 2,7 GHz	(E1)= 6Vrms in ISM bands  (E1)=3V/m	$D=(3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz  $D=(7/E1)(\text{Sqrt } P)$ 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

## 11 EMC Tables

			<p>the recommended separation distance in meters (m).</p>
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<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>			
<p>The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or user of the HyperLight-M should ensure that it is used in such an environment.</p>			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			<p>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:</p> <div style="text-align: center;">  </div>
<p>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.</p>			
<ol style="list-style-type: none"> <li>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.</li> <li>2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.</li> <li>3. The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are</li> </ol>			

## 11 EMC Tables

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-M** 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-M** 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	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810						
870	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

## 11 EMC Tables

		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	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
<b>5500</b>						
<b>5785</b>						



### WARNING

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

#### **Cable information:**

Cable Name	Cable Length (m)	Shielded or not	Remark
Power Adapter	1.2	NO	/
Remote Control Switch	3.2	NO	/

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

### Service Life

The service life of HyperLight-M 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

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc , have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.



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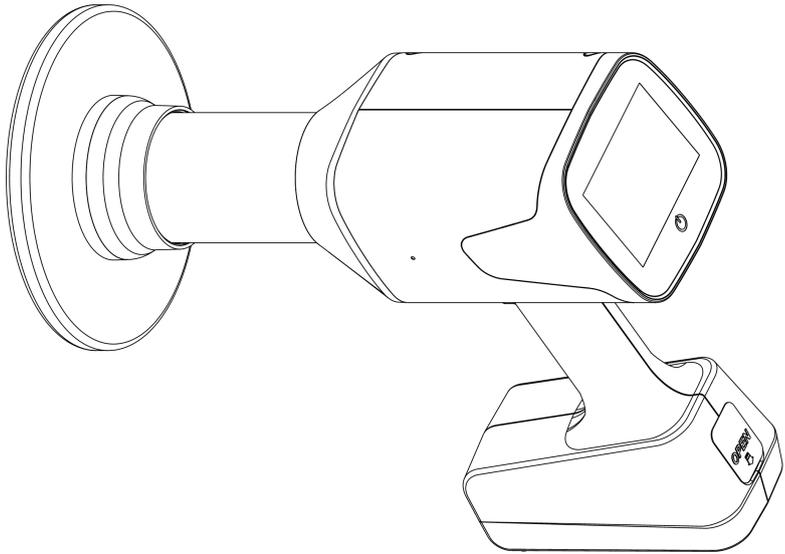
**NOTICE**

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



**Eighteeth**

Model: HyperLight-M



# Hand-held Dental X-ray System USER MANUAL

**Changzhou Sifary Medical Technology Co., Ltd.**

Version: S01  
IFU-7035301  
Issued: 2024.11.14  
Size:197mmX140mm

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## Content

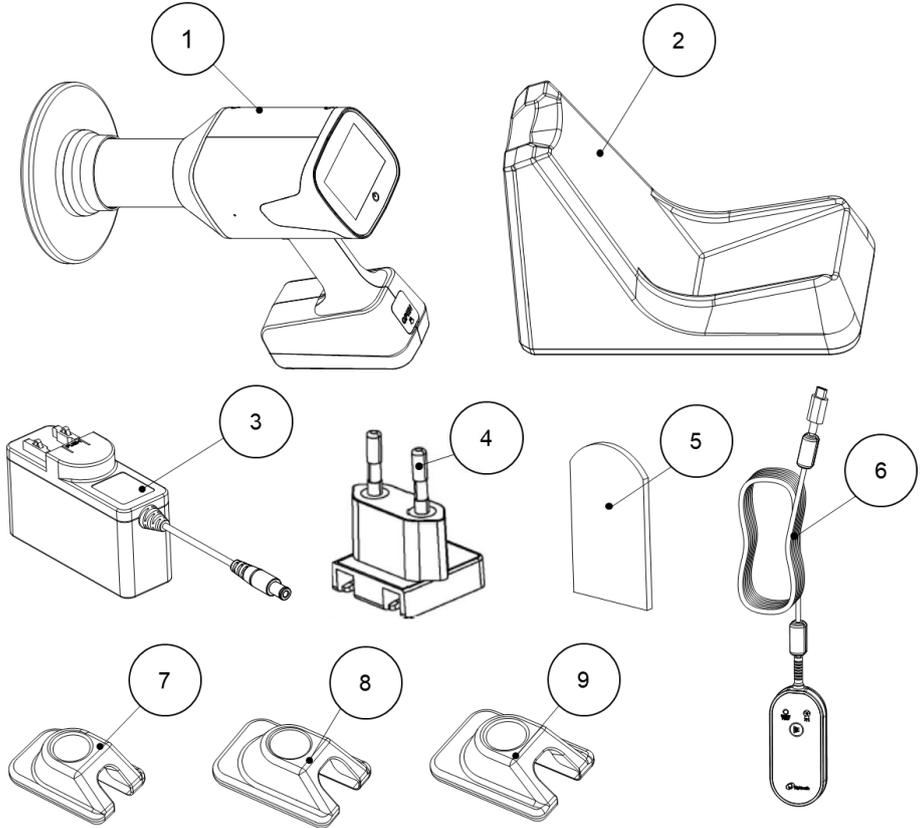
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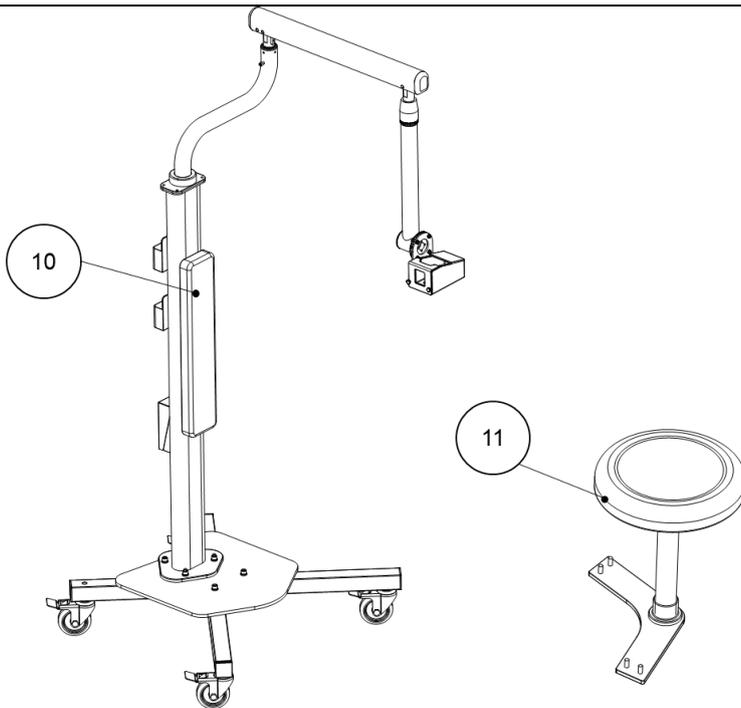
## 1. Overview

### 1.1 Content



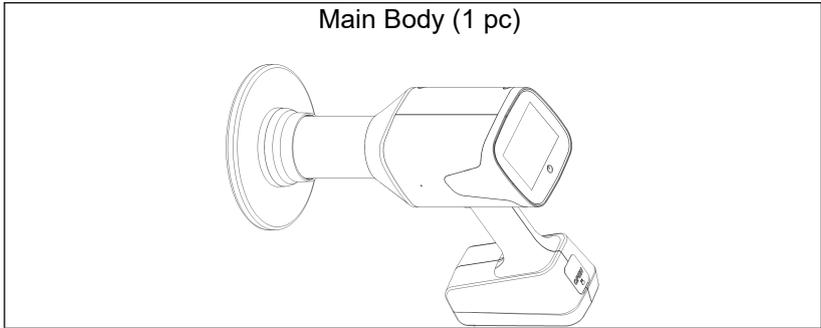
## 1 Overview

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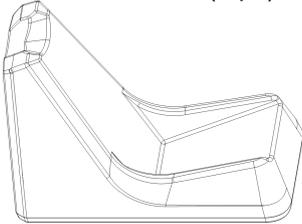
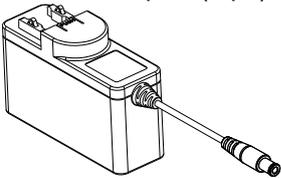
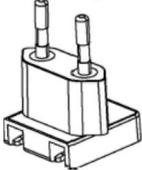
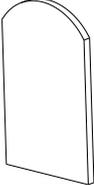


- 12. Main Body
- 13. Base Holder
- 14. Power Adapter
- 15. Power Plug
- 16. Disposable Sleeve (optional)
- 17. Remote Control Switch (optional)
- 18. 1 Inch Sensor Protective Sleeve (optional)
- 19. 1.5 Inch Sensor Protective Sleeve (optional)
- 20. 2 Inch Sensor Protective Sleeve (optional)
- 21. Bracket (optional)
- 22. Bracket seat (optional)

## 1.2 Component

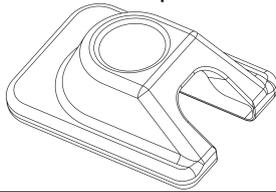


## 1.3 Accessory

<p>Base Holder (1 pc)</p> 	<p>Power Adapter (1 pc)</p> 
<p>Power Plug (1 pc)</p> 	<p>Disposable Sleeve (optional)</p> 
<p>1 Inch Sensor Protective Sleeve (optional)</p> 	<p>1.5 Inch Sensor Protective Sleeve (optional)</p> 

# 1 Overview

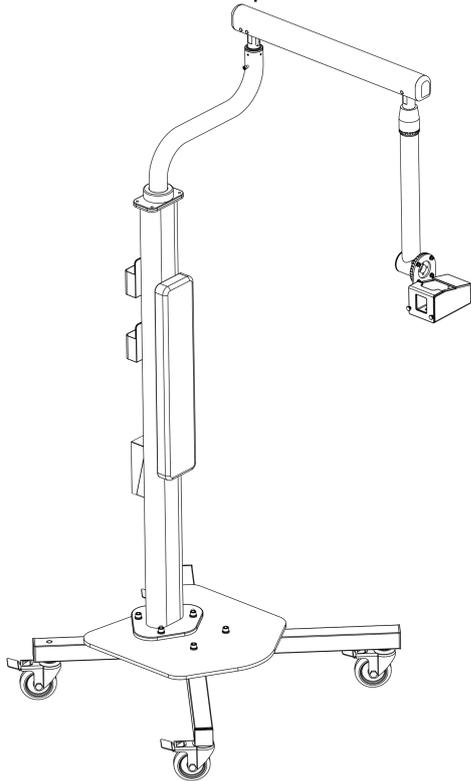
2 Inch Sensor Protective Sleeve (optional)



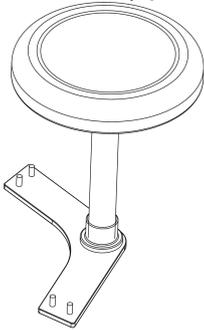
Remote Control Switch (optional)



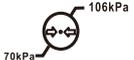
Bracket (optional)



Bracket Seat (optional)



### 2. Symbol Instruction

 <b>WARNING</b>	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
 <b>NOTE</b>	Additional information, explanation of operation and performance.
	Serial number
	Alternating current
	Direct current
	Dispose of in accordance with the WEEE directive
	Keep dry
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Catalogue number
	Manufacturer
	Date of manufacture
	Lot of manufacture
	Manufacturer's LOGO
	Follow instructions for use
	Warning of ionizing radiation
	Medical device
	Dangerous Voltage: Electrical Shock Hazard

### 3. Foreword

#### 3.1 Scope of application

The Hand-held Dental X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

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-M is contraindicated in cases where patient/user carry medical implants such as pace makers or cochlear implants etc.
- Pregnant women. The medical practitioner must weigh the benefits conferred by use of the device against the potential hazard to the pregnant woman and fetus resulting from radiation exposure. 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.
- 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 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.

