Transilluminator

INSTRUCTIONS FOR USE

Keeler

– A world without vision loss –

CONTENTS

	Consult instructions for use		General warning sign
	Date of manufacture		Warning: Electricity
	Manufacturer's name and address		Warning: Floor level obstacle
	Country of manufacture		Warning: Non-ionizing radiation
	Waste Electrical and Electronic Equipment (WEEE) recycling		Warning: Optical radiation
	This way up		Warning: Hot surface
	Keep dry		Conformité Européene
	Fragile		Type B applied part
	Do not use if package is damaged		Class II equipment
	Temperature limit		Atmospheric pressure limitation
	Authorised representative in the European Community		Humidity limitation
	Catalogue number		Serial number
	Translation		Medical device

The Keeler Transilluminator is designed and built in conformity with Directive 93/42/EEC, Regulation (EU) 2017/745 and ISO 13485 Medical Devices Quality Management Systems.

Classification: CE: Class I

FDA: Class II

This IFU is also available on the Keeler UK and Keeler USA websites.

Transilluminator:
Finoff Transilluminator

Handles:
Pocket, Slimline, GenMed Wall Unit

Chargers:
Lithium Duo Charger, Lithium Mini Charger

1. INDICATIONS FOR USE

These devices are intended to be used only by suitably trained and authorised healthcare professionals.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician or practitioner.

Intended use / purpose of instrument

The Keeler Finoff Transilluminator is indicated for the transillumination of tissue, and, in particular, scleral transillumination.

2. SAFETY

2.1 WARNINGS AND CAUTIONS

Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Keeler Ltd. The use of other accessories may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may lead to incorrect operation.

Observe the following precautions in order to ensure safe operation of the instruments.

WARNINGS

- Never use the instrument if visibly damaged and periodically inspect it for signs of damage or misuse.
- Check your Keeler product for signs of transport / storage damage prior to use.
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment.
- US Federal Law restricts this device to sale by or on the order of a physician or practitioner.
- This device is intended to be used only by suitably trained and authorised healthcare professionals.
- This product should not be immersed in fluid.
- The power switch and mains plug are the means of isolating the device from the mains supply - ensure both the power switch and mains plug are accessible at all times.
- Do not position the equipment so that is difficult to press the power switch or remove the mains plug from the wall socket.

- Switch off the electrical supply and disconnect from the mains electrical supply before cleaning and inspection.
- If the product emits a strange odour, heat, or smoke, stop use immediately. The continued use of a damaged product or part may cause injuries.
- Do not touch the terminal contacts of the charging dock or hand unit, or the terminal contacts and the patient simultaneously.

CAUTION

- Use only genuine Keeler approved parts and accessories or device safety and performance may be compromised.
- Use only Keeler approved batteries, chargers, and power supplies as per the accessories listed in section 11.
- Backwards compatibility of the Bulb module has not been tested.
- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C.
- Refraction stand variants or adaptors should only be used in combination with EN/IEC 60601-1 and EN/IEC 60601-1-2 compliant power supplies and devices.
- Keep out of the reach of children.
- To prevent condensation from forming, allow instrument to come to room temperature before use.
- For indoor use only (protect from moisture).
- There are no user serviceable parts inside. Contact authorised service representative for further information.
- Ensure device is securely held in docking station to minimise risk of injury or damage to equipment.
- Follow guidance on cleaning / routine maintenance to prevent personal injury / damage to equipment.
- Failure to carry out recommended routine maintenance as per the instructions in this IFU may reduce the operational lifetime of the product.
- At product end of life dispose of in accordance with local environmental guidelines (WEEE).
- To isolate the equipment, disconnect from the mains or switch off at the mains.
- The product and the ear specula are supplied non-sterile. Do not use on injured tissue.
- Use new or sanitised specula to limit the risk of cross-contamination.
- The disposal of used ear specula must occur in accordance with current medical practices or local regulations regarding the disposal of infectious, biological medical waste.

Chargers

- Do not fit mains power adapter into a damaged mains outlet socket.

