



 LUSTRE

ClearSkin

pure light treatment for acne™

Instructions for Use (IFU)

JANUARY 2021

AMBICARE HEALTH LTD | TRADITIONAL 510K | For the LUSTRE ClearSkin System





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Introduction

Thank you for choosing LUSTRE ClearSkin.

The LUSTRE ClearSkin device is intended to emit light in the blue region of the light spectrum and is indicated for the treatment of **mild to moderate acne** of the face.

(See **'Who should use LUSTRE ClearSkin'** section on page 5, for more information about how to tell if you have mild to moderate acne).



Users of this device can obtain benefit from using it only if they read and comprehend all information in the user manual.


You must follow all the instructions in the user manual.

Please feel free to contact us on our Customer Services number if you have any comments about LUSTRE ClearSkin or this User Guide.



Device description

The LUSTRE ClearSkin light system uses blue light to treat acne.

- 
- + The LUSTRE ClearSkin device contains light emitting diodes (LEDs) designed to emit blue light of a specific brightness and wavelength.
 - + The LUSTRE ClearSkin device attaches to your skin at the site of your acne using the LUSTRESTRIPS adhesive strips. LUSTRE adhesive strips are made from a polyethylene film with a medical-grade acrylic adhesive.
 - + The LUSTRE device is charged from a USB charging socket using the cable provided. The device will not switch on while it is connected to the power source.

Packages & Content

Blue Light Technology System either called a LUSTRE ClearSkin SOLO or TRIO

LUSTRE ClearSkin Device

Solo: 1 x treatment head
Trio: 3 x treatment heads



Charger Cable



LUSTRESTRIPS

Solo: 30 x LUSTRESTRIPS
Trio: 90 x LUSTRESTRIPS



Instruction Manual

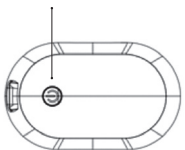


Goggles

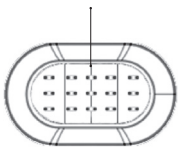
Image for illustration purposes only,
Shape and color may vary.



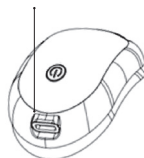
ON/OFF Button



LEDs



USB Port



Indications for use

The LUSTRE ClearSkin device is indicated for the treatment of mild to moderate acne of the face. The LUSTRE ClearSkin device emits light in the blue region of the light spectrum.

- + The areas in which the LUSTRE ClearSkin can be used are shown by the blue shaded areas. **These areas of the face are the forehead, cheeks and chin areas.**
- + LUSTRE ClearSkin should **NOT** be used on or around the nose.
- + The Lustr device is designed with a flexible lip so as to prevent light from shining directly into the eye. However, if you are treating skin close to the eyes and have any concerns, we recommend using the eye protection goggles provided.



The typical appearance of acne is a mixture of the following: a greasy skin, red pimples or spots, yellow pus-filled spots and scars.

Who should use LUSTRE ClearSkin ?

LUSTRE ClearSkin should be used for the treatment of mild to moderate acne only. This can be described as:

1. **Mild acne:** A few pimples or spots, a few pus filled spots, some whiteheads or blackheads.
2. **Moderate acne:** Some pimples or spots, some pus filled spots, only a few small nodules. Many whiteheads or blackheads.





When should LUSTRE ClearSkin NOT be used

- + Do NOT use LUSTRE ClearSkin if your skin is clear. This means your skin does not have any spots, pimples, whiteheads or blackheads.
- + Do NOT use LUSTRE ClearSkin for the treatment of whiteheads or blackheads. Please consult your doctor for a more appropriate treatment.
- + Do NOT use LUSTRE ClearSkin if you suffer from severe acne. Please consult your doctor for a more appropriate treatment.

Contraindications

- + DO NOT use LUSTRE ClearSkin to treat any other bodily areas other than the areas of the face, back or shoulders indicated in "Indications for use". The safety of the treatment on other parts of the body other than the areas of the face indicated in "Indications for use" has NOT been tested and the risk is unknown.
- + DO NOT use LUSTRE ClearSkin to treat any other condition that has not been listed in the 'Indications for Use' section. The LUSTRE ClearSkin has not been tested for any other conditions and the risk is unknown.
- + DO NOT use the LUSTRE ClearSkin if you are pregnant, or if you are planning to become pregnant. DO NOT use the LUSTRE ClearSkin if you are a woman who could become pregnant (unless you are using a reliable form of contraception). The safety for pregnant women has NOT been tested and the risk is unknown. If you do become pregnant when using LUSTRE ClearSkin STOP using the device as soon as you become aware.
- + DO NOT use the LUSTRE ClearSkin if you are a child under 12 years of age or on children under 12 years of age. The safety of the device for children younger than 12 years of age has NOT been tested and the risk is unknown.
- + DO NOT use the LUSTRE CLEARSKIN if you are sensitive to light. If you use the LUSTRE ClearSkin and you are sensitive to light you may cause a severe skin reaction.

