USER'S MANUAL

Luminaire for Diagnosis

LUVIS | E100

* Be sure to read the manual before using this product.

LUVIS | MEDICAL SYSTEMS

CONTENTS

⚠ WARNING : Modification of this equipment is not allowed

1. Standard

* Certification of DENTIS

· EN ISO 13485:2016

· Relevant EC Regulation: REGULATION (EU) 2017/745

* Applied Standards

· EN ISO 15223-1:2016, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

· EN 1041:2008/A1:2013, Information supplied by the manufacturer with medical devices

· EN ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purpose

· EN ISO 14971:2019, Medical devices – Application of risk management to medical devices

· EN 60601-1:2006/A1:2013, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

· EN 60601-1-2:2015, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests

· EN 60601-1-6:2010, Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

· EN ISO 7010:2019, Graphical symbols – Safety colors and safety signs-Registered safety signs

· EN 62471:2008, Photo biological safety of lamps and lamps systems

· EN 62366-1:2015, Medical devices – Application of usability engineering to medical devices

· IEC 60601-2-41:2009/A1:2015, Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

· IEC 62133:2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

· IEC 62304:2006/A1:2015, Medical device software, Software life-cycle processes

2. Cautions and Warnings

⚠ **CAUTION(ATTENTION)** This ME Equipment is intended only for use in the professional healthcare facility environment, e.g. public and private hospitals, specialized medical offices, etc. This ME Equipment is intended for direct use on operation theatres and nearby HF surgical equipments, where the intensity of EM DISTURBANCES complies with the applicable standards. For further instructions please follow the chapter “Electromagnetic compatibility” of the User's Manual.
- Cet équipement ME est destiné uniquement à être utilisé dans l'environnement des établissements de santé professionnels, p. ex. hôpitaux publics et privés, cabinets médicaux spécialisés, etc. Cet équipement ME est destiné à être utilisé directement sur les salles d'opération et les équipements chirurgicaux HF situés à proximité, où l'intensité des perturbations électromagnétiques est conforme aux normes applicables. Pour de plus amples instructions, veuillez suivre le chapitre « Compatibilité électromagnétique » du Manuel de l'utilisateur.

⚠ **CAUTION(ATTENTION)** If this ME Equipment is lost or degraded the performance due to EM DISTURBANCES, result in improper operation and degradation of the performance.
- Si cet équipement est perdu ou dégradé en raison de perturbations électromagnétiques, il en résulte un mauvais fonctionnement et une dégradation de la performance.

⚠ **CAUTION(ATTENTION)** All cables and maximum lengths of coaxial cables that are replaceable by the DENTIS and that are likely to affect compliance of the this ME Equipment with the requirements of EMC(Electro-Magnetic compatibility). Do not modify this ME Equipment.
- Tous les câbles et longueurs maximales des câbles coaxiaux remplaçables par DENTIS et susceptibles d'affecter la conformité de cet ÉQUIPEMENT ME aux exigences de la CEM (Compatibilité Électro-Magnétique).
Ne modifiez pas cet ÉQUIPEMENT ME.

⚠ **CAUTION(ATTENTION)** 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.
- Les caractéristiques d'ÉMISSIONS de cet équipement le rendent adapté à une utilisation dans des zones industrielles et des hôpitaux (CISPR 11 classe A). S'il est utilisé dans un environnement résidentiel (où la classe B CISPR 11 est normalement requise), cet équipement pourrait ne pas offrir une protection adéquate aux services de communication radiofréquence. L'utilisateur pourrait devoir prendre des mesures d'atténuation, telles que déplacer ou réorienter l'équipement.

⚠ **WARNING(AVERTISSEMENT)** Use of this ME Equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- L'utilisation de cet ÉQUIPEMENT ME à proximité ou empilé avec d'autres équipements doit être évitée car cela pourrait entraîner un fonctionnement incorrect. Si une telle utilisation est nécessaire, cet équipement et les autres équipements doivent être surveillés pour vérifier qu'ils fonctionnent normalement.

⚠ **WARNING(AVERTISSEMENT)** Use of accessories, transducers and cables other than those specified or provided by DENTIS of this ME Equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- L'utilisation d'accessoires, de transducteurs et de câbles autres que ceux spécifiés ou fournis par DENTIS pour cet ÉQUIPEMENT ME pourrait entraîner une augmentation des émissions électromagnétiques ou une diminution de l'immunité électromagnétique de cet équipement, et entraîner un fonctionnement incorrect.

