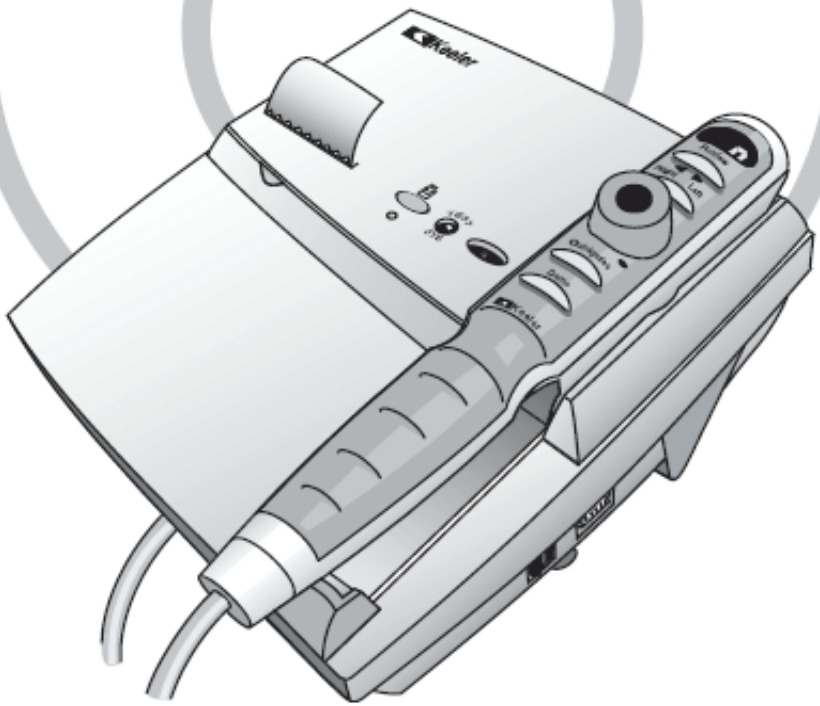
Pulsair EasyEye

User Manual



Keeler

Congratulations and thank you for buying the Keeler Pulsair EasyEye, the only portable, non-contact tonometer. This is an advanced, easy to use product with a wide range of features, designed to make your life easier.

The Pulsair EasyEye is a result of careful research based on feedback from users of the Pulsair 3000 and Keeler's specialist expertise. The features Keeler have incorporated into the Pulsair EasyEye to maximise performance and ease of use are:

- Non-contact measurement of Intra-Ocular Pressure (IOP).
- Hand unit operation allowing IOP to be taken on virtually any patient.
- Portability for domiciliary work or easy transport between different locations, using the rechargeable battery option.
- An automatic averaging system which displays the running average of readings taken.
- Automatic 30+ mode for reading high IOP.
- A non event or bad event detector to advise when the Pulsair EasyEye has fired but has been unable to take a reading because, for instance, the patient has blinked at the wrong moment.
- A built in printer to supply you with a record of the reading taken for the patient.

Copyright and Trademarks

Printed in the UK. October 2001.

Applicable Standards

Approvals; EN 60601-1, EN 60601-1-2, UL 2601-1, EN8612, EN ISO 15004: 1997, Patent Pending.

As part of our policy of continued product improvement we reserve the right to alter and/or amend specifications at any time without prior notice.

Contents

Introduction

This documentation is designed to enhance your understanding of the capabilities of the Pulsair EasyEye by providing comprehensive and easy to follow descriptions and instructions.

The names of buttons are presented in **bold** typeface.
Cross-references are presented in ***bold***, ***italic*** typeface.

Unless stated to the contrary, positions and directions such as left, right, front and rear are given with respect to the unit when viewed from the front.

The fundamental basis upon which the Pulsair EasyEye operates are discussed below.

Accuracy and Calibration

The Pulsair EasyEye calibration has undergone extensive clinical trials to ensure that the instrument is reliable and accurate.

Pressure Variations

It is well known that IOP varies as a result of pulse, respiratory and diurnal fluctuations. In addition blinking, squeezing, fluid intake, physical activity, body position and even the direction of gaze can influence IOP.

Non-contact Tonometers take an instantaneous measurement that may vary due to the pulsatile nature of the IOP. By taking four readings a more accurate indication of IOP can be recorded.

Corneal Response to the Air Pulse

The response of the cornea to the air pulse is known as an *event*. The Pulsair EasyEye has been designed to use the gentlest possible air pulse to achieve good quality events in the majority of eyes.