- + DO NOT use LUSTRE CLEARSKIN if you are known to be sensitive to polyethylene film and/or medical-grade acrylic adhesive, found in the adhesive strips. If you use the adhesive strips and are sensitive to the materials, you may cause a skin reaction.
- + DO NOT use LUSTRE ClearSkin on sunburned skin. The effect of using LUSTRE ClearSkin on sunburned skin has not been tested and the risk is unknown.
- + DO NOT use the LUSTRE CLEARSKIN if you are taking or have taken in the past drugs that may make you sensitive to light. Common examples of drugs that may make you sensitive to light are:

Antihistamines – used in cold and allergy medicines.

Non-steroidal anti-inflammatory drugs (NSAIDs)
– used to control pain and inflammation.

Antibiotics – including the tetracyclines (minocycline or doxycycline) and sulfonamides (or "sulfa" drugs)

Topical (cream) retinoid used to treat acne,
including (Retin A and Tretinoin)

Systemic (tablet) retinoid used to treat acne,
including (Accutance or isotretinoin)

Other substances that you may be exposed to, or that you may have been exposed to in the past, can also make you sensitive to light. Common examples of these substances are: - St John's Wort, Deodorants, antibacterial soaps, artificial sweeteners, naphthalene (mothballs), petroleum products, brightening agents found in laundry detergent, and cadmium sulphide (a chemical injected into the skin during tattooing).



Risks and Benefits

The information in this section was obtained from users of the LUSTRE ClearSkin device.

Known Risks

The known risks of the LUSTRE ClearSkin device are:

1. Temporary darkening of the skin at the treatment site. Reported by some users (< 1 in 100 users).
2. Temporary reddening of the skin at the treatment site. Reported by some users (< 1 in 100 users).
3. Allergy to the adhesive used in the LUSTRE adhesive strips (<1 in 100 users). See **Warnings** section on page 9.

Potential risks

You must follow any contraindications, warnings, and precautions found in this user guide. If you do not follow the contraindications, warning and precautions, the risks are unknown.

- + The risk in children (under 12) or pregnant women has not been studied, and therefore, this device is not indicated for either population. See **Warnings** section on page 9.

- + The risk in treating severe acne or comedonal acne has not been studied, and therefore, this device is not indicated to treat severe or comedonal acne. See **Contraindications** section, page 6.
- + The risk in treating other skin conditions other than those indicated in the indications for use section has not been tested and the risk is unknown. See **Contraindications** section, page 6.

Benefits

- + No users have seen their acne get worse during the treatment.
- + Most users report their acne improves after 4 weeks of using LUSTRE ClearSkin.
- + Most users report their acne continues to improve, 8 weeks after starting to use LUSTRE ClearSkin.
- + Use your LUSTRE ClearSkin as soon as a break out reoccurs.

Warnings and Precautions

Warnings

DO NOT use the LUSTRE device until you have carried out a sensitivity test. If you use the LUSTRE ClearSkin without first carrying out a sensitivity test your skin may become reddened or darkened and painful.

DO NOT use LUSTRE ClearSkin to treat acne on any areas of the face **other than those indicated in “indications for use”.**

DO NOT share the LUSTRE ClearSkin device amongst friends or family. The device is for **individual use only.**

DO NOT use LUSTRE ClearSkin **over or close to the thyroid gland.** Doing so may stimulate the gland.

DO NOT use the LUSTRE ClearSkin without removing creams, lotions or make-up from your face BEFORE treatment. Some ingredients in these products may make you sensitive to light. If you use the LUSTRE ClearSkin without removing these products you may cause a severe skin reaction.

DO NOT shine the light from LUSTRE ClearSkin directly into your eyes or someone’s eyes. The effect of looking directly at the blue light has not been tested and the risk is unknown.

