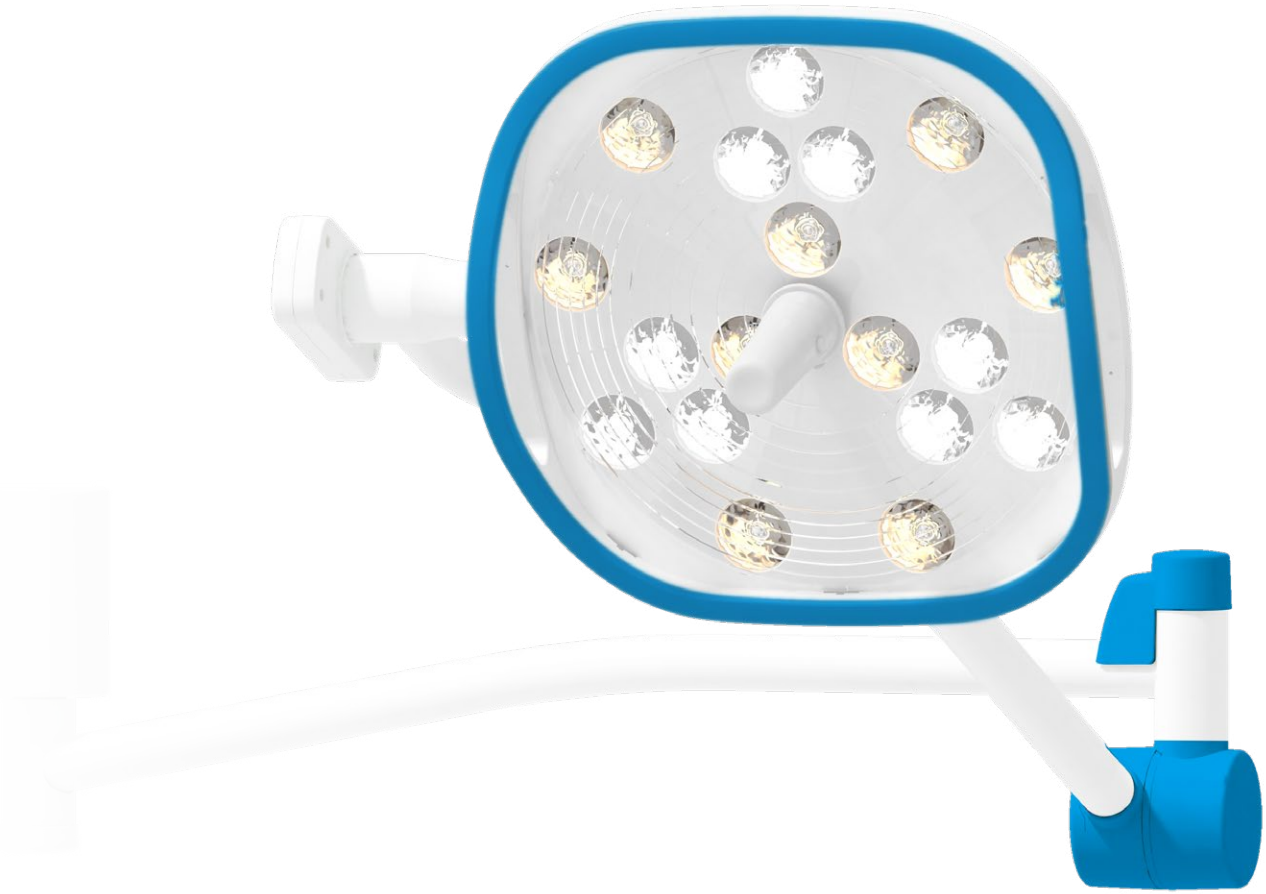
USER'S MANUAL

Minor Surgical Luminaire

LUVIS | S200



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

LUVIS | MEDICAL SYSTEMS

CONTENTS

WARNING: Modification of this equipment is not allowed

1. Standards

* 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+A2:2021, 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 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 S200, including cables specified by DENTIS. Otherwise, degradation of the performance of this equipment could result.
- Les équipements de communication RF portables (y compris les périphériques tels que les câbles d'antenne et les antennes externes) ne doivent pas être utilisés à moins de 30 cm (12 pouces) de toute partie du S200, y compris les câbles spécifiés par DENTIS. Sinon, une dégradation des performances de cet équipement pourrait en résulter.

⚠ **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 maintenance, 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 utilisateurs. 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 doivent être effectuées uniquement par un technicien qualifié.
L'installation électrique doit être planifiée, réalisée et inspectée par des ingénieurs électriciens.

⚠ **WARNING(AVERTISSEMENT)** The LIGHTHEAD is designed to operate using a AC 100-240V, 50-60Hz. Higher or lower voltages may affect the light intensity and operating life of the LEDs.
- La TÊTE D'ÉCLAIRAGE est conçue pour fonctionner sur AC 100-240V 50/60Hz. Des tensions plus élevées ou plus basses peuvent affecter l'intensité lumineuse et la durée de vie des LED.

