USER'S MANUAL



Minor Surgical Luminaire (Luvis S200)

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Please read this USER'S MANUAL before operating this equipment.

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1. IMPORTANT NOTICE

[Classification under the provision of 93/42/EEC(MDD)] Class I

Minor Surgical Luminaire (Luvis) is classified as a Class I device.

[Form of protection against electric shock] Class I

Minor Surgical Luminaire (Luvis) is classified as Class I.

This device is always protected from electric shock when the power cord is connected between the product and wall outlet. Class I is a product in which the protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of the product to the protective (ground) conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure in the basic insulation. Use a power outlet which is equipped with a grounding terminal.

[Degree of protection against electric shock] Class I

[Degree of protection against ingress of liquids] IPX0

Minor Surgical Luminaire (Luvis) is classified as IPX0

[Degree of protection against flammability]

Minor Surgical Luminaire (Luvis) is classified as a device not suitable to be used in a potentially flammable environment. Do not use near flammable materials

[Method(s) of sterilization or disinfection recommended by the manufacturer]

The head handle should be cleaned with cloths, and KNOB should be sterilized with sterilizer regularly to prevent disinfection

[Mode of operation]

Classification of Minor Surgical Luminaire: continuous operation

Electromagnetic waves discharged from mobile phones, radiotelegraphs, and wireless toys can cause malfunction of this product. Please keep away any device that can influence this digital Refractor.

It is a compulsory obligation to learn the operating manual thoroughly, before installation, use, repair, wash or adjustment of the auxiliary parts of this equipment. For user's safety, please use this equipment only after reading all the instructions included in this manual.

Pay a special attention to the word "WARNING" or "CAUTION," which are on all manuals for users and managers.

All the information in this manual has been checked out carefully and discerned as accurate one at the time of publication. However, DENTIS takes no responsibilities of the results caused by default, omission, or misuse of it.

DENTIS has rights to modify the product itself or specifications of the product without any prior notice, as well as rights not to renew that modification on this manual.

2. SAFETY INFORMATION

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60601-2-41 for data processing equipment and IEC/EN 60601-1 for medical equipment).

Furthermore all configurations shall comply with the system standard EN 60601-1-2:2001. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard EN 60601-1-1:2001.

If in doubt, consult the technical service department or your local representative.

For EU Countries

- The following mark, the name & address of the EU Representative shows compliance of the instrument with Directive Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC concerning medical devices.

Europe Representative

CE

EC REP

CALMED INVEST Kft.

1191 Budapest, Attila utca 34., Budapest, Hungary

3. SYMBOL

The following symbols are used in the equipment and/or in this manual.

	Protective earth (ground)
	Alternating current
	Off (power: disconnect to the mains)
	On (power: connection to the mains)
	Do not throw away with general household waste
	Risk of electric shock
	Crushing hazard sign
	Hand hazard sign
	Instruction for user manual
	General mandatory action sign
	General prohibition sign
	General warning, caution sign
	Keep dry symbol
	DO NOT Hand Hooks symbol
	Fragile symbol

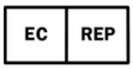

This side up


Handle with care symbol



Do not build up more than 5 boxes


Manufacture



Europe Representative

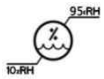

Manufacture Date



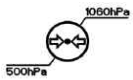
Only one unit in the box



Temperature between - 40˚C ~ 70˚C



Humidity between 10%RH ~ 95%RH



Air pressure between 500hPa ~ 1060hPa

4. WARRANTY REGULATION

DENTIS warrants all products against defects in materials or workmanship for one year from time of delivery. DENTIS's sole obligation under the warranty is to provide parts for the repair, or at its option, to provide the replacement product (excluding labor).
The buyer shall have no other remedy. All special, incidental, and coincidental damages are excluded. Written notice of breach must be given to DENTIS within the warranty period. The warranty does not cover damage resulting from improper installation or maintenance, accident or misuse. The warranty does not cover damage resulting from the use of cleaning, disinfecting or sterilization chemicals and processes. The
Failure to follow instructions provided in the DENTIS Instructions for Use (operation and maintenance instructions) may void the warranty. LED PCB ASSY is covered under DENTIS's Five year warranty.

5. SAFETY

5.1 SAFETY REGULATION

Minor Surgical Luminaire (Luvis) as a medical device complies with the safety regulation EN 60601-1.

Safety is everyone's obligation and responsibility. The safe use of this product is related to everyone such as installer, user, operator and equipment's manager. It must read and learn this user's manual is compulsory before installation, using, cleaning, fixing or operation of this product or its accessories. Pay particular attention and be familiar with warning symbols about safety. If do not follow safety direction of this manual, you can get injured or accident when you operate this product. After read carefully and understand this manual, use this product.

This manual is in keep a place where you can find easily.

5.1.1 WARING SYMBOL

	"Caution Warning" explains that carelessness can lead to serious injury or considerable property damage.
	"Mandatory Action Sign" explains compulsory obligation before use or operation.
	"Prohibition Sign" explains overall prohibition about installation, operation and maintenance. Carelessness can cause considerable personnel and material loss.
NOTE	"Note" explains important information about installation, operation and maintenance, but if careless, it can be associated with disaster.

5.2 PROPER USE

5.2.1 GENERAL INFORMATION

The user must ensure that that the device works properly and is in a satisfactory condition before each use.

This DENTIS device is intended only for use in the field of Medical. It is impermissible to use the device for a purpose for which it was not intended.

"Proper Use" includes following all the instructions for use and ensuring that all inspections and service tasks are performed.

Apply and meet the overarching guidelines and/or national laws, national regulations and the rules of technology for medical devices applicable for startup and use of the device for the intended purpose.

The user must observe the following:

· Only use properly operating equipment.

· Protect himself or herself and third parties from danger.

· Avoid contamination from the device.

During use, the following national regulations must be observed:

· The applicable health and safety regulations.

· The applicable accident prevention regulations.

To ensure that device maintains their value and are always ready for use, they must be serviced once a year as recommended.

The safety checks must be performed every year.

Repair and service of the device is authorized only to those who meet the requirements below:

· Technicians of authorized dealers specially trained by DENTIS.

· The trained technicians of DENTIS branches.

Information on Electromagnetic Compatibility

NOTE	Based on EN60601-1-2 concerning the electromagnetic compatibility of electro-medical devices, we need to point out that: • Medical electrical devices are subject to special measures regarding electromagnetic compatibility and must be operated in accordance with DENTIS assembly instructions. • Portable and mobile high-frequency communications devices can influence medical electronics.
	Damage by using improper parts If parts from other suppliers (not DENTIS) are used, it can influence quality of the device. Use only recommended parts from DENTIS.
	DENTIS cannot guarantee that parts not delivered by DENTIS will correspond with EMC requirements of EN 60601-1-2.
	Disposal • For environment and safety of human, wastes must be recycled or separated. • Please contact the closest DENTIS branch, if you have any questions about recycling of the device.

5.2.2 PRODUCT CHARACTERISTIC

This device illuminates light from the main head's LED light to assist curing and diagnosis of patients.

Intended Use

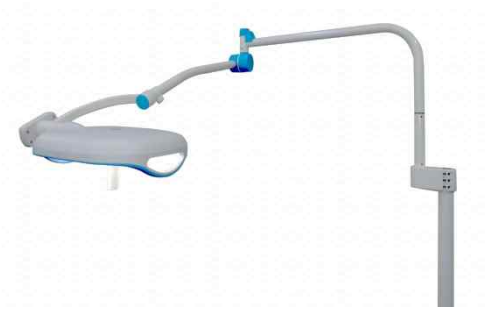
Minor Surgical Luminaire (Luvis) is designed for use in medical clinic to illuminate the specific and

sectional area of patient's body parts and assist curing and diagnosis of the patients including children and adult. The device may only be used by medical professional.