Importance of the need to follow the treatment regime

DO NOT treat for longer than 20 minutes for each treatment. Using LUSTRE ClearSkin for longer than the specified treatment time may lead to a temporary, mild reddening or darkening of your skin.

DO NOT treat for less than 20 minutes. The treatment may **NOT** be effective and the number of acne blemishes may not be reduced if the LUSTRE ClearSkin is used for less than the specified treatment time.

DO NOT treat more often than the specified regimen. Treating more often or longer than the specified regimen may lead to a temporary, mild reddening or darkening of your skin.

DO NOT treat less often than the specified regimen. Treatment may be ineffective and the number of acne blemishes may not be reduced if the LUSTRE ClearSkin is used less often than the specified regimen.

DO NOT use the LUSTRE ClearSkin in any way that is not exactly as specified in these instructions for use. Use of the LUSTRE ClearSkin other than exactly as specified in these instructions for use has not been tested and the risk is unknown.

CONTACT a healthcare professional as soon as possible if you suspect that you have had any kind of harmful reaction when using the LUSTRE ClearSkin. If you do not obtain medical advice the reaction may get worse.

To reduce the risk of injury or electrical shock:

To reduce the risk of electric shock the LUSTRE ClearSkin cannot be used to treat your acne while it is in the battery charging mode and connected to a USB power source.

NEVER use the LUSTRE ClearSkin where it can fall or be pulled into water.

NEVER use the LUSTRE ClearSkin or its Power Supply if you think they may have been immersed in water or if you have spilt any liquids on them.

NEVER remove any covers from the LUSTRE ClearSkin or its Power Supply. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect reassembly could cause an electric shock when the LUSTRE ClearSkin is used again.

DO NOT attempt to operate LUSTRE ClearSkin with any Power Supply other than one approved to deliver 5 Volts at 1 amp maximum per port.

DO NOT use the LUSTRE ClearSkin if the LUSTRE ClearSkin device or charging cable are damaged in any way.

DO NOT use any other charging cable or computer power supply as this may damage your lustre device.

Precautions

Before use; with the device switched off, check the LUSTRE ClearSkin device and charging cable for signs of physical damage.

Before and after use, wash your face with a suitable cleanser.

AVOID using out of date LUSTRESTRIPS adhesive strips. If you use out of date adhesive strips then the treatment device may NOT adhere to your skin.

AVOID touching the treatment surface of the LUSTRE ClearSkin device with your fingers or any utensils. Scratches may reduce the light output of the device. The effect of reducing the light output of the LUSTRE ClearSkin has NOT been tested and the risk is unknown.

Do NOT re-use the LUSTRESTRIPS. The adhesive strips are **single-use only**. If you re-use the adhesive strips the treatment device may NOT adhere to your skin and bacteria may be transferred between treatments.

AVOID placing the LUSTRE ClearSkin unit in a dusty or dirty environment or in direct sunlight. Dirt, dust or sunlight may reduce the light output of the device. The effect of reducing the light output of the device has NOT been tested and the risk is unknown.

When not in use, store the device in its original packaging.

The entire surface of the LUSTRE ClearSkin controller and the device, including the lens cover may be cleaned by following the **cleaning instructions on page 16**.

Do not use any other cleansing products other than those stated in the user guide. Use of other cleansing products may damage the controller and device.

First time Setup

– Charging the LUSTRE ClearSkin

1. Unpack the LUSTRE ClearSkin device from its box and check off all of the parts listed in device description, page 4.
2. Check all of the parts for any signs of visible damage.
3. Do not use any other charging cable or computer power supply as this may damage your LUSTRE device.
4. The red battery indicator on the LUSTRE ClearSkin device indicates that the device is charging.
5. The LUSTRE ClearSkin takes approximately 3 hours to charge.
6. The battery is fully charged when the battery indicator shows green.
7. Unplug the charging cable from the LUSTRE ClearSkin device.

Before using the LUSTRE ClearSkin device to treat your acne you MUST carry out a test on your forearm to decide if you are sensitive to light and/or the adhesive used to attach the device to your skin – See "Testing your skin for sensitivity" – page 12).

To reduce the risk of electric shock the LUSTRE ClearSkin cannot be used to treat your acne while it is in the battery charging mode and connected to a power source.

Skin preparation before and after treatment

Before a treatment, **ALWAYS** cleanse and **dry your face** with a suitable skin cleanser to remove all product residues, pollutants, and any traces of make-up. This will make sure that all the light from the LUSTRE device reaches the skin.