⚠ **WARNING(AVERTISSEMENT)** Damaged wire insulation may result in the risk of electric shock. To protect against the risk of electrocution, connect the power cables carefully.
- L'isolation des fils endommagés peut entraîner un risque de choc électrique. Pour vous protéger contre le risque d'électrocution, branchez soigneusement les câbles d'alimentation.

⚠ **WARNING(AVERTISSEMENT)** Minor Surgical Luminaire(LUVIS S200) is class I equipment. In order to avoid the risk of an electric shock, the equipment must be connected to a mains supply with PE(protective earth).
- Le luminaire chirurgical mineur (LUVIS S200) est un équipement de classe I. Afin d'éviter le risque de choc électrique, l'équipement doit être raccordé à une alimentation principale avec PE (terre protectrice).

⚠ **WARNING(AVERTISSEMENT)** A main control switch must be installed to power off.
- Les alimentations électriques ne peuvent être installées et connectées que par un électricien ou un agent de service autorisé par DENTIS.

⚠ **WARNING(AVERTISSEMENT)** The power supplies may be installed and connected only by an electrician or a DENTIS authorized service agent.
- Les alimentations électriques ne peuvent être installées et connectées que par un électricien ou un agent de service autorisé par DENTIS

⚠ **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)** Check the polarity of all electrical connections before turning on the power.
- Vérifiez la polarité de toutes les connexions électriques avant d'allumer l'alimentation.

⚠ **WARNING(AVERTISSEMENT)** Take care when handling the circuit boards: these boards are supplied in an electrostatic envelope and must be handled with great care.
- Manipulez les cartes de circuit imprimé avec précaution : ces cartes sont fournies dans une enveloppe électrostatique et doivent être manipulées avec grand soin.

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

⚠ **WARNING(AVERTISSEMENT)** The LIGHTHEAD brakes are adjusted during installation. Like all mechanical parts, the brakes are subject to wear.
Read just the brakes if the LIGHTHEAD no longer remains steady in any position.
Check the condition of the mounting surface.
- Les freins de la TÊTE D'ÉCLAIRAGE sont ajustés lors de l'installation. Comme toutes les pièces mécaniques, les freins sont sujets à l'usure. Réajustez les freins si la TÊTE D'ÉCLAIRAGE ne reste plus stable dans toutes les positions. Vérifiez l'état de la surface de montage.

⚠ **WARNING(AVERTISSEMENT)** The operation and safety of the device may be affected by the removal of certain components during servicing operations.
- Le fonctionnement et la sécurité de l'appareil peuvent être affectés par le retrait de certains composants lors des opérations d'entretien.

⚠ **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)** Do not place the Mobile Type ME equipment where it is difficult to disconnect the Power Cord.
- Ne placez pas l'équipement ME de type mobile à un endroit où il est difficile de débrancher le cordon d'alimentation.

⚠ **WARNING(AVERTISSEMENT)** Use a power supply with at least 20A circuit breakers
- Utilisez une alimentation électrique avec des disjoncteurs d'au moins 20A.

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

· Minor Surgical Luminaire(S200) is intended to be used to provide visible illumination of the surgical area or the patient during surgical operations, diagnosis and treatment.

· Classification under the provision of 93/42/EEC(MDR) : Class I
- Minor Surgical Luminaire(S200) is classified as a Class I device.

· Classification under the provision of FDA (U.S. Food and Drug Administration) : Class I
- Minor Surgical Luminaire(S200) is classified as a Class I device.

· Form of protection against electric shock : Class I
  - Minor Surgical Luminaire(S200) is classified as Class I

· Degree of protection against flammability
  - Minor Surgical Luminaire(S200) 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 SIDE HANDLE should be cleaned with cloths, and the MAIN HANDLE should be sterilized with sterilizer regularly to prevent disinfection.

· Mode of operation
  - Classification of Minor Surgical Luminaire(S200) : continuous operation.

4.2 General description

· 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.

· Before using the products, You must receive training by authorized person of the DENTIS.

· 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

· Minor Surgical Luminaire(S200) as a medical device complies with the safety regulation EN/IEC 60601-1.

· Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN/IEC standards (e.g. EN/IEC 60601-2-41 for Particular requirements, EN/IEC 60601-1 for General requirements).

· Furthermore all configurations shall comply with the ME Equipment of Collateral Standard EN/IEC 60601-1-2. Everybody who connects additional equipment to the signal input part or signal output part configures a ME Equipment, and is therefore responsible that the ME Equipment complies with the requirements of standard EN/IEC 60601-1.