When a non event or bad event is detected by the Pulsair EasyEye it displays *ER* and automatically switches to *30+* mode to create a slightly higher pressure air pulse for the next reading.

Autoactivation

The Pulsair EasyEye automatically fires a gentle puff of air at the cornea when the hand unit is correctly aligned with the eye.

Memory

The Pulsair EasyEyes' memory holds the readings taken, on both eyes, for a patient, up to a ma ximum of ten readings per eye. The memory is only cleared when the hand unit is removed from the holster for use on another patient.

You must review the readings taken for a patient or print a patient record before the unit is removed from the holster, reviewing and printing can take place whilst the hand unit is located in the holster.

Warning

Do not use the Pulsair EasyEye near mobile telephones as performance will be affected. Advise patients to switch mobile telephones off before use.

Warning

The Pulsair EasyEye maybe affected by Electro-magnetic interference (i.e. mobile telephone). If this happens:

- Switch off the offending equipment

  or

- Increase the distance between the offending equipment and EasyEye.

Warning

Eyecaps are designed for training use only. The Eyecaps are disposable and must only be used once.

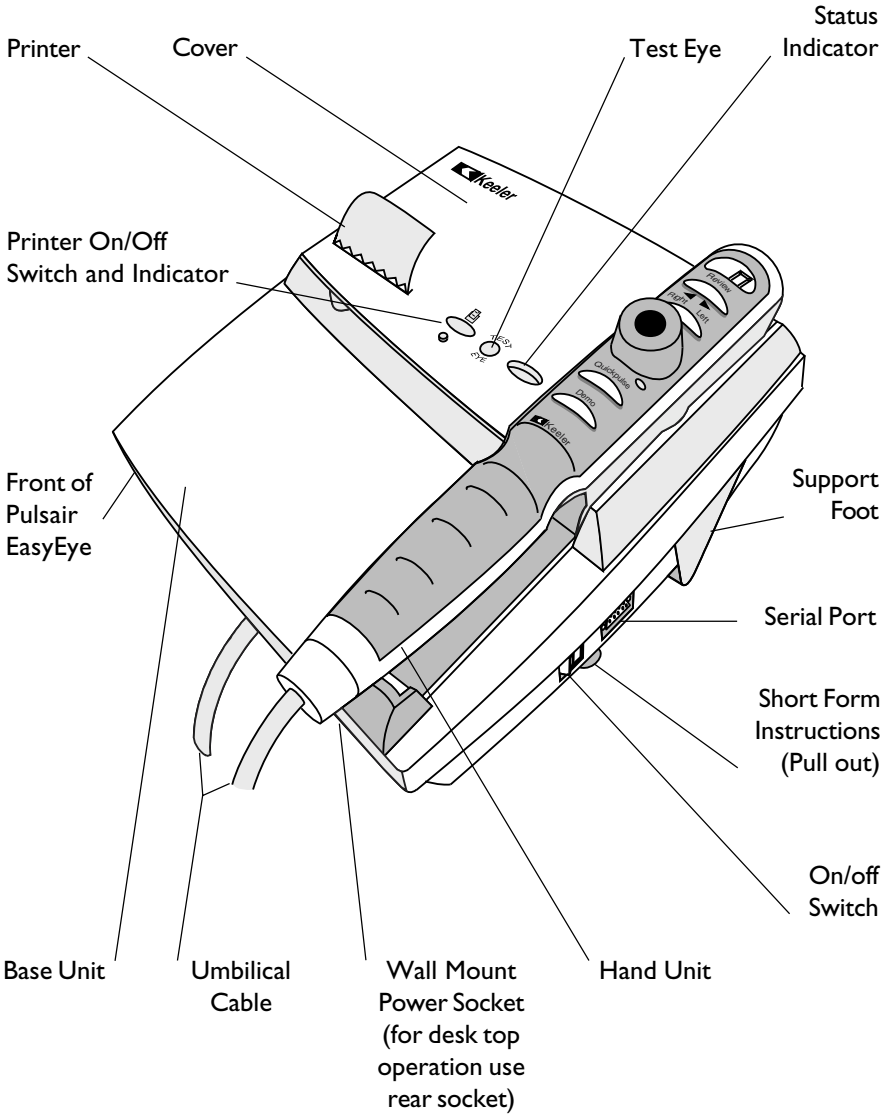
Checklist

Make sure the following items are in the Pulsair EasyEye box when you unpack it:

