CE

skytron

OWNER'S MANUAL

(Includes Operation, Maintenance, Service and Parts)

DoVera DE12

DE12C, DE1212C, DE12S, DE12W SERIES EXAMINATION LIGHTS

Read this manual before operating this light! This information is necessary for the safe and efficient operation of the equipment.

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1-1. Special User Attention

Initial use should not begin until after the users have been instructed by the manufacturer's authorized representative.

Prior to use, all personnel that will operate, clean and maintain the examination light must be instructed in its proper operation and care.

A routine program should be implemented by the facility for proper usage instructions for all personnel that may operate the examination light.

When operating the examination light, all hospital personnel should be aware that sensible care must be taken to maintain patient safety and keep the examination light fixture functioning at peak efficiency.

WARNING

In the event of overlapping lamps, a temperature increase would ensue in the patient area with consequent risk of dehydration and tissue damage.

In case of a reduction in blood flow with start of tissue dehydration, reduce light intensity.

1-2. Safety Precautions

Following is a summary of WARNINGS & CAUTIONS denoted in this manual. These precautions are found throughout this manual where applicable. Carefully read this manual before proceeding.

WARNING

WARNING with the safety alert symbol, is used to indicate a hazardous situation that, if not avoided, could result in death or serious injury.

In the event of overlapping lamps, a temperature increase would ensue in the patient area with consequent risk of dehydration and tissue damage.

In case of a reduction in blood flow with start of tissue dehydration, reduce light intensity.

The equipment is not suitable for use in environments rich in oxygen and in the presence of flammable agents.

To avoid risk of electric shock, the product must only be connected to mains supplied with earth protection.

The product is not suitable for use in the presence of an ANAESTHETIC FLAMMABLE MIXTURE with oxygen or nitrous oxide.

When product use is restricted to the face, the patient's eyes must be covered with adequate protection. Failure to do so could cause potential damage to the retina.

Never place or hang objects on the product. Objects could fall into the operating area.

Avoid personal injury. DO NOT attempt to clean the product unless power is turned off to the fixture and the power cord is disconnected (on wall and portable light fixtures).

An improperly cleaned device may inhibit the ability of the sterilization process to achieve the proper sterility assurance.

Always follow OSHA/EASHW blood borne pathogens standards for protective clothing, including gloves, masks, and eye protection when cleaning the handles.

Always adhere to the correct AAMI and enzymatic cleaning manufacturer's recommendations.

Prior to replacing the fuse, make sure the power cord is disconnected (on portable and wall light fixtures) or the facility circuit breaker is turned off (on ceiling mounted light fixtures).

Troubleshooting or repair by unauthorized personnel could result in the loss of equipment performance and could void applicable safety standards, resulting in personal or patient injury.

This equipment is intended for use by healthcare professionals only. As with all electrical medical equipment, this equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the DoVera DE12 light unit or shielding the location.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the DoVera DE12 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ CAUTION

CAUTION with the safety alert symbol indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

Always inspect product prior to use to ensure safe and correct operation. Any product deemed to be malfunctioning should be removed from service and labeled inoperable. Refer all service to a qualified SKYTRON service representative.

Use care to avoid collisions with personnel or equipment. Damage could result causing parts to fall into the patient area.

DO NOT direct the light source into the patient's and or operator's eyes.

Never cover the lighthead during operation to prevent overheating.

Never hang on the product with the body weight of a person.

Do not rest, push or lie on the product.

The portable light fixture is equipped with four lockable casters. Ensure the casters are unlocked prior to moving the fixture to avoid the risk of damage or injury.

DO NOT forcibly overcome a hurdle. If needed, use a ramp and have a firm grasp on the support post to maintain balance. A lack of balance would cause a risk of falling.

Avoid pulling or attempting to transport the fixture by using the lighthead positioning handles. The fixture may become unstable resulting in potential damage or injury.

Use of incompatible cleaning agents will cause damage to the fixture. Avoid the use of cleaning solutions which contain chlorine or high concentrations of alcohol, ethylene glycol, phenol, iodophors, or glutaraldehyde based disinfectants. Staining, pitting, discoloration and diffuser cracking or personal injury may occur if these are used.

When replacing a fuse on ceiling mounted lightheads, ensure you have a good foothold and use appropriate fall protection measures in accordance with OSHA standards.

CAUTION

CAUTION without the safety alert symbol, is used to address practices not related to personal injury but with a possibility of damage to equipment.

Exercise caution when moving the portable light fixture to avoid obstacles such as power cords or other items that may be in the path. DO NOT transport over rugged or unstable flooring as the casters may become damaged.

Improper use, transport procedures , or storage of the stand light may result in damage to the support post or balance mechanism. Check to be sure there is no horizontal movement of the balance mechanism within the support post before each use.

DO NOT use steam, extremely hot water (over 150°F), or high pressure water sprays to clean the equipment.

DO NOT pour liquids or spray cleaning agents directly onto the equipment.

DO NOT use sharp, pointed or abrasive objects, to avoid the risk of damaging surfaces.

DO NOT use abrasive products, petrol or gasoline, paint thinners, alkaline detergents, acids, containing alcohol or aldehydes.

Avoid using excessive amounts of spray cleaners. Leakage of fluids into the interior of lighthead may cause corrosion of electrical components.

Clean with suitable detergents with low alkaline content and chlorine free.

Dose the detergents strictly according to the percentage indications shown on the manufacturer's technical sheet.

DO NOT exceed a sterilization temperature of 273.2°F [134°C] for the positioning handle.

The DoVera lighting fixture does not utilize internal user serviceable parts. Service must be performed by SKYTRON authorized service technicians using SKYTRON authorized replacement parts and service techniques.

Any parts or assemblies not listed in this section must be serviced or replaced by SKYTRON authorized service personnel only. This is necessary to avoid the possibility of damage to the equipment.

NOTICE

Indicates important information not related to injury

2-1. Intended Use

SKYTRON DoVera DE12 Examination Lights are intended to be used by medical personnel to provide short-term, active, noninvasive, local site illumination to any part of the patient's body for treatments and diagnosis which can be interrupted without danger for the patient in case of a light failure or power outage.

Adequate light intensity is achieved at a distance of between 2.3ft [.7m] and 4.6ft [1.4m]. For optimum light intensity, the light is best used at a distance of 3.28ft [1m].

2-2. Installation

SKYTRON's Installation Manual specifies the installation and testing of the DoVera DE12 Examination Light. Review the Installation Manual prior to beginning the installation of the light. Review local electric codes including the Occupational Health and Safety Act for any requirements that pertain to the proper and successful installation of this light.

2-3. Environmental Conditions

WARNING

The equipment is not suitable for use in environments rich in oxygen and in the presence of flammable agents.

	During Transport and Storage*	During Use (For Dry Locations)
Ambient Temperature	5° to 140° F (-15° to 60°C)	50° to 104°F (10°C to 40°C)
Relative Humidity	10% to 95% (No Condensation)	30% to 75% (No Condensation)
Atmospheric Pressure	14 inHg to 31 inHg (500 hPa to 1060 hPa)	20.7 inHg to 31.3 inHg (700 hPa to 1060 hPa)

**In original packaging materials.*

2-4. Certification

Certified by ETL to these standards:

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance [CSA C22.2#60601-1:2014 Ed.3+A2]

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (R2012) [AAMI ES60601-1:2005+C1;A2:2010]

Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis [IEC 60601-2-41:2009 Ed.2+A1]

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability [IEC 60601-1-6:2010Ed.3+A1]

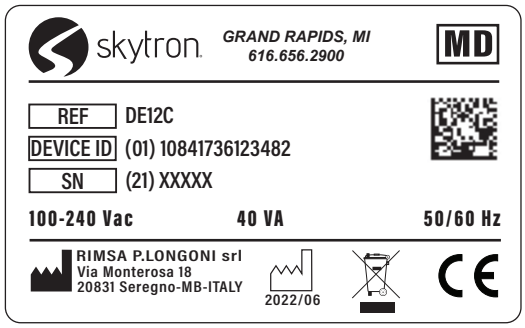
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability [CSA C22.2#60601-1-6:2011 Ed.3+A1;A2]

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: ELECTRO-MAGNETIC disturbances - Requirements and tests [IEC 60601-1-2]

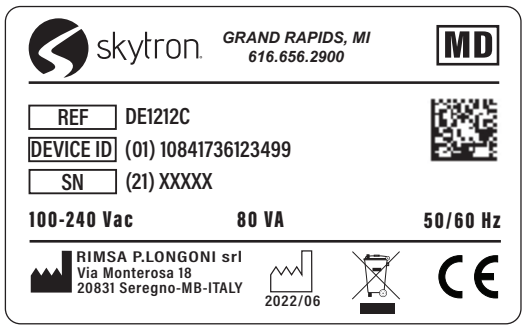
2-5. Equipment Labels and Specifications

The Data Labels contain the model number, fuse type, electrical specifications, and product serial number.

