

Ophthalmic and Diagnostic Instruments

Ophthalmoscope / Retinoscope / Otoscope

Instructions for use



Keeler

Next ▶

Contents

	Page		Page
1. Copyright and trademarks	3	• <i>Upgrading to rechargeable handles</i>	20
2. Introduction	4	• <i>Battery conditioning / charging</i>	21
3. Symbols.....	5	7. GenMed Wall Unit	22
4. Safety	6	• <i>Wall mounting</i>	
• <i>Device classification</i>		• <i>Wall mounting template</i>	23
• <i>Warnings</i>		• <i>Power supply assembly</i>	24
• <i>Cautions</i>		• <i>Connecting / securing heads</i>	25
• <i>Safety considerations</i>	10	• <i>Using the GenMed Wall Unit</i>	26
5. Diagnostic Instrument heads		• <i>Dispos-A-Spec</i>	
• <i>Ophthalmoscope models</i>	11	8. Lithium Chargers	27
• <i>Lens wheels</i>	12	• <i>Lithium Mini Charger</i>	
• <i>Lens ranges</i>		• <i>Lithium Double Charger</i>	
• <i>Graticules and graticule control</i>		• <i>Charging cycle</i>	
• <i>Filters and filter control</i>	13	9. Cleaning instructions	28
• <i>Retinoscope models</i>	14	10. Specifications and electrical ratings	29
• <i>Otoscope models</i>	15	• <i>Electrical specifications</i>	
• <i>Bulb replacement</i>	17	• <i>Transport, storage and operation</i>	
6. Instrument handles	18	11. Annex I – EMC statement and guidelines	30
• <i>Handle models</i>		12. Spare parts and accessories	35
• <i>Handle identification</i>	20	13. Warranty	36
• <i>Inserting / replacing batteries</i>		14. Contact and disposal information	37

Click on the headings above to go directly to that section.

Use the buttons on the right to navigate the document.

Clicking 'Home' from any page brings you back to this contents page.

1. Copyright and trademarks

The information contained within this manual must not be reproduced in whole or in part without the manufacturer's prior written approval.

As part of our policy for continued product development we reserve the right to make changes to specifications and other information contained in this document without prior notice.

The products listed opposite are registered trademarks of Keeler Ltd 2012

Copyright © Keeler Limited 2012

Published in the UK 2012

Ophthalmoscopes:

Pocket, Professional, Practitioner, Specialist, Standard

Retinoscopes:

Professional Combi, Spot, Streak

Otoscopes:

Deluxe, Fibre-Optic, Pocket, Professional, Standard

Handles:

C-size, Pocket, Slimline, GenMed Wall Unit

Chargers:

Lithium Duo Charger, Lithium Mini Charger, C-size NiCad Duo

The logo for Keeler, featuring the word "Keeler" in a blue, sans-serif font.

2. Introduction

Thank you for purchasing your Keeler diagnostic instrument.


We have taken the greatest care in the design, development and manufacture of this product to ensure that you get many years of trouble free service. However, it is important that you read the descriptions, installation and operating instructions carefully prior to installing or using your new instrument.





Please read and follow these instructions carefully.


Keeler


3. Symbols


 Read user instructions for warnings, cautions and additional information


 The CE mark on this product indicates it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive


 Consult instructions for use


 Double insulated

 Manufacturer's name and address

 This Symbol on the product or on its packaging and instructions indicates that it was put on the market place after August 2005 and that this product shall not be treated as Household Waste


 Type B protections against shock (otoscope only)


 Mandatory action sign


 Follow instructions for use

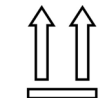
 High voltage

 Trip hazard

 Optical radiation hazard


 Hot surface


 Non-ionizing radiation


 This way up

 Keep dry


 Fragile

 Material suitable for recycling

 Symbol for humidity limitation

 Symbol for temperature limitation

 RoHS Compliant

 Do not use if package is damaged

Keeler

4. Safety

Device classification

CE Regulation 93/42 EEC: Class I

FDA: Class II

Ophthalmoscopes and retinoscopes are intended to illuminate the interior of the eye. Otoscopes are intended to illuminate the interior of the ear.

Carefully read this Instruction Section before using your Keeler product. For your own safety and that of your customers observe all cautionary information provided in this section. The following information is intended to highlight potential safety hazards that can be associated with misuse, or damage.

Warnings and cautions - General



Warning



- Check your Keeler product for signs of transport / storage damage prior to use
- Do not use if the product is visibly damaged, and periodically inspect for signs of damage
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment

- This product should not be immersed in fluids
- Do not position the device so access to the mains plug is limited or obscured



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 12
- Backwards compatibility of the LED module has not been tested

Keeler

4. Safety

Warnings and cautions – General (cont'd)

- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C
- 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

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 equipment.

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.

Keeler

4. Safety

Diagnostic 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
- Keeler Professional Retinoscopes contain strong magnets. Pacemakers and magnetically stored data will be affected or damaged by magnets
- Strong magnetic fields may influence or distort sensitive electronic or mechanical test instruments. Very sensitive devices may even be destroyed. Always keep magnets at a safe distance from such devices
- Do not use Keeler Retinoscopes in ambient temperatures above 30°C
- Disposable speculae should not be used for insufflation testing

- Plastic reusable Speculae will degrade if exposed to ultra-violet light, dry heat or gamma irradiation. These methods of sterilization must not be used
- 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 40°C or fall below 0°C

Keeler

4. Safety

Batteries and bulbs (cont'd)

- 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 LED 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 / LED's can reach high temperatures in use – allow to cool before handling. If the ophthalmoscope has been in the charging position for over 15 minutes, it must be left to cool for at least 10 minutes before use.

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



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

Refer to the instructions on page 17 for bulb replacement.

Keeler

4. Safety



Safety considerations

It is well established that exposure of the eye to intense light sources for extended periods of time poses a risk of retinal photic injury. Many ophthalmic instruments illuminate the eye with intense light. The decision about the intensity of the light level to use in any procedure must be made on a case to case basis. In each case, the clinician must take a risk benefit judgement about the intensity of light to be used. Use of insufficient intensity may result in inadequate visualization and in adverse effects more serious than retinal photic damage. Further, despite all efforts taken to minimise the risk of retinal damage, damage may still occur. Retinal photic injury is a possible complication of the need to use bright light to clearly visualize ocular structure during delicate ophthalmic surgical procedures.