⚠ **WARNING(AVERTISSEMENT)** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm(12 inches) to any part of the E100, including cables specified by DENTIS. Otherwise, degradation of the performance of this equipment could result.
- L'équipement haute fréquence et l'équipement de communication RF portable (y compris les périphériques comme les câbles d'antenne et les antennes externes) ne doivent pas être utilisés à moins de 30 cm de toute partie du E100, y compris les câbles spécifiés par DENTIS. Sinon, il pourrait en résulter une dégradation de la performance de cet équipement.

⚠ **WARNING(AVERTISSEMENT)** The instructions given in this document must be followed when handling the product. Failure to do so may endanger the safety of the installers or users.
As well as specific information on operating the entire product and conducting preventive main tenance, are provided in the USER’S MANUAL.
For further information, please contact our sales network or our local network.
- Les instructions données dans ce document doivent être suivies lors de la manipulation du produit. Ne pas le faire peut mettre en danger la sécurité des installateurs ou des utilisa teurs. Des informations spécifiques sur le fonctionnement du produit dans son ensemble et sur l'exécution de la maintenance préventive sont fournies dans le MANUEL DE L'UTILISATEUR.
Pour plus d'informations, veuillez contacter notre réseau de vente ou notre réseau local.

⚠ **WARNING(AVERTISSEMENT)** The electrical connections must be performed by a qualified technician only.
The electrical installation must be planned, performed and inspected by electrical engineers.
- Les connexions électriques ne doivent être effectuées que par un technicien qualifié.
L'installation électrique doit être planifiée, exécutée et inspectée par des ingénieurs élec triciens.

⚠ **WARNING(AVERTISSEMENT)** The LIGHTHEAD is designed to operate using a AC 100-240V, 50-60 Hz. Higher or lower voltages may affect the light intensity and operating life of the LEDs.
Damaged wire insulation may result in the risk of electric shock.
To protect against the risk of electrocution, connect the power cables carefully.
Luminaire for diagnosis is class II for protection against electric shock.
- La LIGHTHEAD est conçue pour fonctionner à AC 100 - 240 V 50 - 60 Hz. Des tensions plus ou moins fortes peuvent affecter l'intensité lumineuse et la durée de vie utile des DEL.
Le luminaire pour le diagnostic (Luvis E100) est de classe II pour la protection contre les chocs électriques.

⚠ **WARNING(AVERTISSEMENT)** Damaged wire insulation may result in the risk of electric shock.
- L'isolation des fils endommagés peut entraîner un risque de choc électrique.

⚠ **WARNING(AVERTISSEMENT)** This product may only be repaired and special assembly work may only be carried out by DENTIS or a company that has been authorized by DENTIS.
- Ce produit ne peut être réparé et des travaux d'assemblage spéciaux ne peuvent être effectués que par DENTIS ou une entreprise autorisée par DENTIS.

⚠ **WARNING(AVERTISSEMENT)** Do not look directly into light source(LED).
- Ne regardez pas directement la source lumineuse (LED)

⚠ **WARNING(AVERTISSEMENT)** 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.
- Toutes les informations contenues dans ce manuel ont été soigneusement vérifiées et jugées exactes au moment de la publication. Cependant, DENTIS décline toute responsabilité pour les résultats causés par des défauts, des omissions ou une mauvaise utilisation de celles-ci.

⚠ **WARNING(AVERTISSEMENT)** 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.
- DENTIS se réserve le droit de modifier le produit lui-même ou les spécifications du produit sans préavis, ainsi que le droit de ne pas renouveler cette modification dans ce manuel.

⚠ **WARNING(AVERTISSEMENT)** Do not press more than two buttons simultaneously.
In case of abnormal operation (overpower) of this product, stop the medical treatment and contact the place of purchase.
- Ne pas appuyer sur plus de deux boutons simultanément. En cas de fonctionnement anormal (surcharge) de ce produit, arrêtez le traitement médical et contactez le lieu d'achat.

⚠ **WARNING(AVERTISSEMENT)** The circuit of medical device must be installed in the state with the means to electrically separate with in all poles from the POWER SUPPLY.
- Le circuit du dispositif médical doit être installé dans un état permettant une séparation électrique de tous les pôles de l'ALIMENTATION.

⚠ **WARNING(AVERTISSEMENT)** When using the Adapter type, be sure to make easy connect and disconnect the power cord.
- Lorsque vous utilisez le type Adaptateur, assurez-vous de faciliter la connexion et la déconnexion du cordon d'alimentation.