### 3.3 Intended 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 liquids.
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 Hand-held Dental X-ray System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment

### 3 Foreword

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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 device 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. Replacing batteries by untrained service personnel can lead to hazards (over-temperature, fire or explosion).
18. If the package or equipment is damaged, contact the supplier or manufacturer.
19. No modification of this equipment is allowed.
20. Under normal use, the Beam Limiting Device must not be removed. Including intended use, inspection, maintenance, transportation, cleaning and disinfection, adjustment.
21. No parts can be maintained or serviced while in use with the patient.



**Disclaimer:**

The device 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 focal spot to skin distance without authorization may cause the patient to receive unnecessary radiation.

### 4. Safety Precautions

#### 4.1 Radiation Safety

The HyperLight-M 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.



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

The HyperLight-M provides a high degree of protection from 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 use 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 minimize dose to the fetus.

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



Operator exposure to radiation will increase due to proximity.

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 are 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.

## 4 Safety Precautions

### Compliance with Applicable Standards

<b>Standard</b>	<b>Title</b>
IEC 60601-2-65:2012+A1 :2017+A2:2021	Medical electrical equipment-Part 2-65:Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 60601-1-3:2008+A1: 2013+A2:2021	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

### A list of protective devices and accessories

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

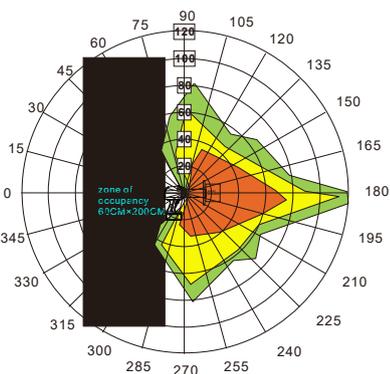
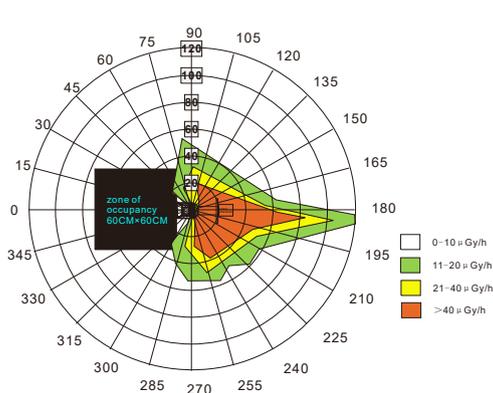
### 4.2 Leakage Dose

Leakage Dose	Permissive Range
70 kV, 3 mA, 2s (Max. Exposure Condition) At any point on the outer surface of HyperLight-M 1 : 30 Duty Cycle	$\leq 0.05$ mGy/h

In order to verify compliance with this leakage requirement, device is tested for radiation leakage at any point on the outer surface of HyperLight-M. The highest measurement out must be lower than 0.05mGy/h in order for the device to successfully pass product release testing.

### 4.3 Scatter

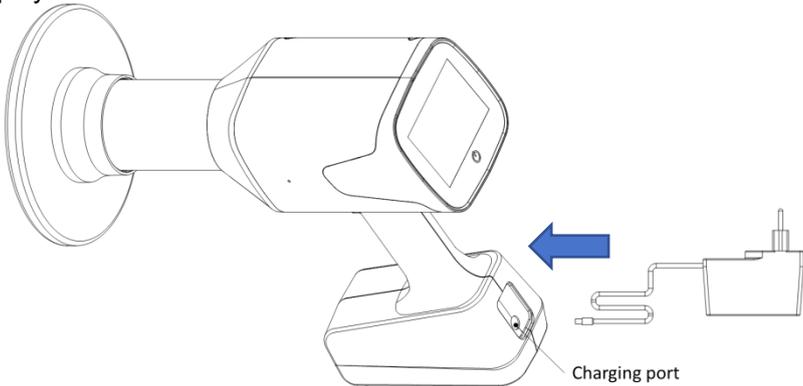
The significant zone of occupancy for operators has been further verified by internal testing. A HyperLight-M device was remotely fired into a water phantom ( 25 X 25 X 10cm ) repeatedly, with an ion chamber recording radiation readings in the room, first to establish the vertical significant zone of occupancy and then to establish the horizontal significant zone of occupancy. Each exposure was taken at 2 seconds. The vertical significant zone of occupancy measures 60 cm X 200 cm, while the horizontal significant zone of occupancy is 60 cm X 60 cm. A calibrated survey dosimeter can be used in order to confirm 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 charger into the machine and the other end into the socket. The charging icon will be displayed on the screen at this time.



If plug the charger in the off state, the following interface will be displayed



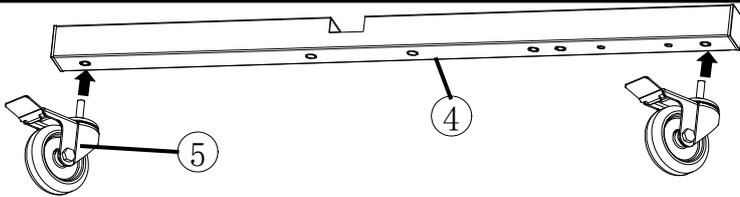
#### **WARNING**

- Don't position the device where it is difficult to operate the disconnection device.
- Only original adapter can be used.

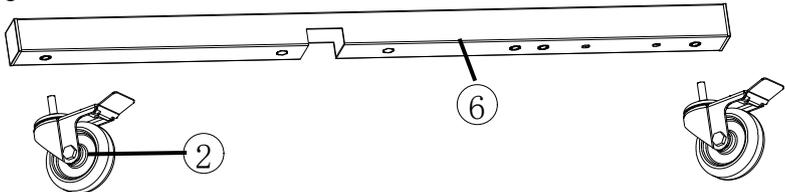
#### 5.2 Install Bracket

3. Rotate the casters ① clockwise into the threaded holes at both ends of the below base pipe ② as shown in the figure and tighten them;

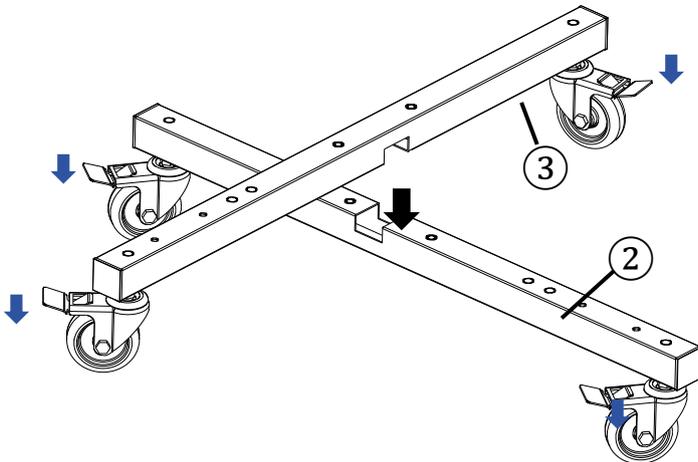
## 5 Installation



4. Similarly Rotate the casters ① clockwise into the threaded holes at both ends of the upper base pipe ③ as shown in the figure and tighten them;



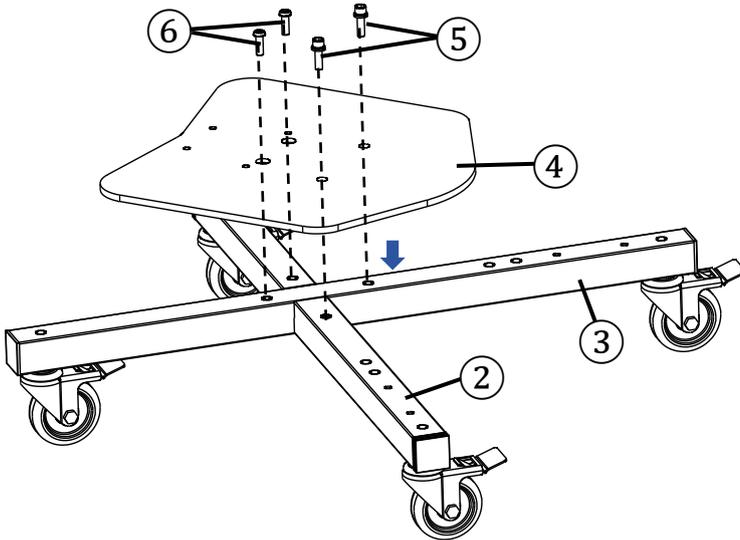
14. Insert the upper base pipe ③ into the corresponding slot of the below base pipe ② as shown in the figure, and press the four casters locking switch as shown in the figure to lock the four casters. The base is installed.



15. Place the bottom plate ④ at the cross position of the base pipe ③ and the below base pipe ② in the direction indicated in the figure. Align the four installation holes with dotted lines as shown in the figure.

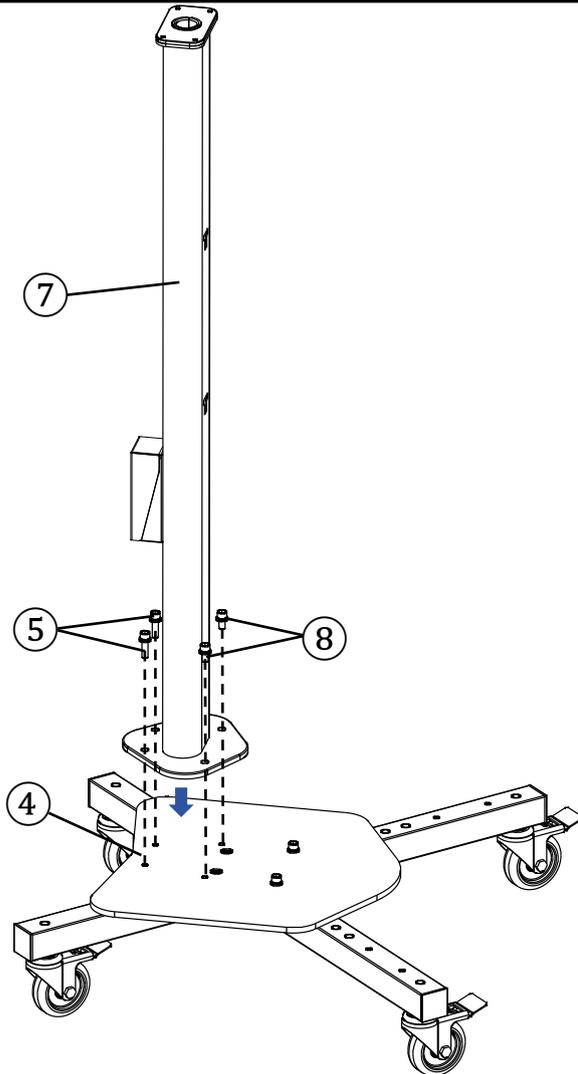
## 5 Installation

Secure the bottom plate (4) to the base pipe (3) and the below base pipe (2) using two M10\*35 hexagon assembly bolts (5) in the two through holes and two M10\*30 round head hexagon bolts (6) in the two countersunk holes.



16. Place the support column (7) at the bottom plate (4) in the direction shown in the figure, align the four mounting holes as shown in the figure, and use two M10\*35 hexagon assembly bolts (5) and two M10\*20 hexagon assembly bolts (8) to lock the support column with the bottom plate.