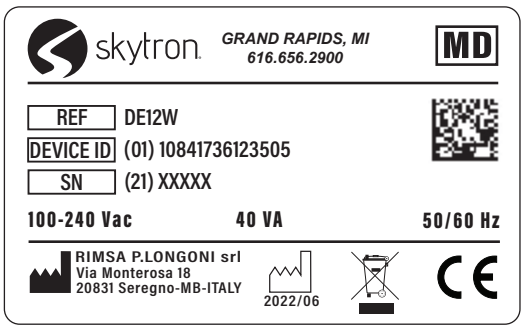
DE12C SINGLE LIGHT CEILING MOUNT LABEL



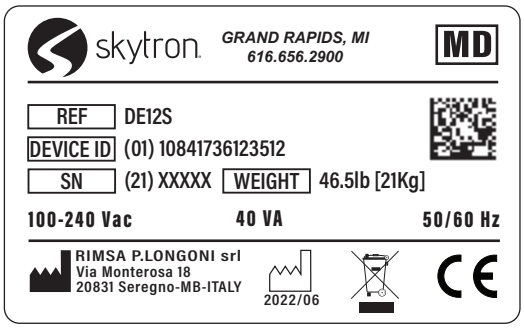
DE1212C DUAL LIGHT CEILING MOUNT LABEL



DE12 W WALL MOUNT LABEL



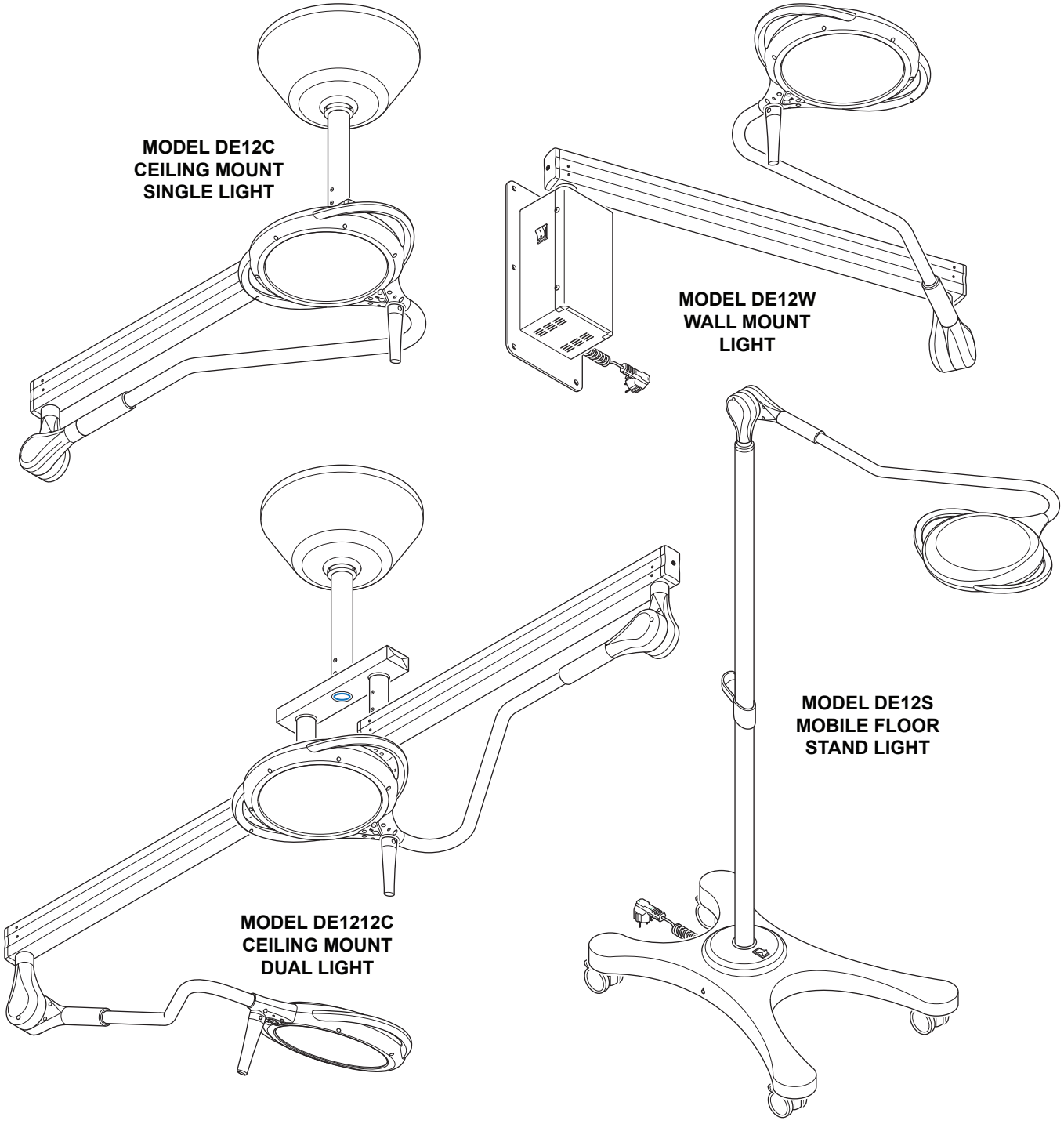
DE12S MOBILE FLOOR STAND LABEL



2-6. Label Symbols

Symbol	Description
	With the word WARNING, indicates a hazardous situation that, if not avoided, could result in death or serious injury.
	With the word CAUTION, indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.
	Indicates waste disposal information.
	Indicates Consult instructions for use.
	Fuses used in the device.
	Protection earth (ground).
SN	Serial Number.
REF	Reference Number.
EC REP	Indicates authorized representative in the European community
	Indicates Manufacturer.
	Indicates production information (year) of the manufactured device.
	Indicates dangerous pinch points that can cause serious injury.
	Indicates Dangerous Voltage 100-240V ~, 50/60Hz.
	Indicates no stepping on surface.
CE	CE marking indicating the Product conforms to REGULATION (EU) 2017/745 and subsequent amendments and supplements.
'N'	Neutral lead connection point.
'L'	Line lead connection point.
'I'	ON
'O'	OFF
	Standby and switch-on.

2-7. Model Identification



Dimensions	
Lamp Body Diameter	15.75 in. [40cm]
Light Emission Surface	47.28 in². [305 cm²]
Fixture Weight	Single ceiling 28.7 lbs. [13kg] Double ceiling 44 lbs. [20kg] Mobile 46.3 lbs. [21kg] Mobile battery 53lbs. [24kg] Wall light 26.5 lbs. [12kg]

2-8. Technical properties

Lighthead	
Illumination Ec at 1 m distance ± 10% [Lux]	119,330
Color temperature (±5%) [K]	4,350
Color rendering index R_a [-]	92
R_9 [-]	>90
Light range diameter d_{50} [mm]	89.75
Light range diameter d_{10} [mm]	157
Lighting depth L1+L2 [mm] at 60%	850
Lighting depth L1+L2 [mm] at 20%	1500
Max irradiation [W/m²]	372.4
Irradiation / Illumination [mW/m²lx]	3.12
Max irradiation in UV [W/m²]	0.0145

Power Connection	
Primary alternate voltage [Volt ac]	100 – 240
Frequency [Hz]	50/60
Power input [VA]	40
Light source	12 LEDs
Duration of LED diode light source [hr] (This figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	20 - 100
Fuses incorporated	T2AH 250V, 5x20

General Data	
Color	RAL 9003
Directive	(EU) 2017/745

General Data (continued)	
Classification of Medical Device	Class I
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use; the colour temperature and the color rendering index are stable and are within the range 3000K-6700K and 85-100, respectively; Ec value shall be ≥ 40,000 lux and ≤ 160,000 lux). Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m2 and the total irradiance Ee in the lighted area does not exceed 1000 W/m2 at a distance of 1000 mm; Ec value shall be ≥ 40,000 lux and ≤ 160,000 lux; Ee/Ec ≤ 6 mV/m2lx).
IP degree of protection	IP20
Operating conditions	Continuous operation
Grip steam sterilization	270°F [132°C] for 4 minutes.
Mains power voltage insulation means	Outside the product (main switch) for ceiling versions Main switch for mobile and wall versions.