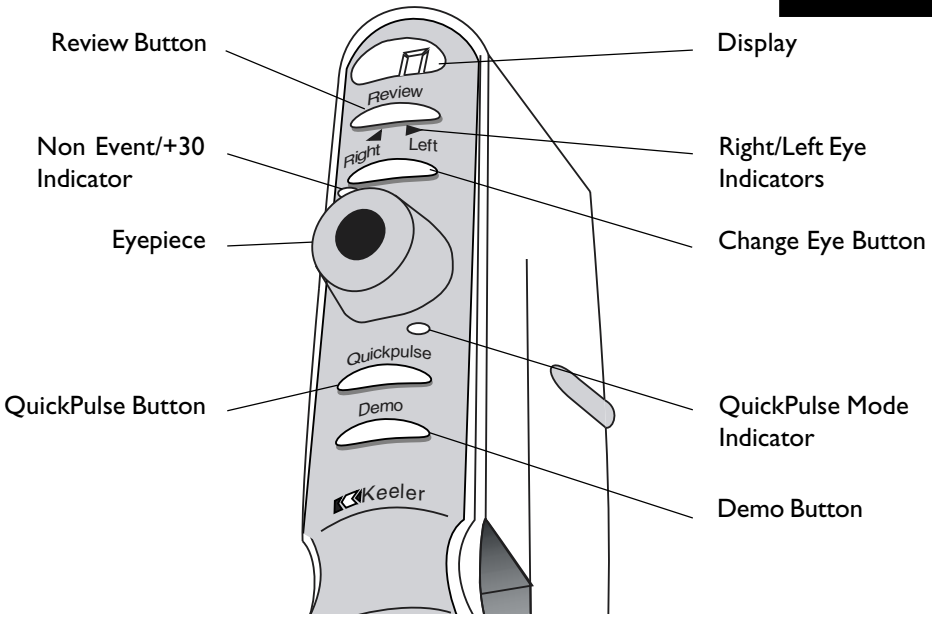
- Pulsair EasyEye unit
- Orange Dust Cap (fitted)
- Power supply and four plugs (Australian, UK, USA and Euro)
- Dust Cover for unit
- Wall Mount Kit
- Two printer paper rolls (1 fitted and 1 replacement)
- Two rubber eyecaps
- Blister pack of two spare bulbs
- One Users Guide

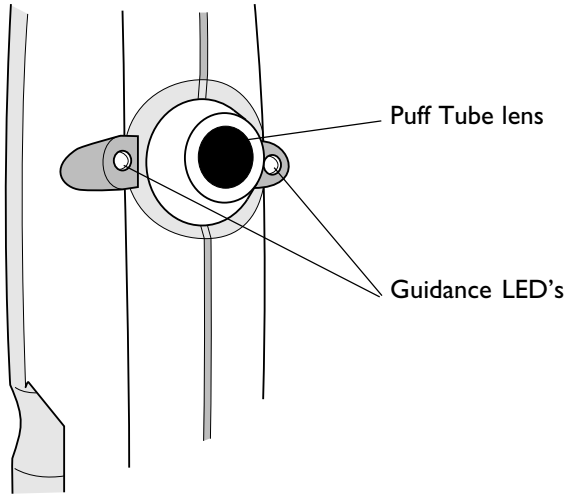
Optional Extras (supplied on request)

- Rechargeable battery
- Hand carry bag



Pulsair EasyEye Unit





Pulsair EasyEye Hand Unit

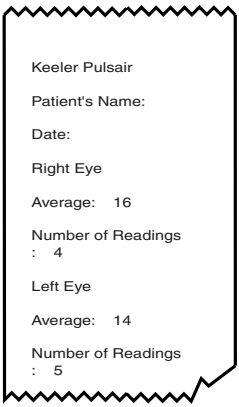
Overview of the Base Unit

The following overview discusses all the main parts of the Pulsair EasyEye and their use. All the parts covered below are listed on the diagrams located on pages 8 and 9.

The Printer

To turn the printer on, press the **Print** on/off switch, which is located on the cover of the unit. A green indicator underneath the **Print** button illuminates.

A typical printout is displayed below:



You need to manually write the patient's name and date on to the printout.

Test Eye

Use the Test Eye located on the cover of the Pulsair EasyEye to practice taking readings.

Status Indicator

Status Indicator displays:

Green light - The Pulsair EasyEye is powered up and ready for use.