6. PRODUCT INFORMATION

6.1 PRODUCT TYPE

⚠	**Modification of this equipment is not allowed**



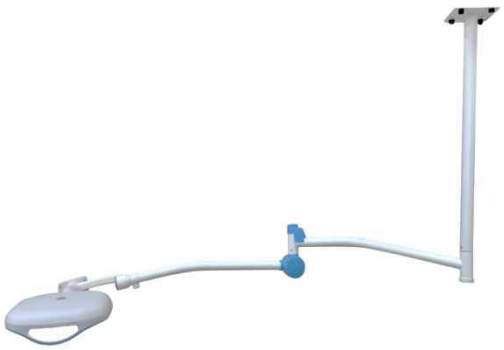
PL2S20-002B0 (Dual connection type)



PL2S30-002C0 (Wall mount type)



PL2S10-002A0 (Mobile type)

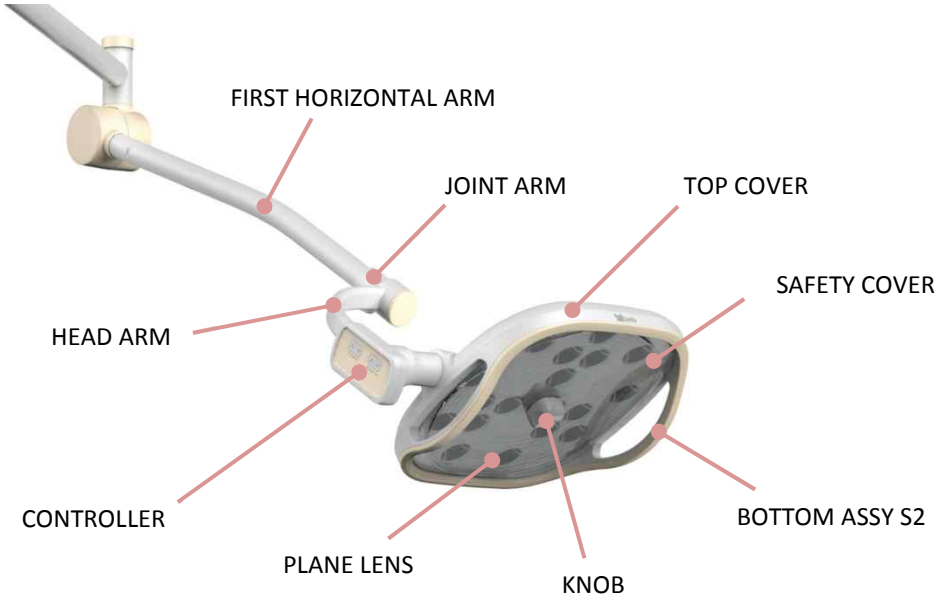


PL2S40-002D0 (Single ceiling type)

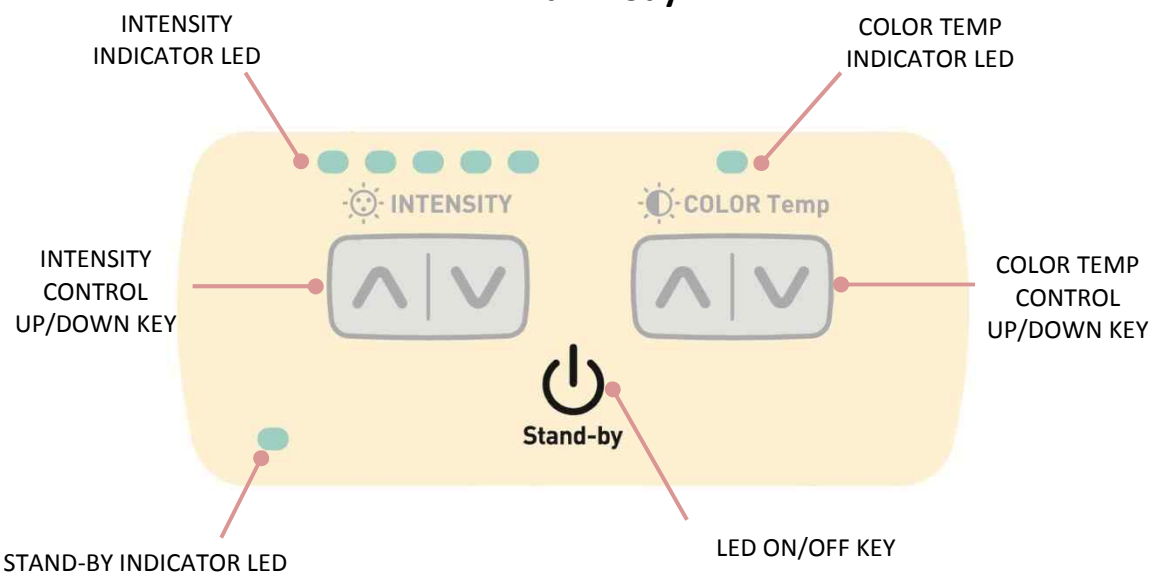


PL2S50-002E0 (Dual ceiling type)