3. Symbol

Symbol (Symbole)	Meaning (Signification)	Remark (Remarque)
CE	**CE Mark** The device bears the CE mark and complies with the requirements of Regulation (EU) MDR 2017/745 for medical device. - L'appareil porte le marquage CE et est conforme aux exigences du Règlement (UE) MDR 2017/745 relatif aux dispositifs médicaux.	④, ⑤, ⑥
CLASSIFIED c UL us	MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECH ㅋANICAL HAZARDS ONLY IN ACCORDANCE WITH [ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14] - MATÉRIEL MÉDICAL – GÉNÉRALITÉS CONCERNANT LES CHOCS ÉLECTRICAUX, LES INCENDIES ET LES DANGERS MÉCANIQUES SEULEMENT CONFORMÉMENT AUX [ANSI/AAMIES 60601-1:2005/(R)2012 et A1:2009/(R)2012/(R)2012, CAN/CSA C222 No. 60-114]	④, ⑤, ⑥
	Recommendation - Recommandation	⑤
	Protective earth (ground) - Terre de protection	②
	Alternating current - Courant alternative	②
	Stand-by - Mode veille	③
	Do not throw away with general household waste - Ne pas jeter avec les déchets ménagers ordinaires	④, ⑤, ⑥
	Caution - ATTENTION	⑤
	Warning - AVERTISSEMENT	⑤
	Operating instructions - Suivre les instructions d'utilisation	⑤
	Follow instructions for use - Action obligatoire générale	⑥
	General mandatory action - Pousser interdit	①
	Pushing prohibited - GARDER À L'ÉCART DE LA PLUIE	①
	KEEP AWAY FROM RAIN - NE PAS UTILISER DE CROCHETS À MAIN	④
	USE NO HAND HOOKS - FRAGILE, MANIPULER AVEC PRÉCAUTION	④
	FRAGILE, HANDLE WITH CARE - TOUJOURS GARDER DANS CE SENS	④
	THIS WAY UP	④

Symbol (Symbole)	Meaning (Signification)	Remark (Remarque)
5	Do not build up more than 5 boxes - Ne pas empiler plus de 5 boîtes	④
	Manufacturer - Fabricant	④, ⑤, ⑥
EC REP	Europe Representative - Représentant en Europe	⑤, ⑥
	Date of manufacture - Date de fabrication	⑤, ⑥
40℃ max 0℃ min	Temperature between 0 - 40˚C - Température entre 0 - 40˚C	④
80% 0%	Humidity between 0 - 80%RH - Humidité entre 0 - 80 %HR	④
106Kpa 80Kpa	Atmospheric pressure between 80Kpa – 106Kpa - Pression atmosphérique entre 80 kPa – 106 kPa	④
	Recycling - Recyclage	④, ⑤

No	Location
①	Marking on the outside of ME EQUIPMENT
②	Marking on the inside of ME EQUIPMENT
③	Marking on the controls of ME EQUIPMENT
④	Marking on the packing label of ME EQUIPMENT
⑤	Marking on the manual of ME EQUIPMENT
⑥	Marking on the label of ME EQUIPMENT

4. Introduction

4.1 Intended use

· Luvis Luminaire for Diagnosis(E100) is used for treatment or diagnosis in operating theatres or in medical rooms (groups 0, 1 and 2 according to IEC 60364-7-710)

· Classification under the provision of 93/42/EEC(MDD) : Class I
- Luvis Luminaire for Diagnosis(E100) is classified as a Class I device.

· Form of protection against electric shock : Class II
- Luvis Luminaire for Diagnosis(E100) is classified as Class II

· Degree of protection against flammability
- Luvis Luminaire for Diagnosis(E100) is classified as a device not suitable to be used in a potentially flammable environment.
- Do not use near flammable materials.

· Method(s) of cleaning recommended by the manufacturer.
- The LIGHTHEAD should be cleaned with cloths and a specified disinfectant.

· Mode of operation
- Classification of Luvis Luminaire for Diagnosis(E100) : continuous operation.

4.2 General description

· The user must ensure 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.