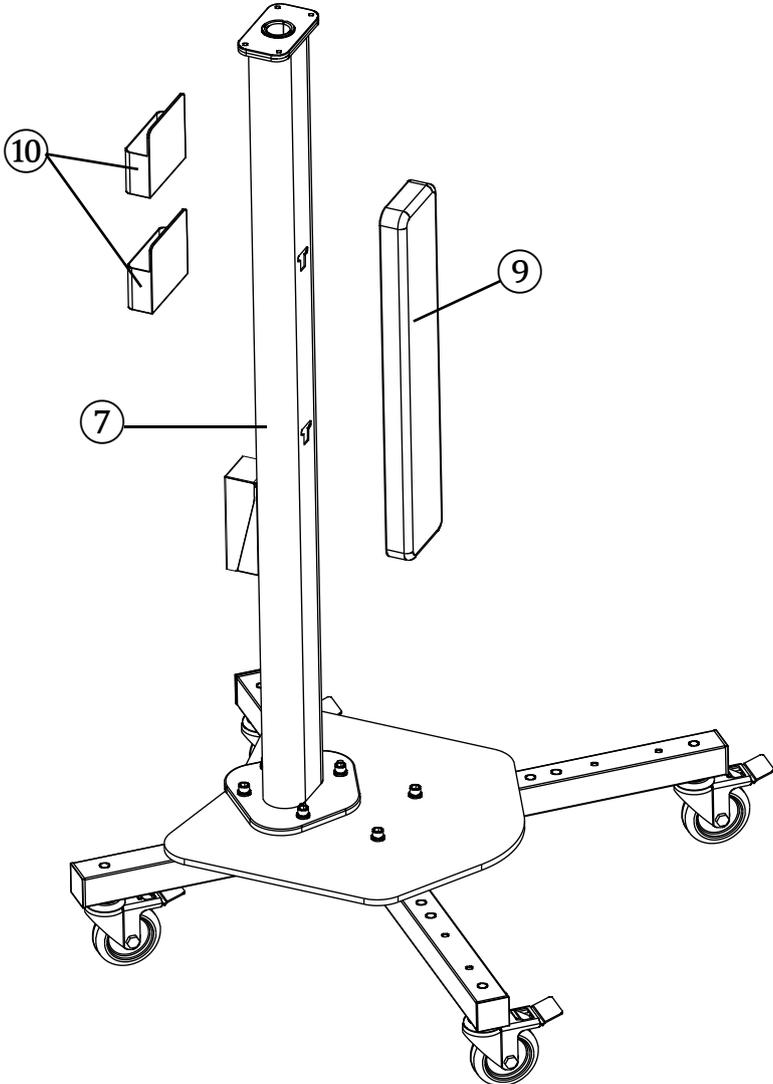
## 5 Installation



17. Hang the buckle on the wooden side of the column back (9) into the corresponding slot of the support column (7), and then press it in the direction shown in the figure.

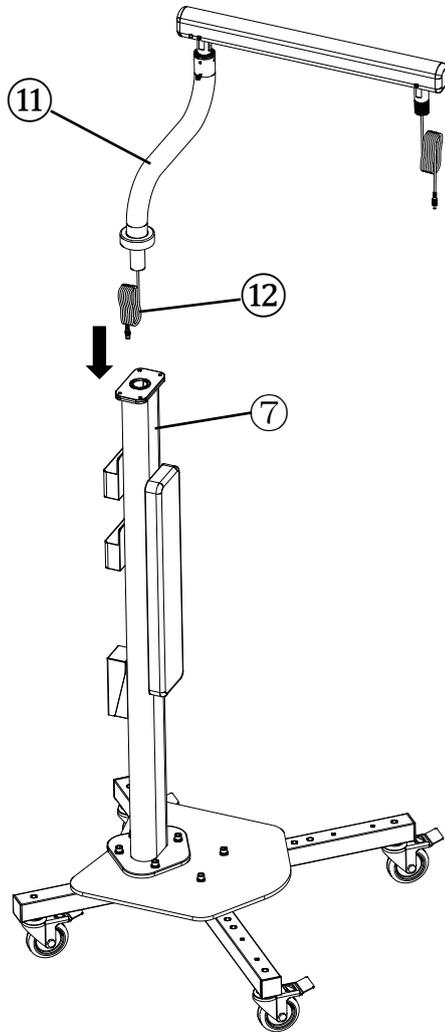
## 5 Installation

18. Attach two magnetic absorption nanoboxes (10) to the other side of the support column, and adjust the height according to personal habits.



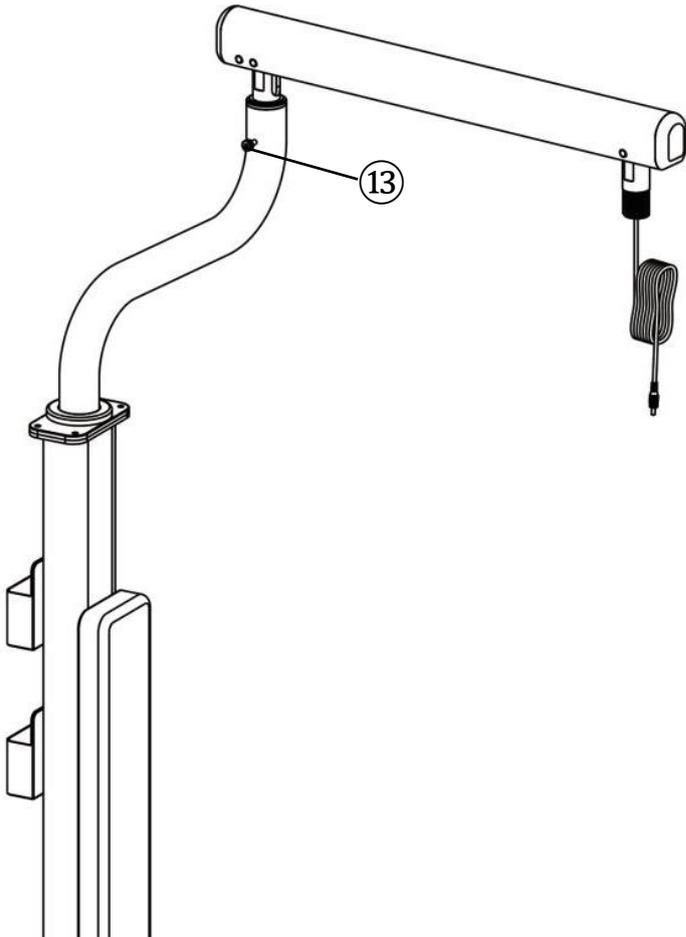
## 5 Installation

19. Straighten the input part of the power extension cable (12) and put it into the support column (7). Insert the balance arm assembly (11) into the hole at the top of the support column (7) in the direction shown in the figure and press it to the bottom.



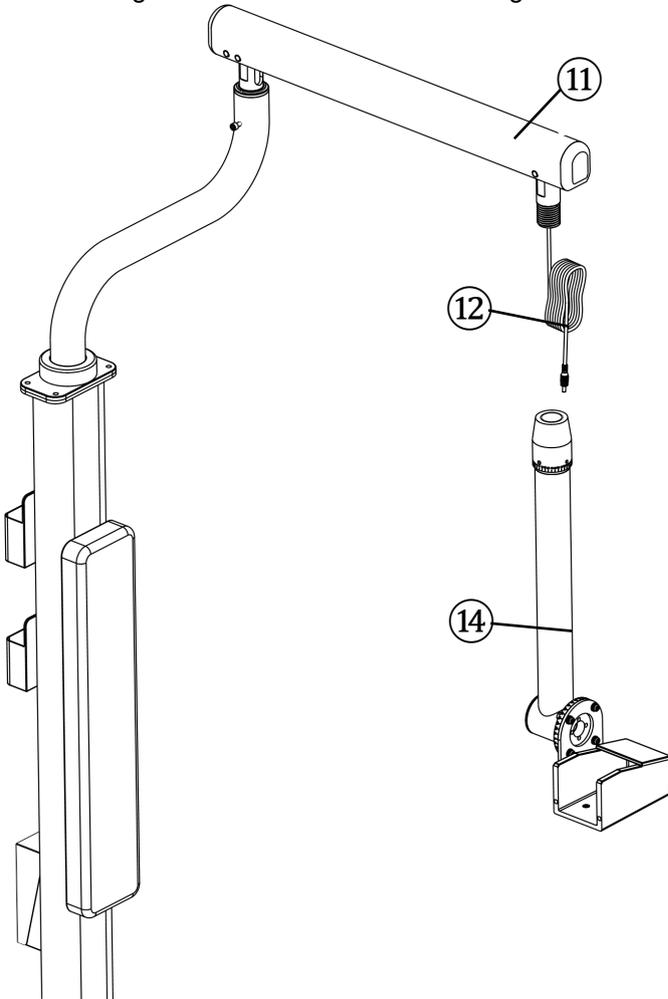
## 5 Installation

20. After the balance arm assembly ⑪ is installed into the hole and pressed to the bottom, cut the binding band of the balance arm assembly ⑪, and then the balance arm will spring up. Please pay attention to safety.
21. Turn the balance arm assembly to the position as shown in the figure, and then tighten the screw ⑬ on the rotating arm as shown in the figure.



## 5 Installation

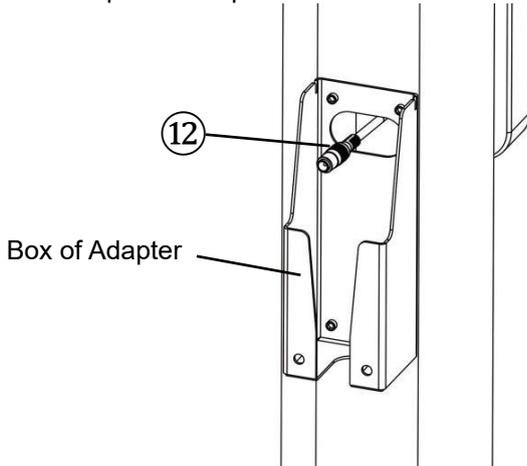
22. Straighten the output port of the power extension cable (12) and put it into the main arm assembly (14). Screw the main arm assembly (14) anti-clockwise into the thread of the balance arm assembly (11) and tighten it according to the direction shown in the figure.



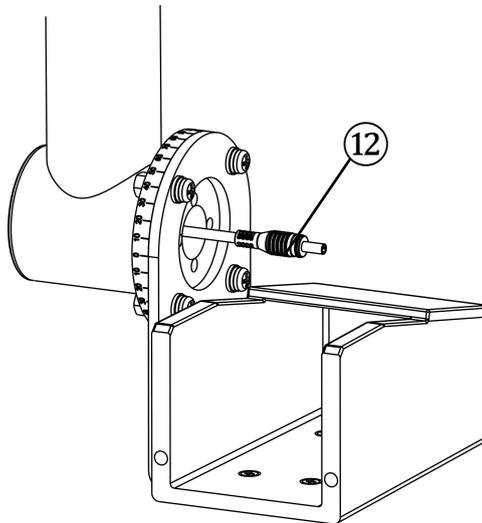
23. Pull out the input port of the power extension cable (12) from the waist hole shown in the adapter box (for placing the power adapter) to

## 5 Installation

connect the power adapter.



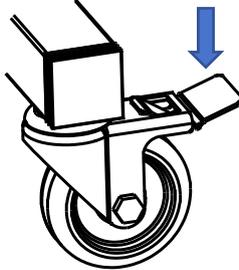
24. Pull out the output port of the power extension cable ⑫ from the round hole shown in the main arm assembly to connect the mainbody charging port.