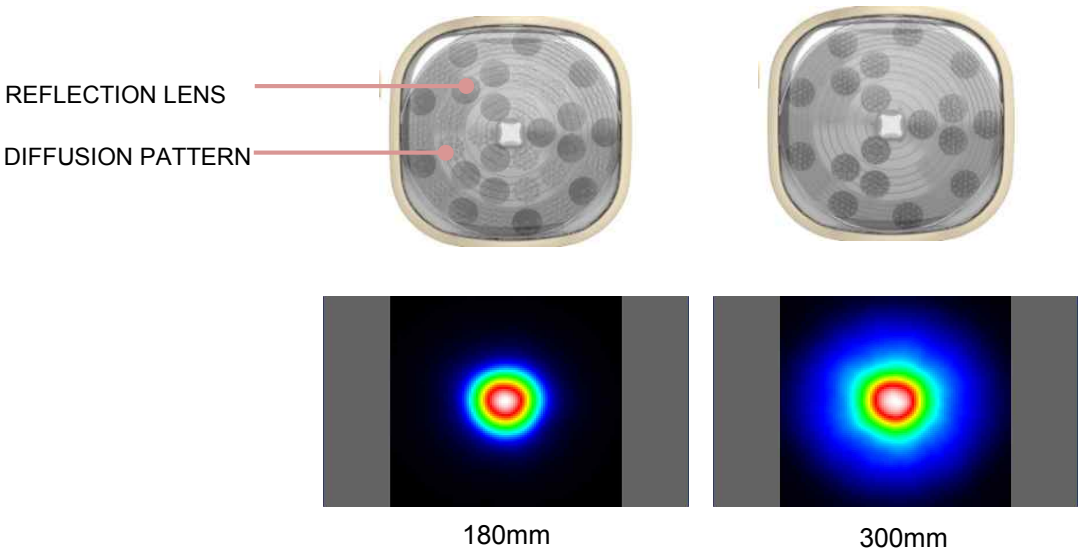
6.2 PRODUCT DESCRIPTION



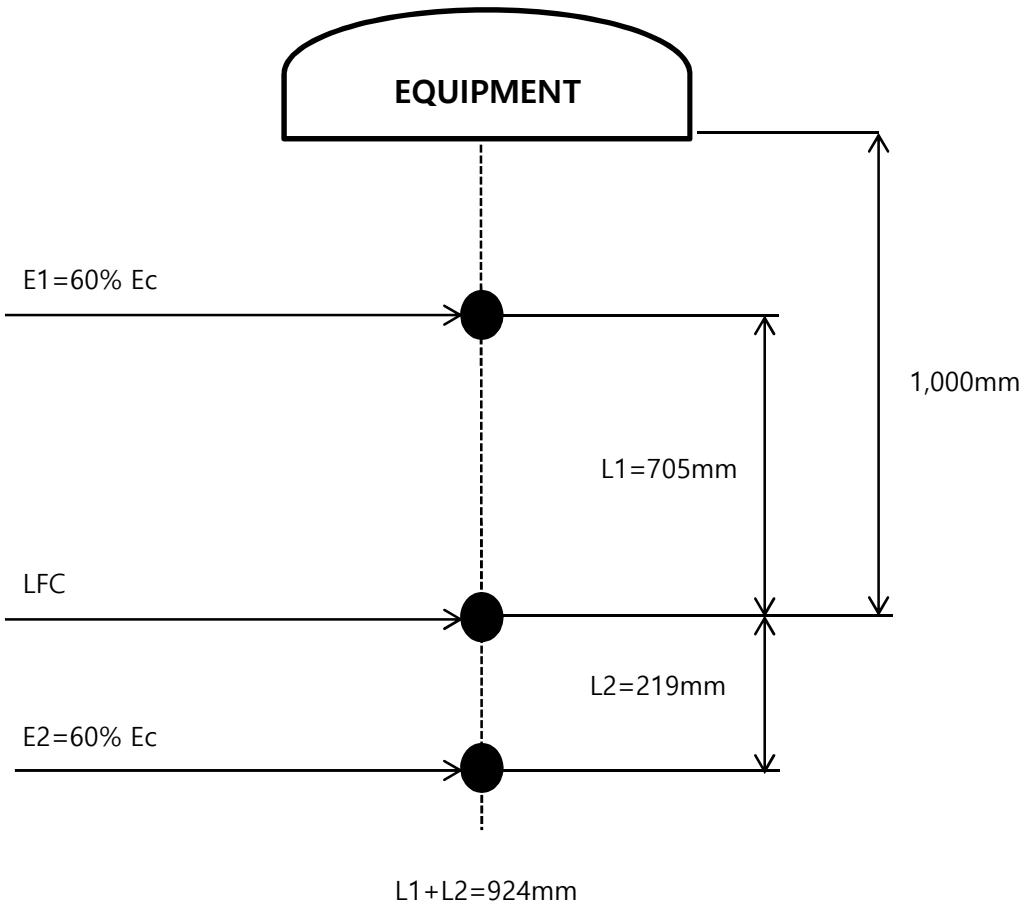
Main Body



Controller Panel



INTENSITY

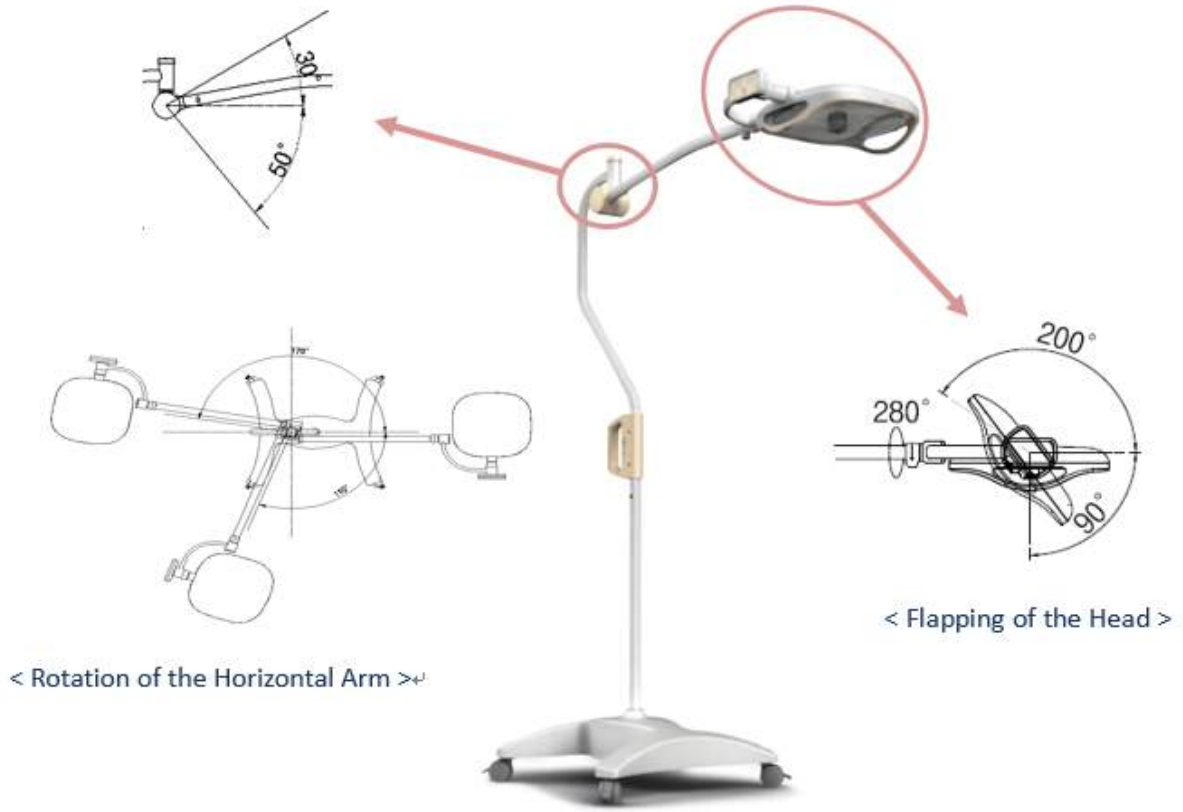


DEPTH OF ILLUMINATION=L1+L2

Professional LED Light System for All of Surgery Application

6.3 PERFORMANCE CHARACTERISTIC

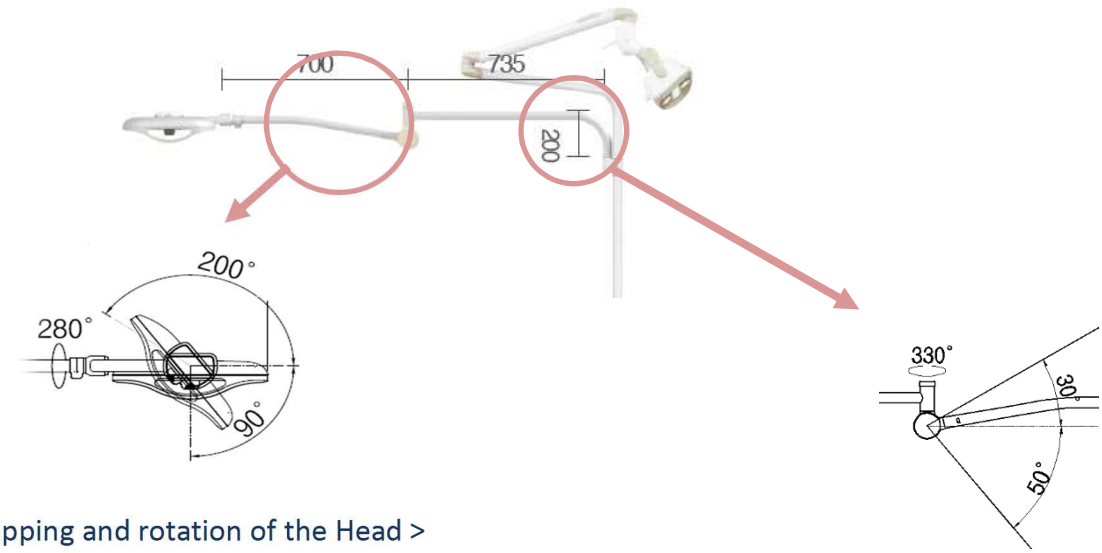
MOBILE



< Rotation of the Horizontal Arm >

< Flapping of the Head >

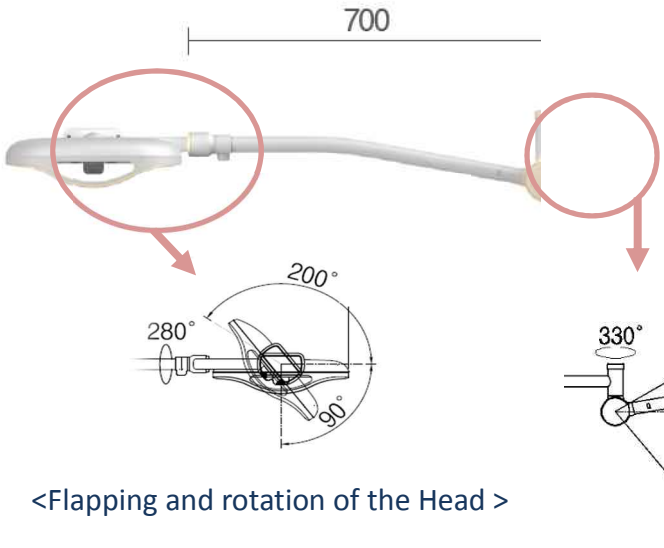
DUALCONNECTION



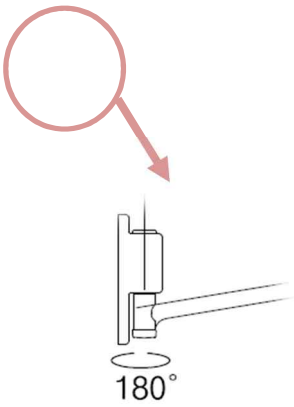
<Flapping and rotation of the Head >

< Flapping and rotation of the Horizontal Arm >

WALL



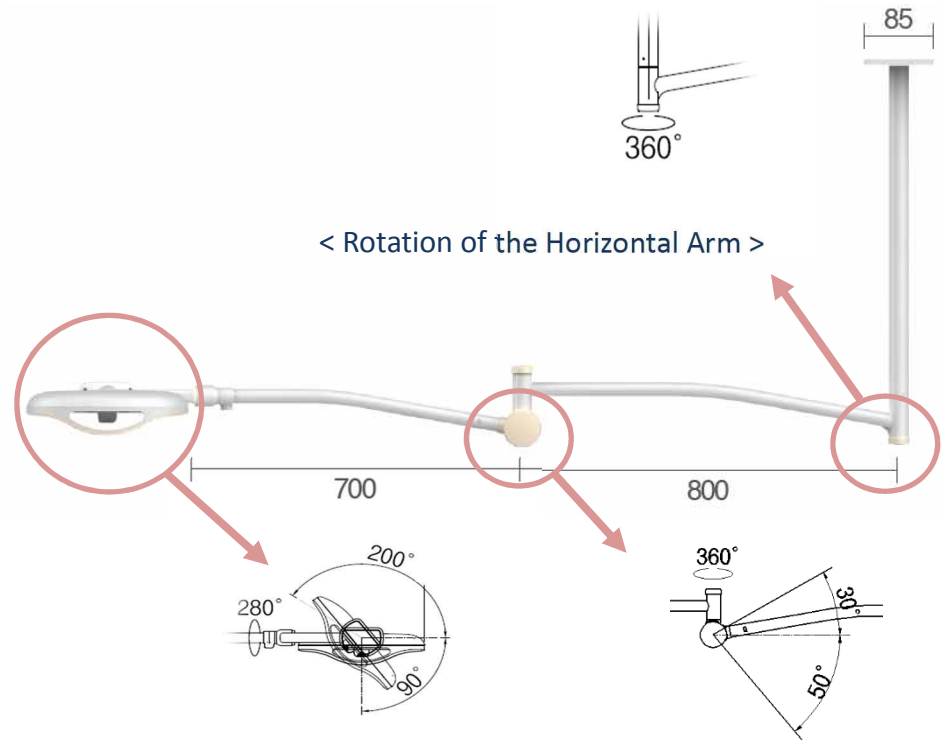