4.3 Environmental requirement

· Conditions of the usage environment
- Temperature : 0 - 40°C
- Relative Humidity : 30 - 90%RH
- Atmospheric pressure : 0-2,000 m (106-80 kpa)

· Conditions of storage and transportation environment
- Temperature : 0 - 40 °C
- Relative Humidity : 0 - 80 %
- Atmospheric pressure: 0 - 2,000 m (106 – 80 Kpa)

4.4 Safety information

· Luvis Luminaire for Diagnosis(E100) as a medical device complies with the safety regulation EN/IEC 60601-1.

· Furthermore all configurations shall comply with the system standard EN 60601-1-2:2015.

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

· For EU Countries
Europe Representative
KTR Europe GmbH
Mergenthalerallee 77, 65760 Eschborn, Germany

· 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.

4.5 Warranty regulation

· DENTIS warrants all products against defects in materials or workmanship for two 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 Ass'y is covered under 60,000 hrs warranty.

4.6 Electromagnetic Compatibility

4.6.1 Emission

This ME equipment is intended for use in Professional healthcare facility environment.		
Emission test	**Compliance**	**Guidance**
Conducted Disturbance CISPR 11(EN 55011)	Complies (Group 1, Class A)	This ME equipment 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.
Radiated Disturbance CISPR 11(EN 55011)		
Harmonic current IEC 61000-3-2	Complies	This ME equipment is suitable for use in all establishments other than domestic premises and those directly connected to the public low-voltagepower supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

4.6.2 Immunity

<table>
<tr><th colspan="3">This ME equipment is intended for use in Professional healthcare facility environment.</th></tr>
<tr><th>Immunity test</th><th>EN 60601-1-2:2015</th><th>Compliance</th></tr>
<tr><td>Electrostatic Discharge(ESD) IEC 61000-4-2</td><td>Direct: ± 8 kV Contact
± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air
Indirect: ± 8 kV HCP/VCP</td><td>Complies</td></tr>
<tr><td>Radio Frequency Electromagnetic Fields IEC 61000-4-3</td><td>3 V/m @ 80 MHz ~ 2.7 GHz
80 % AM at 1 kHz</td><td>Complies</td></tr>
<tr><td>Proximity fields from RF wireless communications equipment IEC 61000-4-3</td><td>
<table>
<tr><th>Frequency (MHz)</th><th>Modulation</th><th>Immunity Level (V/m)</th></tr>
<tr><td>385</td><td>**Pulse Modulation: 18 Hz</td><td>27</td></tr>
<tr><td>450</td><td>*FM + 5Hz deviation: 1 kHz sine</td><td>28</td></tr>
<tr><td>710
745
780</td><td>**Pulse Modulation: 217 Hz</td><td>9</td></tr>
<tr><td>810
870
930</td><td>**Pulse Modulation: 18 Hz</td><td>28</td></tr>
<tr><td>1 720
1 845
1 970</td><td>**Pulse Modulation: 217 Hz</td><td>28</td></tr>
<tr><td>2 450</td><td>**Pulse Modulation: 217 Hz</td><td>28</td></tr>
<tr><td>5 240
5 500
5 785</td><td>**Pulse Modulation: 217 Hz</td><td>9</td></tr>
</table>
** The carrier shall be modulated using a 50 % duty cycle square wave signal.
* As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</td><td>Complies</td></tr>
<tr><td>Fast Transients IEC 61000-4-4</td><td>
<table>
<tr><th>Voltage</th><th>AC/DC power ports</th><th>Signal ports</th></tr>
<tr><td>Test voltage</td><td>± 2 kV</td><td>± 1 kV</td></tr>
</table>
- 100 kHz repetition frequency</td><td>Complies</td></tr>
<tr><td>Surges IEC 61000-4-5</td><td>
<table>
<tr><th>Voltage</th><th>Power lines</th></tr>
<tr><td>Test voltage</td><td>Line to Line : ± 0.5 kV, ± 1 kV
Line to ground: ± 0.5 kV, ± 1 kV, ± 2 kV</td></tr>
</table></td><td>Complies</td></tr>
<tr><td>RF Continuous Conducted IEC 61000-4-6</td><td>3 V @ 0.15 MHz ~ 80 MHz
6 V @ in ISM bands between 0.15 MHz and 80 MHz
80 % AM at 1 kHz</td><td>Complies</td></tr>
<tr><td>Power Frequency Magnetic Fields IEC 61000-4-8</td><td>30 A/m @ 50 Hz or 60 Hz</td><td>Complies</td></tr>
<tr><td>Voltage Dips, Interruptions, and Variations IEC 61000-4-11</td><td>• Voltage Dips
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°
• Voltage Interruptions
0 % UT; 250/300 cycle
• Voltage Variations
<table>
<tr><th>Frequency (Hz)</th><th>Ranges</th></tr>
<tr><td>50</td><td>49, 50, 51</td></tr>
<tr><td>60</td><td>59, 60, 61</td></tr>
</table></td><td>Complies</td></tr>
</table>