After a treatment, **ALWAYS** cleanse and **dry your face** with a suitable skin cleanser, this will remove any traces of adhesive from device adhesive strips.

Testing your skin for sensitivity

Before using the LUSTRE ClearSkin device for the first time to treat your acne you **MUST** carry out a test on your inner forearm to decide if you are sensitive to light and/or the adhesive used to attach the device to your skin.

This is a one time test that **MUST** be carried out before you use the LUSTRE ClearSkin device for the first time.

1. Follow the set-up instructions on page 12 to fully charge the battery.
2. After the battery has charged you can carry out the test.
3. Before carrying out a sensitivity test, cleanse and dry the inside of your forearm with a suitable skin cleanser to remove all product residues, pollutants, and any traces of sunscreen. This will make sure that all the light from the LUSTRE device reaches the skin.
4. Unpeel one side of the LUSTRE ClearSkin adhesive strip.
5. Place the sticky side of the strip onto the flat surface of one LUSTRE ClearSkin device. Ensure the strip aligns with the shape of the LUSTRE ClearSkin device.
6. Press down across the entire surface of the adhesive strip.
7. Peel the top layer of the backing paper from the adhesive strip.
8. Attach the device to the **inside of your left or right forearm** and push down gently.
9. When the LUSTRE device is in place on your skin, press the green button

10. LUSTRE ClearSkin device will automatically switch off after 20 minutes
11. Remove the LUSTRE ClearSkin device from your forearm by using thumb and first finger to take hold of the blue tab.

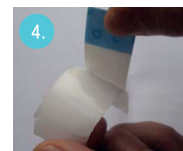
Always pull the blue tab slowly. If you pull quickly you may cause your skin to become red.

12. Remove the LUSTRESTRIP from the device.
13. Discard the used adhesive strip in the garbage.
14. **Immediately after the treatment** your forearm **may** look like these pictures. This is a normal reaction. **Wait 24 hours.**
15. If the test area **STILL** looks like this **after 24 hours**, this is an adverse reaction. You **ARE sensitive to the light or adhesive strips** used in the LUSTRE ClearSkin device.

The LUSTRE ClearSkin is **NOT** suitable for you.

16. If you **do NOT** show signs of sensitivity to the light or the adhesive strip then you are unlikely to be sensitive and you may begin your acne treatment.

An adverse reaction is any pain, discomfort, redness or darkening of the skin that appears up to 24 hours of you testing the LUSTRE ClearSkin.



Using the LUSTRE ClearSkin device to treat your acne

Before using the LUSTRE ClearSkin device for the first time to treat your acne you **MUST** carry out a sensitivity test on your forearm to decide if you are sensitive to light and/or the adhesive used to attach the device to your skin (page 12).

You should always adhere to a recommended cleaning regimen. Failure to follow the regimen may result in a reduction in the output of the light or possible skin infection.

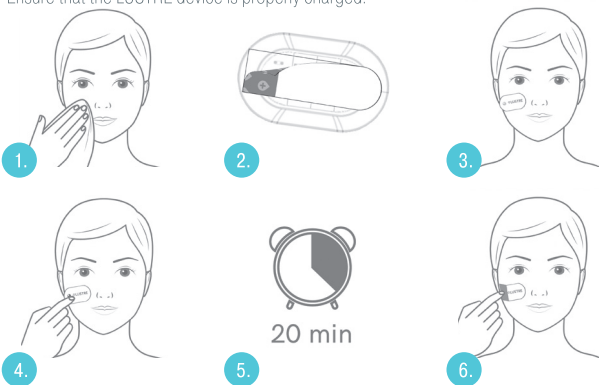
Always check the expiry date of the LUSTRE adhesive strips before each use. Avoid using out of date LUSTRE adhesive strips. If you use out of date adhesive strips then the treatment device may NOT adhere to your skin.

Treatment regime

Use LUSTRE ClearSkin every day for 20 minutes, for 6 weeks to treat your acne, and then stop. You may continue to use LUSTRE ClearSkin thereafter to treat breakouts.

Using LUSTRE ClearSkin to treat your acne is a 6 step process.

Before use; clean the device(s). Follow the cleaning instructions on page 16. Ensure that the LUSTRE device is properly charged.