<Flapping and rotation of the Head >



< Rotation of the Horizontal Arm >

< Flapping and rotation of the Horizontal Arm >

SINGLE CEILING

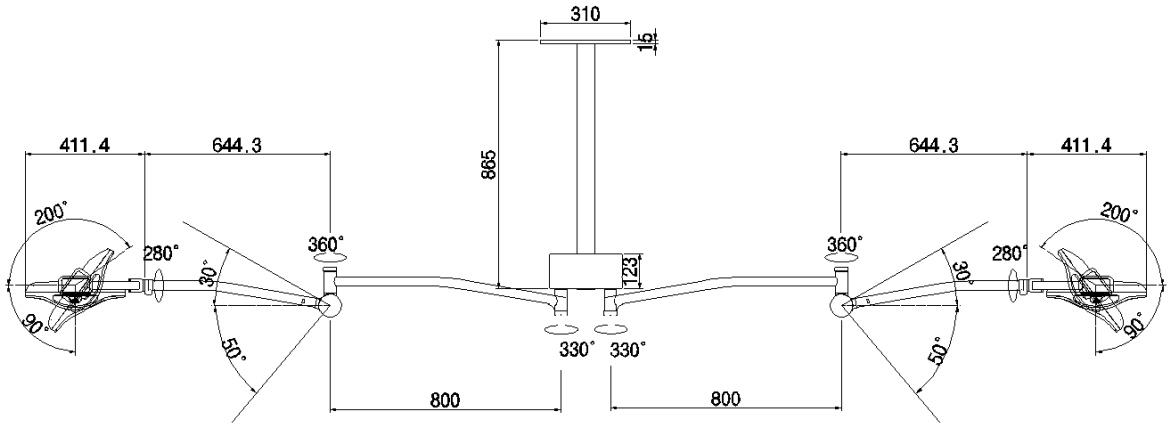


< Rotation of the Horizontal Arm >

< Flapping and rotation of the Head >

< Flapping and rotation of the Horizontal Arm >

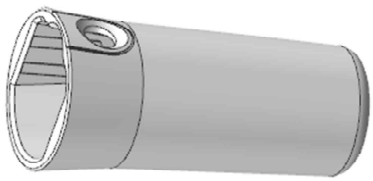
DUAL CEILING



⚠	If this device is operated beyond the indicated angles, it can be damaged.

⚠	This image was constructed to demonstrate the product's operating range. The image may differ from the actual product.

6.4 ACCESSORY

Accessory	KNOB 2ea	

⚠	Before using KNOB, please conduct a sterilization treatment.