5. Product Specification

5.1 Technical specification (In accordance with EN/IEC 60601-2-41)

· STANDARD SPECIFICATION

Specifications	Unit	E100	Remark
Central illuminance Ec (@50cm)	lx	30,000 / 45,000 / 60,000	
Electronic adjustment range	%	50~100	
Light field diameter d10	cm	17	
colour temperature (3 levels)	K	3,500 / 4,000 / 4,500	
colour rendering index, Ra	N/A	95	

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

5.2 Electrical specification (In accordance with EN/IEC 60601-1)

· ADAPTER TECHNICAL DATA

Content	Luvis E100
Input	AC 100–240 V, 50-60 Hz, 0.6 A
Output	DC 15 V, 1.67 A
Power	Max 25 W

Wall Plug-in SMPS
(Interchangeable Blades)

· E100 RATING

Content	Rating	Remark
E100	AC 100-240 V, 28-46 VA, 50-60 Hz	

⚠ WARNING : Use the special adapter, which Must provided by the DENTIS.

5.3 Mechanical specification

· Component

Content	Weight(kg)
LIGHTHEAD + FIRST HEAD ARM + SECOND HEAD ARM	1.9
Mobile Stand (VERTICAL ARM + BASE)	4.9
CLAMP	0.5
WALL BRACKET	0.5
CEILING BRACKET	1.0
CEILING ARM	4.6

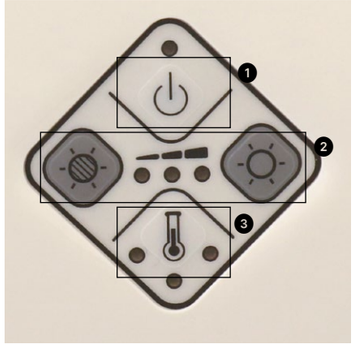
6. Other characteristic

Specifications	Luvis E100	Remark
Protection against electric shock	Class II Protection	
Protection against harmful ingress of water or particulate matter	Ordinary	Head part : IP43

7. Use

7.1 HEAD CONTROLLER

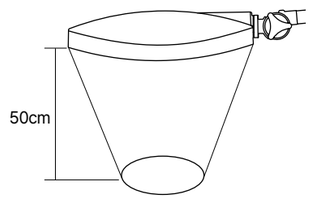
· The LIGHT HEAD can be controlled using the HEAD CONTROLLER



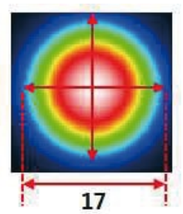
No.	Name	Description
❶	Standby Button	Power On/Off
❷	Intensity Control Button	3 Steps adjustable : 30,000/45,000/60,000 lx
❸	Color Temp. Control Button	3 Steps adjustable : 3,500/4,000/4,500 K