Dimensions	
Diameter of lamp body	15.75 in. [40cm]
Light emission surface	47.28 in². [305 cm²]
Fixture weight	Single ceiling 28.7 lbs. [13kg] Double ceiling 44 lbs. [20kg] Mobile 46.3 lbs. [21kg] Mobile battery 53lbs. [24kg] Wall light 26.5 lbs. [12kg]

Markings	
CE	In conformity with regulation (EU) 2017/745

All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons.

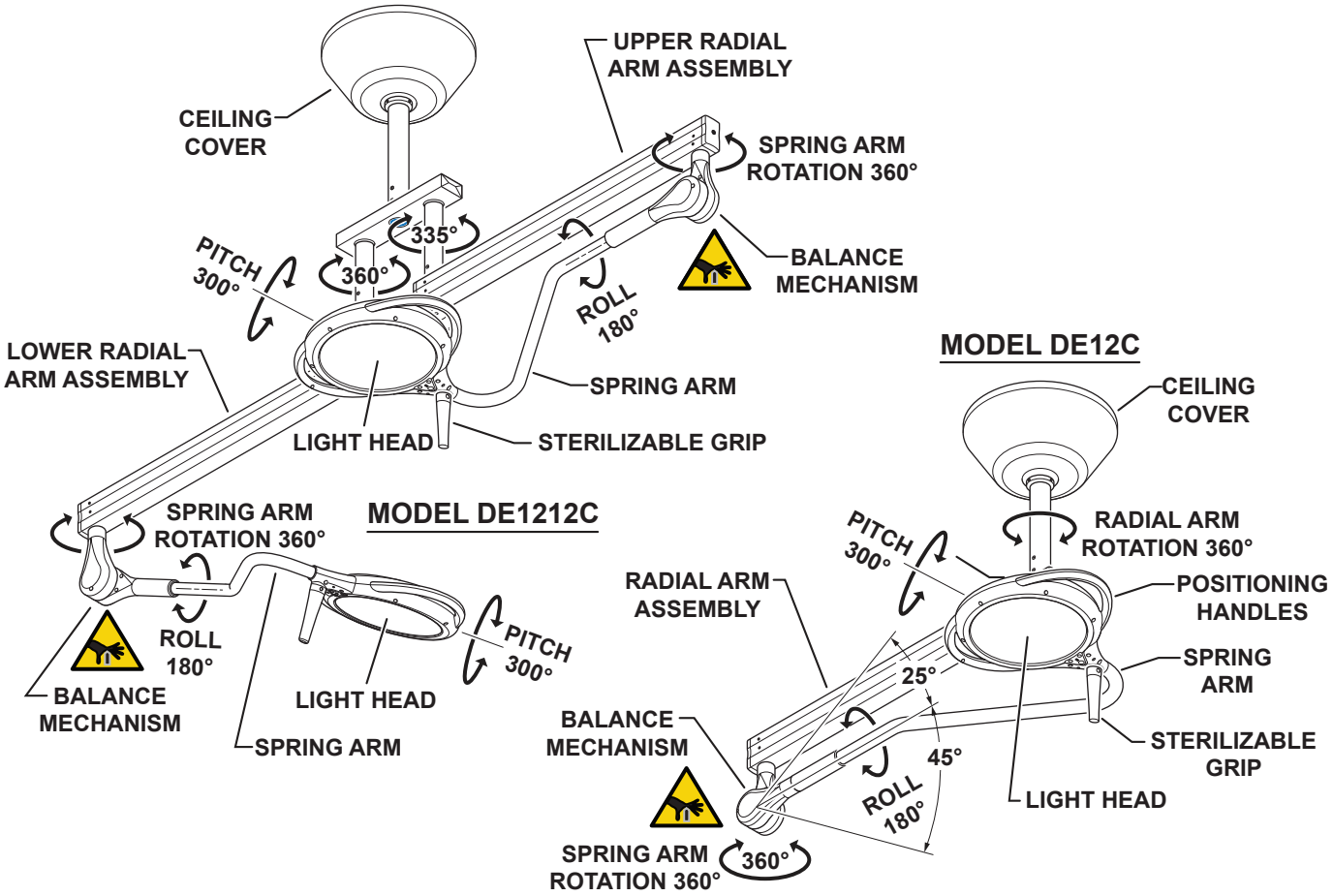


Figure 1. DE12C Single & DE1212C Dual Light Fixtures

3-1. Introduction

The lighthead consists of twelve (12) LEDs (Light Emitting Diodes). The indirect light technology guarantees an augmented lighting emitting surface ensuring good illumination. LEDs offer low heat radiation and increased illumination longevity.

This fixture is single-point ceiling mounted with an infinitely continuous 360° rotation capability at the ceiling mount end of the radial arm assembly (Figure 1).

The balance mechanism provides the lighthead an additional infinitely continuous 360° rotation point. The balance mechanism is an enclosed spring tension system. This allows vertical movement of the lighthead while maintaining the lighthead position without drifting. The spring arm provides the lighthead with an additional 300° of pitch and 180° of roll.

3-2. Electrical Requirements

⚠ WARNING

To avoid risk of electric shock, the product must only be connected to mains supplied with earth protection.

SKYTRON DoVera Exam Lights require all electrical connections be made by a licensed electrician in accordance with state, local and national electrical codes using UL (Underwriters Laboratory) recognized materials.

3-3. Visual Checks Prior to Start-Up

⚠ CAUTION

Always inspect product prior to use to ensure safe and correct operation. Any product deemed to be malfunctioning should be removed from service and labeled inoperable. Refer all service to a qualified SKYTRON service representative.

- Ensure the light has been properly disinfected.
- Check for cracks, damaged or broken lens. Avoid use if such damage is evident.
- Check mechanical movements by rotating and articulating each joint. Ensure proper operation and emittance of light throughout the range of movement.
- Ensure the spring arm maintains its correct position without drift.
- Check the operation of the intensity control on the lighthead control pad.

3-4. Operation

The Product has been designed to ensure a fixed light diameter without any need for adjustment.

Adequate light intensity is achieved at a distance of between 2.3ft [.7m] and 4.6ft [1.4m]. For optimum light intensity, the light is best used at a distance of 3.28ft [1m].

WARNING

The product is not suitable for use in the presence of an ANAESTHETIC FLAMMABLE MIXTURE with oxygen or nitrous oxide.

When product use is restricted to the face, the patient's eyes must be covered with adequate protection. Failure to do so could cause potential damage to the retina.

Never place or hang objects on the product. Objects could fall into the operating area.

CAUTION

Use care to avoid collisions with personnel or equipment. Damage could result causing parts to fall into the patient area.

DO NOT direct the light source into the patient's and or operator's eyes.

Never cover the lighthead during operation to prevent overheating.

Never hang on the product with the body weight of a person.

Use the following steps to operate the light fixture:

1. Position the lighthead by grasping the sterilizable grip or positioning handles and moving the lighthead to the desired position (Figure 1).
2. Press and hold the ON/OFF button on the control pad to turn the light fixture on (Figure 2).