6.5 SPECIFICATIONS

Operating Specifications

- Rated Input

  Max 60,000 lux Model: AC 100-240 V, 50/60 Hz, 33-61 VA

  Max 80,000 lux Model: AC 100-240 V, 50/60 Hz, 35-50 VA

  Max 100,000 lux Model: AC 100-240 V, 50/60 Hz, 45-61 VA

- Focal range: Adjustable; 1,000mm (970 – 1,030mm)
- Color temperature: 3,800K / 4,300K / 4,800K

  Tcp: 3,953K

  △UV: + 0.0018

  Ra: 90

  R9: 80

- Light pattern: 180/300mm
- Light Field Diameter

  d50: 93mm / d10: 183mm

- Light Intensity

Classification	Color temp	Illuminance	Remark
Max 60,000 lux Model	3,800K	40,000 lux	1,000mm
	4,300K	60,000 lux	1,000mm
	4,800K	60,000 lux	1,000mm
Max 80,000 lux Model	3,800K	60,000 lux	1,000mm
	4,300K	80,000 lux	1,000mm
	4,800K	80,000 lux	1,000mm
Max 100, 000 lux Model	3,800K	80,000 lux	1,000mm
	4,300K	100,000 lux	1,000mm
	4,800K	100,000 lux	1,000mm

* Optical values are measured with a tolerance of ±10%

- Shadow Dilution

d) Illuminance measured at the LFC (Fig. 201.107) when the beam is obstructed by one mask, given as a percentage of the CENTRAL ILLUMINANCE (%) (IEC 60601-2-41) ..... :	0.015 % (LFC = 62 400 LX, REMAINING ILLU. = 9.24 LX) 0.025 % (LFC = 79 000 LX, REMAINING ILLU. = 20 LX), REV.1 0.005 % (LFC = 98 800 LX, REMAINING ILLU. = 4.75 LX), REV.1
e) Average of four illuminance measurements performed at the LFC, with the pair of masks in four successive positions 45° apart without motion of ME EQUIPMENT under test and the photometer head of the illuminance test (Figs 201.108 and 201.109) (IEC 60601-2-41)	See appended Table 201.12.1.102.1.3e
f) Remaining illuminance as a percentage of CENTRAL ILLUMINANCE with a tube as defined in Fig. 201.110 positioned around the detector of the illuminance meter at the LFC (%) (IEC 60601-2-41) ..... :	102.08 % (LFC = 62 400 lx, LFC with a tube illu. = 63 700 lx) 104.43 % (LFC = 79 000 lx, LFC with a tube illu. = 80 500 lx) 100.70 % (LFC = 98 800 lx, LFC with a tube illu. = 99 500 lx)
g) Remaining illuminance as a percentage of CENTRAL ILLUMINANCE with a tube and one mask (Fig. 201.112) (%)(IEC 60601-2-41) :	0.002 % (LFC = 62 400 lx, remaining illu. = 1.32 lx) 0.002 % (LFC = 79 000 lx, remaining illu. = 2.30 lx) 0.002 % (LFC = 98 800 lx, remaining illu. = 3.31 lx)
h) Average of four measurements performed at the LFC, with a tube and the pair of masks in four successive positions 45° apart without any motion of the ME EQUIPMENT under test and the photometer head of the illuminance test (Figs. 201.113 and 201.114) (IEC 60601-2-41)	See appended Table 201.12.1.102.1.3h

201.12.1.102.1.3e	Table: Measurement of remaining illuminance performed at LFC with a pair of masks in four successive positions, 45° apart - Figs. 201.108 and 201.109		P
Position of two masks	Illuminance, lx measured at LFC	Average as % of CENTRAL ILLUMINANCE	Remarks
1	30 800	47.4 % (31 877 lx)	LFC = 67 200 lx
2	36 200	47.4 % (31 877 lx)	
3	32 300	47.4 % (31 877 lx)	
4	28 210	47.4 % (31 877 lx)	
Position of two masks	Illuminance, lx measured at LFC	Average as % of CENTRAL ILLUMINANCE	Remarks
1	36 600	47.7 % (37 650 lx)	LFC = 79 000 lx
2	36 100	47.7 % (37 650 lx)	
3	38 000	47.7 % (37 650 lx)	
4	39 900	47.7 % (37 650 lx)	
Position of two masks	Illuminance, lx measured at LFC	Average as % of CENTRAL ILLUMINANCE	Remarks
1	42 800	48.6 % (48 100)	LFC = 98 900 lx
2	50 400	48.6 % (48 100)	
3	56 100	48.6 % (48 100)	
4	43 100	48.6 % (48 100)	

201.12.1.102.1.3h	Table: Measurement of remaining illuminance performed at LFC with tube and a pair of masks in four successive positions 45° apart - Figs. 201.113 and 201.114		P
Position of two masks	Illuminance, lx measured at LFC	Average as % of CENTRAL ILLUMINANCE	Remarks
1	33 700	45.5 % (27 145 lx)	LFC = 59 700 lx
2	27 000	45.5 % (27 145 lx)	
3	26 530	45.5 % (27 145 lx)	
4	21 350	45.5 % (27 145 lx)	
Position of two masks	Illuminance, lx measured at LFC	Average as % of CENTRAL ILLUMINANCE	Remarks
1	35 950	48.0 % (37 938 lx)	LFC = 79 000 lx
2	36 700	48.0 % (37 938 lx)	
3	38 700	48.0 % (37 938 lx)	
4	40 400	48.0 % (37 938 lx)	
Position of two masks	Illuminance, lx measured at LFC	Average as % of CENTRAL ILLUMINANCE	Remarks
1	43 600	49.5 % (48 925 lx)	LFC = 98 900 lx
2	51 300	49.5 % (48 925 lx)	
3	56 900	49.5 % (48 925 lx)	
4	43 900	49.5 % (48 925 lx)	

6.6 CONDITIONS OF THE USAGE ENVIRONMENT

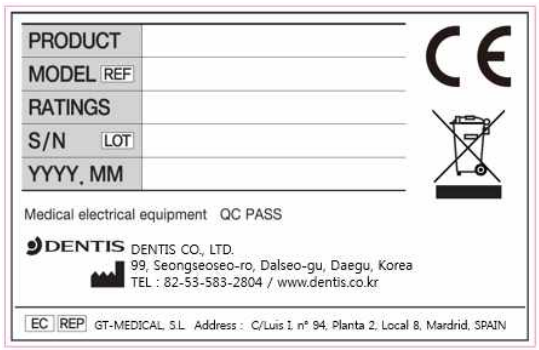
- Temperature: 0 ~ 40 oC
- Humidity: 30 ~ 90%
- Atmospheric pressure: 0-2000M (106-80Kpa)

6.7 CONDITIONS OF THE TRANSPORTATION ENVIRONMENT

- Temperature: 0 ~ 40 °C
- Humidity: 0 ~ 80%

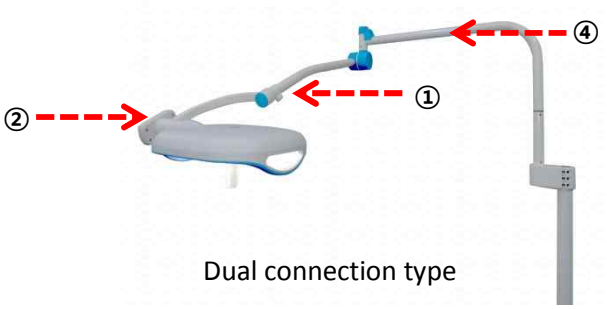
7. LABELLING REQUIRMENT

7.1 NAME PLATE

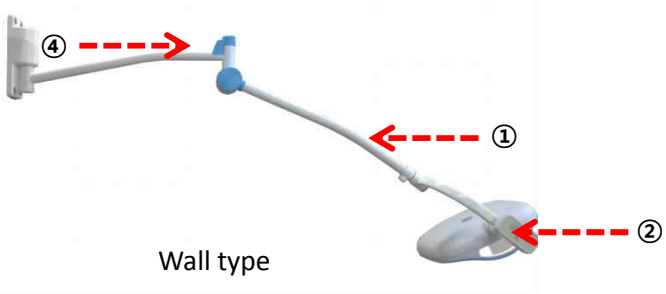
LABEL NAME	LABEL IMAGE	SIZE(mm)	NO.
PRODUCT LABEL		83 X 65	①
No pushing		20 X 20	③
Do not use this device in a bathtub, shower or water-filled reservoir		20 X 20	④
KNOB LABLE (On the plastic cover of KNOB)	PRODUCT: KNOB LOT NO: 2014.02.11 Manufacturer: DENTIS CO.,LTD 99, Seongseo seo-ro Dalseo-gu, Daegu, Korea	100 X 45	⑤

7.2 CAUTION AND INFORMATION MARK

⚠	Below is the reference for label positions. Please refer to 7.1 Name Plate for matching the indicated numbers to their name plates.