Flashing yellow light - Rechargeable battery power is low. The unit must be connected to the mains as soon as possible.

Yellow light - The battery is charging, however the unit can still be used via the mains power.

Serial Port

The serial port allows you to connect your Pulsair EasyEye to any piece of equipment that complies to EN 60950, e.g. a PC to download results or for the service engineer to calibrate the unit. For further details on PC use please see your local distributor.

On/Off switch

The On/Off switch is located on the side of the base unit, ***see the Pulsair EasyEye unit illustration on page 8***.

To turn the Pulsair EasyEye on, switch to **I**.

To turn the Pulsair EasyEye off, switch to **O**.

Note: *If the unit isn't going to be used for a long period unplug it from the mains.*

Short Form Instructions

The Short Form Instructions are located underneath the base unit, you can access them from either side of the unit, they are supplied fitted on the right side. The Short Form Instructions show how to take patient readings.

Cover

The cover lifts up to allow access to the printer and the rechargeable battery. When closing ensure the cover clips into place.

Umbilical Cable

The Umbilical Cable links the base unit to the hand unit.

Wall Mount Power Socket

The Pulsair EasyEye can be mounted on the wall or the desk. If the unit is wall mounted the power socket you should use is located at the front of the base unit.

Desk Mount Power Socket

The Pulsair EasyEye can be mounted on the wall or the desk. If the unit is located on a desk the power socket you should use is located at the rear of the base unit.

Overview of the Hand Unit

Display

The display shows the recorded IOP reading or the averaged IOP reading.

After the first reading is taken the display shows the measured IOP. After each of the consecutive reading is taken the display shows the average of the readings taken so far, i.e. the first figure displayed is the actual reading, the second figure is an average of the first two readings etc., up to a maximum of ten readings, per eye.

Note: *The displayed figure is rounded to the nearest whole number.*

The displayed average is based on the actual readings which are taken to one decimal place. For example, readings of 15.4, 16.3, 14.2 and 16.9 are averaged by adding them together which equals 62.8 and dividing by the number of readings taken, 4. This gives a final figure of 15.7, so the display shows 16.

When all the required readings have been taken the figure displayed is the IOP that is recorded for the patient.

Review Button

You can review the readings taken at any time:

Press the **Review** button. The display shows the readings taken in the order they were taken, the final figure displayed is the cumulative average.

The Pulsair EasyEye's memory is capable of holding a maximum of ten individual readings, per eye. When the memory is full no further readings can be taken.

To clear the memory you can either replace the hand unit in the holster and remove again or press the **Change Eye** button.

Right/Left Eye Indicators

The Right/Left Eye Indicators are two arrows located above the **Change Eye** button. The illuminated LED indicates the eye that readings are currently being taken from.

Change Eye Button

The **Change Eye** button is used to change the eye readings are taken on. The right eye is always selected first by default, when the necessary number of readings (four is recommended) have been taken press the **Change Eye** button. The right eye Indicator extinguishes and the left eye indicator illuminates, readings can now be taken on the left eye.

When the **Change Eye** button is pressed QuickPulse, Non Event and 30+ modes are all turned off if they are active.

Non Event and 30+ Indicator

This LED illuminates if the Pulsair EasyEye has registered a non event, bad event or a reading over 30.

The majority of individuals have IOP's of 30 mm Hg or less, IOP's of this value can be measured with a gentle air pulse. The Pulsair EasyEye has two pulse modes.

- *Normal* which can measure IOP's up to and a little over 30 mm Hg.
- *30+* which can measures IOP's up to 50 mm Hg.

If the Pulsair EasyEye detects a bad event or a non event it automatically switches to *30+* mode, this mode is only deactivated when the **Change Eye** button is pressed or the unit is returned to the holster.

When the bad event or non event occurs between valid readings the display shows *ER* and a flashing average. This indicates that the required minimum of 4 valid readings has not been reached. The **Non Event/30+** indicator illuminates, denoting that a slightly stronger air pulse will be used for the remaining readings. Use the standard method to operate the Pulsair EasyEye and continue as normal (minimum of four reading recommended).

The most common causes of bad or non events are;

- movement of the eye during the measurement process
- interference of the air pulse by the eyelashes or eyelids if the eyes are partly closed
- blinking
- eyes which need a slightly stronger pulse of air to achieve applanation of the cornea.

Eyepiece

The Eyepiece allows the user to view the patients eye and align the targetting system.