- Route power cords safely to eliminate risk of tripping or damage to user.

- Only Keeler handles with a red base can be used in the Keeler Lithium Chargers. Do not try to insert a Keeler handle with a blue base into the Keeler Lithium Chargers. Refer to Keeler handle and bulb identification.

Direct Instruments

- When connecting instrument heads to handles please check that the voltage of the bulb in the instrument corresponds with the voltage of the handle.
- Care should be taken when fitting heads to handles not to trap skin between parts.
- Please ensure that the control is in the off position when the examination has been completed.
- This device must only be used by clinicians trained in the use of ophthalmic devices.

Batteries and Bulbs

- Do not use a battery that is deformed, leaking, corroded or visually damaged. Handle a damaged or leaking battery with care. If you come into contact with electrolyte, wash exposed area with soap and water. If it contacts the eye, seek medical attention immediately.
- Ensure battery orientation is correct, or personal injury / damage to equipment may occur.
- Do not mix battery types.
- Do not attempt to charge non-rechargeable batteries.
- Do not charge battery in an environment where the temperature may exceed 35˚C or fall below 10˚C.
- When replacing rechargeable cell, turn handle off and insert new cell. Replace bottom cap, and place handle into charging well.
- If a short circuit occurs, reactivate the battery by placing the handle in the charger until the Bulb flashes. This is a built-in protection device to protect the battery from damage.
- Dry cell batteries should be removed if your instrument is not to be used for long periods.
- Do not disassemble or modify the battery. There are no serviceable parts inside
- Do not dispose of battery in fire, puncture or short circuit.
- Dispose of batteries in line with local environmental regulations.
- Tape over battery contacts to avoid short circuiting during disposal.

- After removal of the battery do not touch the battery contacts and the patient simultaneously.

- Note: Lithium Ion and NiMH batteries contain no toxic heavy metals such as mercury, cadmium, or lead.

- Do not exceed maximum recommended exposure time.

- Always ensure that the handle rheostat is turned off before fitting an instrument head or changing a bulb.

- Bulbs can reach high temperatures in use – allow to cool before handling. The ophthalmoscope and retinoscope should not be continuously switched on for more than 15 minutes. If they are in the charging position or left on for 15 minutes or longer then they must be switched off and left to cool for at least 10 minutes before the next use.

- Care should be taken when handling halogen bulbs. Halogen bulbs can shatter if scratched or damaged.

- After removal of the bulb do not touch the bulb contacts and the patient simultaneously.

- Refer to the instructions on page 7 for bulb replacement.

2.2 CONTRAINDICATION

There is no restriction to the patient population this device can be used with.

3. CLEANING AND DISINFECTION INSTRUCTIONS

Before any cleaning of the instrument or the base unit, ensure the power lead is disconnected.

Only manual non-immersion cleaning as described should be used for this instrument. Do not autoclave or immerse in cleaning fluids. Always disconnect power supply from source before cleaning.

1. Wipe the external surface with a clean absorbent, non-shedding cloth dampened with de-ionised water / detergent solution (2% detergent by volume) or water / isopropyl alcohol solution (70% IPA by volume). Avoid optical surfaces.
2. Ensure that excess solution does not enter the instrument. Use caution to ensure cloth is not saturated with solution.
3. Surfaces must be carefully hand-dried using a clean non-shedding cloth.
4. Safely dispose of used cleaning materials.

4. INSTRUMENT HEADS

4.1 TRANSILLUMINATOR

For use when the presence of intraocular tumors in patients with cloudy media is suspected. The Finoff Transilluminator illuminates the fundus via the sclera and any tumors present in the light path will dim the normally bright red fundal reflex as seen through the pupil.

It is recommended that the examination if undertaken in a darkened room. Ensure that the surface of the patient's eye in anaesthetised prior to scleral transillumination. Rest the end of the transilluminator flat on the bulbus without exerting pressure. Note that the intense light may be uncomfortable for the patient and complicate recognising areas of thin tumor growth.

4.2 BULB REPLACEMENT

Bulbs can reach high temperatures in use – allow to cool before handling.