· 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

CE EC REP

· 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)	The S200 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	The S200 is suitable for use in all establishments other than domestic premises and those directly connected to the public low-voltage power 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. LIGHTHEAD specification

5.1 Product colors : BLUE, IVORY, WHITE

5.2 Technical specification (In accordance with EN/IEC 60601–2–41)

· STANDARD SPECIFICATION

Specifications		Unit	Luvis S200		
Normal Mode			60,000 lx	80,000 lx	100,000 lx
Central illuminance Ec (@1m)		lx	60,000	80,000	100,000
Electronic adjustment range		%	8.3~100	6.3~100	5~100
Light field diameter (d10)		cm	18	18	18
Light field diameter (d50)		cm	9.5	9.5	9.5
Light field uniformity (d50/d10)		N/A	> 0.5	> 0.5	> 0.5
Depth of Illumination (60%)		cm	78	78	78
Color temperature (3 levels)		K	3,800 / 4,300 / 4,800		
Color rendering index (Ra)		N/A	90	90	90
Special color rendering index (R9)		N/A	-	-	-
Shadow dilution	With tube	%	100	100	100
	With one mask	%	-	-	-
	With two mask	%	48	48	48
	With one mask, at base of tube	%	-	-	-
	With two mask, at base of tube	%	46	46	46
Radiation energy		$mW/m^2 \cdot lx$	3.26	3.32	3.32
Illumination energy(Ee)		W/m^2	204	265	319

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

5.3 Electrical specification (In accordance with EN/IEC 60601–1)

· SMPS TECHNICAL DATA

Content	Description
Input voltage	AC 100-240 V, 50/60 Hz
Output voltage	DC 33 V, 0.5 A

· RATING

Content	Rated Input	Remark
60,000 lx	AC 100–240 V, 50/60 Hz, 27-43 VA	-
80,000 lx	AC 100–240 V, 50/60 Hz, 34-52 VA	-
100,000 lx	AC 100–240 V, 50/60 Hz, 45-67 VA	-

5.4 Mechanical specification

Specifications	Length(mm)	Weight(kg)	Remark
LIGHT HEAD	346 × 348 × 98	3.5	+HEAD ARM
TENSION SPRING ARM	Φ32 × 650	2.50	-
WALL SECOND ARM	Φ34 × 707	2.04	-
DUAL CEILING SECOND ARM	Φ34 × 707	2.04	-
CEILING SECOND ARM	Φ32 × 695	1.61	-
CHAIR SECOND ARM	Φ32 × 777	4.15	-
MOBILE VERTICAL ARM	Φ31.8 × 1,693	3.05	+MOBILE VERTICAL ARM1 +MOBILE VERTICAL ARM2
MOBILE BASE	575 × 575	17.05	+CASTER 4EA + BASE WEIGHT 2EA
DUAL CONNECTOR	132 × 71	1.26	+ARM BOLT
WALL BRACKET	100 × 270	2.60	-
CEILING VERTICAL ARM	Φ42.7 × 733	4.82	-
DUAL CEILING VERTICAL ARM	Φ60.5 × 865	17.10	+DUAL BRACKET
CEILING COVER & BRACKET	Φ500 × 50	1.15	-
CEILING MOUNT	-	13.36	GUIDE BRACKET + FIX BRACKET + STUD BOLT

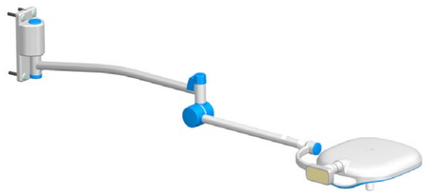
5.5 Other characteristic

Specifications	Luvis S200	Remark
Protection against electric shock	Class I Protection	-
Protection against harmful ingress of water or particulate matter	Ordinary	Head part: IP43
Method of sterilization	See the USER'S MANUAL 8. Sterilization and Cleaning	-