Step 1. Cleanse your face

Step 2. Attaching the LUSTRESTRIPS adhesive strip to the device

1. To attach the LUSTRE ClearSkin device to the area of acne you want to treat, use the LUSTRESTRIPS adhesive strips. One adhesive strip is used per LUSTRE ClearSkin device.
2. Unpeel the coloured tab and cover sheet away from the backing paper of the LUSTRESTRIPS adhesive strip.
3. Place the sticky side of the strip onto the flat surface of the LUSTRE ClearSkin device ensuring that the strip aligns with the shape of the LUSTRE ClearSkin device.
4. Press down across the entire surface of the adhesive strip.
5. Repeat steps 1-4 depending on how many LUSTRE ClearSkin device are required.

Step 3. Attaching the LUSTRE ClearSkin device(s) to the area(s) of acne you want to treat

1. Peel the top cover paper from the adhesive strip.
2. Using a mirror attach the LUSTRE ClearSkin device to the area of acne you want to treat and apply light pressure to the rear of the device.
3. Repeat steps 1-3 depending on how many LUSTRE ClearSkin devices are being used.

Step 4. Begin the treatment

Press the ON/OFF button for 1 second to

begin treatment. The device should only be switched on AFTER it has been affixed to the treatment area of skin. The on/off button will show a green light.

Step 5. End of the treatment

LUSTRE will turn off automatically after 20 mins. A short beep will signal the end of the treatment. You may wish to repeat steps 3 and 4 on different areas of problem skin.

Step 6. Removing the LUSTRE ClearSkin device(s) from your skin

To remove The LUSTRE ClearSkin device from the treatment area carefully and very slowly peel device away from the skin with the adhesive strip tab. **Always pull the blue tab slowly. If you pull quickly you may cause your skin to become red.**

Remove and discard the LUSTRESTRIP after each treatment.

Remove the LUSTRESTRIPS adhesive strip from each device.

1. Using your thumb and first finger take hold of the blue tab of the LUSTRE ClearSkin adhesive strip and slowly pull the adhesive strip off the device.
2. Discard the used adhesive strip in the garbage.

Do NOT re-use the LUSTRESTRIPS adhesive strip. The adhesive strips are single use only. If you re-use the adhesive strips the treatment device may NOT adhere to your skin and will transfer acne bacteria between treatment sites.

3. Clean the device (see page 16).

Cleaning Instructions for the ClearSkin Device

It is important that the LUSTRE ClearSkin device is switched off before cleaning.

- + The entire surface of the LUSTRE ClearSkin device, including the lens cover may be cleaned by wiping them with a fresh individual hand wipe.
- + Please refrain from using any other cleansing products as these may damage the plastics.

Care and Maintenance

- + **AVOID** scratching the lens cover as scratches may reduce the efficiency of the treatment.
- + **AVOID** placing the LUSTRE ClearSkin unit in a dusty or dirty environment or in direct sunlight. Dirt, dust or sunlight may reduce the light output of the device.
- + **AVOID** touching the treatment surface of the LUSTRE ClearSkin device with your fingers or any utensils. Scratches may reduce the light output of the device.
- + When not in use, store the device in its original packaging.

Disposal

Do NOT dispose of the LUSTRE ClearSkin controller, device or power adaptor in domestic garbage.

For protection of the environment, please package and return this unit to Ambicare health at the end of its working life.



Troubleshooting

Ambicare Health Ltd record and analyze all problems reported to them. The majority of problems reported have a simple cause and can be readily put right by the user. They are listed in the troubleshooting table on www.lustreclearskin.com.

If the actions suggested fail to fix the problem, or the problem reoccurs, please refer to Ambicare Health to arrange servicing of your LUSTRE ClearSkin device.

Do not attempt to investigate any further; LUSTRE ClearSkin has no parts you can repair yourself.

Replacing your LUSTRE ClearSkin device.

- + All LEDs, including those used in the LUSTRE ClearSkin device, gradually lose brightness the longer they are used. This loss of brightness is very slow.
- + The brightness and lifetime of the LEDs used in the LUSTRE ClearSkin have been carefully selected so that you can rely on it to give effective treatments for 5 years.
- + Replacement devices are available from customer services (see below warranty section).

Warranty

Under normal use this product is guaranteed for 1 year after its original purchase date against manufacturing defects in materials or workmanship.

This warranty extends only to the original purchaser and only when purchased from an authorized retailer.

If the product should become faulty within the warranty period, contact the Customer Service Centre.