- Always ensure that the handle rheostat is turned off before fitting an instrument head or changing a bulb.

- Care should be taken when handling halogen bulbs. Halogen bulbs can shatter if scratched or damaged.

- After removal of the bulb do not touch the bulb contacts and the patient simultaneously.
- Keeler bulbs can only be used in the instrument for which they are designed – refer to part number list in section 11. Ensure the replacement bulb is the correct voltage. See base of bulb.

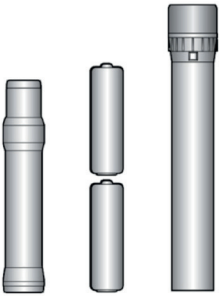
Blue = 2.8V for dry cell battery handles.

Red = 3.6V for rechargeable handles.

- Loosen the set screw securing the instrument head to the handle. (GenMed Wall Unit only)
- Remove the head by holding it horizontally with one hand while rotating the handle counterclockwise with the other.
- Take care to ensure the battery / bulb does not drop out when the head and handle are separated.
- Remove the faulty bulb and dispose of in accordance with local environmental regulations.
- Replace the bulb with one of the correct voltage and type. Ensure that the location key is aligned with the aperture in the instrument head.
- Refit the handle to the head by rotating it clockwise while horizontal. If required, secure the head in place with the set screw provided. (GenMed Wall Unit only)

5. INSTRUMENT HANDLES

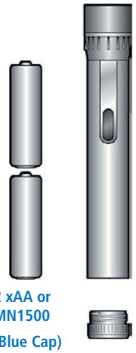
Slimline



Rechargeable Battery (Red Cap)

2 xAA or MN1500 (Blue Cap)

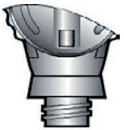
Pocket



2 xAA or MN1500 (Blue Cap)

Connection of the instrument heads to the handle

The connection between the instrument head to the handle is a screw thread. To connect our instrument head connect as shown and rotate in clockwise direction. Ensure the connection between the head and handle is positive.



Compatibility

The Keeler Transilluminator is compatible with Keeler 2.8V and 3.6V Keeler handles.

On / Off brightness control

To switch the instrument on, rotate the brightness control as indicated to the right.

To switch off the instrument, rotate the brightness control as indicated to the left.

Keeler Slimline Handles have a power indicator. This will show if the instrument is on or off.

Silver = off

Off

Half On

Red = on

On

5.1 HANDLE IDENTIFICATION

Keeler slimline handles are colour coded to allow you to distinguish between a dry cell battery handle (2.8v) and a rechargeable handle (3.6v).

The handles and Keeler bulbs are colour coded as follows:

Blue base = 2.8V for dry cell batteries.

Red base = 3.6V for rechargeable batteries.

- Please ensure when replacing batteries and bulbs that the voltage corresponds to the handle.

Disconnect from charger prior to removing instrument head.

Dispose of old batteries safely.

5.2 INSERTING/REPLACING BATTERIES

Unscrew battery cap, insert batteries, and replace battery cap as shown on page 8.

- Please note Keeler rechargeable handles are normally supplied complete with a rechargeable battery (3.6V).

Dry cell batteries

The following dry cell batteries should be used:

- Keeler Pocket Handle – 2 x AA size dry cell batteries – Duracell MN 1500 or equivalent.

5.3 UPGRADE FROM BATTERY TO RECHARGEABLE HANDLES

Your Keeler 2.8V slimline (blue base) dry cell battery handle can be upgraded to a 3.6V (red base) rechargeable handle. Refer to section 11 for details of part numbers required.

Please note the bulb in your instrument will also need to be upgraded from 2.8V to 3.6V.

Battery charging

- Do not attempt to charge non-rechargeable batteries.

5.4 BATTERY CONDITIONING

Your Keeler rechargeable batteries need to be conditioned to ensure you achieve the maximum life from the product. Follow the conditioning instructions as indicated.

Step 1

Fully charge your new Keeler rechargeable battery. This will take approximately 15 hours.