6. USE

6.1 Product type

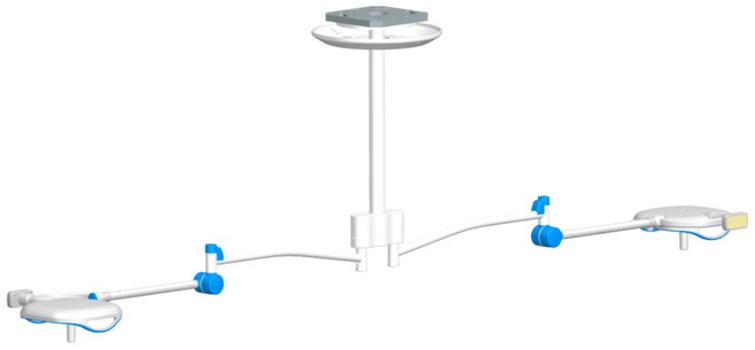
Dual connection type



Wall type

Mobile type

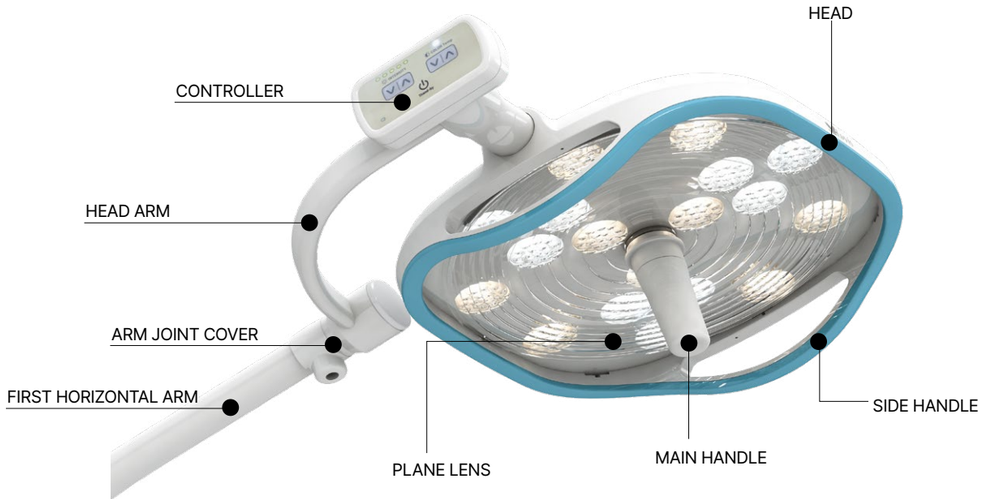
Single ceiling type



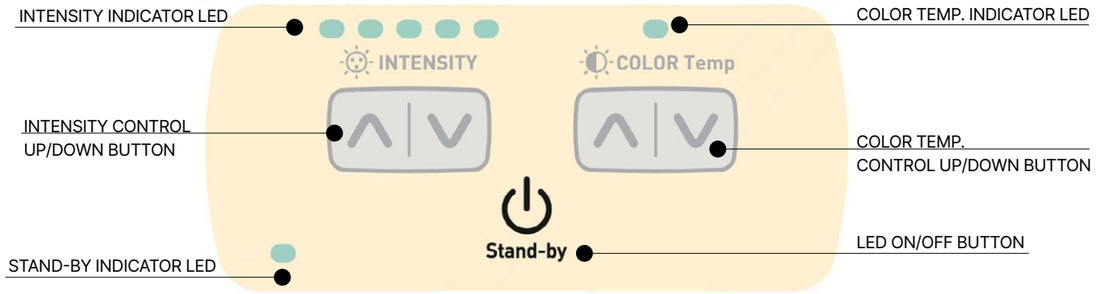
Dual ceiling type

6.2 Product descripton

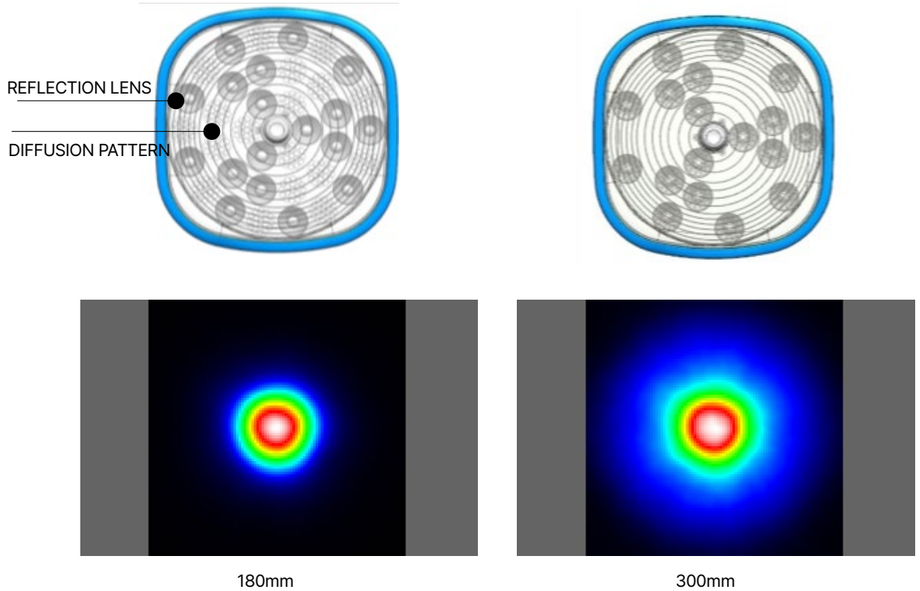
· LIGHTHEAD



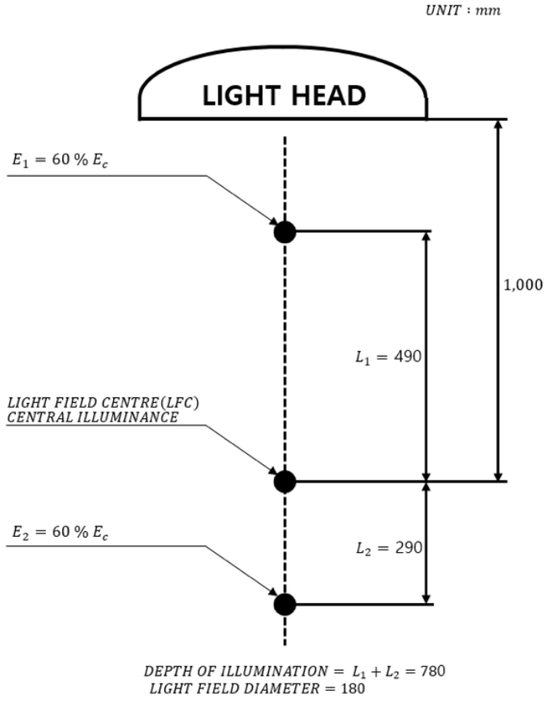
· Controller Panel



· Pattern Size



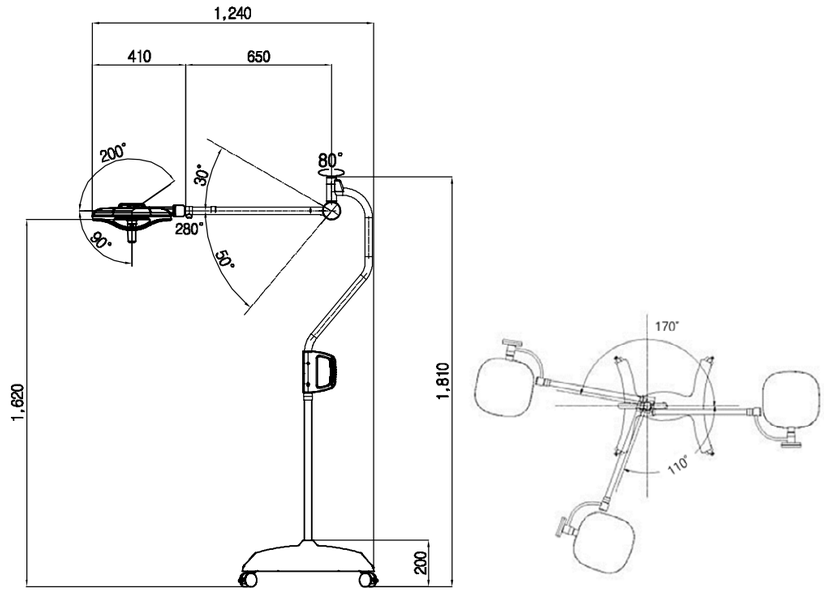
· Depth



6.3 Performance characteristic

· MOBILE

(unit : mm)



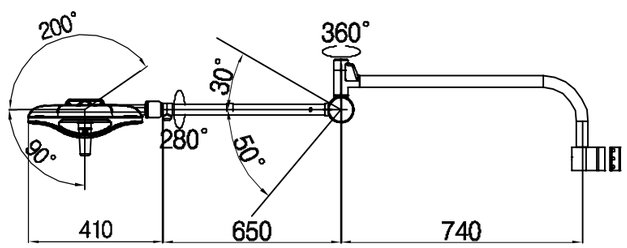