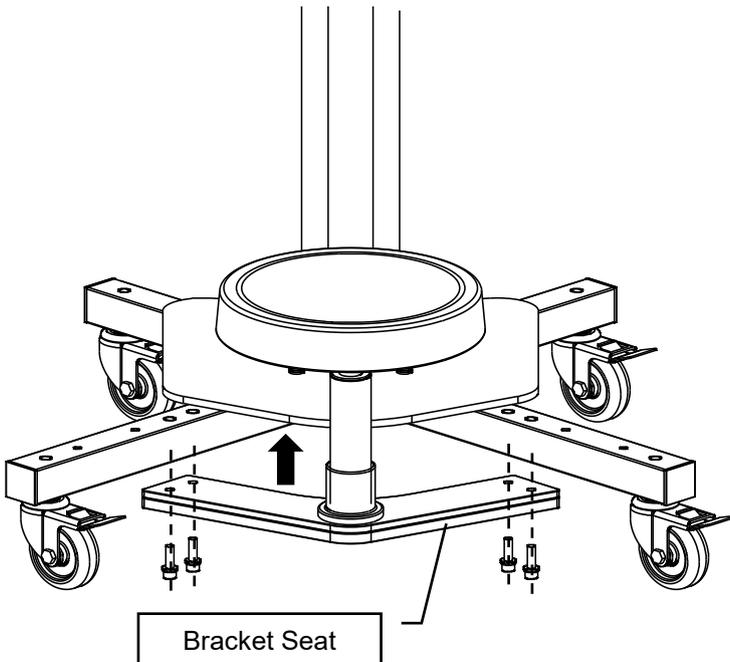
## 5 Installation

### 5.3 Install Bracket Seat

4. Before installing the bracket seat or using the bracket, be sure to press the locking switch as shown in the figure to ensure that the four casters are locked. When the bracket needs to be moved, move the locking switch upward to unlock it.

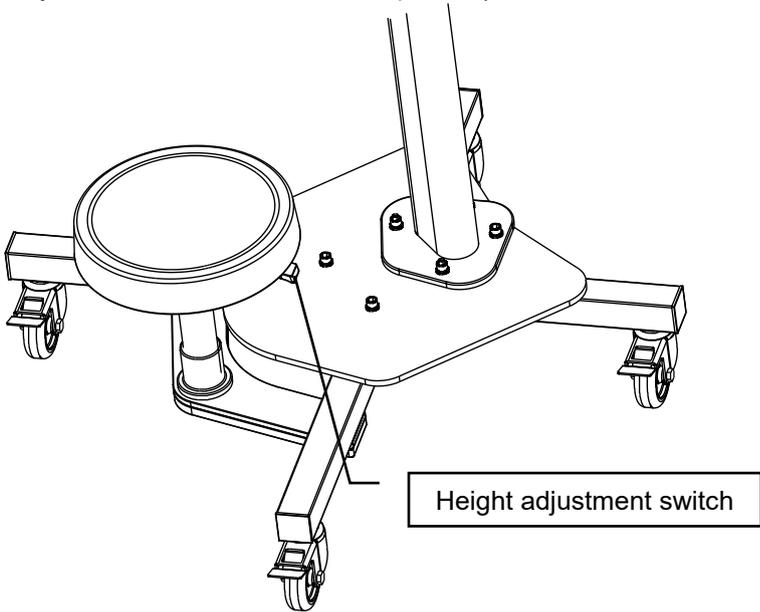


5. Use four bolts to secure the Bracket Seat assembly to the bottom of the bracket as shown



## 5 Installation

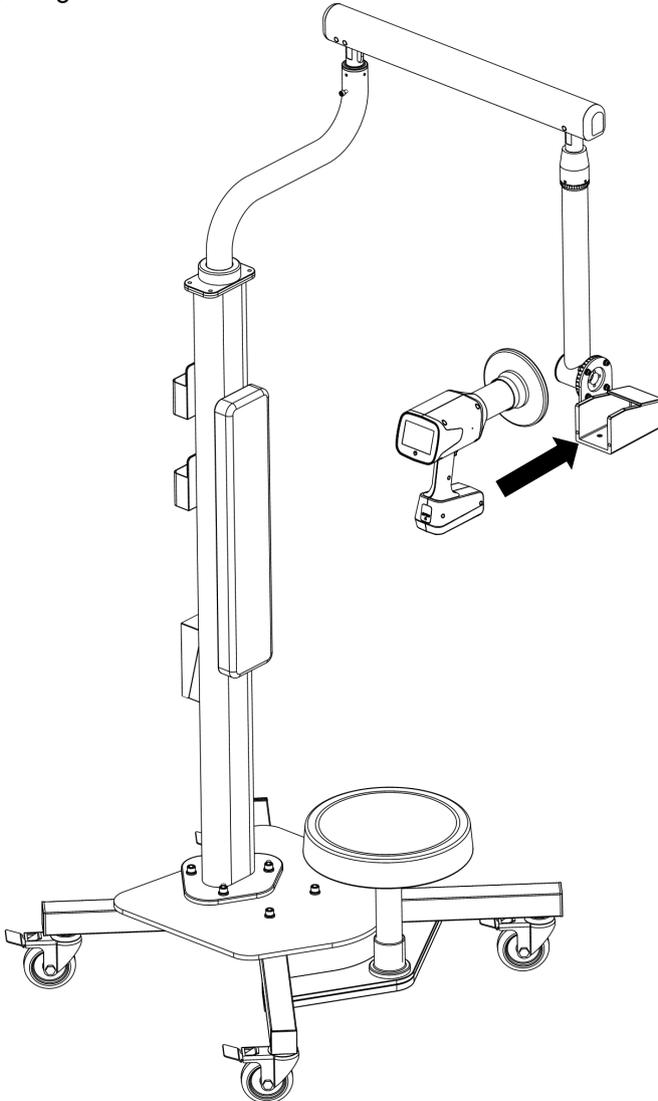
6. After installation, the seat can be rotated freely and the height can be adjusted according to individual needs. (The Bracket Seat is optional and only needs to be installed if it is optional.)



## 5 Installation

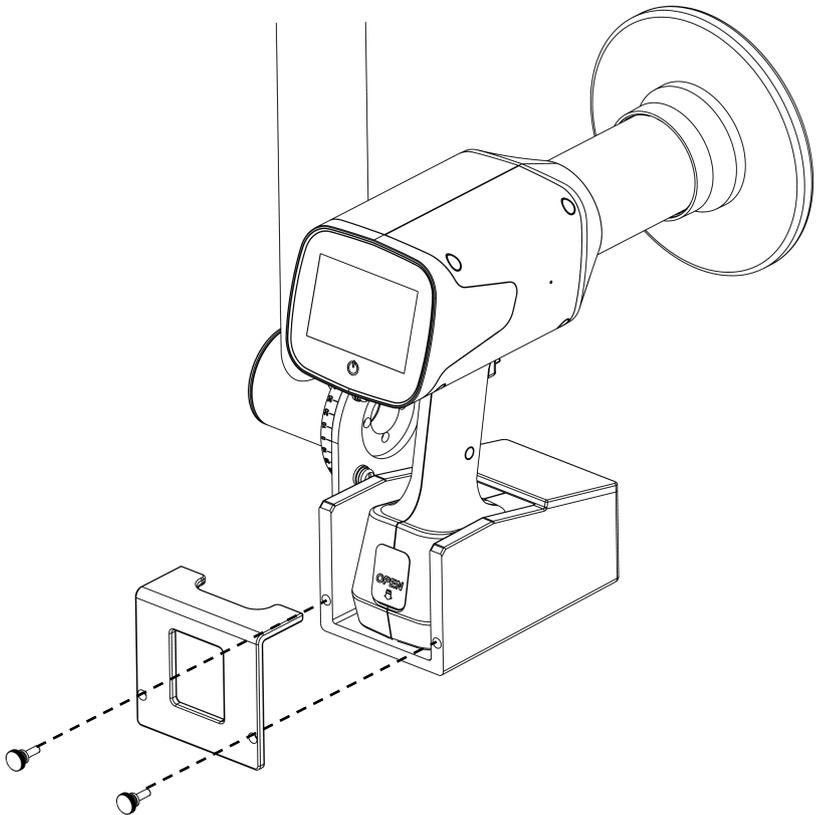
### 5.4 Install main body to Bracket

Push HyperLight-M into the holder of Bracket in the direction shown.



## 5 Installation

2. Use the screws to lock the rear cover into mounting holes of the holder.

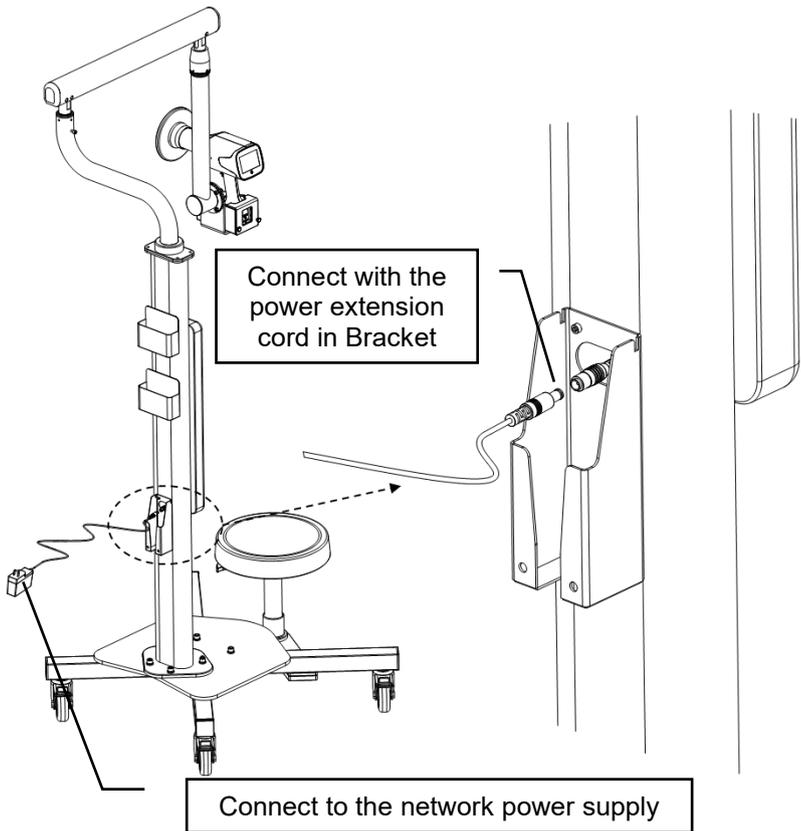


(The bracket is optional and only needs to be installed if it is optional.)

## 5 Installation

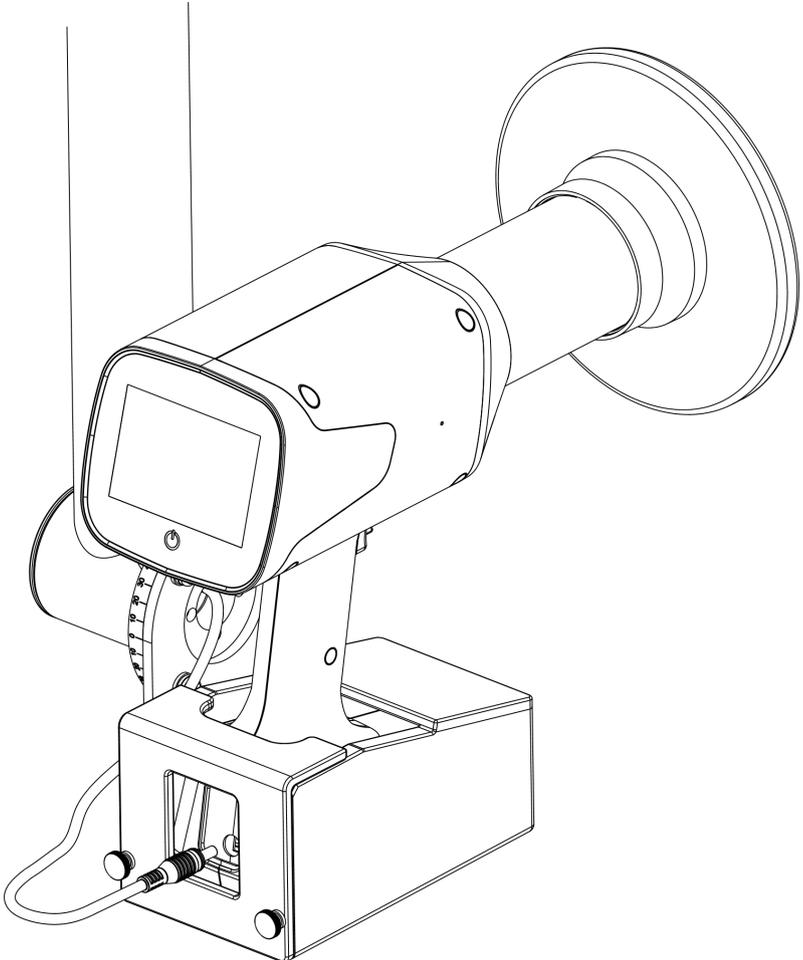
### 5.5 Charging with Bracket

1. Connect the power adapter output plug of HyperLight-M to the power extension cord plug drawn out from the bracket.
2. Connect the power adapter input plug of HyperLight-M to the network power supply.