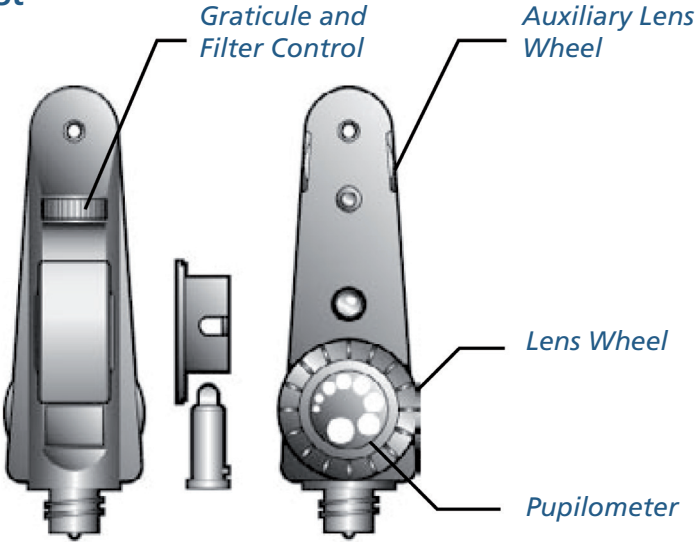
While no visible retinal lesions have been identified for ophthalmic instruments, it is recommended that illumination levels be set to the minimum level necessary to perform the diagnostic function. Young children and persons with diseased eyes may be at a higher risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using an intense visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

CAUTION - The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 3 minutes. The ophthalmoscope should not be continuously switched on for more than 15 minutes. If it is left on for 15 minutes or longer then it must be switched off and left to cool for at least 10 minutes before the next use.

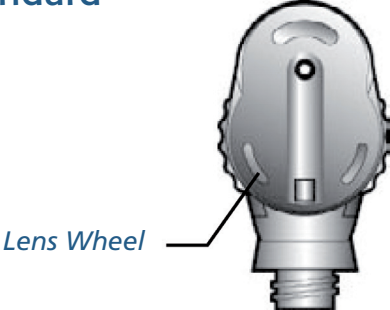
Keeler

5. Instrument heads - Ophthalmoscopes

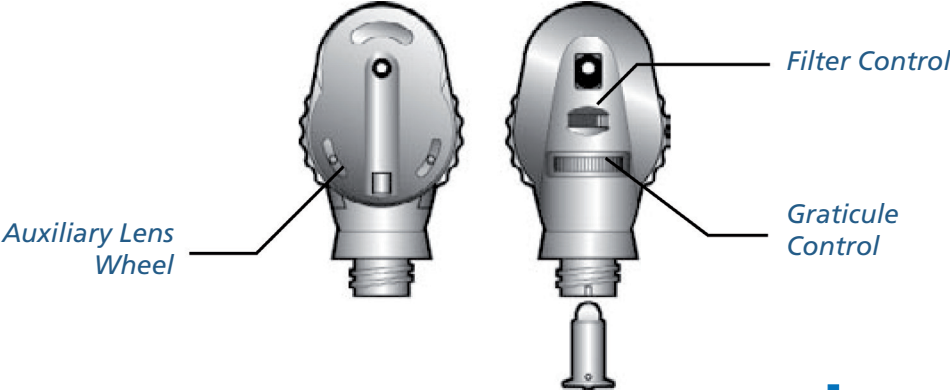
Specialist



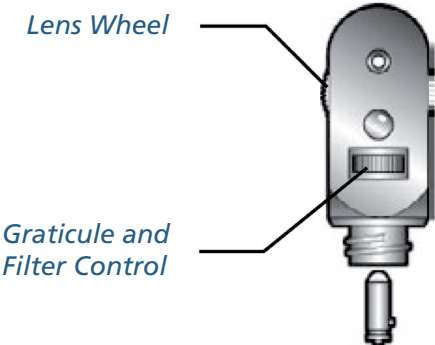
Standard



Practitioner / Professional



Pocket



5. Instrument heads - Ophthalmoscopes

Lens Wheel

The lens wheel is rotated to select the required lens. Lens powers are displayed in the viewing window as follows:

Black = (+) power lenses

Red = (-) power lenses

Auxiliary lens wheel

Swings in +/- 20 in one Dioptr step* (**Professional only*).

Specialist Auxiliary lens wheel

Rotate to align +10, +15, +30/ -10, -15, -30 Dioptr lenses.

Lens ranges

Specialist

+44D to -45D in single Dioptr steps

Professional

+29D to -30D in single Dioptr steps

Practitioner and Standard

+40D to -25D

Pocket

+20D to -20D

Graticule Control

The graticule control is used to select the required beam for examination. The choice of graticules is as follows.



Wide Angle

Illuminates the largest area of fundus for the best possible general diagnosis through a dilated pupil.



Intermediate

Permits easier access through an undilated pupil in peripheral examination. Particularly useful in paediatric examination.



Macular

Designed specifically for viewing the macular area of the fundus. Reduces pupillary reaction and improves patient comfort.



Slit

Used primarily to determine retinal elevations and depressions but may also be used to assess anterior chamber depth.

Keeler

5. Instrument heads - Ophthalmoscopes

Graticule Control (cont'd)



Glaucoma

Projects a graticule onto the retina to assess the optic disc/cup ratio as an aid to glaucoma diagnosis and monitoring.



Fixation Cross

Projects a graticule on to the retina for assessment of the degree and direction of eccentric fixation. This is particularly useful when examining children.

The Graticule Range for each ophthalmoscope is as follows:

Specialist							
Professional							
Practitioner							
Standard							
Pocket							

Filter Control*

The filter control is used to select the required filter.
 (*Professional/Practitioner/Standard only.)

Filter Applications



Red Free (Green filter)

Is used to examine the blood vessels in fine detail. The green filter blocks red rays showing blood vessels as black against a dark green background. This filter is particularly useful for diabetic retinopathy.