Step 2

Use the instrument without recharging until the battery is completely empty.

Step 3

Once empty recharge the battery until full. This will take approximately 15 hours.

Repeat steps 1, 2 and 3 three times, i.e. fully charge and discharge the battery three times to complete the conditioning process. Once you have conditioned your batteries as described above you may place your instrument in the charger when not in use between examinations.

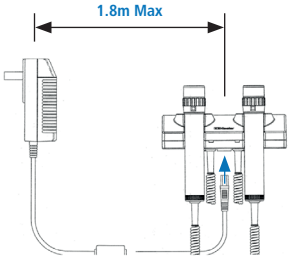
Charger Compatibility

- Keeler Rechargeable Handles can be used in the following Keeler chargers only:
  - Keeler Mini charger
  - Keeler Duo charger
- Note: Handheld diagnostic instruments can become hot during use and charging.

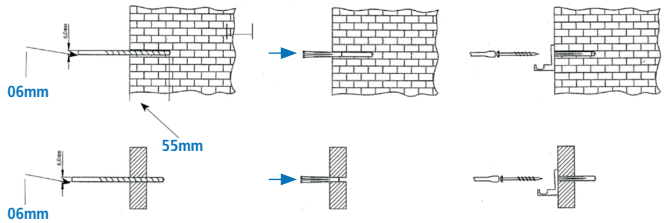
6. GENMED WALL UNIT

6.1 WALL MOUNTING

Check the distance from the wall socket to the intended mounting position.

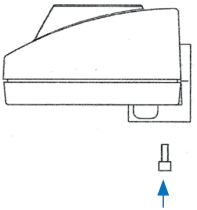


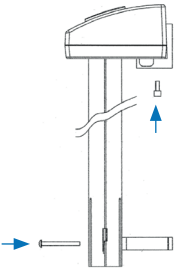
For the Gen Med Wall Units drill two holes Ø6mm x 55mm deep and 100mm apart.



For the Dispenser Unit drill an additional two holes 249mm below the existing holes.

Secure the GenMed Wall Unit and Dispenser Unit as shown.





6.2 POWER SUPPLY ASSEMBLY

Set Plug

Replace the blanking plate with the appropriate mains plug adaptor if required, or use IEC 60320 TYPE 7 connector (not supplied).

Please note:

- This equipment may be affected by electromagnetic interference.
- Other electrical equipment in the close vicinity may also be affected by the GenMed Wall Unit.
- If such effects are suspected, switch off the offending equipment.

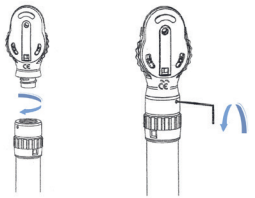
6.3 CONNECTING YOUR INSTRUMENT HEAD TO THE WALL UNIT HANDLE

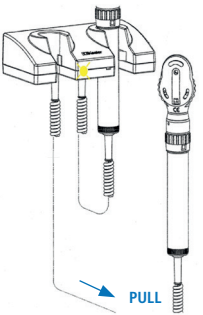
The instrument head should be screwed positively onto the handle as shown.

As an additional security measure, instrument heads may be locked onto Keeler cord handles by tightening the built in screw with the hexagonal key provided.

To use the required instrument, remove the relevant handle from its cradle as shown.

A yellow light (LED) will illuminate when a cord handle is removed from its cradle. This will occur whether or not an instrument head is fitted.





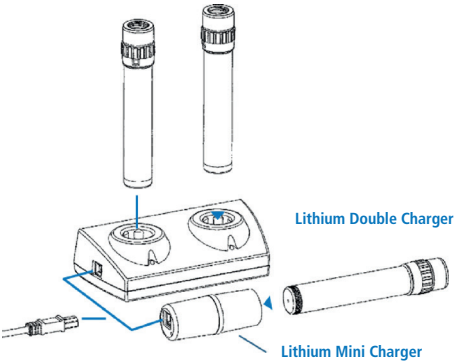
When the instrument is no longer required always ensure that the handle is returned correctly to its cradle and that the LED goes out.