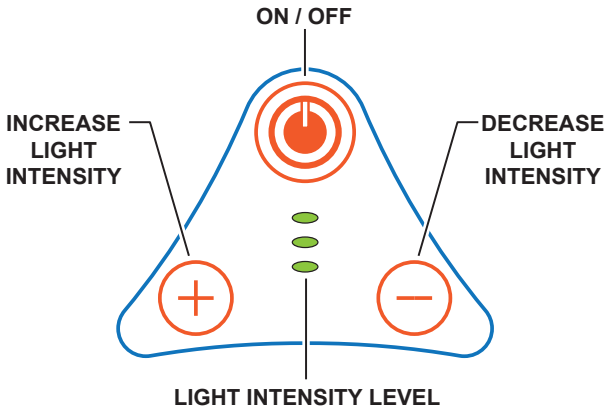


Figure 2. Control Pad

3. Press the "+" or "–" buttons to increase or decrease the light intensity. Three green micro-LEDs display the selected intensity level. There are seven adjustment levels available.

NOTICE

With the facility mains power on, a green micro-led remains on to indicate standby function.

4. Press and hold the ON/OFF button on the control pad to turn off light fixture.

3-5. Sterilizable Grip

The sterilizable grip can be easily removed and installed as follows: For sterilization process see section 6-2.

1. Press the stop catches at the top of the grip to remove (Figure 3).

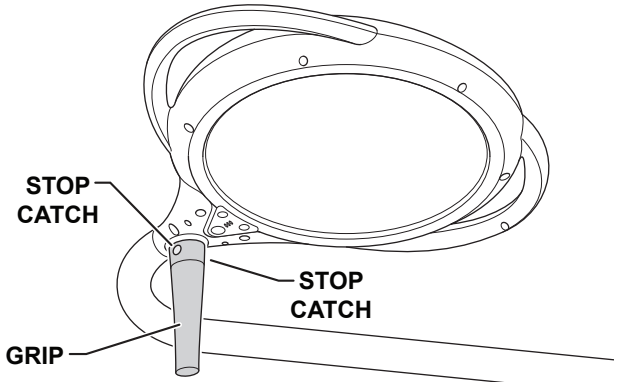


Figure 3. Sterilizable Grip

2. Insert the grip until the stop catches click into the handpiece holes to install.

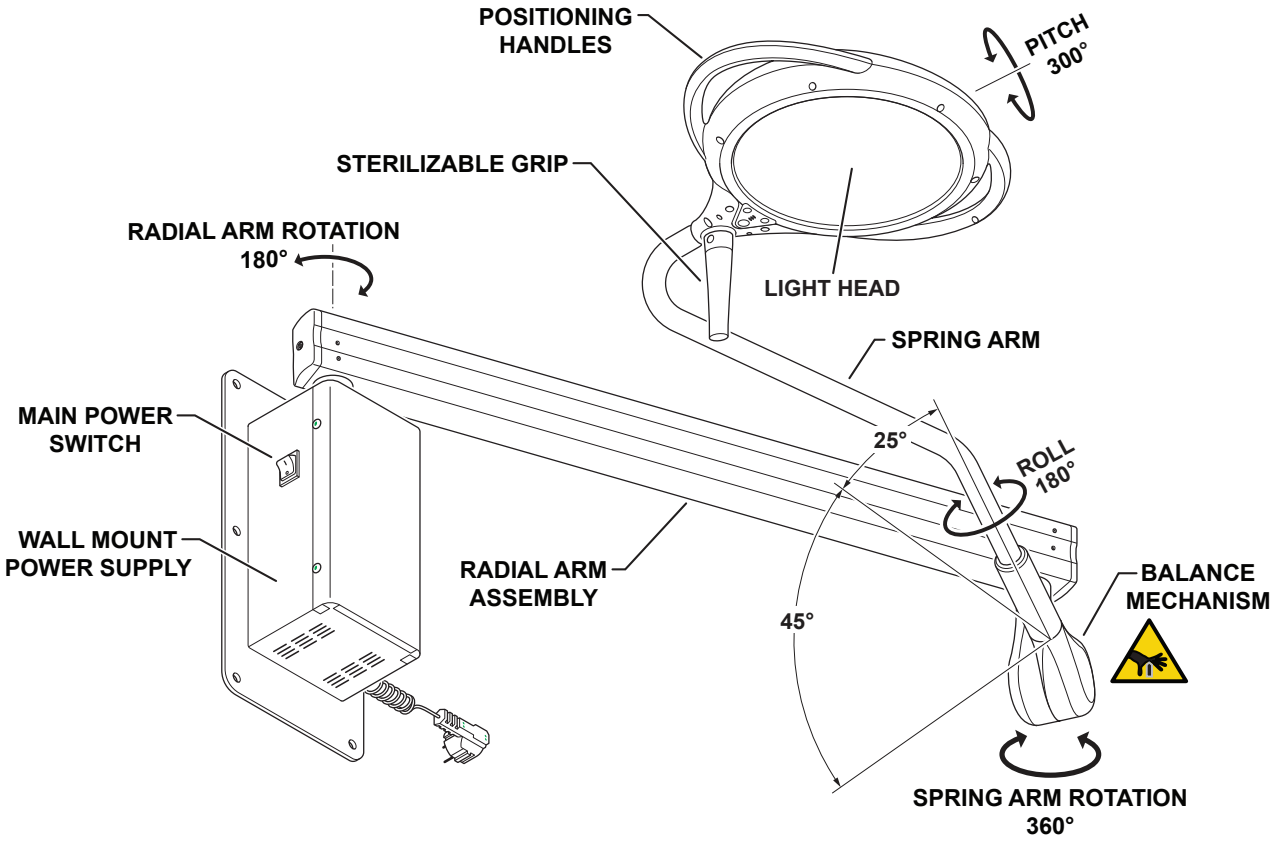


Figure 4. DE12W Light Fixture

4-1. Introduction

The lighthead consists of twelve (12) LEDs (Light Emitting Diodes). The indirect light technology guarantees an augmented lighting emitting surface ensuring good illumination. LEDs offer low heat radiation and increased illumination longevity.

This fixture is wall mounted and provides the radial arm assembly with 180° rotation capability (Figure 4).

The balance mechanism provides the lighthead an additional infinitely continuous 360° rotation point. The balance mechanism is an enclosed spring tension system. This allows vertical movement of the lighthead while maintaining the lighthead position without drifting. The spring arm provides the lighthead with an additional 300° of pitch and 180° of roll.

4-2. Electrical Requirements

⚠ WARNING

To avoid risk of electric shock, the product must only be connected to mains supplied with earth protection.

SKYTRON DoVera Exam Lights require all electrical connections are made by a licensed electrician in accordance with state, local and national electrical codes using UL (Underwriters Laboratory) recognized materials.

4-3. Visual Checks Prior to Start-Up

⚠ CAUTION

Always inspect product prior to use to ensure safe and correct operation. Any product deemed to be malfunctioning should be removed from service and labeled inoperable. Refer all service to a qualified SKYTRON service representative.

- Ensure the light has been properly disinfected.
- Check for cracks, damaged or broken lens. Avoid use if such damage is evident.
- Check mechanical movements by rotating and articulating each joint. Ensure proper operation and emittance of light throughout the range of movement.

- Ensure the spring arm maintains its correct position without drift.
- Check the operation of the intensity control on the lighthead control pad.

4-4. Operation

The product has been designed to ensure a fixed light diameter without any need for adjustment.

Adequate light intensity is achieved at a distance of between 2.3ft [.7m] and 4.6ft [1.4m]. For optimum light intensity, the light is best used at a distance of 3.28ft [1m].

⚠ WARNING

The product is not suitable for use in the presence of an ANAESTHETIC FLAMMABLE MIXTURE with oxygen or nitrous oxide.

When product use is restricted to the face, the patient's eyes must be covered with adequate protection. Failure to do so could cause potential damage to the retina.

Never place or hang objects on the product. Objects could fall into the operating area.

⚠ CAUTION

Use care to avoid collisions with personnel or equipment. Damage could result causing parts to fall into the patient area.

DO NOT direct the light source into the patient's and or operator's eyes.

Never cover the lighthead during operation to prevent overheating.

Never hang on the product with the body weight of a person.