Ambicare Health Ltd,
ALBA Innovation Centre,
ALBA Campus
Livingston, EH54 7GA,
United Kingdom

Tel +44 (0)1506 592239

Alternatively you can contact us at:
customerservices@ambicarehealth.com

Ambicare Health Ltd reserves the right to replace a defective product with the most compatible product currently available.

This warranty does not cover damage caused by the following:

- + Accident, misuse, abuse or alteration
- + Servicing by unauthorized persons
- + Connection to incorrect power sources
- + Use with unauthorized accessories

Ambicare health Ltd shall not be responsible for any incidental, special or consequential damages resulting from the use of this product. All implied warranties, including but not limited to implied warranties of fitness and merchantability are limited in duration to one year from date of original purchase.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, or limitations on how long an implied warranty lasts, so some of the above limitations and exclusions may not apply to you.

Contact us

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Specifications

Product Name: LUSTRE ClearSkin Light System

Model Number: SOLO: PR3105US - TRIO:PR3305US

Operating Wavelength: 415nm +/- 15nm

Operating Temperature / Humidity: 10°C to 40°C / 20% to 85%

Storage and Transport Temperature / Humidity: 5°C to 60°C / less than 85%

USB power supply delivering 5 Volts at 1 amp maximum per port.

1. General Safety

- 1.1. The LUSTRE device is an electrical device, which under certain circumstances could present an electrical shock hazard to the user. Please read the accompanying user manual thoroughly and follow directions stated in the manual to assure maximum safety during charging and operation.
- 1.2. EN/IEC 60601-1:2006
 - 1.2.1. Protection against electrical shock – Class II
 - 1.2.2. Degree of protection against electrical shock – Type BF Applied Part
 - 1.2.3. Protection against dripping water when tilted up to 15° – IP22
- 1.3. EMI/EMC
 - 1.3.1. Compliance against standard EN/IEC 60601-1-2:2015
- 1.4. LED lighting (Blue Light)
 - 1.4.1. Compliance against standard EN62471:2008

2. Electromagnetic Compatibility (EMC)

- 2.1. Magnetic Compatibility (EMC).

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN 60601-1-2:2015 standard has been implemented. This standard defines levels of electromagnetic emissions for medical device.

The LUSTRE Device manufactured by Ambicare Health Ltd conforms to this EN/IEC 60601-1-2:2015 standard for both immunity and emissions. Refer to further EMC test results.

Radiated Emission	EN 60601-1-2: 2015 CISPR 11:2015 + A1: 2016	PASS
Conducted Disturbance (0.15-30MHz)	EN 60601-1-2: 2015 CISPR 11:2015 + A1: 2016	N/A
Harmonic Current	EN 60601-1-2: 2015 EN 61000-3-2: 2014	N/A
Voltage Fluctuation and Flicker	EN 60601-1-2: 2015 EN 61000-3-3: 2013	N/A

Electrostatic Discharge	EN 60601-1-2: 2015 EN 61000-4-2: 2009	PASS
RF Field Strength Susceptibility (80-2700MHz)	EN 60601-1-2: 2015 EN 61000-4-3: 2006 +A1:2008+A2: 2010	PASS
Electrical Fast Transient/ Burst Test	EN 60601-1-2: 2015 EN 61000-4-4: 2012	N/A
Surge Test	EN 60601-1-2: 2015 EN 61000-4-5: 2014	N/A
Conducted Susceptibility Test	EN 60601-1-2: 2015 EN 61000-4-6: 2014	N/A
Power Frequency Magnetic Field Susceptibility Test	EN 60601-1-2: 2015 EN 61000-4-8: 2010	PASS
Voltage Dips and Interruptions Test	EN 60601-1-2: 2015 EN 61000-4-11: 2004	N/A

Symbol Glossary

 Refer to operating Instructions

 Class II equipment
– provides double Isolation to protect against electric shock

IP22 Degree of protection – IP22 Protection against penetration by solid objects with diameters larger than 12.5 mm. Protection against dripping water when tilted up to 15°.

 Type BF Applied Part

LOT Batch/Lot/ID Number
This is the unique identifying number for each batch

REF Catalogue number

 Manufacturer

 Store in a clean dry area up to 24°C - LUSTRESTRIPS

 Expiry date of the LUSTRESTRIPS

 WEEE Compliance

 Keep Dry

 Do not reuse – single use



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