7.2 Positioning

· Positioning the E100 LIGHTHEAD



* Recommended distance : 50cm

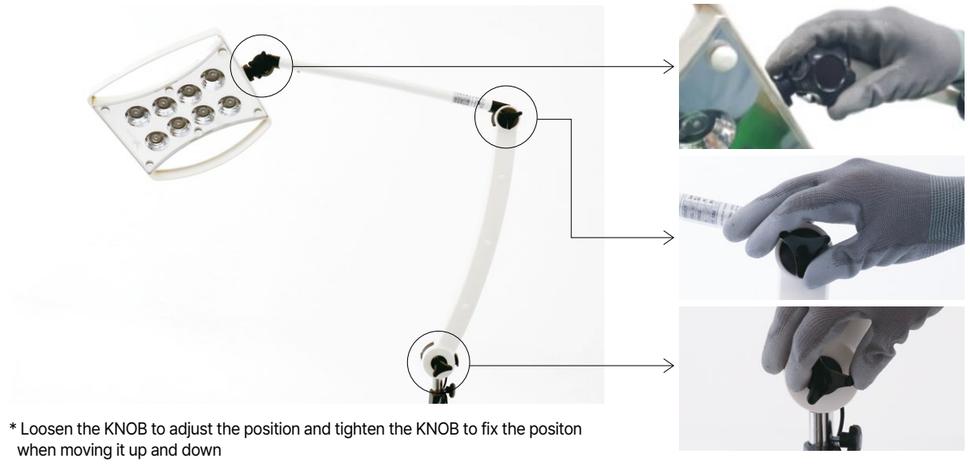


* Light field Dlametor : 17cm

8. Performance characteristic

8.1 HEAD and MAIN ARM

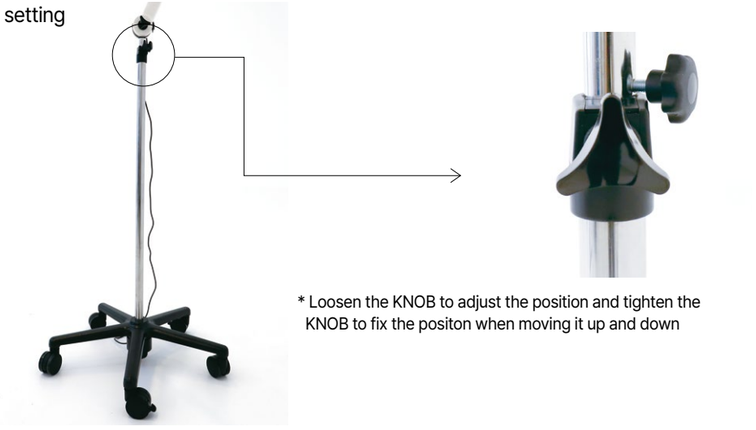
· HEAD and ARM PART Tension setting



* Loosen the KNOB to adjust the position and tighten the KNOB to fix the positon when moving it up and down

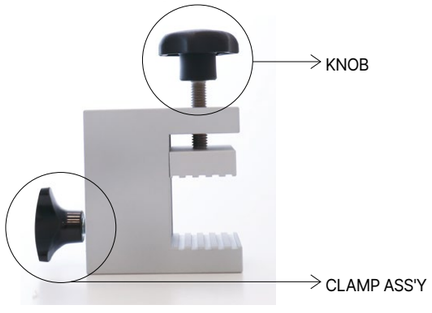
8.2 E100 Mobile(E1-M)

· VERTICAL ARM Height setting



* Loosen the KNOB to adjust the position and tighten the KNOB to fix the positon when moving it up and down

8.3 E100 Clamp(E1-C)

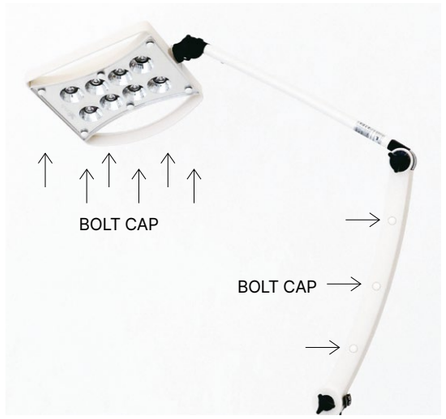


* Loosen the KNOB to adjust the position and tighten to fix the positon.

8.4 E100 Wall(E1-W)

* Loosen the KNOB to adjust the position and tighten the KNOB to fix the positon.