⚠ While moving the mobile type device for use, please do not step on the power adapter and do not place it on the ground.

⚠ 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.

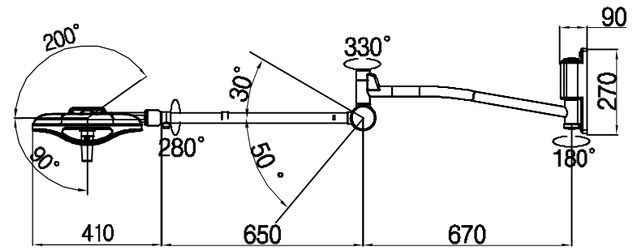
· DUAL CONNECTION

(unit : mm)



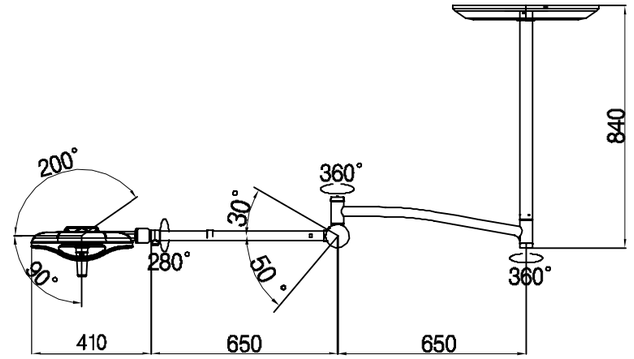
· WALL

(unit : mm)



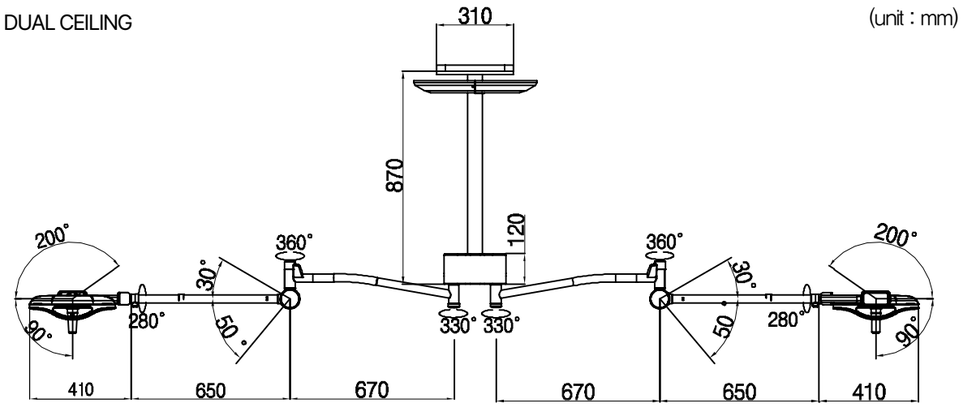
· SINGLE CEILING

(unit : mm)



· DUAL CEILING

(unit : mm)



⚠ 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 Detachable part

MAIN HANDLE	2ea	

⚠ Before using MAIN HANDLE, please conduct a sterilization treatment.