## 5 Installation

3. Connect the power extension cord plug drawn out from the Bracket to the charging port of HyperLight-M.

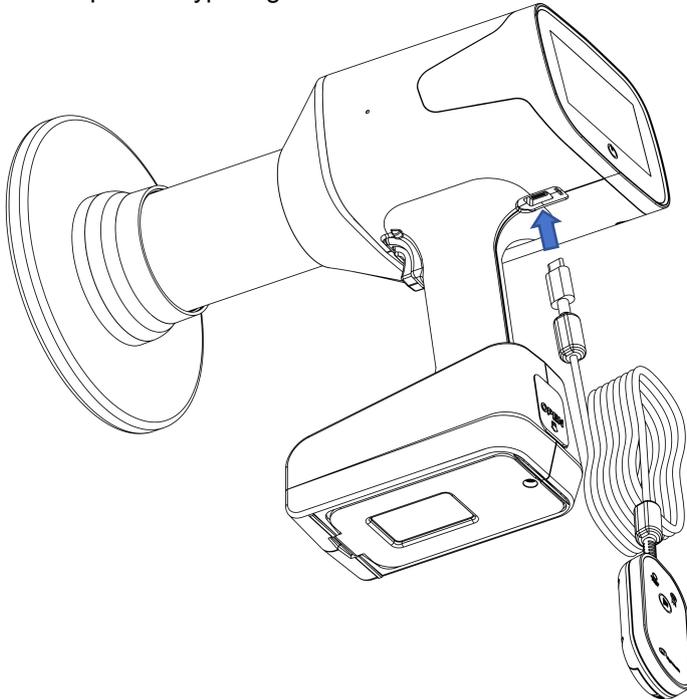


(The bracket is optional and only needs to be installed if it is optional.)

## 5 Installation

### 5.6 Plug in the Remote Control Switch

When using Remote Control Switch, connect its plug to the Remote Control Switch port of HyperLight-M.



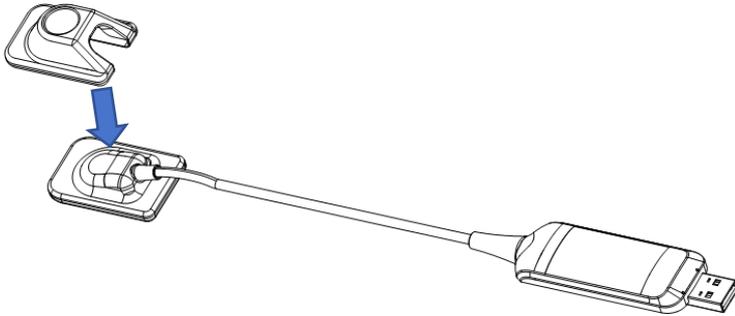
(The Remote Control Switch is optional and only needs to be installed if it is optional.)

### 5.7 Install Sensor Protective Sleeve

When using our sensor products NanoPix to achieve the M-TECH function of HyperLight-M, please follow the instructions below to install the Sensor Protective Sleeve on NanoPix first, then wrap it with the Disposable Sleeve before use. The detailed correspondence is shown in the table below. The corresponding Sensor Protective Sleeve must be used for installation.

(1 Inch Sensor Protective Sleeve, 1.5 Inch Sensor Protective Sleeve, 2 Inch Sensor Protective Sleeve, Disposable Sleeve are optional and only needs to be installed if it is optional.)

## 5 Installation



NO.	Sensor Protective Sleeve	Corresponding sensor model
1	1 Inch Sensor Protective Sleeve	NanoPix1
2	1.5 Inch Sensor Protective Sleeve	NanoPix1.5
3	1 Inch Sensor Protective Sleeve	NanoPix2



### **WARNING**

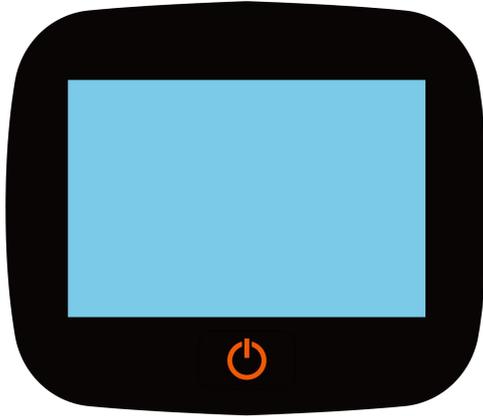
- Please make sure that the backscatter shield is securely installed on the machine before use.
- Do not remove the backscatter shield and do not operate if the backscatter shield is broken.
- The optional Bracket and Bracket Seat are heavy. Please pay attention to safety during installation and handling.
- The optional Bracket must be placed in the right direction when using. It is prohibited to put it on the side or upside down.
- When using the optional Bracket, be careful to place it stably, otherwise it may hurt people or equipment.
- Pay attention to the direction and height of the cantilever when using the optional Bracket, otherwise people or equipment may be injured.
- When the optional Bracket is used with HyperLight-M, all casters must be placed in a fully braked state to avoid involuntary movement during use.
- Make sure that used disposable sleeves are disposed of as infected

## 5 Installation

waste which is potentially biologically hazardous.

## 6 Operation

### 6.1 Operation panel instructions

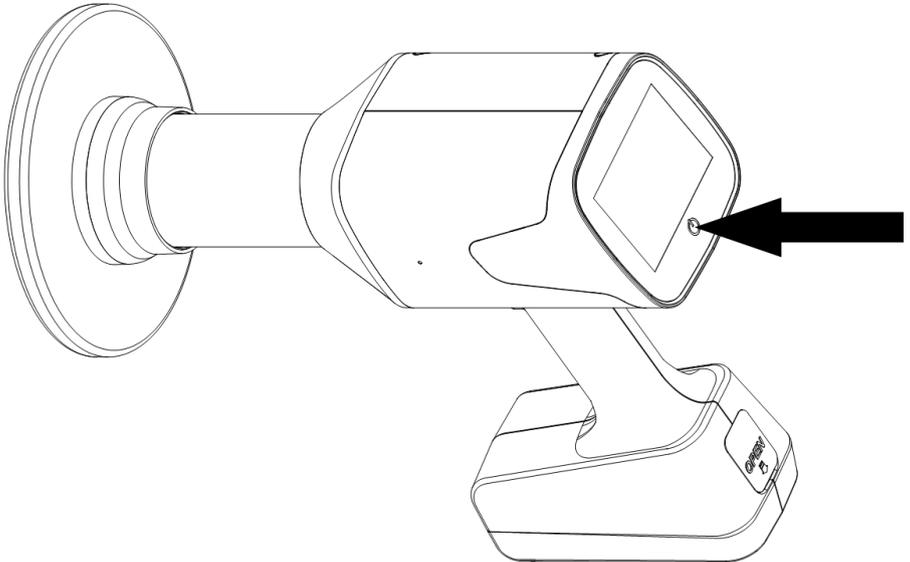


Symbol	Type
	Power Button

### 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.

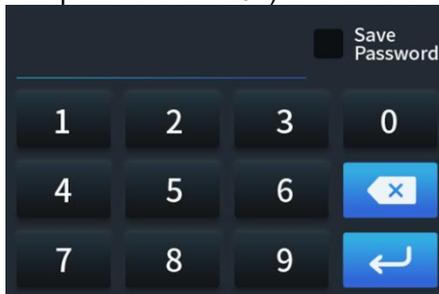


2. Make sure that the battery level is not lower than the figure below.



Battery level 1

3. After the Logo animation is over, the password screen is displayed. Enter the password (the initial password is 1234) to enter the main screen.

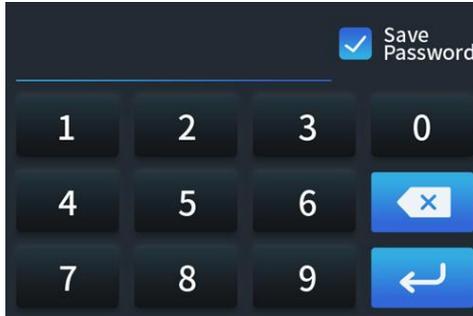


## 6 Operation

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It's not necessary to enter the password next boot after choosing the Save

Password in top right corner of screen, just just press  to enter the boot interface.



4. Please ensure that there are no magnetic objects around the machine before starting. Otherwise, the machine will enter the following interface.



Remove the magnetic object and click Yes to enter the boot interface.

### 6.2.2 Power Off

Long press the power button to shut down.

## 6.3 Screen instructions



No.	Item	Description
1		Remaining Battery Indicator  Indicates remaining battery level. When the indicator light starts to red glow, it means the battery needs to be charged.
		Battery Charging Indicator  Indicates the battery charger is connected to the device.

## 6 Operation

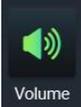
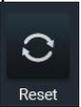
2		Tube Voltage/Curre nt Indicator	Indicates the tube voltage and tube current of the system.
3	 <b>Adult</b>	Adult/Child Selection	Indicates a patient type (adult or child).
	 <b>Child</b>		
4		Digital Sensor	Use the sensor to receive X-rays
		Phosphor Plate	Use the Phosphor Plate to receive X-rays
		Film	Use the Film to receive X-rays
5		Time Display	Displays the X-ray exposure time.
6		Bitewing	Selects the tooth type.
		Lower Molar	
		Upper Molar	
		Canine	
		Incisor	

## 6 Operation

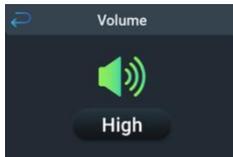
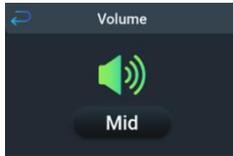
7		M-TECH switch	Close M-TECH function
			Open M-TECH function
8		Machine lock	The machine is locked and cannot be exposed.
			The machine is unlocked and can be exposed.

## 6.4 Set interface

After starting up, you can swipe down the  to enter the setting interface, Press the six options on the screen to enter the corresponding Settings page.

Display content	Meaning
	<p>Press  to enter The receptor selection page;</p> <p>Press  to enter The Volume adjustment page;</p> <p>Press  to enter The Light adjustment page;</p> <p>Press  to enter The Language selection page;</p> <p>Press  to enter The password setting page; Press</p> <p> to enter The restore factory setting page;</p>

## 6 Operation



Adjust the volume of the machine.



Adjust the light of the machine.

## 6 Operation

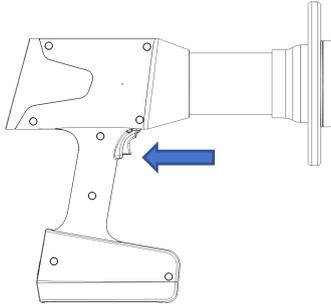
	<p>Select the type of receptor.</p>
	<p>Choose a language.</p>
	<p>Choose whether to restore factory settings.</p>

## 6 Operation

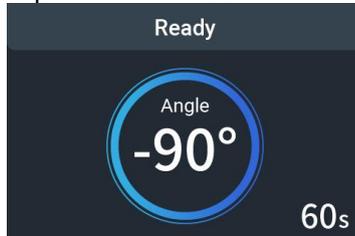
	
	<p>Choose whether to enable password.</p>

### 6.5 Use of exposure function

13. After starting up, press M-TECH switch to follow state , Close the M-TECH function.
14. After selecting the exposure time, short press the exposure button to enter the ready state.