Use the following steps to operate the light fixture:

1. Position the device so it is easy to reach and remove the power plug in case of an emergency.
2. Position the lighthead by grasping the sterilizable grip or positioning handles and moving the lighthead to the desired position (Figure 4).
3. Place the main power switch in the ON position at the wall mount power supply.
4. Press and hold the ON/OFF button on the control pad to turn the light on (Figure 5).

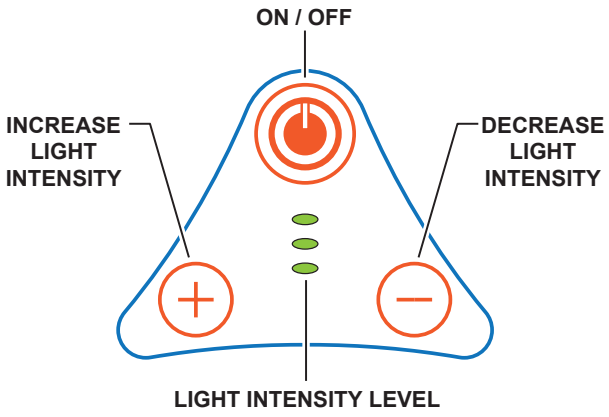


Figure 5. Control Pad

5. Press the "+" or "−" buttons to increase or decrease the light intensity. Three green micro-LEDs display the selected intensity level. There are seven adjustment levels available.

NOTICE

With the facility mains power on, a green micro-led remains on to indicate standby function.

6. Press and hold the ON/OFF button on the control pad to turn the light off.
7. Place the main power switch in the OFF position at the wall mount power supply.

4-5. Sterilizable Grip

The sterilizable grip can be easily removed and installed as follows: For sterilization process see section 6-2.

1. Press the stop catches at the top of the grip to remove (Figure 6).

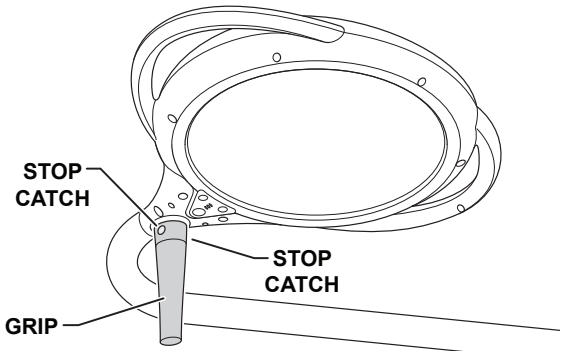


Figure 6. Sterilizable Grip

2. Insert the grip until the stop catches click into the handpiece holes to install.

5-1. Introduction

The lighthead consists of twelve (12) LEDs (Light Emitting Diodes). The indirect light technology guarantees an augmented lighting emitting surface ensuring good illumination. LEDs offer low heat radiation and increased illumination longevity.

This fixture is mounted on a portable base (Figure 7).

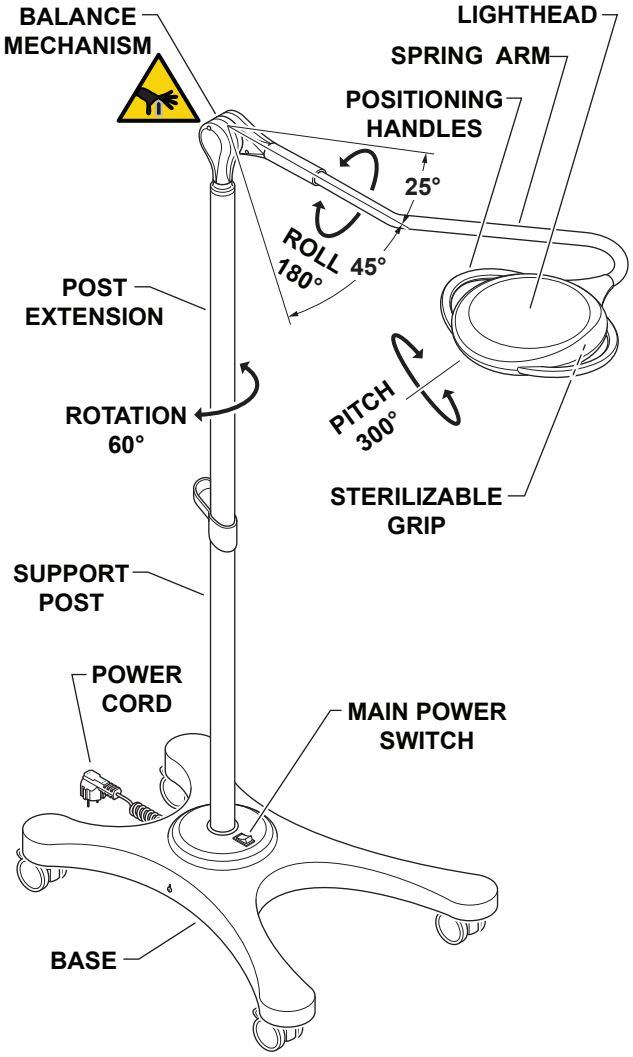


Figure 7. DE12S Mobile Floor Stand Light

The balance mechanism provides the lighthead an additional 60° rotation point. The balance mechanism is an enclosed spring tension system. This allows vertical movement of the lighthead while maintaining the lighthead position without drifting. The spring arm provides the lighthead with an additional 300° of pitch and 180° of roll and a vertical travel capability of 70°.

The support post has a fixed mounting to the base, which is supported on four lockable casters. The base also contains the power cord.

5-2. Power Requirements

WARNING

To avoid risk of electric shock, the product must only be connected to mains supplied with earth protection.

SKYTRON DoVera portable exam lights requires a properly grounded 100-240VAC, 50/60Hz electrical power supply. The stand is equipped with a power cord and hospital grade plug. The power cord is located at the rear of the base in the center. The main power ON/OFF switch is located on top of the base.

5-3. Visual Checks Prior to Start-Up

CAUTION

Always inspect product prior to use to ensure safe and correct operation. Any product deemed to be malfunctioning should be removed from service and labeled inoperable. Refer all service to a qualified SKYTRON service representative.

- Ensure the light has been properly disinfected.
- Check for cracks, damaged or broken lens. Avoid use if such damage is evident.
- Check mechanical movements by rotating and articulating each joint. Ensure proper operation and emittance of light throughout the range of movement.
- Check light emission from the lighthead.
- Check the operation of the intensity control on the lighthead control pad.
- Ensure that power cord is properly connected at the base and that it is not damaged.

Move the portable light fixture to the desired location using the following steps:

1. Ensure the lighthead is in a lowered position.
2. Ensure the power cord is stowed in a safe position.

CAUTION

The portable light fixture is equipped with four lockable casters. Ensure the casters are unlocked prior to moving the fixture to avoid the risk of damage or injury.

3. Lift the caster brake pedal with your foot to disengage the four caster brakes.

⚠ CAUTION

DO NOT forcibly overcome a hurdle. If needed, use a ramp and have a firm grasp on the support post to maintain balance. A lack of balance would cause a risk of falling.

4. Position yourself behind the support post, and use the support post to position or transport the fixture.

⚠ CAUTION

Avoid pulling or attempting to transport the fixture by using the lighthead positioning handles. The fixture may become unstable resulting in potential damage or injury.

CAUTION

Exercise caution when moving the portable light fixture to avoid obstacles such as power cords or other items that may be in the path. DO NOT transport over rugged or unstable flooring as the casters may become damaged.

5. For maximum stability, position the base so the longer legs will be facing the examination area. The stand should be positioned in such a way that it is clinically functional but will not interfere with medical staff or equipment.
6. Position the device so it is easy to reach and remove the power plug in case of an emergency.
7. Once the light fixture is in the desired position, press each brake pedal with your foot to lock the four casters. DO NOT kick or continuously press the brake pedal once the stop position has been reached.

CAUTION

Improper use, transport procedures , or storage of the stand light may result in damage to the support post or balance mechanism. Check to be sure there is no horizontal movement of the balance mechanism within the support post before each use.

5-4. Operation

The Product has been designed to ensure a fixed light diameter without any need for adjustment.