Cobalt Blue*

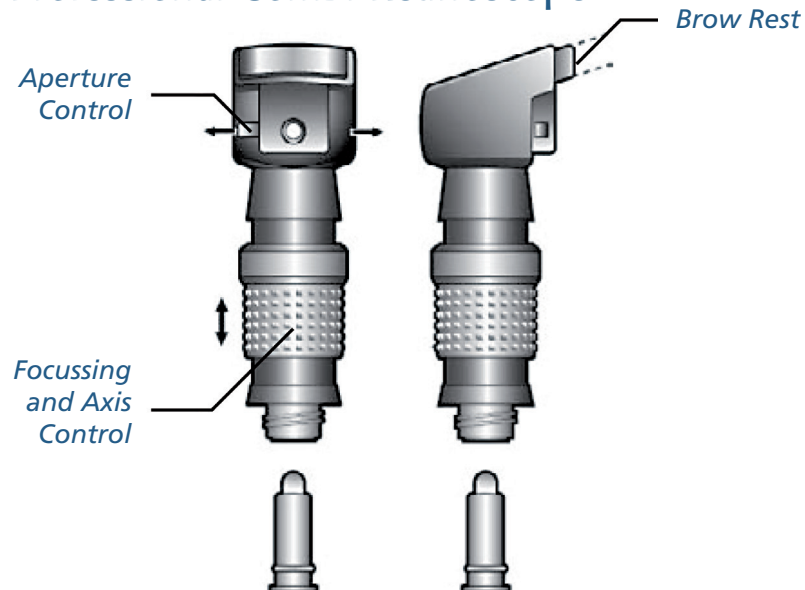
Is used in conjunction with fluorescein dye for the detection and examination of corneal scars and abrasions.
 (*Practitioner and Specialist only).

Pupillometer*

Hold the pupillometer adjacent to the patients eye to estimate pupil size. 1=1mm. The range is 1mm to 8mm.
 (*Applies to Specialist only.)

5. Instrument heads - Retinoscopes

Professional Combi Retinoscope



Focussing and axis control (Streak)

The vergence is altered by sliding the focussing control up and down as indicated. In the top position the effect is a concave mirror. Mid position produces a streak behind the patient. The mid position is used to determine the presence and axis of any astigmatism. In the bottom position the effect is a divergent plane mirror effect. Refraction is normally performed between the mid position and the bottom position. The focussing and axis control can be rotated continuously in any direction.

Focussing and axis control (Spot)

The vergence is altered by sliding the focussing control up and down as indicated. For all positions the effect is a plane mirror effect.

Brow Rest

The Keeler retinoscope is supplied with a choice of brow rests to accommodate spectacle wearers. To interchange the brow rest disconnect and attach as indicated.

Aperture Control

The aperture control has two positions. To change from the large to the small aperture slide the control from left to right as indicated.



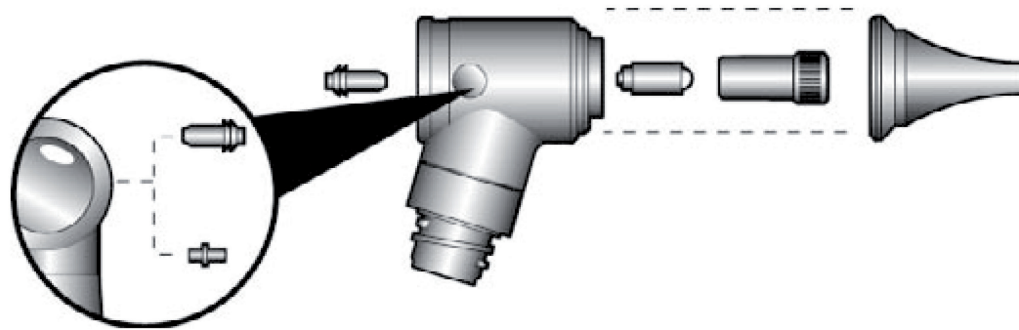
Note: Handheld diagnostic instruments can become hot during use and charging.

Keeler

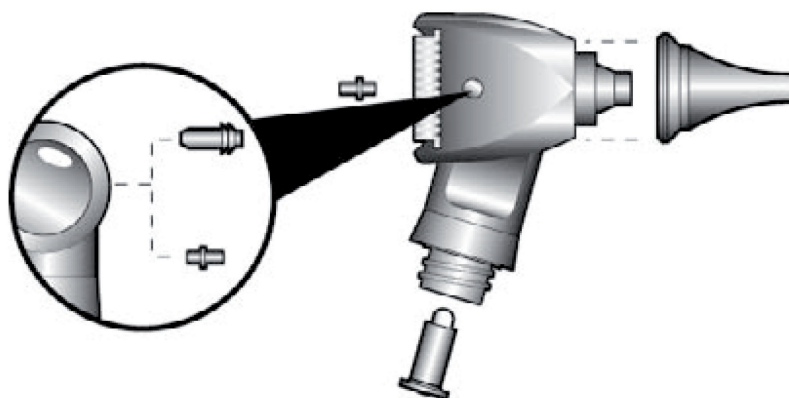
5. Instrument heads - Otoscopes

Five permanent Speculae are provided with each Otoscope/Set. The diameters are as follows: 2.5, 3.5, 4.5, 5.5 & 8mm. These are attached to the Otoscope head as shown in the following diagrams.

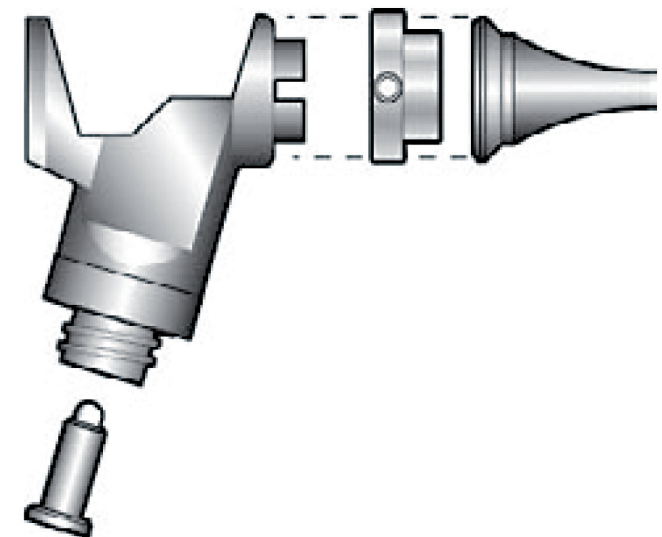
Standard / Pocket



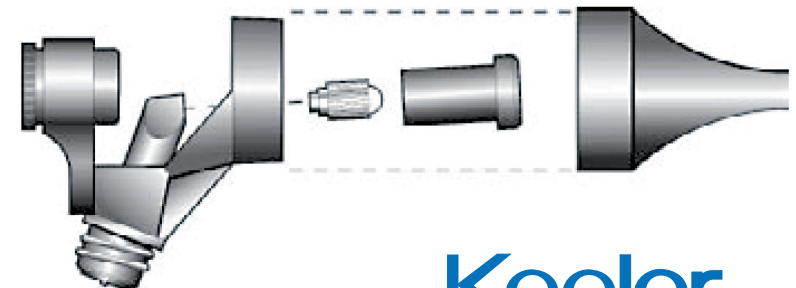
Fibre Optic



Practitioner



Deluxe



Keeler

5. Instrument heads - Oscopes

Disposable Speculae*

Disposable speculae can be fitted to the Standard, Practitioner, Fibre Optic and Pocket Oscopes.