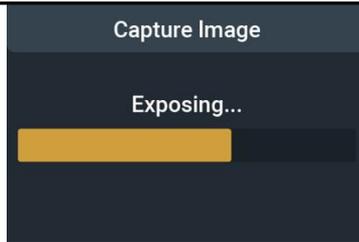


15. In the ready state, the screen will display the inclination angle of the machine to the ground plane and the 60S countdown.

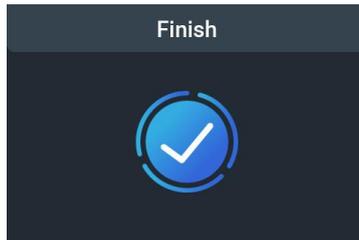


16. Before the countdown ends, press the exposure button for exposure. At this time, the interface will display "Exposing", HyperLight-M will also make a "beep" sound until the end of the exposure.

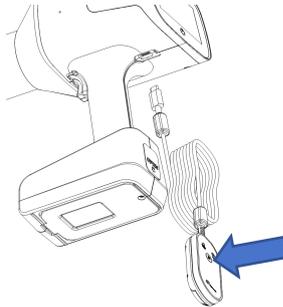
## 6 Operation



17. When the screen displays "Finish", it means that the exposure has completed.



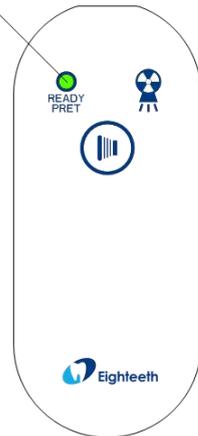
18. When using Remote Control Switch, connect its plug to Remote Control Switch port of HyperLight-M. After selecting the exposure time, short press the exposure button on Remote Control Switch to enter the ready state.



19. In the ready state, the screen will display the inclination angle of the machine to the ground plane and the 60s countdown, and the green light of the Remote Control Switch will be on. (In the ready state, press the switch button to exit the ready state)

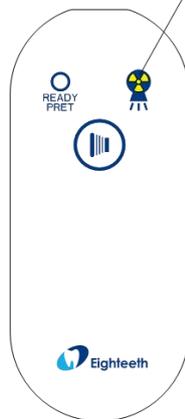
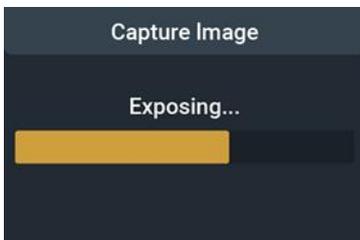
## 6 Operation

Green Light



20. Before the countdown ends, press and hold the exposure button for exposure. At this time, the interface will display "Exposing", the yellow light of the Remote Control Switch will turn on, and HyperLight-M will also make a "beep" sound.

Yellow Light



21. When the screen displays "Finish", it means that the exposure has completed.

## 6 Operation

Finish

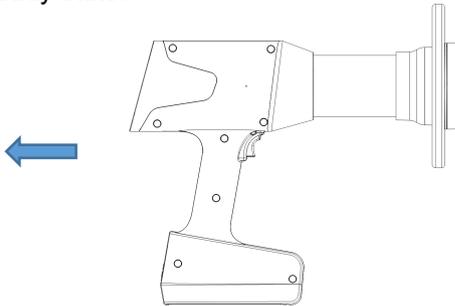


### **WARNING**

- 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.

## 6.8 Use of M-TECH function

10. After starting up, press M-TECH switch to follow state , open the M-TECH exposure function.
11. After selecting the exposure time, short press the exposure button to enter the ready state.



12. In the ready state, the horizontal relative position of the tube head and the receiver will be displayed in the center of the screen, the vertical relative distance between the tube head and the receiver will be displayed in the upper right corner of the screen, and the Angle and countdown of 60s will be displayed on the right side of the screen (In the ready state, press the switch button to exit the ready state)

## 6 Operation



13. Observe the relative position of the blue circular cross cursor and the gray sensor icon which is in the center of the screen. If they don't overlap, move the tube head in the opposite direction until they overlap. For example, if the blue circular cross cursor is on the right of the gray sensor icon, move the tube head to the left until they overlap. And the device will make a "beep" sound when they overlap. It means the horizontal relative distance between the tube head and sensor is suitable. And so on in other directions .



14. The approximate distance between the tube head and the sensor will be displayed on the right side of the screen. In this interface, observe the icon indicating the distance between the



tube head and the sensor in the upper right corner. indicates that the distance between the tube head and the sensor is too far. Move the tube head closer to the sensor, the icon will change to



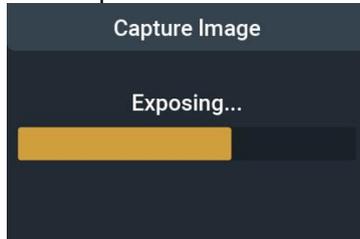
, it means the distance is closer. Till the icon changes to



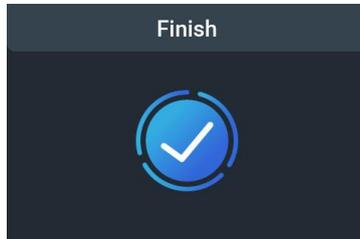
, it means the vertical distance is close.

## 6 Operation

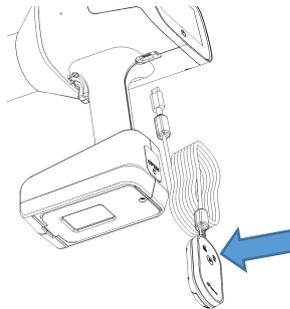
15. After moving the tube head to suitable position to the sensor, Before the countdown ends, press the exposure button for exposure. At this time, the interface will display "Exposing", device will also make a "di..." sound until the end of the exposure.



16. When the screen displays "Finish", it means that the exposure has completed.



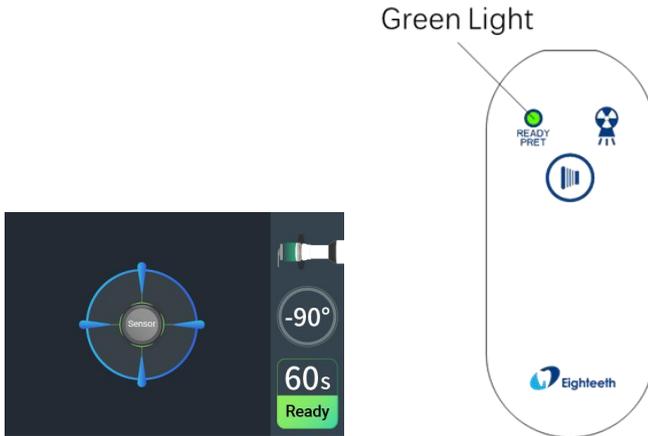
17. When using Remote Control Switch, connect its plug to Remote Control Switch port of HyperLight-M. After selecting the exposure time, short press the exposure button on Remote Control Switch to enter the ready state.



18. Then adjust tube head to suitable position with the same method in Article 4/5 of this table.

## 6 Operation

22. In the ready state, the screen will display the inclination angle of the machine to the ground plane and the 60s countdown, and the green light of the Remote Control Switch will be on. (In the ready state, press the switch button to exit the ready state)

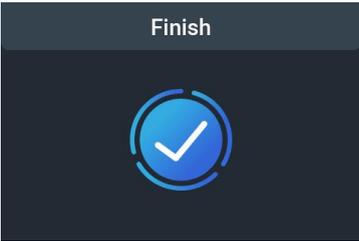


23. After moving the tube head to suitable position to the sensor, Before the countdown ends, press and hold the exposure button for exposure. At this time, the interface will display "Exposing", the yellow light of the Remote Control Switch will turn on, and HyperLight-M will also make a "beep" sound.

## 6 Operation



24. When the screen displays “Finish”, it means that the exposure has completed.



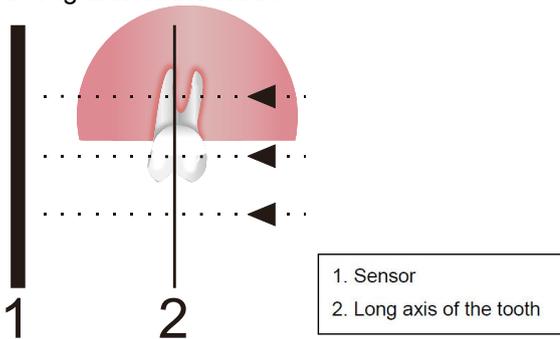
**WARNING**

- 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.

## 6.9 Positioning Instructions

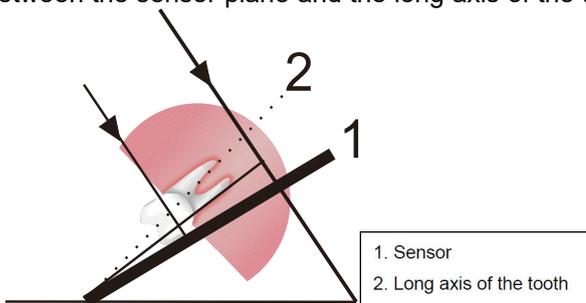
### 6.7.1 Paralleling technique

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



### 7.7.2 Bisected angle technique

The patient holds the sensor in place with his/her finger. 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.

### 7.7.3 Recommended angle and default exposure time for each tooth type

The parameters built into the tooth position are set for people of average size. Individual results 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 particularly important for pediatric patients. When using HyperLight-M, consider the patient's age, body size, physical habits, and clinical indications when validating 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°	0.32
				Lower Molar	-5°	0.16
				Upper Molar	+30°	0.25
				Canine	Maxilla: +45° Mandible: -20°	0.2
				Incisor	Maxilla: +45° Mandible: -25°	0.13

## 6 Operation

<b>P</b>	Phosphor Plate	Child		Bitewing	+5° ~ +8°	0.25	
				Lower Molar	-5°	0.1	
				Upper Molar	+30°	0.16	
				Canine	Maxilla: +45° Mandible: -20°	0.08	
				Incisor	Maxilla: +45° Mandible: -25°	0.06	
		Adult		Bitewing	+5° ~ +8°	0.63	
				Lower Molar	-5°	0.32	
				Upper Molar	+30°	0.5	
				Canine	Maxilla: +45° Mandible: -20°	0.4	
				Incisor	Maxilla: +45° Mandible: -25°	0.25	
			Child		Bitewing	+5° ~ +8°	0.5
					Lower Molar	-5°	0.2
					Upper Molar	+30°	0.32
					Canine	Maxilla: +45° Mandible: -20°	0.16

## 6 Operation

				Incisor	Maxilla: +45° Mandible: -25°	0.13
	Film	Adult		Bitewing	+5° ~ +8°	1.0
				Lower Molar	-5°	0.5
				Upper Molar	+30°	0.8
				Canine	Maxilla: +45° Mandible: -20°	0.63
				Incisor	Maxilla: +45° Mandible: -25°	0.4
		Child		Bitewing	+5° ~ +8°	0.8
				Lower Molar	-5°	0.32
				Upper Molar	+30°	0.5
				Canine	Maxilla: +45° Mandible: -20°	0.25
				Incisor	Maxilla: +45° Mandible: -25°	0.2

### 7.8 Ensuring Image Quality

The following HyperLight-M features contribute to high image quality:

- DC voltage X-ray generation is efficient in delivering energy at the level optimized for diagnostics, with shorter exposure times required.
- The smaller the focal spot, the better the resolution. The HyperLight-M has a small 0.4mm focal spot.