8.5 Checking cover and cap

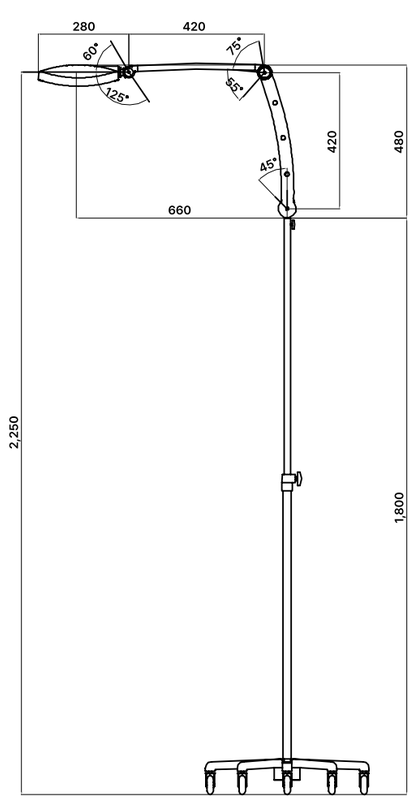


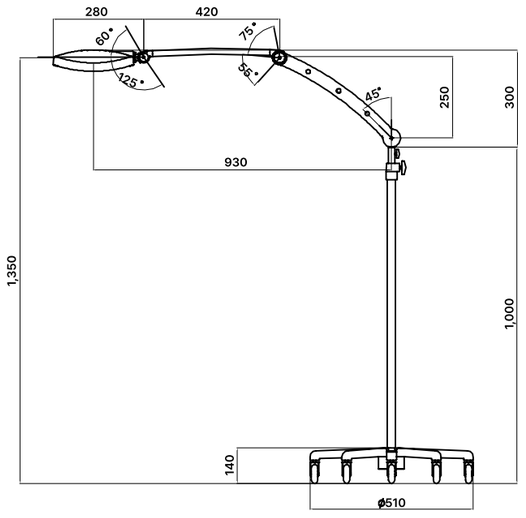
* Check that all covers and bolt caps are in place.

8.6 Operating range of E100

· MOBILE TYPE

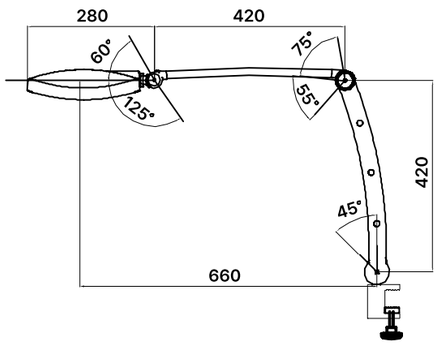
(Unit : mm)





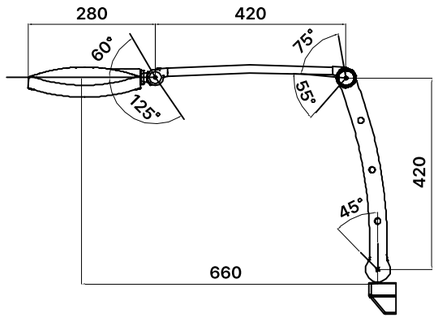
· CLAMP TYPE

(Unit : mm)



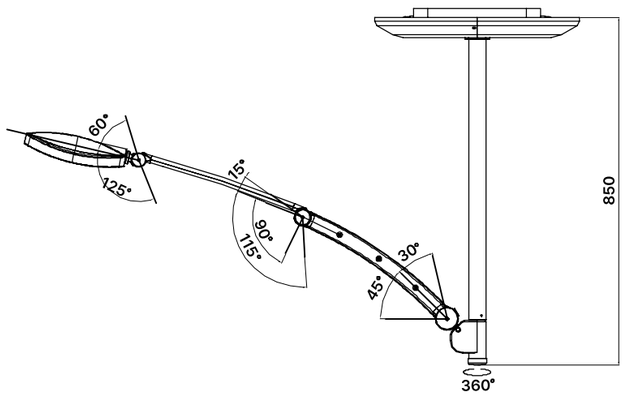
· WALL TYPE

(Unit : mm)



· CEILING TYPE

(Unit : mm)



⚠ WARNING
1. Do not place things on or hang on MAIN ARM.
2. If this device is operated beyond the indicated angles, it can be damaged.

9. Cleaning

⚠ WARNING
Before and after use, clean the LIGHTHEAD with alcohol or ethanol.
It is not allowed to use agents which contain the following substances :
High-concentration organic and inorganic acids, Chlorinated hydrocarbons.

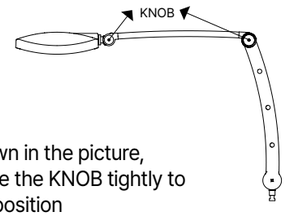
10. Maintenance

⚠ WARNING
1. A electrical and mechanical check-up should be done every year.
Disconnect the pendant system from the mains before any maintenance work to prevent electric shock.