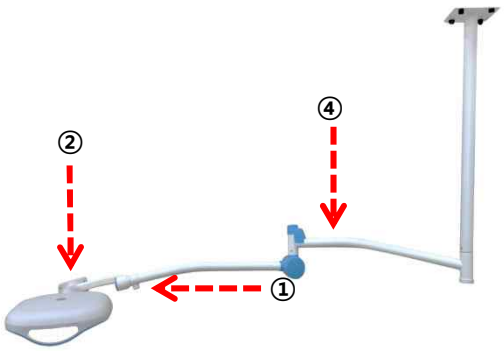
Dual connection type



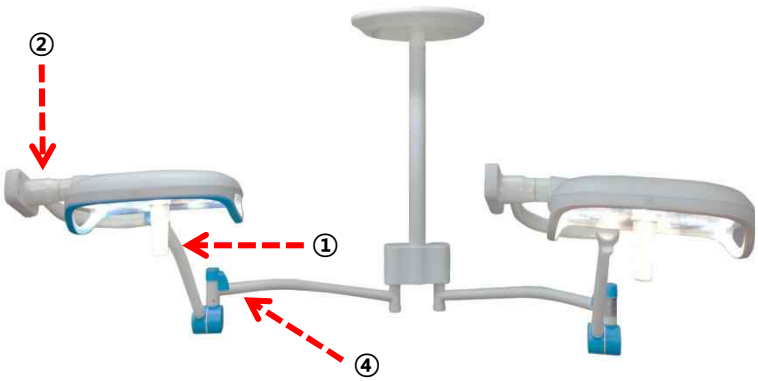
Wall type



Mobile type



Single ceiling type

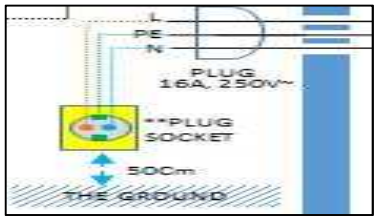
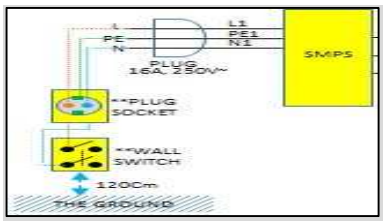
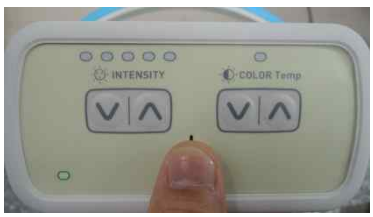


Dual ceiling type

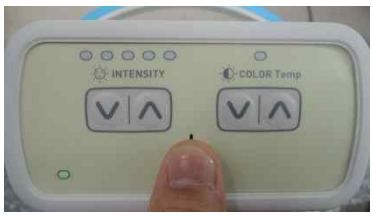
8. PRECAUTION BEFORE USE

	While moving the mobile type device for use, please do not step on the power adapter and do not place it on the ground.
	While moving the mobile type device for use, please refer to the instruction and the picture on the step 10 of 9. OPERATION.
	Do not push the mobile type device when wheels are locked.
	Please contact our branch office, if the power adapter is damaged.
	Please use the device after the power adapter and the grounded receptacle are connected.
	Before and after use, clean the head and handle with alcohol or ethanol.
	Use the SINGLE CEILING & DUAL CEILING device, after installing a wall switch.

9. OPERATION

Step 1	Before using the device, check the maneuverability of BOTTOM ASSY S2 by moving it up and down, left and down.	
Step 2	As shown in the image next, please plug the power code to the installed outlet. (DUAL CONNECTION, WALL, MOBILE) Plug the power cord to an outlet, shown and described in the picture. For a Mobile device, turn on the power switch, located at the bottom of the VERTICAL ARM's handle.	 
	For a Single Ceiling / Dual Ceiling device, a wall switch, as shown in the picture, must be installed first. To use the device, turn on the switch.	
	For a Dual Connection / Wall device, plug the power cord to the outlet first. Press STAND-BY ON/OFF button on the controller to turn ON the device.	
Step 3	When you press the STAND-BY ON/OFF button the first time, the LED light will turn on. When you press it again, the light will turn off.	

Step 4	Before and after using BOTTOM ASSY S2 HANDLE, please sterilize it with a specified disinfectant.	
Step 5	Select the desired color temperature (Orange, Pink, White) Select the desired luminosity(5steps)	  
Step 6	Move the head part to the desired position.	
Step 7	When KNOB is rotated clockwise, Pattern size is 180mm	

<table>
<tr><td></td><td>When KNOB is rotated counterclockwise, Pattern size is 300mm</td><td></td></tr>
<tr><td>Step 8</td><td>After using of device, turn off the STAND-BY button.</td><td></td></tr>
<tr><td rowspan="4">Step 9</td><td>After using the device, KNOB should be detached and sterilized.</td><td></td></tr>
<tr><td>⚠ Please pull out KNOB by pressing the fixing key, marked with a red arrow.</td><td></td></tr>
<tr><td>⚠ Always use the sterilized KNOB.</td><td></td></tr>
<tr><td>⚠
Sterilization (Autoclave: Picture 3)– Service Condition
Temperature: 125 ± 5℃
Pressure: 160 ± 50kPa (1.6 ±0.5 kgf/㎠)
Time: < 20 min</td><td>
<Picture 3></td></tr>
</table>

Step 10	The picture 1 demonstrates the method of moving the mobile type Check the wheel LOCK is OFF Storage method of device: Devices other than the mobile type must be positioned so that the user and patient can avoid any collisions with the devices. (Refer to the picture 1 and picture 2)	 <Picture 1>  <Picture 2>

	For the cleanliness of device, please clean the item with alcohol or ethanol by using a soft cloth or cotton and dry it. But, do not use thinner or benzene as it might cause discoloration or deformation of the device.

	DO NOT USE too much alcohol or ethanol.

	As this item is unprotected from water infiltration of IPXO, cleaning with water is prohibited.

	When the product is not being used, store it with its head directed upward, as indicated by a red arrow in the Picture 1 of STEP 10. The product may get damaged if not directed upward.

	Do not illuminate the light directly to the patient's eye during the operation. If it needs to be used for the patient's face, cover the patient's eyes with an eye path.

10. ADJUSTMENT AND MAINTENCANCE

10.1 ADJUSTMENT

⚠	A yearly checkup on the intensity and color temperature of the device at an authorized dealer is recommended.

If the head does not stay fixed and slides left or right,
Use a M5 wrench to adjust the tension of head joint.

Clockwise: Higher tension
Counterclockwise: Lower tension

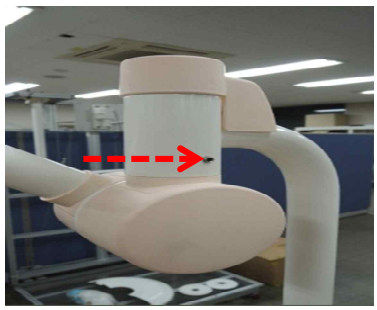




⚠	If the joint is wrenched clockwise too tightly, the joint arm may get damaged.

⚠	Do not attempt to repair any damage or wear and tear on the device. Please contact an authorized dealer for help.