As with the suspended tubehead of a conventional wall-mounted X-ray system, some motion of the tubehead during actual exposures is possible.

## 6 Operation

Use both hands to hold the HyperLight-M 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) so as to achieve a quality image and avoid cone-cutting or retakes.

Image degradation or blurriness does not result due to motion of the handheld X-ray source.

### 7.9 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 <sup>2</sup> )
70kV, 3mA	0.02	0.06	1.53
	0.03	0.09	2.30
	0.04	0.12	3.06
	0.05	0.15	3.83
	0.06	0.18	4.59
	0.08	0.24	6.12
	0.1	0.30	7.66
	0.13	0.39	9.95
	0.16	0.48	12.25
	0.2	0.60	15.31
	0.25	0.75	19.41
	0.32	0.96	24.50
	0.4	1.20	30.62
	0.5	1.50	38.28
	0.63	1.89	48.23
	0.8	2.40	61.24
	1	3.00	76.55
	1.25	3.75	95.69
1.6	4.80	122.48	
2	6.00	153.11	

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,  $DAP = mGy \times \pi (5.7CM/2)^2$



## 6 Operation

- 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.

### 7.10 Essential performance

Accuracy of loading factors (see below):

X-ray tube voltage:  $70\text{kV} \pm 10\%$

X-ray tube current:  $3\text{mA} \pm 20\%$

Exposure time:  $0.02 \sim 2\text{s}, \pm 5\%$  or  $\pm 20\text{ms}$ , 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

### 7.11 Calibration Checks

The HyperLight-M 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-M. 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	$70\text{kV} \pm 10\%$	63-77 kV	63-77 kV	63-77 kV	63-77 kV	63-77 kV
Timer Accuracy	0.02-2s ( $\pm 5\%$ or $\pm 20\text{ms}$ , whichever is larger)	0.03-0.07s	0.08-0.12s	0.475-0.525s	0.95-1.05s	1.9-2.1s
Tube Current	$3\text{mA} (\pm 20\%)$	2.4-3.6 mA	2.4-3.6 mA	2.4-3.6 mA	2.4-3.6 mA	2.4-3.6 mA
Dose rate	2.5-3.5mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s	2.5-3.5 mGy/s

## 8 Cleaning and disinfection

### 7.5 Foreword

The parts for clinical application contamination are the outer surfaces of the main body 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.

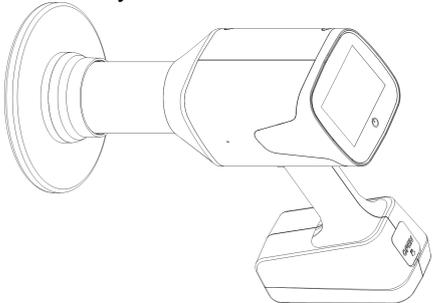
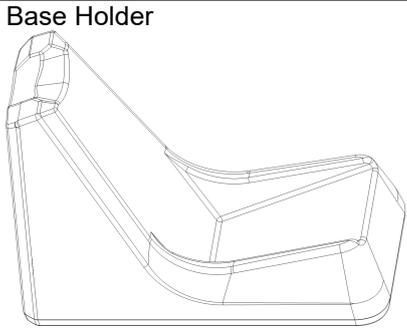
Reprocessing procedures have only limited implications to these parts. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.

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

### 7.6 General recommendations

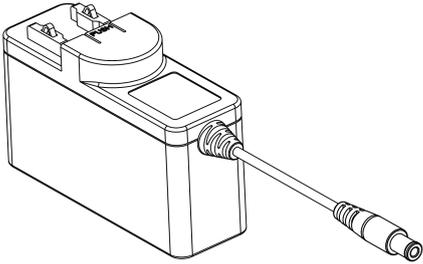
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
- Do not use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

### 7.7 Reprocessing Instructions

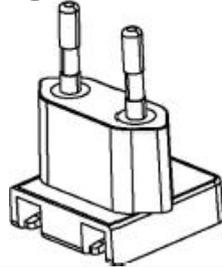
Disinfection devices	
Main Body 	Base Holder 

## 7 Cleaning

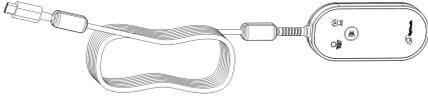
Power Adapter



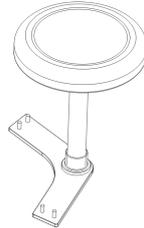
Power Plug



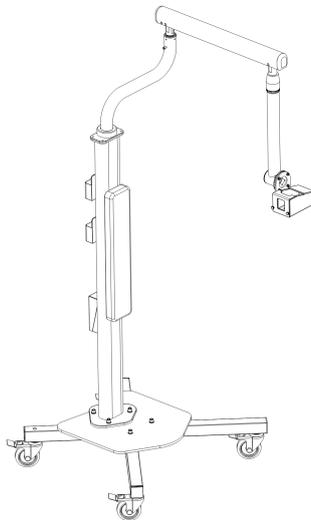
Remote Control Switch



Bracket Seat



Bracket



**WARNING**

## 7 Cleaning

Before first use, after each use and whenever there is a risk of contamination, disinfect the above devices.

Do not sterilize the Main Body, Base Holder, Power Adapter, Power Plug, Remote Control Switch, Bracket, Bracket Seat by heating, autoclaving or UV.

### Reprocessing Instructions

#### Preparation before cleaning:

Before cleaning and disinfecting, make sure the power is off.



#### **WARNING**

Make sure that used Disposable Sleeves are disposed of as infected waste which is potentially biologically hazardous.

#### Cleaning:

Wipe all the exterior surfaces of Main Body, Base Holder, Power Adapter, Power Plug, Remote Control Switch, Bracket, Bracket Seat 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 Main Body, Base Holder, Power Adapter, Power Plug, Remote Control Switch, Bracket, Bracket Seat thoroughly with a cloth lightly moistened with Ethanol (Ethanol 70 to 80 vol%) at least 3 min, repeat for 5 times.

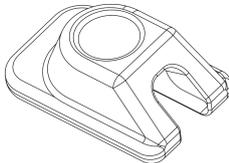
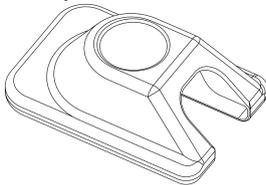
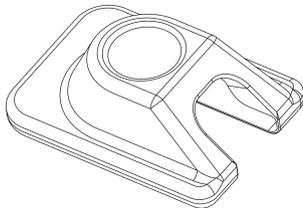
#### Drying:

Use a lint free cloth to wipe the surfaces.

#### Storage:

Storage of the processed device in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

**7.8 Autoclavable accessories**

<p>1 Inch Sensor Protective Sleeve (optional)</p> 	<p>1.5 Inch Sensor Protective Sleeve (optional)</p> 
<p>2 Inch Sensor Protective Sleeve (optional)</p> 	

 **WARNING**

1. Only the above devices can be automated cleaning, disinfection and sterilization.
2. The Sensor Protective Sleeve should be cleaned, disinfected and sterilized for the first use and whenever they are used between patients. The Sensor Protective Sleeve are verified to be able to withstand 250 times reprocessing cycles. Please contact the local distributor to request for repair or exchange in case of damage of the two parts during the claimed service life.
3. Before first use and after each use, clean, disinfect and sterilize the above devices.

**Reprocessing Instructions**

**Preparation at the Point of Use:**

1. Disconnect the Sensor Protective Sleeve before cleaning. Remove

## 7 Cleaning

gross contaminations from the devices with 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.

2. Store the devices in a humid surrounding.



### **WARNING**

Do not submerge the devices or wipe them 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 metal corrosion and adhesion of the residual medical agents to the devices.

### **Preparation for Decontamination:**

The devices must be reprocessed in a disassembled state.



### **WARNING**

Observe suitable personal protective measures.

### **Pre-Cleaning:**

Do a manual pre-cleaning, until the devices are visually clean. Submerge the devices in a clean water. Clean the surfaces with a soft bristol brush.

### **Cleaning:**

Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.

#### Automated Cleaning:

Carefully put the devices 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);

## 7 Cleaning

- emptying
- 5 min washing with a mild alkaline cleaner at 55°C;
- emptying
- 3 min neutralising with warm water ( $\geq 40^{\circ}\text{C}$ );
- emptying
- 5 min intermediate rinsing with warm water ( $\geq 40^{\circ}\text{C}$ );
- emptying

Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.



### **WARNING**

1. Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly.
2. Follow instructions and observe concentrations given by the manufacturer (see general recommendations).

### **Disinfection:**

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see 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.

### **Drying:**

Automated Drying:

Dry the devices according to the drying program of the washer/disinfector by setting parameter to 120 °C, 15 min.

If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of devices by using sterile compressed air.

### **Packaging:**

Pack the devices in an appropriate packaging material for sterilization.



### **WARNING**

## 7 Cleaning

1 Check the validity period of pouch given by the manufacturer to determine the shelf life.

2 Use pouches which resist to a temperature up to 141°C and in accordance with EN ISO 11607.

### **Sterilization:**

Sterilization of devices 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.

Sterilization parameters: 134°C, 5 minutes, dry 8 minutes.



### **WARNING**

1 Use only approved autoclave devices according to EN 13060 or EN 285.

2 Use a validated sterilization procedure according to EN ISO 17665.

3 Respect the maintenance procedure of the autoclave device given by the manufacturer.

4 Use only this recommended sterilization procedure.

5 Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycle parameters).

6 Wait for cooling before touching.

### **Functional Testing, Maintenance:**

Visual inspection for cleanliness of the devices and reassembling.

Functional testing according to instructions of use. If necessary, perform reprocessing process again until device is visibly clean.

### **Packaging:**

Pack the devices in an appropriate packaging material for storage.

### **Storage:**

Storage of sterilized devices in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

## 7 Cleaning

### **Reprocessing validation study information:**

The above-mentioned reprocessing process (cleaning, disinfection and sterilization) has been successfully validated.



#### **NOTE**

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. 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.



#### **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-M plastic prematurely.
- Do not remove the Beam Limiting Device when cleaning, disinfecting and maintaining.
- Never apply sprays or liquids directly on the surfaces of the device.
- The main body, base holder, the power adapter and power cord are not designed to be subjected to any kind of sterilization procedure.



#### **WARNING**

- The external surface of the Hand-held Dental X-ray System must be protected by recognized isolation film to avoid cross-contamination.

### 8 Maintenance

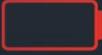
Incorrect operation or failure to maintain the device in accordance with the maintenance schedule relieves the manufacturer or his agent from all the responsibilities for subsequent non-compliance, damage, injury, defect and/or other malfunction. Only authorized Service Representatives, trained specifically on the HyperLight-M device, maintain and service the device. Annual Maintenance: Observe the following steps for annual maintenance of the HyperLight-M.

8. Verify that the Power button is working properly. When the device is powered on, the display should illuminate and an indicator alarm should sound.
9. Verify that the Panel key is working properly.
10. Check whether all interfaces on the screen are normal.
11. Enter the Settings screen to check whether the Settings function is normal.
12. Use the exposure function to test whether the machine can be exposed properly.
13. Check whether the protective panel is damaged.
14. 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.

<b>Maintenance Test</b>	Year 1	Year 2	Year 3	Year 4	Year 5
Power Button					
Screen					
Setting interface.					
The exposure function					
Backscatter Shield					
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
 <p>Low power!</p>	Insufficient charge	Use the charger to charge the machine.
 <p>Overheating!</p>	The machine temperature is too high.	Let stand for more than half an hour.
 <p>Abnormal exposure time!</p>	Abnormal exposure time	During the exposure process, the finger released the exposure button, causing the exposure to be forcibly terminated.
 <p>Drop detected!</p>	Drop detected	A fall of the machine is detected, which may cause damage to the machine.
 <p>Check the battery</p>	Check the battery	Frequent use of the machine for a long time causes the battery temperature to be too high.