Adequate light intensity is achieved at a distance of between 2.3ft [.7m] and 4.6ft [1.4m]. For optimum light intensity, the light is best used at a distance of 3.28ft [1m].

⚠ WARNING

The product is not suitable for use in the presence of an ANAESTHETIC FLAMMABLE MIXTURE with oxygen or nitrous oxide.

When product use is restricted to the face, the patient's eyes must be covered with adequate protection. Failure to do so could cause potential damage to the retina.

Never place or hang objects on the product. Objects could fall into the operating area.

⚠ CAUTION

Use care to avoid collisions with personnel or equipment. Damage could result causing parts to fall into the patient area.

DO NOT direct the light source into the patient's and or operator's eyes.

Never cover the lighthead during operation to prevent overheating.

Do not rest, push or lie on the product.

Use the following steps to operate the light fixture:

1. Position the lighthead by grasping the sterilizable grip or positioning handles and moving the lighthead to the desired position (Figure 7).
2. Place the main power switch in the ON position at the base.

3. Press and hold the ON/OFF button on the control pad to turn the light on (Figure 8).

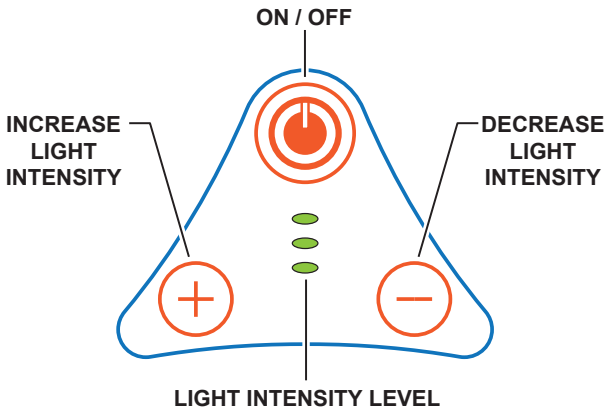


Figure 8. Control Pad

4. Press the "+" or "–" buttons to increase or decrease the light intensity. Three green micro-LEDs display the selected intensity level. There are seven adjustment levels available.

NOTICE

With the facility mains power on, a green micro-led remains on to indicate standby function.

5. Press and hold the ON/OFF button on the control pad to turn the light off.
6. Place the main power switch in the OFF position at the base.

5-5. Sterilizable Grip

The sterilizable grip can be easily removed and installed as follows: For sterilization process see section 6-2.

1. Press the stop catches at the top of the grip to remove (Figure 9).

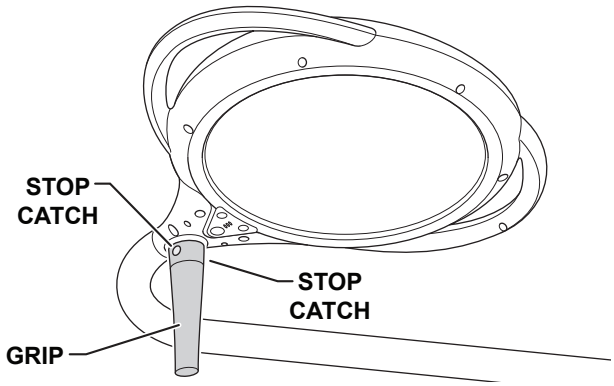


Figure 9. Sterilizable Grip

2. Insert the grip until the stop catches click into the handpiece holes to install.

6-1. Cleaning and Disinfecting

It is good practice to maintain the appearance and function of your DoVera lighting fixture by the means of daily cleaning practices. Moving parts will perform optimally when they are routinely cleaned to avoid build up of dirt or corrosion which may restrict articulation or prohibit ease of movement.

WARNING

Avoid personal injury. DO NOT attempt to clean the product unless power is turned off to the fixture and the power cord is disconnected (on wall and portable light fixtures).

CAUTION

Use of incompatible cleaning agents will cause damage to the fixture. Avoid the use of cleaning solutions which contain chlorine or high concentrations of alcohol, ethylene glycol, phenol, iodophors, or glutaraldehyde based disinfectants. Staining, pitting, discoloration and diffuser cracking or personal injury may occur if these are used.

CAUTION

DO NOT use steam, extremely hot water (over 150°F), or high pressure water sprays to clean the equipment.

DO NOT pour liquids or spray cleaning agents directly onto the equipment.

DO NOT use sharp, pointed or abrasive objects, to avoid the risk of damaging surfaces.

DO NOT use abrasive products, petrol or gasoline, paint thinners, alkaline detergents, acids, containing alcohol or aldehydes.

Avoid using excessive amounts of spray cleaners. Leakage of fluids into the interior of lighthead may cause corrosion of electrical components.

Clean with suitable detergents with low alkaline content and chlorine free.

Dose the detergents strictly according to the percentage indications shown on the manufacturer's technical sheet.

The lighthead exterior should be wiped down daily or between cases with a mild cleaning agent which will not affect the painted or polycarbonate parts.

- Only disinfectants and cleaners that are certified from the manufacturer for compatibility with the following materials may be used:
  - Polycarbonate (PC)
  - polylsulfone (PSU)
  - Silicones
- Always consult the manufacturer of the cleaning agent for proper application and use. Always spot test on an inconspicuous area before use.

Wipe painted surfaces with a dampened cloth using a mild cleaning agent and dried with a soft, lint-free cloth. DO NOT use harsh cleaners on painted surfaces.

- **Stains:** Most stains can be prevented by immediately removing the liquid or substance.
- **Rubber and Plastic Components:** Clean rubber moldings, grips, covers, and plastic handles with a mild soap and water solution. Rinse with clear water and dry with a soft, lint-free cloth

1. Allow the equipment to cool down and only clean it when it is cold.
2. Spray the approved cleaner on lint-free cloth to dampen it, then wipe down the exterior surfaces.
3. Dry thoroughly using a soft, lint free cloth.

6-2. Grip Sterilization

WARNING

An improperly cleaned device may inhibit the ability of the sterilization process to achieve the proper sterility assurance.

Always follow OSHA/EASHW blood borne pathogens standards for protective clothing, including gloves, masks, and eye protection when cleaning the handles.

Always adhere to the correct AAMI and enzymatic cleaning manufacturer's recommendations.

The grips are made of heat and impact resistant plastic (PSU - Polysulfone).

The following cleaning methods are based on AAMI/ISO guidelines for reusable medical devices to assure that health care facilities properly and safely reprocess the devices.

Replace the grips as soon as they become cracked or deformed, as they could fall in the patient area.

The grips must be sterilized before use and can withstand about 200 steam sterilization cycles in accordance with the following parameters:

1. Clean and disinfect the grips before sterilization (see section 6-1).
2. After disinfecting, rinse off the detergent residues with plenty of water.
3. Fit the grips into a suitable sterilization pack before being sterilized.

CAUTION

DO NOT exceed a sterilization temperature of 273.2°F [134°C] for the positioning handle.

4. Steam sterilize the grips at 270°F [132°C] for 4 minutes.

NOTICE

When placing grips in the sterilizer, ensure the open side of the grip is turned downwards. The grips must be free and not blocked by other material being sterilized.

6-3. Operator Maintenance

CAUTION

The DoVera lighting fixture does not utilize internal user serviceable parts. Service must be performed by SKYTRON authorized service technicians using SKYTRON authorized replacement parts and service techniques.

Users are responsible for the thorough inspection of the equipment prior to and after each use. Should any problems or deficiencies arise the results must be reported to the facilities maintenance personnel. The safety of personnel and patients relies on the proper and routine maintenance of this equipment.

Perform inspections prior to and after each use for the following conditions. Report any problems to the SKYTRON authorized representative.

- Missing warning or usage labels.
- Excessive wear, gouges, damaged handles, missing covers, and other physical problems
- Drifting out of position
- Difficulty during routine positioning requiring excessive push/pull force
- Missing or loose screws and fasteners
- Electrical burns
- Evidence of high temperature traces indicating a possible concentration of heat
- Accumulation of lint
- Evidence of ingress of fluid

6-4. Routine Inspections

6-4-1. All Models

- Check all attaching hardware (e.g., screws, nuts, bolts) for tightness. Any missing hardware MUST be replaced.
- Inspect main power ON/OFF switch operation and Intensity ON/OFF button operation.
- Articulate the balance mechanism and rotate each articulation point while observing for lighthead function and the ability of the arm to remain in any position throughout the entire range of movement.
- Inspect polycarbonate diffuser for damage or scratches.
- Check the operation of the intensity control on the lighthead control pad.
- Clean and disinfect according to cleaning instructions.
- Inspect power cord (wall model). Avoid use if any damage is evident.