The disposable speculae is attached as shown on the previous page.

Pneumatic Testing*

An insufflation tube can be fitted to your Oscope to enable you to carry out pneumatic testing.

For Practitioner, Standard, Pocket & Fibre Optic Oscopes attach the insufflation adaptor into port. The insufflation tube can then be attached to this.

An Insufflation adaptor is also available for Practitioner as shown on the previous page.

Minor surgical Procedures

Should you wish to use surgical instruments such for minor procedures the following notes may be of assistance.

Standard and Pocket Oscopes

The magnifier can be removed to allow the introduction of surgical instruments.

Fibre Optic/Practitioner

The Fibre Optic magnifier can be moved to one side or removed completely to aid the introduction of surgical instruments.

Deluxe Oscope

The Deluxe magnifier may be swung to the side to aid the introduction of surgical instruments. The magnifier can also be rotated clockwise to bring the focus closer to the end of the specula.

5. Instrument heads

Bulb replacement



Bulbs / LED's can reach high temperatures in use – allow to cool before handling.

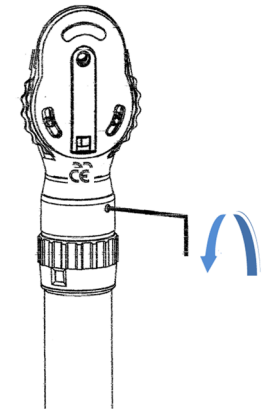
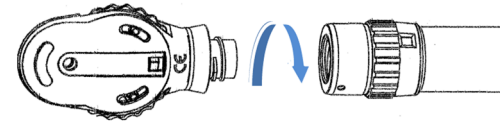


- Always ensure that the handle rheostat is turned off before fitting an instrument head or changing a bulb
- Care should be taken when handling halogen bulbs. Halogen bulbs can shatter if scratched or damaged
- After removal of the bulb / LED do not touch the bulb / LED contacts and the patient simultaneously
- Keeler bulbs can only be used in the instrument for which they are designed – refer to part number list in section 12
- 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
- Black = LED

- Loosen the set screw securing the instrument head to the handle (GenMed Wall Unit only)

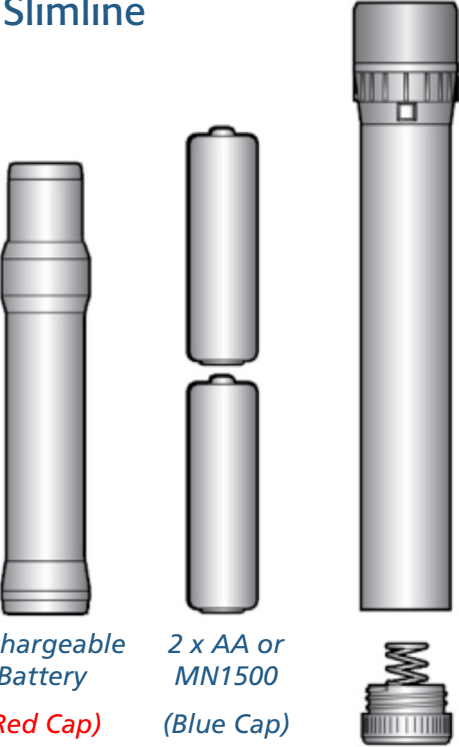


- Remove the head by holding it horizontally with one hand while rotating the handle counterclockwise with the other
- Take care to ensure the battery / bulb does not drop out when the head and handle are separated
- Remove the faulty bulb and dispose of in accordance with local environmental regulations
- 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)

Keeler

6. Instrument handles

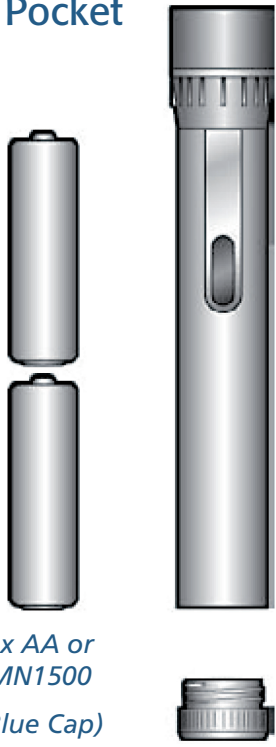
Slimline



Rechargeable Battery
(Red Cap)

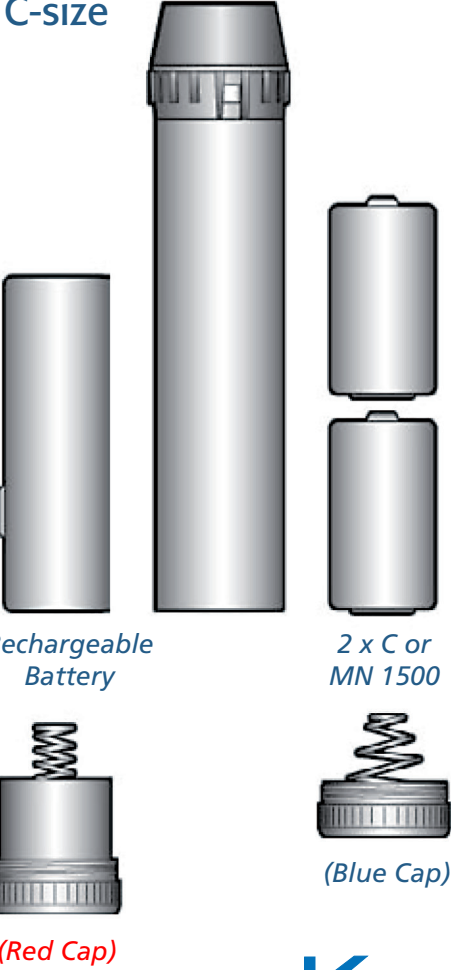
2 x AA or MN1500
(Blue Cap)