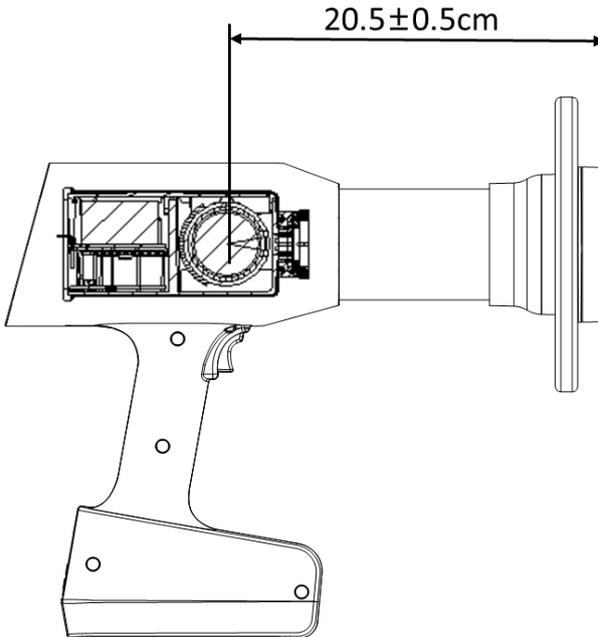
## 10 Technical Data

### 10.1 Main Body Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	HyperLight-M
Software version	HLM 1
Charger power supply	~100-240V 50/60Hz
Power supply	Lithium ion battery: L1-18650 4S1P 14.8V, 2500mAh $\pm 10\%$
Input AC Current	0.5A max
Charger power output	20V $\overline{\text{---}}$ 0.9A
Charging overcurrent protection	0.9A
Discharge overcurrent protection	50A
Ray type	X Ray
X-ray tube model	KL11-0.4-70
Tube voltage	70kV( $\pm 10\%$ )
Tube Current	3mA ( $\pm 20\%$ )
Fuse	F 20AL 65V Size:6.1mm $\times$ 2.69mm $\times$ 2.69mm
Exposure time adjustment range	0.02-2s( $\pm 5\%$ or $\pm 20\text{ms}$ whichever is larger)
Nominal power	210W nominal at 70kV, 3mA
Inherent Filtration	0.8mm Al
Added filter	1mm Al (1mm Al)
Total Filtration	$\geq 1.8\text{mm Al}$ (0.8mm glass, 1mm Al)
Duty Cycle	1:30
Minimum source to skin distance	20cm (from focal spot to cone tip)
X-ray exit field size and configuration	57mm diameter circle
Electrical safety class	Class II
IPX specification	IPX0; do not operate under wet conditions
Apparent resistance of supply main	$\leq 2\Omega$
Mode of operation	Intermittent operation 20s ON/600s OFF
Ambient conditions	Use: in enclosed spaces

## 10 Technical Data

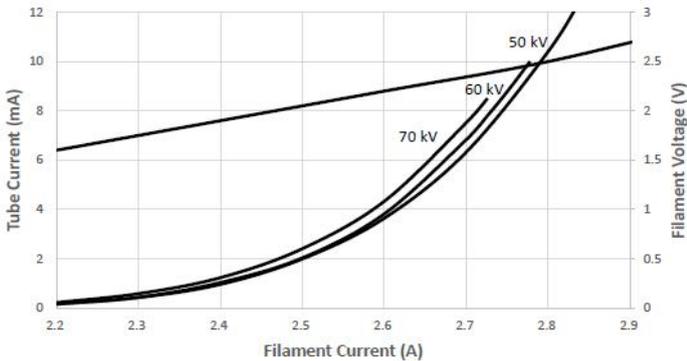
	Ambient temperature: 10°C ~ 40°C Relative humidity: 30%-75% Atmospheric pressure: 70 kPa - 106 kPa
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% - 80 % Atmospheric pressure: 70 kPa - 106 kPa



**10.2 X-ray Tube Assembly Specifications and Characteristics**

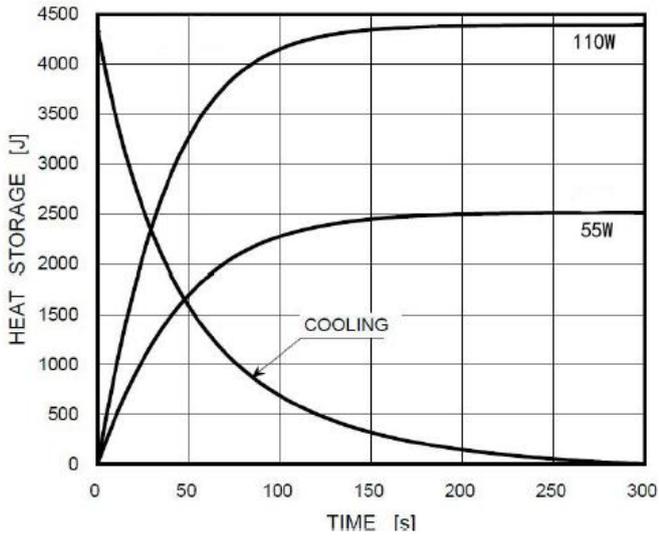
Filament voltage	2.8-3.4V
Maximum filament current	3A
Nominal tube voltage	70kV
X-ray source assembly maximum heat content	4500J
Maximum anode cooling rate	110W
Nominal anode input power	600W
Target material	Tungsten
Minimum target angle	12°
Filament voltage (at maximum filament current 2.9A)	2.4~ 3.0V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

**Emission & Filament Characteristics (Half Wave Self-Rectified)**

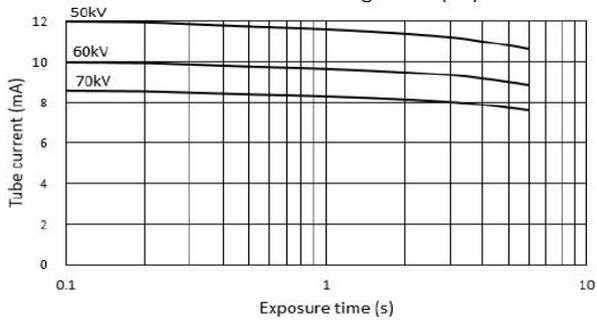


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## 10 Technical Data

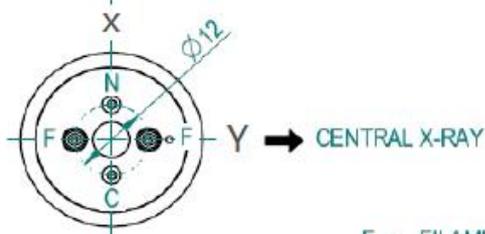
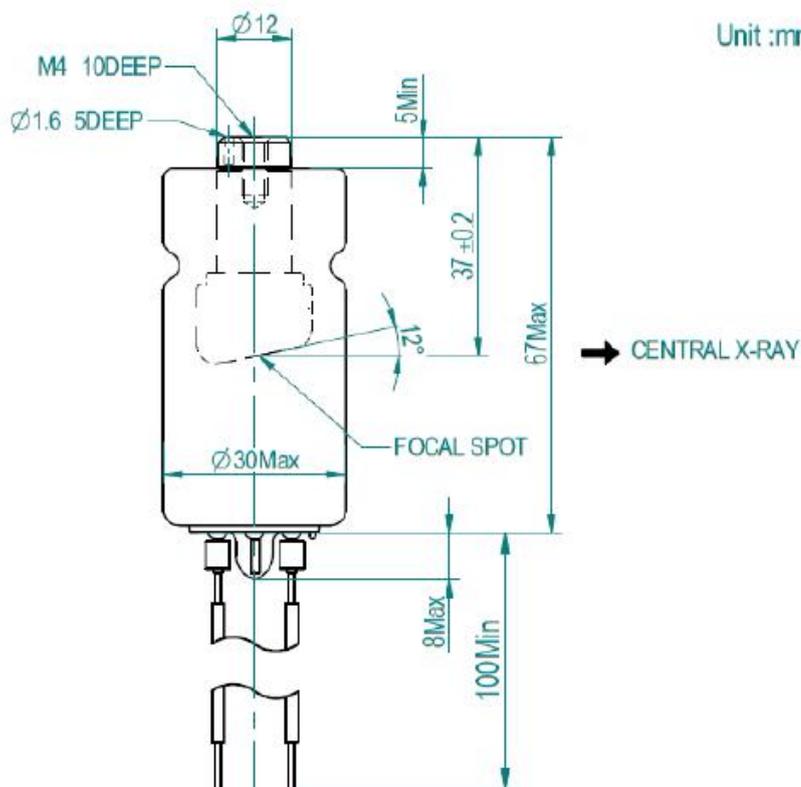


Maximum Rating Charts (AC)



# 10 Technical Data

Unit :mm



F : FILAMENT  
 C : CATHODE  
 N : NOT FOR USE

## 11 EMC Tables

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
<p>The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or the user of the HyperLight-M should assure that it is used in such an environment.</p>		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The HyperLight-M 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	<p>The HyperLight-M 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:</p> <p>Warning: This HyperLight-M 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-M or shielding the location.</p>
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
<p>The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or the user of the HyperLight-M should assure that it is used in such an environment.</p>			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>

## 11 EMC Tables

<p>Electrostatic Discharge (ESD) IEC 61000-4-2</p>	<p>+/-8 kV contact +/-15kV air</p>	<p>+/-2, 4, 6 &amp; 8kV contact +/-2, 4, 8, &amp; 15 kV air</p>	<p>Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%</p>
<p>Electrical fast Transient/burst IEC 61000-4-4</p>	<p>+/-2 kV for power supply lines +/-1 kV for input/output lines</p>	<p>+/-0.5, 1 &amp; 2 kV for power supply lines +/-0.5 &amp; 1 kV for input/output lines</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Surge IEC 61000-4-5</p>	<p>+/-1 kV differential mode +/-2 kV common mode</p>	<p>+/-0.5 &amp; 1 kV differential mode +/-0.5, 1 &amp; 2 kV</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>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</p>	<p>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</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the <b>HyperLight-M</b> requires continued operation during power mains interruptions, it is recommended that the <b>HyperLight-M</b> be powered from an uninterruptible power supply or battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>30A/m</p>	<p>3 &amp; 30A/m</p>	<p>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</p>

## 11 EMC Tables

<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>			
The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or user of the HyperLight-M should ensure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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-M by no less than the distances calculated/listed below:  $D=(3.5/V1)(\text{Sqrt } P)$ 150kHz to 80MHz
Radiated RF IEC 61000-4-3	6Vrms in ISM bands between 0,15 MHz and 80 MHz  3 V/m 80 MHz to 2,7 GHz	(E1)= 6Vrms in ISM bands  (E1)=3V/m	$D=(3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz  $D=(7/E1)(\text{Sqrt } P)$ 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

## 11 EMC Tables

			<p>the recommended separation distance in meters (m).</p>
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<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>			
<p>The HyperLight-M is intended for use in the electromagnetic environment specified below. The customer or user of the HyperLight-M should ensure that it is used in such an environment.</p>			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			<p>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:</p> <div style="text-align: center;">  </div>
<p>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.</p>			
<p>4. 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.</p> <p>5. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.</p> <p>6. The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are</p>			

## 11 EMC Tables

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-M** 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-M** 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	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810						
870	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

## 11 EMC Tables

		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	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
<b>5500</b>						
<b>5785</b>						



### WARNING

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

#### **Cable information:**

Cable Name	Cable Length (m)	Shielded or not	Remark
Power Adapter	1.2	NO	/
Remote Control Switch	3.2	NO	/

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

### Service Life

The service life of HyperLight-M 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

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to CHANGZHOU SIFARY MEDICAL TECHNOLOGY CO., LTD. The industrial design, inner structure, etc , have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.



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**NOTICE**

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