10.2 MAINTENANCE

Trouble 1	If the LED light on the head does not operate.	- Check if the power code is plugged in the outlet properly. - Check if the STAND-BY INDICATOR LED in front of the control panel is on and green. - Press the Control panel stand-by button and check that the LED turns on. (If green light does not light on, do not attempt to repair it yourself, contact your local authorized dealer.)
Trouble 2	If head is not fixed after handling, moves left and right.	-Check that the verticality and horizontality of the installed device using circular leveler.  As shown in the picture, use the M3 wrench to tighten it. If the condition does not improve, do not attempt to repair. Please contact your local authorized dealer for help.
Trouble 3	If there is an error in the pattern formation.	Hold KNOB and check if rotation is prospered. (Refer operation step) If the condition does not improve, do not attempt to repair. Please contact your local authorized dealer for help.
Trouble 4	If the light shield cover is polluted.	Cleanse it with designated chemicals (Alcohol, Ethanol). If the essential performances of the device (Intensity of Illumination, Color Temperature) are seriously impaired, please contact your local authorized dealer for repair.

11. PACKING

11.1 MOBILE TYPE

Step 1	After packing the head part with an air cap, put it into the box.	
Step 2	Cover the component with the shock-absorbing packing materials.	
Step 3	Seal a box with tape.	
Step 4	After packing HORIZONTAL ARM with a woven fabric, put it into the box.	
Step 5	Pack VERTICAL ARM 1 and VERTICAL ARM 2 with a woven fabric, put it into the box. As shown the picture, put the box of HORIZONTAL ARM into the box of VERTICAL ARM 1 and VERTICAL ARM 2	
Step 6	Seal a box with tape.	

Step 7	After packing BASE PART with an air cap, put it into the box.	
Step 8	Cover the component with the shock-absorbing packing materials.	
Step 9	Spread some shock-absorbing packing materials on the bottom before putting BASE into the box.	
Step 10	After spreading some shock-absorbing packing materials on BASE, put SMPS.	
Step 11	Cover BASE & SMPS with the shock-absorbing packing materials.	
Step 12	Seal a box with tape.	

11.2 FIXED TYPE

Step 1	After packing the head part with an air cap, put it into the box.	
Step 2	Cover the component with the shock-absorbing packing materials.	
Step 3	Seal a box with tape.	
Step 4	After packing Fix ARM and the other components with an air cap or a woven fabric, put them into the box.	
Step 5	Seal a box with tape.	

12. APPENDIX

Manufacturer's Declaration

This Minor Surgical Luminaire (Luvis) is classified as Medical Electrical Equipment, requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the accompanying product documentation. Portable and mobile RF communications equipment can be effected to the Medical Electrical Equipment. This product complies with EMC requirements when the product is used with supplied accessories. The use of accessories that are not sold from DENTIS Co., Ltd. and specified as replacement parts for internal components may result in increased emissions or decreased immunity of this product. This product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used.

Table 201 - Guidance and manufacturer's declaration - Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS

This Minor Surgical Luminaire (Luvis) is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment – guidance
RF emissions CISPR 11	Group 1	This Minor Surgical Luminaire (Luvis) 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	This Minor Surgical Luminaire (Luvis) is suitable for use in all establishments other than domestic circumstance and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complied	

Table 202 - Guidance and manufacturer's declaration - Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

This Minor Surgical Luminaire (Luvis) is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment–guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact: ±6 kV	Contact : ±2, 4, 6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	Air: ±8 kV	Air: ±2, 4, 8 kV	
Electrical Fast Transient/BURST IEC 61000-4-4	Power supply lines: ±2 kV	Power supply lines: ±2 kV	The quality of main power should be that of a typical commercial or hospital environment.
	Input/output lines: ±1 kV	Not applicable	
Surge IEC 61000-4-5	Differential mode: ± 0.5, ± 1 kV	Differential mode: ± 0.5, ± 1 kV	The quality of main power should be that of a typical commercial or hospital environment.
	Common mode: ± 0.5, ± 1, ±2 kV	Common mode: ± 0.5, ± 1, ±2 kV	
Dips and Interruptions IEC 61000-4-11	0 %UT (Dip/Int. 100 %UT) for 0.5 Period	0 %UT (Dip/Int. 100 %UT) for 0.5 Period	The quality of main power should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during main power interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
	40 %UT (Dip/Int. 60 %UT) for 5 Period	40 %UT (Dip/Int. 60 %UT) for 5 Period	
	70 %UT (Dip/Int. 30 %UT) for 25 Period	70 %UT (Dip/Int. 30 %UT) for 25 Period	
	0 %UT (Dip/Int. 100 %UT) for 250 Period	0 %UT (Dip/Int. 100 %UT) for 250 Period	
Magnetic Field Immunity IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE The Dips/Interruption test is only applicable to AC mains.			

Table 204 - Guidance and manufacturer's declaration - Electromagnetic Immunity - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

This Minor Surgical Luminaire (Luvis) is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz	3 V	Portable and mobile RF communications equipment should not be used close to any part of this minor surgical luminaire, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ $d = 2{,}3\sqrt{P}$ 80 MHz- 1 GHz 1 GHz- 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a) should be less than the compliance level in each frequency range. b)Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1 GHz 1 GHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) 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 this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.

b) Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206 - Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

This minor surgical luminaire is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter M**		
	0.15 MHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 1 GHz $d = 1{,}2\sqrt{P}$	1 GHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

Declaration of Conformity

CE Declaration of Conformity

27 February 2017

In accordance with EC directives 93/42/EEC Medical Device Directive as amended by 2007/47/EC, Annex I and Annex VII. We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the requirements of the above EC Directive. If the device is modified without the agreement of the undersigned, this declaration becomes invalid.

* T.C.F. No. .....: TCF-002 (Rev.2)
* Product name.....: Minor Surgical Luminaire
* Type designation .....: S200
* Model designation.....: See the next page
* Classification.....: Class I (Rule 12)
* GMDN code .....: 37332 Light system, surgical
* Trade marks.....: Luvis DENTIS

* Relevant EC Directives: 93/42/EEC Medical Device Directive as amended by 2007/47/EC, Annex I and Annex VII.
* Applied Standards:

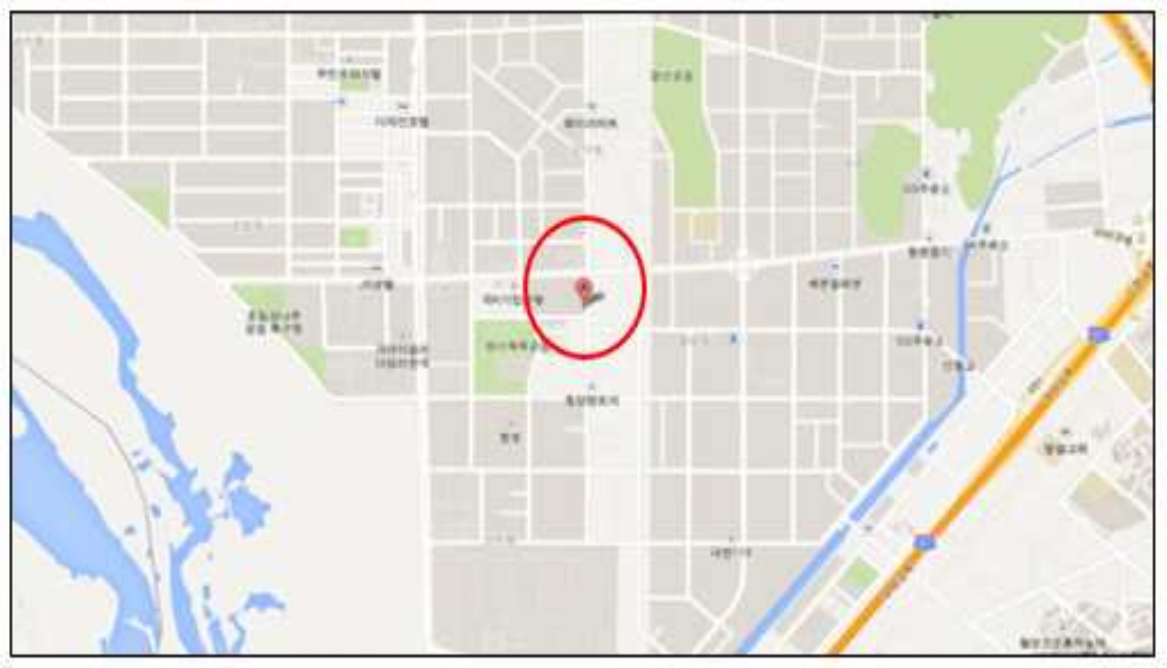
EN ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 1041:2008, Information supplied by the manufacturer with medical devices
EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purpose
EN ISO 14971:2012, Medical devices – Application of risk management to medical devices
IEC 60601-1:2005+A1:2012, Medical electrical equipment – Part 1: General requirements for safety
EN 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests
EN 60601-1-6:2010, Medical electrical equipment-Part 1-6: General requirements for safety – Collateral Standard: Usability
EN ISO 7010:2012, Graphical symbols – Safety colors and safety signs-Registered safety signs
EN 62471:2008, Photo biological safety of lamps and lamps systems
EN 62366:2008, Medical devices – Application of usability engineering to medical devices
IEC 60601-2-41:2009, Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
IEC 62304:2006, Medical device software, Software life cycle process