Pocket



2x AA or MN1500
(Blue Cap)

C-size



Rechargeable Battery
(Red Cap)

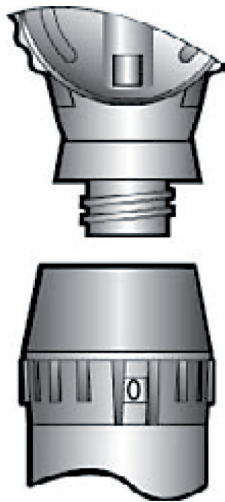
2 x C or MN 1500
(Blue Cap)



6. Instrument handles

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 Specialist, Professional, Standard and Practitioner Ophthalmoscopes and Keeler Retinoscopes are compatible with Keeler 2.8v and 3.6v Keeler handles.

The Keeler LED module is only compatible with Keeler 2.8V and 3.6V slimline 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 C sizes Handles have a power indicator. This will show if the instrument is on or off.



Keeler

6. Instrument handles

Handle Identification

Keeler C size and pocket 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.

Black base = LED for dry cell and 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.

Inserting/Replacing Batteries

Unscrew battery cap, insert batteries and replace battery cap as shown on page 18.

Please note Keeler rechargeable handles are normally supplied complete with a rechargeable battery (3.6v - 0.7Ah Ni-Cd).

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.
- Keeler C size handle – 2 x 1.5v C size batteries. – Duracell MN 1400 or equivalent.

Upgrade from Battery to Rechargeable Handles

Your Keeler 2.8 v C Size Handle (blue base) dry cell battery handle can be upgraded to a 3.6v (red base) rechargeable handle. Refer to section 12 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.

Contact Keeler for details:

Tel: +44 (0) 1753 857177

Fax: +44 (0) 1753 827145.

Keeler

6. Instrument handles

Battery charging



Do not attempt to charge non-rechargeable batteries.

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



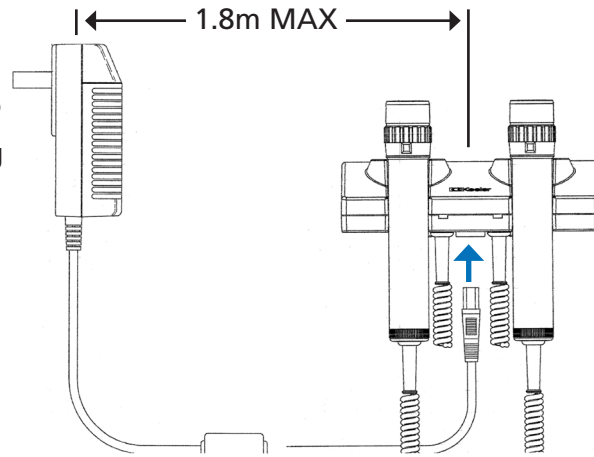
Note: Handheld diagnostic instruments can become hot during use and charging.

Keeler

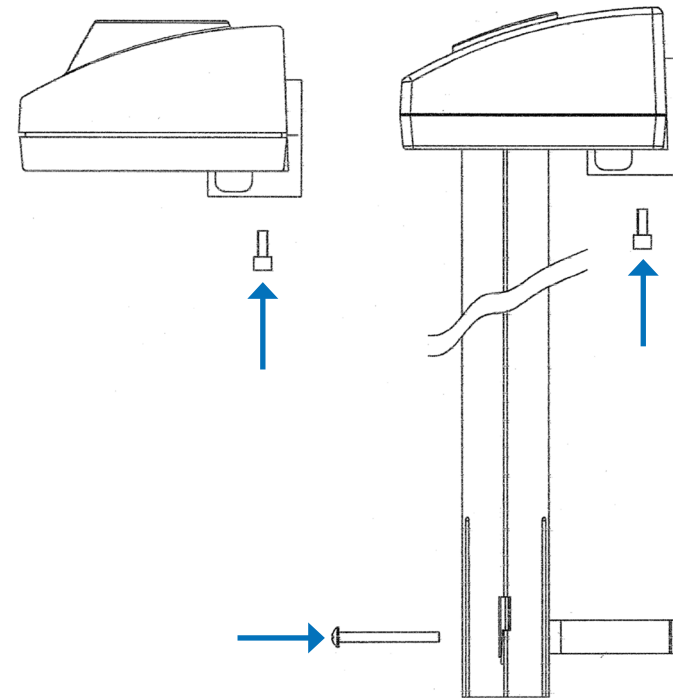
7. GenMed Wall Unit – wall mounting

Wall mounting

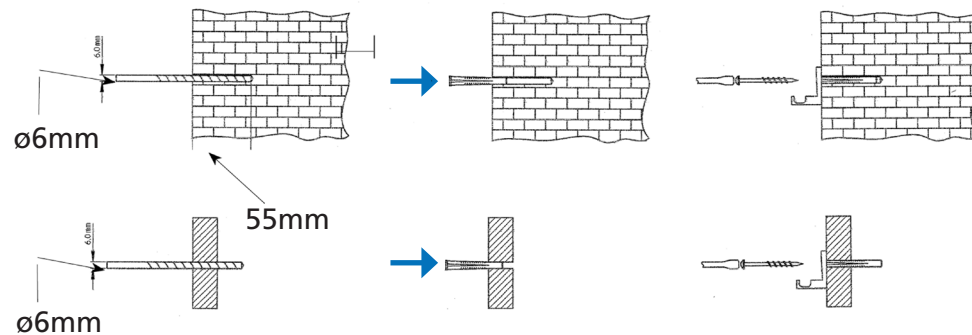
Check the distance from the wall socket to the intended mounting position.