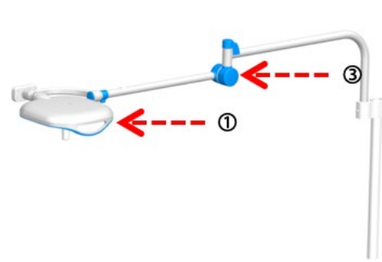
7. Labelling requirement

7.1 MARKING PLATE

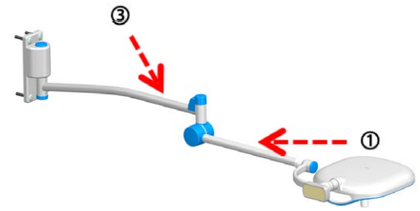
NO.	LABEL NAME	LABEL IMAGE	SIZE(mm)
①	PRODUCT LABEL	PRODUCT MODEL REF RATINGS S/N LOT YYYY, MM Medical electrical equipment QC PASS DENTIS DENTIS CO., LTD. 99, Seongseoseo-ro, Dalseo-gu, Daegu, Korea TEL : 82-53-583-2804 / www.dentis.co.kr EC REP GT-MEDICAL, S.L. Address : C/Luis I, nº 94. Planta 2, Local 8, Mardrid, SPAIN	84 X 54
②	No pushing		20 X 20
③	Do not use this device in a bath-tub, shower or water-filled reservoir		20 X 20
④	MAIN HANDLE LABLE (On the plastic cover of MAIN HANDLE)	PRODUCT : MAIN HANDLE LOT NO: Manufacturer : DENTIS CO., LTD. 99,Seongseoseo-ro, Dalseo-gu, Daegu, Korea	100 X 45

7.2 CAUTION AND INFORMATION MARK

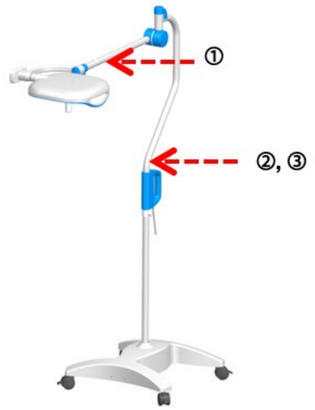
⚠ Below is the reference for label positions. Please refer to 7.1 Marking Plate for matching the indicated numbers to their name plates.



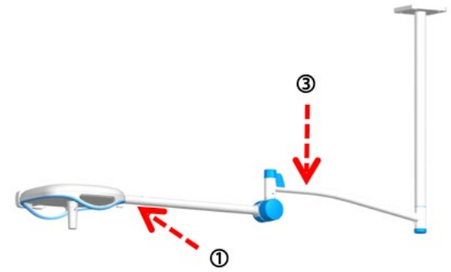
Dual connection type



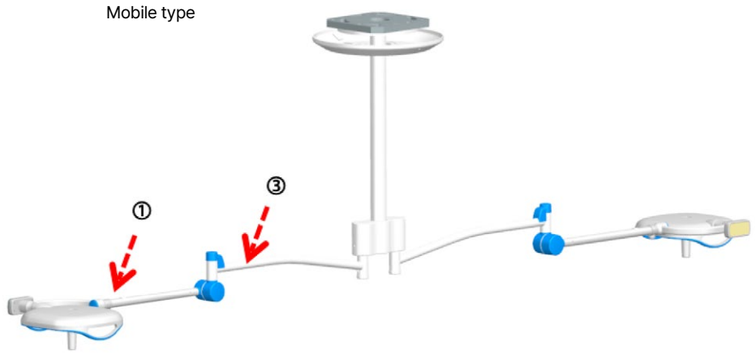
Wall type



Mobile type



Single ceiling type



Dual ceiling type

8. Sterilization and Cleaning

⚠ Cleaning and sterilization procedures vary from facility to facility and therefore it is not possible to specify a single procedure. The user should contact a specialist in the hospital and apply the recommended procedures according to the product. If you have any questions about the compatibility of your medication, please contact the DENTIS Customer Center.
The treatment level required for cleaning and disinfection of the MAIN HANDLE is a low level of disinfection. It is classified as non-critical devices with a low risk of infection, except for the use of sterilizable handles.
Contact your place of purchase in case of failure or damage.