Manufacturer's Name: DENTIS CO., LTD.
Manufacturer's Address: 99, Seongseoseo-ro, Dalseo-gu, Daegu, Korea
EC Representative Address: CALMED INVEST Kft. 1182 Budapest, Fiume utca 3., Budapest, Hungary
Date: 27 February 2017
President: Sim Ki-Bong

Location of Head office& EC REP

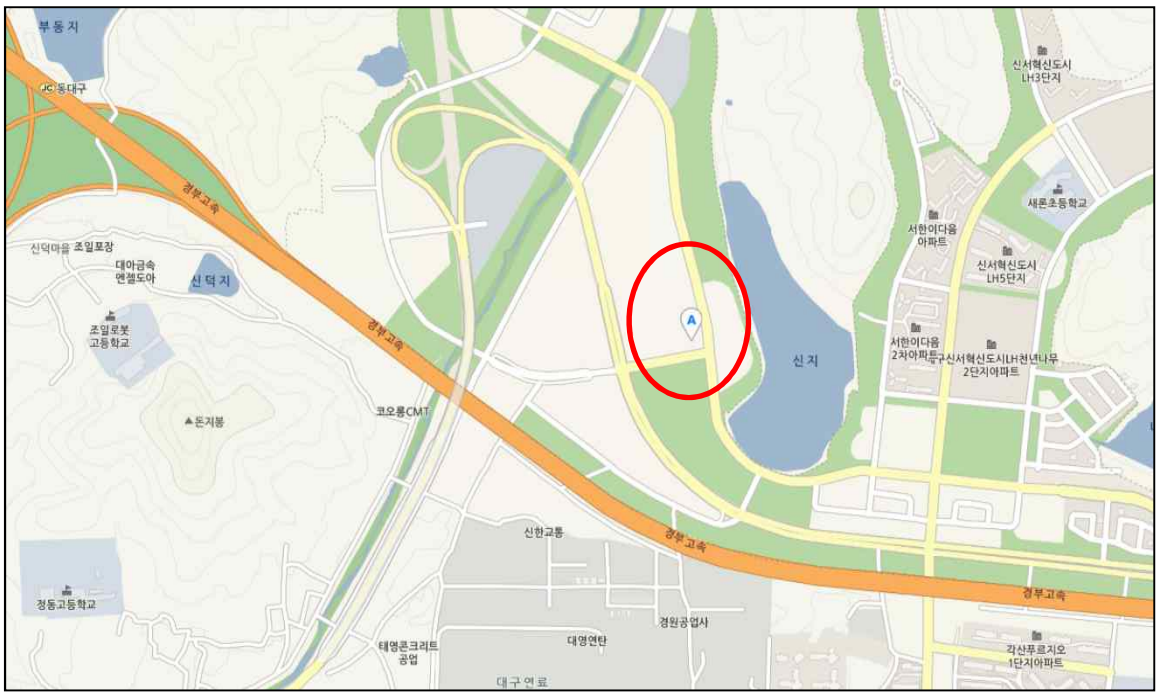
- Manufacturer: DENTIS CO., LTD.

  99, Seongseoseo-ro, Dalseo-gu, Daegu, Korea



- Factory : DENTIS MEDICAL DIVISION

  6, Yuram-ro, Dong-gu, Daegu, Korea

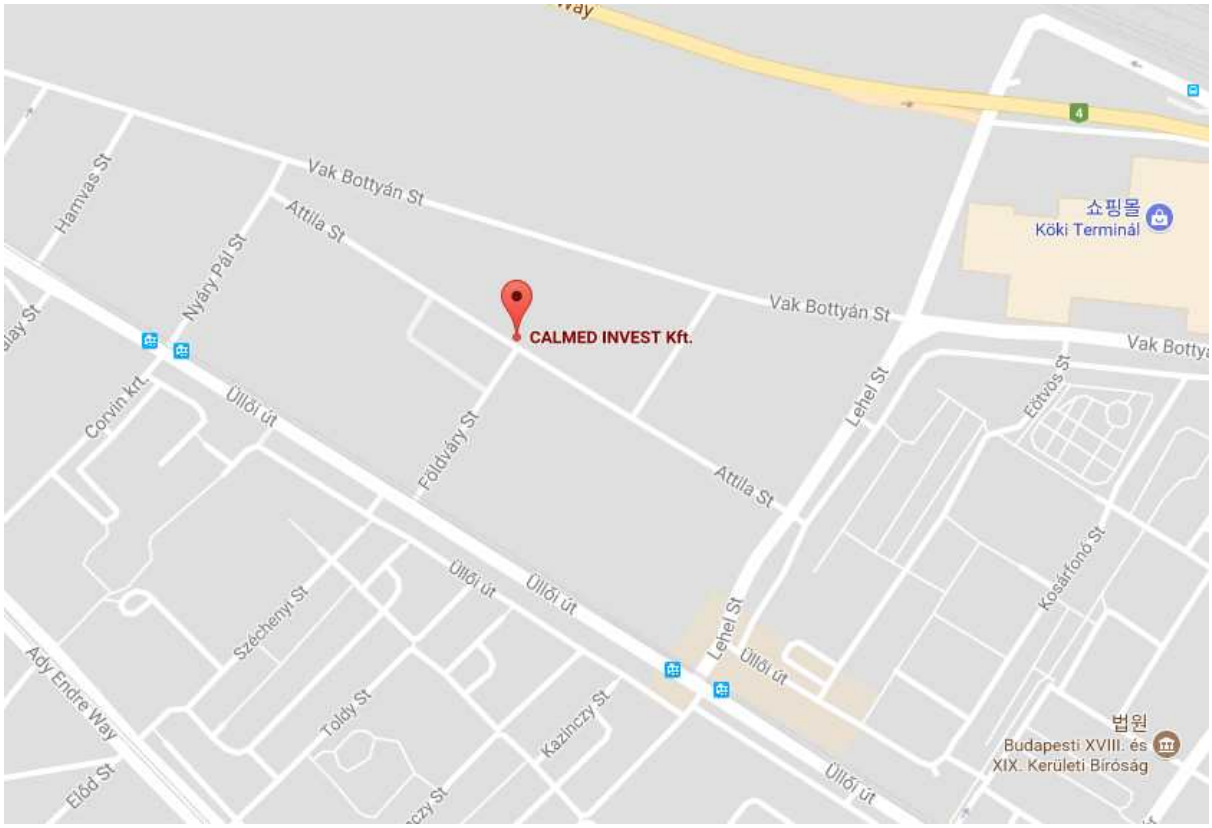




LOCATION OF EC REP

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MEMO

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