Secure the GenMed Wall Unit and Dispenser Unit as shown below:

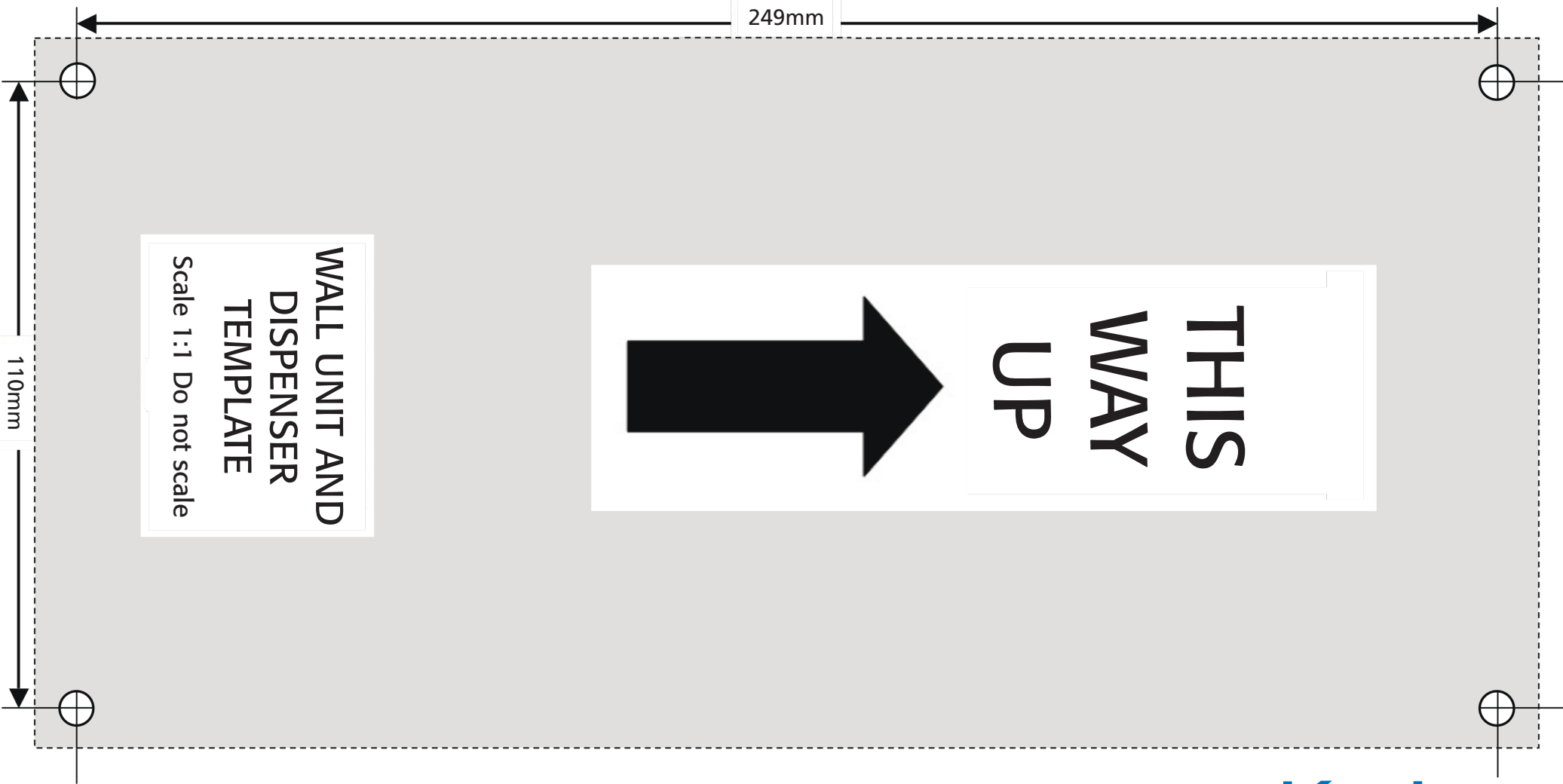


For the Gen Med Wall Units drill two holes $\text{Ø}6\text{mm}$ x 55mm deep and 110mm apart.



For the Dispenser Unit drill an additional two holes 249mm below the existing holes using the template on the following page.

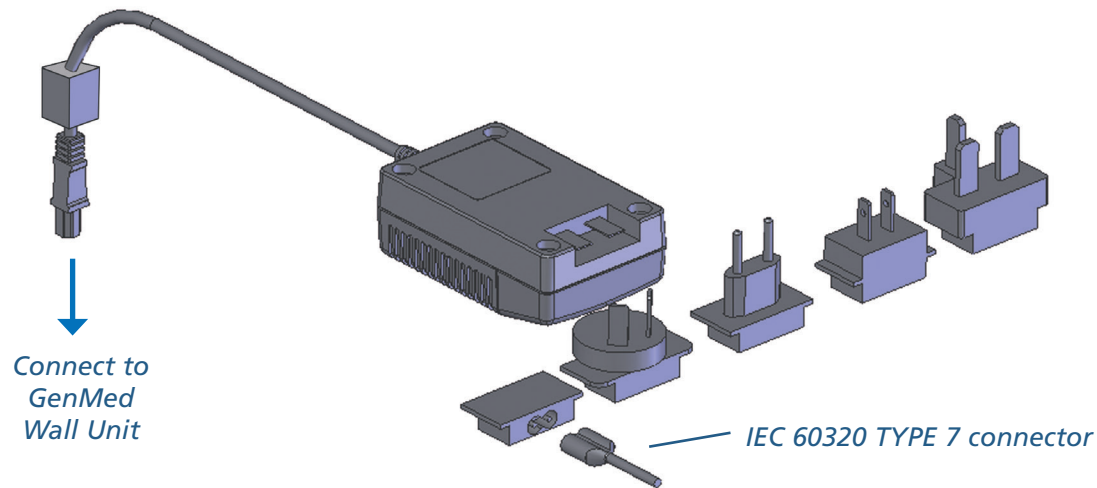
7. GenMed Wall Unit and Dispenser mounting template



7. GenMed Wall Unit – 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).



7. GenMed Wall Unit



Please note:

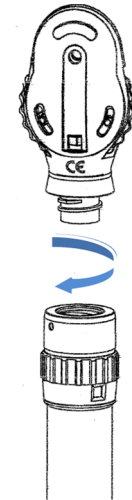
This equipment may be affected by electromagnetic interference.

Other electrical equipment in the close vicinity may also be affected by the GenMed Wall Unit.