Only one handle can be used at a time. Replace the handle before using the other instrument.

7. LITHIUM MINI CHARGER AND LITHIUM DOUBLE CHARGER

7.1 POWER SUPPLY

Assemble the power supply as per the instructions in section 7 and connect the lead to the power input port on the charger.



Charging

No LED	Battery is fully charged.
Flashing LED	Top up charge (Not displayed with NiMH battery)
Solid LED	Battery is charging

The handle can be used at any time during the charging cycle and will automatically resume charging when handle is placed back in the charging well.

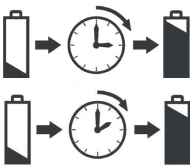
When using the Mini charger the handle can be left in place.

- The instrument must not be used while charging.

Charging cycle

The Lithium-Ion battery will take approximately 2-3 hours to fully charge. The Lithium-Ion battery will last approximately 2-3 hours on full power.

The NiMH battery will take approximately 1-2 hours to fully charge. The NiMH battery will last approximately 1-2 hours on full power.



8. WARRANTY

Your Keeler product is guaranteed for 3 years and will be replaced, or repaired free of charge subject to the following:

- Any fault due to faulty manufacture.
- The instrument and accessories have been used in compliance with these instructions.
- Proof of purchase accompanies any claim.

Please note:

- Batteries are covered by this warranty statement for 1 year only.
- Bulbs are not covered by this warranty statement.

The manufacturer declines any and all responsibility and warranty coverage should the instrument be tampered with in any manner or should routine maintenance be omitted or performed in manners not in accordance with these manufacturer's instructions.

There are no user serviceable parts in this instrument. Any servicing or repairs should only be carried out by Keeler Ltd. or by suitably trained and authorised distributors. Service manuals will be available to authorised Keeler service centres and Keeler trained service personnel.

9. SPECIFICATIONS AND ELECTRICAL RATINGS

Keeler Transilluminator and associated power systems are medical electrical instruments. These instruments require special care concerning electromagnetic compatibility (EMC). This section describes the suitability in terms of electromagnetic compatibility of these instruments. When installing or using these instruments, please read carefully and observe what is described here.

Portable or mobile-type radio frequency communication units may have an adverse effect on these instruments, resulting in malfunctioning.

Instrument heads and handles are considered to be inherently EMC benign[1], with the exception of the GenMed Wall Unit, to which the following table refers, in addition to the Lithium Chargers.

[1] Refer to section 1.4.4 of the Guide for the EMC Directive 2014/30/EU (1st March 2018).

9.1 ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions

Keeler Transilluminator is intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.

Emissions test		Compliance	Electromagnetic environment – guidance
Chargers and GenMed Wall Unit only	RF emissions CISPR 11	Group 1	Keeler chargers and power systems use RF energy only for their internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	RF emissions CISPR 11	Class B	Keeler chargers and power systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2		Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3		Complies	

Battery operated Keeler Transilluminator is considered to be inherently EMC benign[1], and therefore are not covered by the statements in this section.

[1] Refer to section 1.4.4 of the Guide for the EMC Directive 2014/30/EU (1st March 2018).

9.2 ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

Keeler Transilluminator is intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD). IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 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. IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines N/A *± 1 kV for input/ output lines	Mains power quality should be that of a typical professional healthcare facility environment. *GenMed Wall Unit only
Surge. IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) N/A	Mains power quality should be that of a typical professional healthcare facility environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	U_T = 0% 0.5 cycle (0, 45, 90, 135, 180, 225, 270, 315°) U_T = 0%; 1 cycle U_T = 70%; 25/30 cycles (@ 0°) U_T = 0%; 250/300 cycle	U_T = 0% 0.5 cycle (0, 45, 90, 135, 180, 225, 270, 315°) U_T = 0%; 1 cycle U_T = 70%; 25/30 cycles (@ 0°) U_T = 0%; 250/300 cycle	Mains power quality should be that of a typical professional healthcare facility environment. If the user of the Keeler Transilluminator requires continued operation during power mains interruptions, it is recommended that the charger be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at a level characteristic of a typical location in a typical professional healthcare facility environment.