⚠ The use of cleaning agents containing the following substances is not permitted.
- High concentrations of organic and inorganic acids and chlorinated hydrocarbons

8.1 Cleaning the equipment

⚠ Before cleaning turn off the power and wait until LIGHTHEAD is sufficiently cooled.
Wear gloves when cleaning and disinfecting.
Do not spray cleaning and disinfectant directly into the LIGHTHEAD.

· Make sure that the system is powered off and the LIGHTHEAD is sufficiently cooled.
· Prepare cleaning agents and disinfectants. For cleaning agents, follow the manufacturer's instructions for use.
· Moisten a clean, lint-free, soft cloth with cleaning solution and remove excess moisture.
· Clean the area using a cloth soaked with cleaning agent.
· Clean the device using a cloth soaked with clean water.
· Wipe all surfaces with a clean, dry cloth to remove any residue.
· Make sure all cleaning and disinfectant residues have been removed before using the light.

8.2 MAIN HANDLE AUTOMATIC CLEANING

· After the treatment, remove the MAIN HANDLE from the dental lamp.
· Remove visible foreign substances using a soft brush and cloth in warm water flowing through the MAIN HANDLE for at least 1 minute.
· Place the MAIN HANDLE in the cleaning equipment and carry out the cleaning using an enzyme detergent according to the following cleaning conditions.

No.	Condition	Temperature(°C)	Minimum time(Min)
1	Pre-cleaning	20-40	1
2	Cleaning	20-40	5
3	Cleaning	20-40	2
4	Rinsing	20-40	10
5	Rinsing	20-40	10
6	Dry	50-70	90

· Remove the MAIN HANDLE from the cleaning equipment and ensure that the cleaning is complete.
· Check for foreign substances left inside and outside the MAIN HANDLE, if it is necessary, repeat the cleaning process
· Protect the cleaned and dried MAIN HANDLE from re-contamination.

8.3 MAIN HANDLE MANUAL CLEANING

· After the treatment, remove the MAIN HANDLE from the dental lamp.
· Immerse the MAIN HANDLE in the washing tank for at least 5 minutes in the diluted enzyme detergent. (Follow the manufacturer's instructions for use of the cleaner.)
· To prevent blood or foreign substances from drying out, soak the separated MAIN HANDLE in distilled water or tap water for 15 minutes to remove any foreign substances, then clean it with a soft brush and a lint-free cloth.
· Check inside and outside of the MAIN HANDLE for debris, and repeat cleaning if any debris remains.
· Rinse thoroughly with clean water and wipe clean with a lint-free cloth to dry.
· Protect the cleaned and dried main handle from re-contamination

8.4 MAIN HANDLE Sterilization

⚠ Do not allow foreign substances to enter the MAIN HANDLE during sterilization.
MAIN HANDLE is guaranteed for up to 100 sterilization cycles when the same sterilization conditions are applied.
In the case of MAIN HANDLE, sterilization may cause wear, cracks, and discoloration. If these signs are detected, stop using the handle and replace it.
The MAIN HANDLE being stored must be kept clean and sterile before use.
If you are not wearing a sterile suit, be careful and do not touch the sterilized MAIN HANDLE.

· Sterilize the cleaned MAIN HANDLE according to the process below.

· Make sure the MAIN HANDLE is clean, wrap the HANDLE in sterile packaging (double packaging or equivalent) and seal it.

· When putting the MAIN HANDLE into the sterilizer, ma ke sure that the hole is facing down to allow water to flow down.

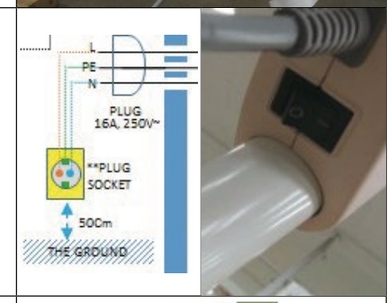
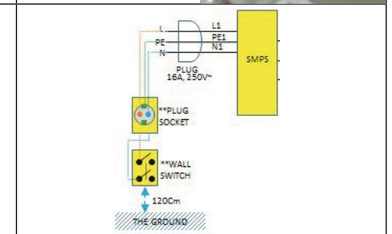
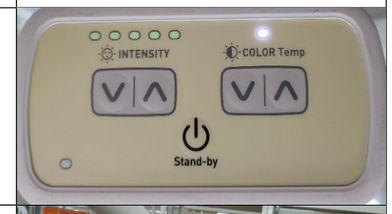
· Place the MAIN HANDLE in the Pressurized Steam Sterilizer (AUTO CLAVE) and proceed with the sterilization cycle according to the sterilization conditions. Using chemical sterilization is prohibited

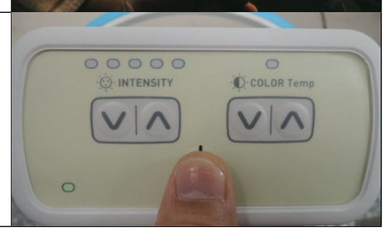
· Follow the sterilizer manufacturer's instructions and sterilization conditions of your counrty.