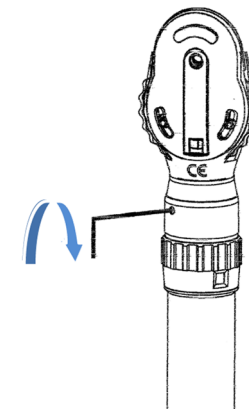
If such effects are suspected, switch off the offending equipment.

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.



Keeler

7. GenMed Wall Unit

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.

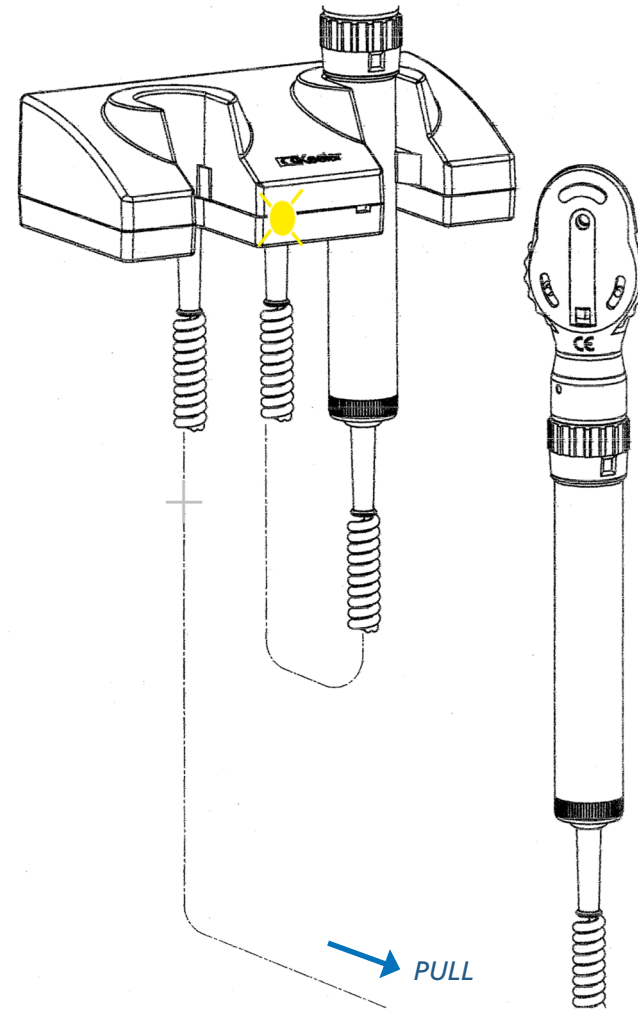
When the instrument is no longer required always ensure that the handle is returned correctly to its cradle and that the LED goes out.

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

Refer to the instructions in section 5 for information on the controls and operation of Ophthalmoscope, Otoscope and Retinoscope heads.

Dispos-A-Spec

To dispense a speculum, simply grasp the end of the required speculum and gently pull vertically. When a dispenser tube is empty, reorder speculum using the order form EP59-48483. Remove the lid from the unit and refill the required tube.



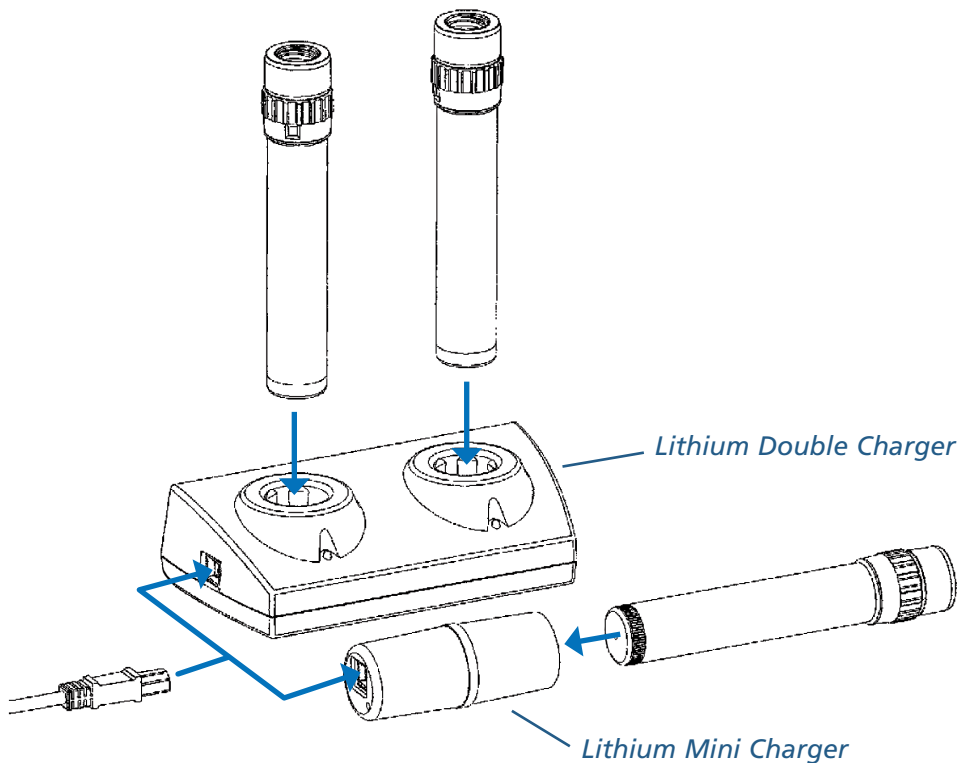
Keeler

8. Chargers

Lithium Mini Charger and Lithium Double Charger

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

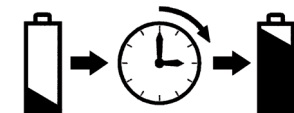
The handle can be used at any time during the charging cycle and will automatically resume charging when handle is placed back in the charging well.

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

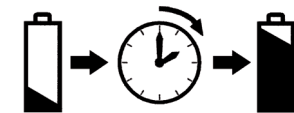
  The instrument must not be used while charging.

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.



Keeler

9. Cleaning

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.

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

Sterilization

Plastic reusable Speculae will degrade if exposed to ultra-violet light, dry heat or gamma irradiation. These methods of sterilization must not be used.