Note: U_T is the a. c. mains voltage prior to application of the test level.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Digital Camera Assembly, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	6 Vrms 150kHz to 80MHz	6 V	**Recommended separation distance** $d = 1.2 \sqrt{p}$
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	10 V/m	$d = 1.2 \sqrt{p}$ 80MHz to 800 MHz $d = 2.3 \sqrt{p}$ 800MHz to 2.7GHz
			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[1], should be less than the compliance level in each frequency range.[2]  Interference may occur in the vicinity of equipment marked with this symbol.

Note 1: At 80MHz and 800MHz, 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.
1 Field strengths from fixed transmitters, such as base stations (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 Transilluminator is used exceeds the applicable RF compliance level above, the Transilluminator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Transilluminator.

2 Over the frequency range 150kHz to 80 MHz, field strengths should be less than 10 V/m.

9.3 RECOMMENDED SAFE DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and Keeler Transilluminator.

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80MHz $d = 1.2\sqrt{p}$	80MHz to 800MHz $d = 1.2\sqrt{p}$	800MHz to 2.7GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1: At 80MHz and 800MHz, 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.

10. TECHNICAL SPECIFICATIONS

The Transilluminator , the power supply (EP29-32777) with its charging dock (1941-P-5289 and 1941-P-5326) together constitute a Medical Electrical System as defined in EN/IEC 60601-1.

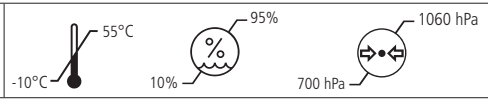
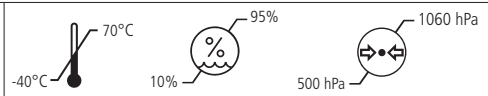
Power Supply

Input mains data	100-240V – 50/60Hz
Power supply rating	12V: 2.5amps
Operation	Maximum 15 minutes ON Minimum 10 minutes OFF
Classification:	Class II equipment Type B protection against shock

Instrument heads and handles

Input voltage (DC)	3V 2xAA Alkaline Batteries - BLUE 3.75V Lithium-Ion Rechargeable Battery - RED (EP39-18918) 3.65V NiMH Rechargeable Battery - Black (1919-P-7149)

Environmental Conditions:

USE		
		
	Shock (without packing)	10 g, duration 6 ms
STORAGE CONDITIONS		
		
TRANSPORT CONDITIONS		
		
	Vibration, sinusoidal	10 Hz to 500 Hz: 0.5g
	Shock	30 g, duration 6 ms
	Bump	10 g, duration 6 ms

11. ACCESSORIES AND SPARES

Item	Part Number
Pack of 2x 3.6V bulbs	1015-P-7058
pack of 2x 2.8V bulbs	1015-P-7066
Other – Chargers	
Lithium Double Charger	1941-P-1368
Lithium Mini Charger	1941-P-1341
3.6V Lithium Battery	EP39-18918
Other – Colour coded grips	
Slimline Handle Sleeve – Pink	1901-P-7028
Slimline Handle Sleeve – Green	1901-P-7036
Slimline Handle Sleeve – Blue	1901-P-7044
Slimline Handle Sleeve – Black	EP29-05365
Slimline Handle Sleeve Assorted Colours	1901-P-7052

12. PACKAGING AND DISPOSAL INFORMATION

Disposal of old electrical and electronic equipment

This symbol on the product or on its packaging and instructions indicates that this product shall not be treated as household waste.

To reduce the environmental impact of WEEE (Waste Electrical Electronic Equipment) and minimise the volume of WEEE entering landfills we encourage at product end of life that this equipment is recycled and reused.

If you need more information on the collection reuse and recycling then please contact B2B Compliance on 01691 676124 (+44 1691 676124). (UK only).

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of your Member State.

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EP59-49990 Issue A Date of Issue 12/05/2021

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