2. Check points on maintenance work
- Defects of paint
- Plastic fissures
- Loosened parts.
- Free rotatability / limit stops and deformation of the suspension
- The connection between LIGHTHEAD and components
- Defect of the KNOB

3. In case of failure or damage, please contact your supplier.

11. Troubleshooting

No.	Problem	Cause	Corrective action
1	the LED light on the LIGHT-HEAD does not turn on.	Power cut	Check if supply mains are operating.
		Others	Press the stand-by button of the control panel and check that the LED turns on. (If green light does not light on, do not attempt to repair it yourself, please contact your supplier)
2	If LIGHTHEAD is not fixed after handling, moves up and down.	KNOB incorrectly adjusted Loosen the KNOB to adjust the position and tighten the KNOB to fix the positon when moving it up and down	 As shown in the picture, Immerse the KNOB tightly to fix the position
3	If there is an error in the light field diameter.	Inappropriate distance	Check if recommended distance(50cm) between the LIGHTHEAD to the patient's body. If the condition does not improve, do not attempt to repair. Please contact your supplier.
4	If the SAFETY COVER of the LIGHTHEAD is polluted.	Pollution	Cleanse it with designated chemicals (Alcohol, Ethanol). If the essential performances of the device (Intensity of Illumination, colour temperature) are seriously impaired, please contact your supplier.

12. Disposal

1. For environment and safety of human, wastes must be recycled or separated.
   - The materials should be carefully separated.
   - The electrical boards should be submitted to an appropriate recycling proceeding
   - The cardboard box may be recycled with other paper products.

2. Please contact the closest DENTIS branch or your supplier, if you have any questions about recycling of the device.

13. Model designation

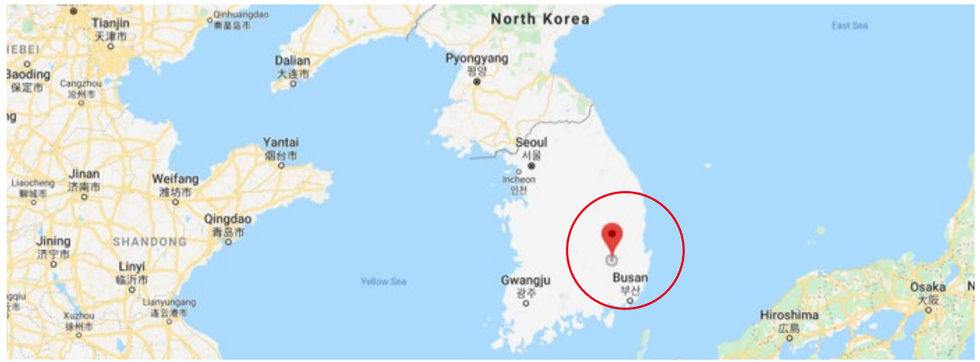
Model	-	Mount Type
E100	-	E=Ceiling Type W=Wall Type C=Clamp Type M=Mobile Type

14. List of components

LIGHTHEAD + HEAD ARM	MOBILE VERTICAL ARM	CLAMP	WALL BRACKET	CEILING BRAKET & ARM HOUSING CAP
				
CEILING VERTICAL ARM	**CEILING COVER and BRACKET**	**ADAPTER**		
				

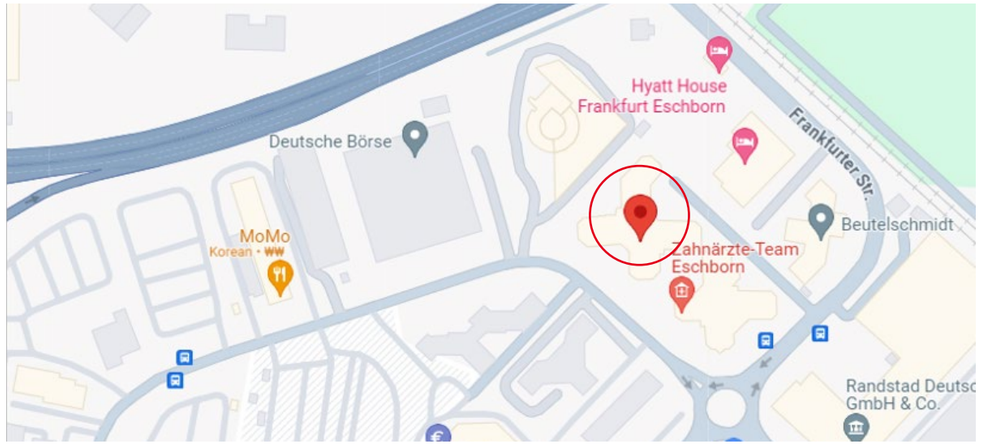
15. Manufacturer and Factory

Manufacturer, Factory : DENTIS MEDICAL DIVISION
6, Yuram-ro, Dong-gu, Daegu, Republic of Korea



16. Europe Representative

Location of KTR Europe GmbH. Mergenthalerallee 77, 65760 Eschborn, Germany



LUVIS | MEDICAL SYSTEMS

DENTIS

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