The cleaning and sterilization of reusable speculum, metal tongue depressor, nasal dilator, laryngeal and post natal mirrors can be accomplished as follows:

- a Manually clean all surfaces of the units using a suitable brush and water/detergent solution (2% detergent by volume). Ensure that hinged versions of specula are cleaned in both open and closed positions. Ensure all crevices are accessed. Solution can be heated to no more than 35°C.
- b Carefully examine to ensure that all visible contamination has been removed.
- c Safely dispose of used cleaning materials.
- d Sterilize using a validated steam sterilizer complying with BS 3970 or equivalent standard. Operating cycle condition as below:
134 - 138°C sterilizing temperature at 2.25 bar operating pressure for minimum of 3 minutes hold time.
- e Inspect for any visible damage prior to use.
- f Nominal life of 400 sterilization cycles for reusable Speculum.



Disposable Speculae - use once only and dispose of safely.

Keeler

10. Specifications and electrical ratings

The ophthalmoscope/retinoscope/otoscope, 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 60601-1.

- 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)

Transport, storage and operating conditions			
	Transport	Storage	Operation
Temperature range	-40°C to +70°C	+10°C to +55°C	+10°C to +35°C
Relative humidity	10% to 95%	10% to 95%	30% to 75%
Atmospheric pressure	500hPa to 1060hPa	700hPa to 1060hPa	700hPa to 1060hPa

11. Annex I – EMC statement and guidelines

Keeler Diagnostic Instruments 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 benign¹, 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).

11. Annex I – EMC statement and guidelines

Guidance and manufacturer's declaration – electromagnetic immunity			
Keeler Diagnostic Instruments are 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 commercial or hospital 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 commercial or hospital environment.
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 commercial or hospital environment. If the user of the Keeler Diagnostic Instruments 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 commercial or hospital environment.

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


11. Annex I – EMC statement and guidelines

Guidance and manufacturer's declaration – electromagnetic emissions			
Keeler Diagnostic Instruments are 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	
Harmonic emissions IEC 61000-3-2		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.
Voltage fluctuations / flicker emissions IEC 61000-3-3		Complies	

Battery operated Keeler Diagnostic Instruments are considered to be inherently EMC benign¹, 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).

11. Annex I – EMC statement and guidelines

Guidance and manufacturer's declaration – electromagnetic immunity			
Keeler Diagnostic Instruments are 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
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Keeler Diagnostic Instruments, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2 \sqrt{p}$</p> <p>$d = 1.2 \sqrt{p}$ 80MHz to 800 MHz $d = 2.3 \sqrt{p}$ 800MHz to 2.7GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey², should be less than the compliance level in each frequency range.³</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	10 V/m	

Note 1 At 80MHz and 800MHz, the higher frequency range applies.

Note 2 These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

² 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 Keeler Diagnostic Instruments are used exceeds the applicable RF compliance level above, the instruments should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the instruments.

³ Over the frequency range 150kHz to 80 MHz, field strengths should be less than 10 V/m.

11. Annex I – EMC statement and guidelines

Recommended separation distances between portable and mobile RF communications equipment and Keeler Diagnostic Instruments

Keeler Diagnostic Instruments are intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Keeler Diagnostic Instruments 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	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d 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 guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12. Spare parts and accessories

The following replacement bulbs are available for Keeler diagnostic instruments:

Part Number	Description
1011-P-7050	2x 2.8v Halogen Pocket ophthalmoscope bulbs
1011-P-7106	2x 2.8v Xenon ophthalmoscope bulbs
1011-P-7114	2x 3.6v Xenon ophthalmoscope bulbs
1011-P-7210	1x Ophthalmoscope LED
1011-P-7229	1x Specialist LED
1013-P-7006	2x 2.8v Professional Spot retinoscope bulbs
1013-P-7007	2x 3.6v Professional Spot retinoscope bulbs
1013-P-7008	2x 2.8v Professional Streak retinoscope bulbs
1013-P-7009	2x 3.6v Professional Streak retinoscope bulbs
1305-P-7000	1x Professional Streak retinoscope LED
1015-P-7023	2x 3.6v Halogen Standard/Deluxe otoscope bulbs
1015-P-7031	2x 2.8v Halogen Standard/Deluxe otoscope bulbs
1015-P-7058	2x 3.6v Practitioner/Fibre Optic otoscope bulbs
1015-P-7066	2x 2.8v Practitioner/Fibre Optic otoscope bulbs

Upgrading your C-size handle from dry cell to rechargeable:
 Replace 2.8v bulb with correct 3.6v version as per table above

Part Number	Description
1911-P-5229	Battery cap (red)
1919-P-7069	3.6v NiCad battery
1941-P-5246	Double charger

In addition the following accessories are available from the distributor:

Part Number	Description
EP29-32777	Power supply
EP39-18918	Slimline 3.6v Lithium Battery
1919-P-7149	Slimline 3.6v NiMH Battery
1501-P-7117	Airtight Chamber with Lens for Pocket and Standard otoscopes
1501-P-7133	Pneumatic Testing Adaptor for 'old type' Standard and Pocket otoscopes
1513-P-7034	Viewing lens for Practitioner otoscope
1514-P-7028	Pneumatic Testing Adaptor for Practitioner, Fibre Optic, Standard and Pocket otoscope
1531-P-5016	3x Magnifier for Deluxe otoscope
1599-P-7237	Bulb extractor for Deluxe, Standard and Pocket otoscope
1599-P-7245	Insufflator bulb for all otoscopes
1941-P-1341	Lithium Mini Charger
1941-P-1368	Lithium Double Charger

13. Warranty



Warning: Do not modify this equipment without authorization of Keeler.



No user serviceable parts – all preventative maintenance and servicing must only be performed by authorised Keeler representatives.

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

Keeler

14. Contact and disposal information



Keeler Limited
Clewer Hill Road
Windsor
Berkshire SL4 4AA
UK

Freephone: 0800 521 251
Tel: +44 (0)1753 857177
Fax: +44 (0)1753 827145

Keeler Instruments Inc
3222 Phoenixville Pike
Building #50
Malvern, PA 19355
USA

Toll Free: 1 800 523 5620
Tel: +1 610 353 4350
Fax: +1 610 353 7814

Disposal of old Electrical and Electronic Equipment

(Applicable in the European Union and other European Countries with separate Collection Systems).



This symbol on the product or on its packaging and instructions indicates that it was put on the market place after August 2005 and 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).



EP59-11234 Issue 8 Feb 2020

Keeler