6-4-2. DE12S Mobile Floor Stand Light

- Inspect Caster/Wheel Assembly for excessive wear or damage.
- Inspect balance mechanism and support post connection point and Phillips screw fasteners. Observe any play or movement in the joint.
- Inspect support post and base hardware for rigidity of attachment point.
- Inspect power cord. Avoid use if any damage is evident.

6-5. Preventive Maintenance

This device requires periodic inspection administered by a SKYTRON authorized service representative.

Required maintenance must be performed by SKYTRON authorized service technicians using SKYTRON authorized replacement parts and service techniques.

WARNING

Prior to replacing the fuse, make sure the power cord is disconnected (on portable and wall light fixtures) or the facility circuit breaker is turned off (on ceiling mounted light fixtures).

SKYTRON Maintenance Manuals are available upon request; however, non-authorized service personnel are required to complete applicable service training. For a syllabus, schedule, availability, cost and overview; logon to www.skytron.us and click on TRAINING. If interested in attending a training session, contact your SKYTRON representative for sponsorship.

To obtain SKYTRON authorized service or preventive maintenance contracts, contact your nearest SKYTRON representative.

The specific items in the MAINTENANCE MATRIX must be inspected and repaired as necessary. The suggested time intervals are intended as a guideline only and actual maintenance will vary by use and conditions. For optimal usage, safety, and longevity of the product, have it serviced only by a SKYTRON authorized service representative using SKYTRON authorized replacement parts and service techniques.

6-5-1. MAINTENANCE MATRIX

Component	Before Use	6 Mo.	1 Yr.
Mounting Hub Hardware (Tighten/Torque)			X
Mounting Hub Level			X
Spring arm Tension Adjustment			X
Friction Adjustment			X
Inspect Electrical Connections at Mounting Hub			X
Covers & Attachment Hardware are Tight			X
Overall Aesthetic Condition	X		
Product Caution & Warning Labels	X		
Stand Model:			
Caster Wheels & Wheel Locks		X	
Power Cord Assembly		X	
Fixture Ground Test		X	
Retention Screws are Tight			X

The expected operating life of the LEDs is approximately 60,000 hours before any degradation of illuminance output occurs. Continued use of the examination luminary after the expected operating life expectancy will result in diminished illuminance values, reducing intensity and affecting color temperature.

6-6. End of Useful Life and Disposal

The end of useful life for the SKYTRON Examination Light is 10 years under normal operating conditions. Service parts are available for this period.

Please contact your SKYTRON authorized representative for disposal of Examination Light products or parts in accordance with environmental regulations for medical products.

6-7. Environmental Protection

Ensure the proper disposal methods whenever disposing of old or damaged Examination Light parts. Always follow compliance to regulatory standards pertaining to Federal, State, and Local regulations.

7-1. Radial and Spring Arm Adjustment

Only Authorized, trained technical staff are allowed to perform service to this product.

WARNING

Troubleshooting or repair by unauthorized personnel could result in the loss of equipment performance and could void applicable safety standards, resulting in personal or patient injury.

All exam lights described in this manual are already balanced and need no further adjustment. In the event of the spring arm becoming stiff or loose over time, mechanical intervention is possible by regulating the compression of the internal spring.

In the case of the radial arm assembly not maintaining position, the clutches will need to be adjusted.

The following instructions apply to all DE12 models.

7-1-1. Spring Arm Adjustment

Spring arm adjustments are the same for all ceiling, wall and mobile models.

1. Slide the silicone gasket and cover forward along the spring arm (Figure 10).

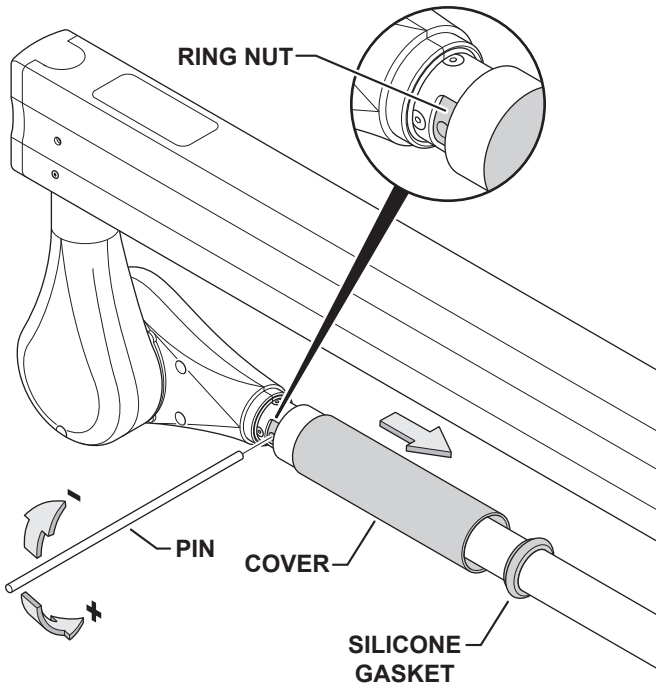


Figure 10. Spring Arm Tension Adjustment

2. Insert a 4mm pin into the holes of the ring nut and turn in the direction indicated by the arrows to increase or decrease the load on the spring.

Adjust Spring arm according to the following conditions:

- The spring arm drops indicating insufficient spring force.
  - Turn the ring nut downwards to increase spring load.
- The spring arm lifts indicating spring force is too high.
  - Turn the ring nut upwards to decrease spring load.

3. Return the cover and silicone gasket to its original position.

7-1-2. Friction Adjustment

If the arm does not maintain position the friction will need to be adjusted.

To prevent the arm from drifting turn the arm brake set screws clockwise to increase braking force using a 2.5mm Allen wrench (Figure 11).