· When storing after sterilization, store in a tray in a sterile packaging material.(room temperature storage)

Sterlization Condition	
· Operating Condition - Temperature : 132 °C - Pressure : 160 ± 50kPa (1.6 ±0.5 kgf/cm²) - Time : 10 min - Dry : 16 min	 **Autoclave**
Sterlization Condition	
· Sterile Clothing - KIMGUARD sterile clothing - Model : KC500	

9. Operation

Step 1	Before using the device, check the maneuverability of BOTTOM ASS'Y 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 type, turn on the power switch, located at the bottom of the VERTICAL ARM's handle.	
	For a Single Ceiling / Dual Ceiling type, a wall switch, as shown in the picture, must be installed first. To use the device, turn on the switch.	
Step 3	The LED turns on when the power is applied.	
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) - Orange : 3,800K - Pink : 4,300K - White : 4,800K Select the desired luminosity(5steps)	
Step 6	Move the head part to the desired position.	
Step 7	When MAIN HANDLE is rotated clockwise, Pattern size is 180mm	
	When MAIN HANDLE is rotated counterclockwise, Pattern size is 300mm	
Step 8	After using of device, turn off the STAND-BY button.	

Step 9	After using the device, MAIN HANDLE should be detached and sterilized.	
	⚠ Please pull out MAIN HANDLE by pressing the fixing key, marked with a red arrow.	
	⚠ Always use the sterilized MAIN HANDLE.	
	⚠ Sterilization (Autoclave)– Service Condition Temperature: 132 °C Pressure: 160 ± 50kPa (1.6 ±0.5 kgf/cm²) Time: 10 min Dry: 16 min	
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)	

10. Adjustment and Maintenance

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 MAIN HANDLE 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 pol-luted.	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. Disposal

· 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.

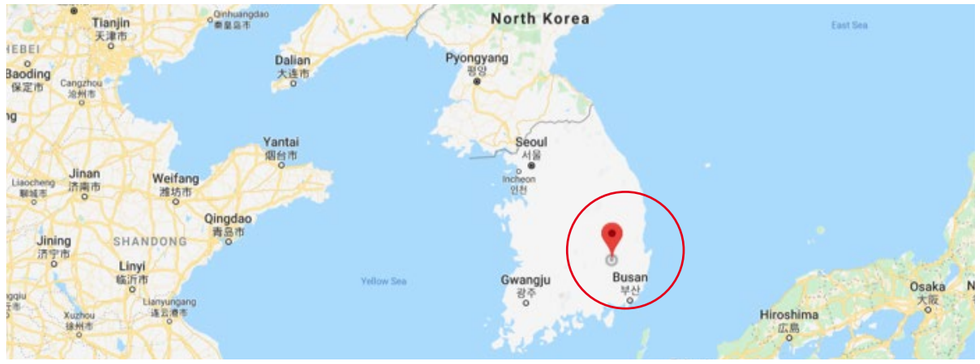
· Please contact the closest DENTIS branch or your supplier, if you have any questions about recycling of the device

12. Model designation

Model	ARM Axis	Mount Type	Colour	Intensity	Power supply
S200	2=2 Axis	0=Head Only 1=Ceiling Type 2=Dual Ceiling Type 3=Wall Type 4=Dual Connection Type 5=Mobile Type	0=Blue 1= Ivory 2=White	0=100,000	0 = PLUG 1=External SWITCH 2=POWER SWITCH

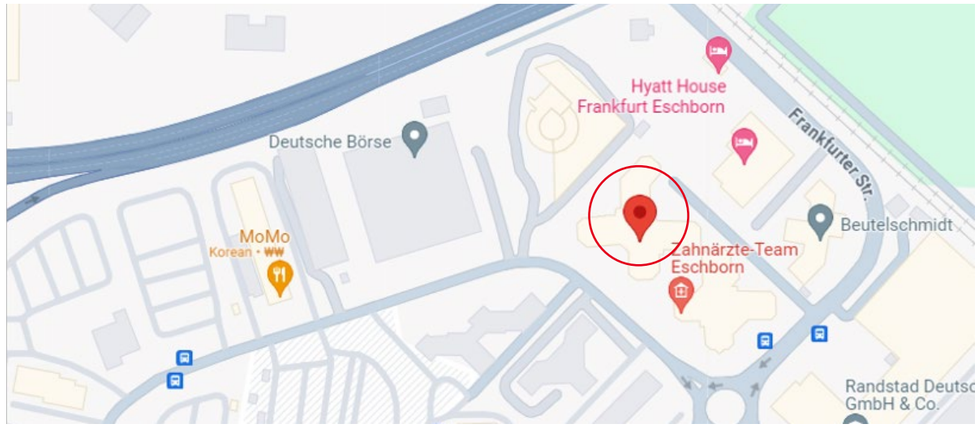
13. Manufacturer and Factory

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



14. Europe Representative

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



LUVIS | MEDICAL SYSTEMS

DENTIS

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DENTIS MEDICAL DIVISION(FACTORY) 6, Yuram-ro, Dong-gu, Daegu, Korea Tel. +82-70-7730-4146 Email. luvis@luvis.co.kr