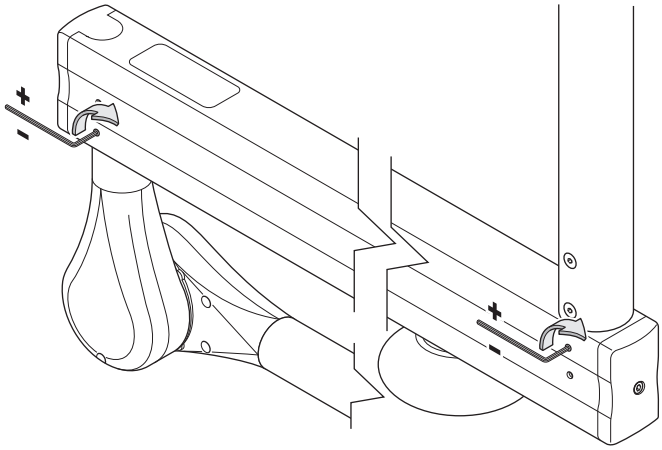


Figure 11. Friction Adjustment

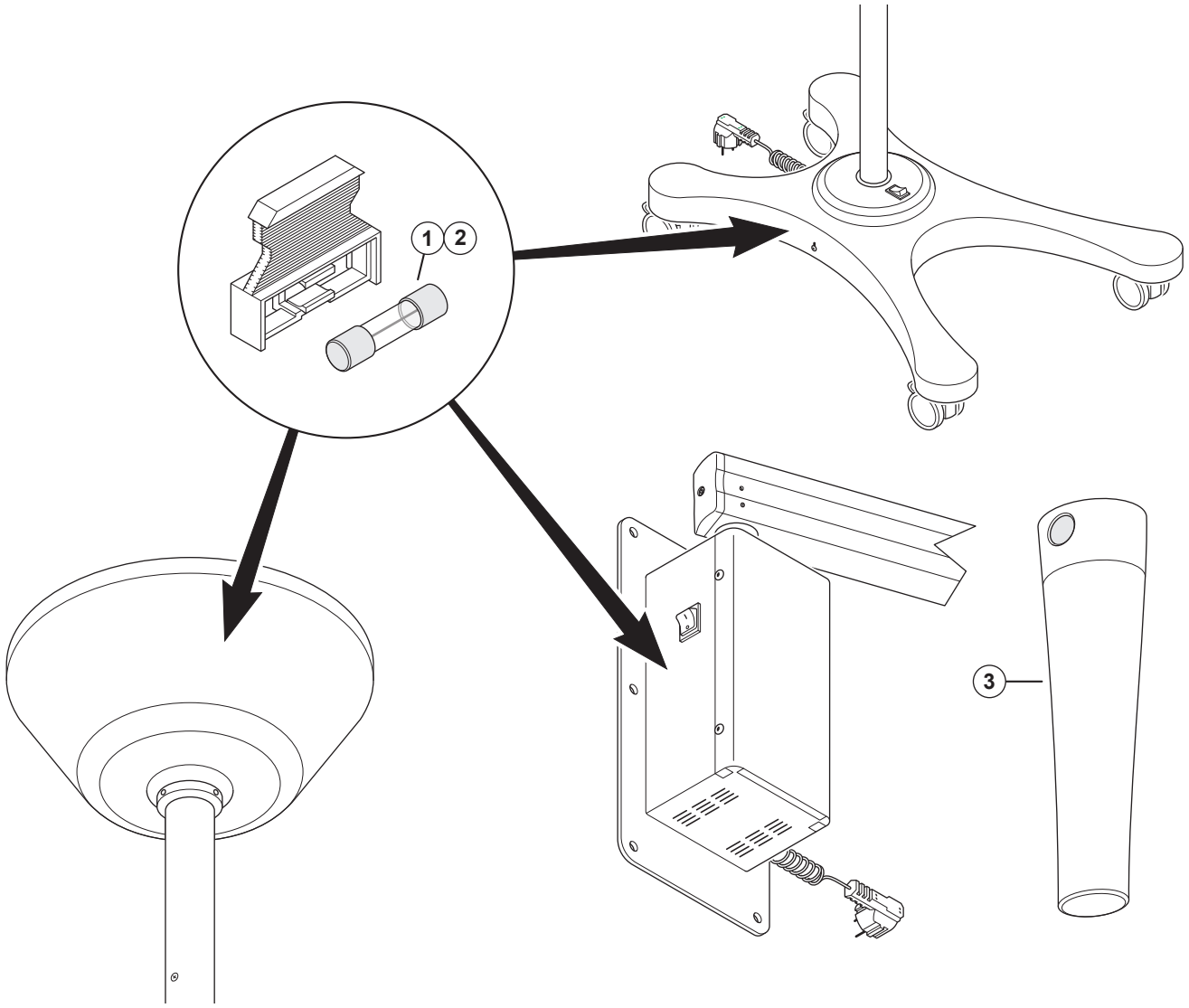
DoVera examination light replacement parts listed in this section have been identified by SKYTRON as serviceable by SKYTRON trained facility personnel and are available for purchase. To obtain SKYTRON certified parts and authorized service, contact your authorized SKYTRON representative.

CAUTION

Any parts or assemblies not listed in this section must be serviced or replaced by SKYTRON authorized service personnel only. This is necessary to avoid the possibility of damage to the equipment.

⚠ CAUTION

When replacing a fuse on ceiling mounted lightheads, ensure you have a good foothold and use appropriate fall protection measures in accordance with OSHA standards.



Item	Part No.	Description	Qty.
1	Z400208	FUSE, T1AH	AR
2	Z400195	FUSE, T2AH	AR
3	Z180045	STERILIZABLE HANDLE	AR

Electromagnetic Compatibility (EMC)

Although this equipment conforms to the intent of the 2004/108/EC EMC Directive, all medical equipment may produce electromagnetic interference or be susceptible to electromagnetic interference. The following are guidance and manufacturer's declarations regarding EMC for the DoVera DE12 Light.

- The DoVera DE12 Light needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following pages.

⚠ WARNING

This equipment is intended for use by healthcare professionals only. As with all electrical medical equipment, this equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the DoVera DE12 light unit or shielding the location.

- This manual contains all necessary instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life.
- Portable and Mobile RF communications equipment can affect the performance of the DoVera DE12 Light. Please use the guidelines and recommendations specified in Tables 4 and 6 (IEC 60601-1-2, Edition 4.0).
- Other Medical Equipment or Systems can produce electromagnetic emissions and therefore can interfere with the functionality of the DoVera DE12 Light. The DoVera DE12 Light should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the DoVera DE12 Light should initially be observed to verify normal operation in the configuration in which it will be used.
- In certain cases electromagnetic disturbances may cause a disruption of normal operation (flicker or dimming) of the exam light.
- The electrical cables, external power supplies, and accessories listed or referenced in this manual have been shown to comply with the test requirements listed in the following tables. Care should be taken to use only manufacturer-recommended cables, power supplies, and electrical accessories with the DoVera DE12 Light. If a third-party supplier offers cables, external power supplies, and electrical accessories for use with the DoVera DE12 Light and they are not listed or referenced in this manual, it is the responsibility of that third-party supplier to determine compliance with the standards and tests in the following tables.
- The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from the DoVera DE12 Light or decreased electromagnetic immunity of the DoVera DE12 Light.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The DoVera DE12 Light is intended for use in the electromagnetic environment specified below. The customer or the user of the DoVera DE12 Light should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF Emissions - CISPR 11
(Radiated & Conducted)</td><td>Group 1</td><td>The DoVera DE12 Light 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.</td></tr>
<tr><td>RF Emissions - CISPR 11
(Radiated & Conducted)</td><td rowspan="2">Class A</td><td rowspan="3">The DoVera DE12 lights are suitable for use in professional healthcare environments only.

⚠ WARNING
This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the DoVera DE12 Light or shielding the location.</td></tr>
<tr><td>Harmonic Emissions
EN/IEC 61000-3-2</td></tr>
<tr><td>Voltage fluctuations/
Flicker Emissions
EN/IEC 61000-3-3</td><td>Complies</td></tr>
</table>

NOTE: 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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The DoVera DE12 Light is intended for use in the electromagnetic environment specified below. The customer or the user of the DoVera DE12 Light should assure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Intended Electromagnetic Environment**
Electromagnetic Discharge (ESD) EN/IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst EN/IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips EN/IEC 61000-4-11 (r)	0 % UT; 0,5 cycle (g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° (q) 0 % UT; 1 cycle and 70 % UT; 25/30 cycles (h) Single phase: at 0°	0 % UT; 0,5 cycle (g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° (q) 0 % UT; 1 cycle and 70 % UT; 25/30 cycles (h) Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DoVera DE12 Light requires continued operation during power mains interruptions, it is recommended that the DoVera DE12 Light be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC 61000-4-11 (r)	0 % UT; 250/300 cycle (h)	0 % UT; 250/300 cycle (h)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DoVera DE12 Light requires continued operation during power mains interruptions, it is recommended that the DoVera DE12 Light be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field EN/IEC 61000-4-8	30 A/m g) 50 Hz or 60 Hz	30 A/m g) 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_T is the a.c. mains voltage prior to application of the test level.			

(g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.
(h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
(q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an over current protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
(r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25% of the highest RATED input voltage shall be tested at one RATED input voltage within the range.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (continued)

The DoVera DE12 Light is intended for use in the electromagnetic environment specified below. The customer or the user of the DoVera DE12 Light should assure that it is used in such an environment.

Immunity Test	EN/IEC 60601-1-2 Test Level	Compliance Level	Intended Electromagnetic Environment
			⚠ WARNING **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the DoVera DE12 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
Conducted RF EN/IEC 61000-4-6	3Veff 150kHz to 80MHz	3Veff 150kHz to 80MHz	**Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 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 metres (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 EN/IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m 80MHz to 2.5GHz	

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 the DoVera DE12 Light is used exceeds the applicable RF compliance level above, the DoVera DE12 Light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DoVera DE12 Light.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Date	Revision	Revision History
01/09/2023	0	Initial release.

NOTES

NOTES

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