QuickPulse Indicator

This indicator illuminates if the **QuickPulse** mode is active.

QuickPulse Button

QuickPulse mode may need to be invoked for patients who have corneal scarring, a high level of astigmatism, or a less reflective eye than normal.

The patient should be asked to blink several times and further readings attempted before engaging QuickPulse.

The Pulsair EasyEye checks that the eye focus is correct and if so, produces an air pulse.

Before invoking QuickPulse mode ensure that the correct image is seen through the eyepiece.

If this is the case and no air pulse occurs, it may be that the particular eye is less reflective than normal. Press the **QuickPulse** button. It should now be easier to obtain a reading. QuickPulse should always be used on post operative eyes with corneal scarring. QuickPulse mode can be toggled on and off by pressing the button, the QuickPulse Indicator illuminates if the mode is active.

The QuickPulse facility should only be used when necessary.

QuickPulse can also aid in training new operators. They may have difficulty initially in obtaining the correct focus (refer to the pull out instructions, located underneath the Pulsair EasyEye).

Demo Button

In order to reassure the patient you can demonstrate the procedure on the back of their hand before taking a reading:

- Position the hand unit above the patient's hand and press **Demo**. The patient experiences a gentle puff of air.

The **Demo** button can also help to indicate that the unit is in calibration. A reading of 30/50 flashes alternatively in the display, when the button is pressed.

To maintain accuracy, we strongly recommend that the unit is calibrated annually.

Guidance LED's

The two green LED's located on the front of the hand unit act as a guide when you are lining up the patients eye to take a reading.

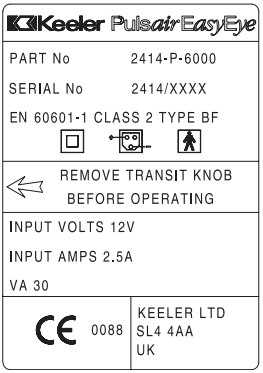
Puff Tube Lens

The puff tube lens is the part of the Pulsair EasyEye through which a gentle puff of air is emitted.

Getting Started

Before you can start to use your Pulsair EasyEye, follow the procedures outlined below.

1. Remove the hand unit from the base unit. Turn the Pulsair EasyEye over to display the label and transit knob.

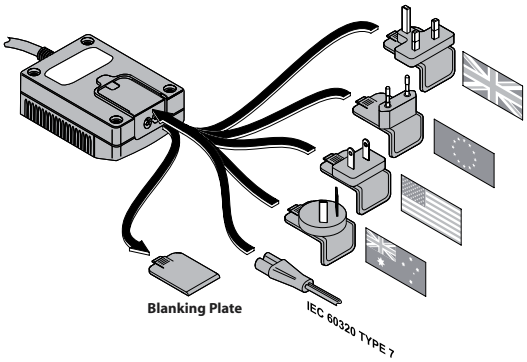


   The label displays the IEC and CE classifications for the Pulsair EasyEye, and also the serial and part numbers which will be required for registration and re-ordering.

2. Remove the transit knob from the bottom of the Pulsair EasyEye unit as instructed by the label.

Note: *The transit knob should be replaced whenever the unit is transported.*

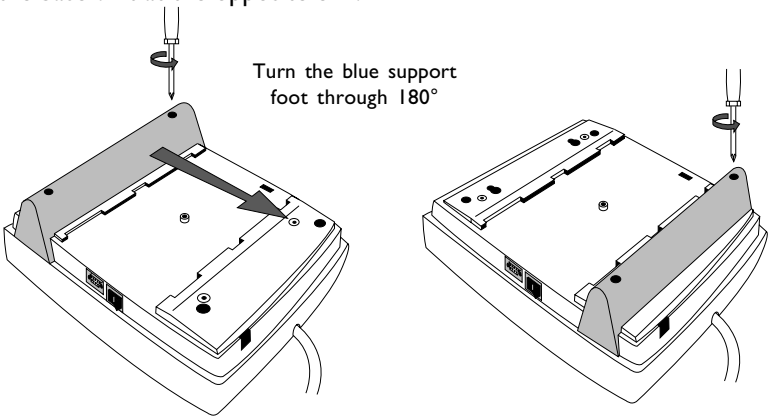
3. Take the power supply unit and replace the blanking plate with the appropriate mains plug adapter. Alternatively you can use an I.E.C. 60320 Type 7 extension lead (not supplied), see your local distributor for more details.



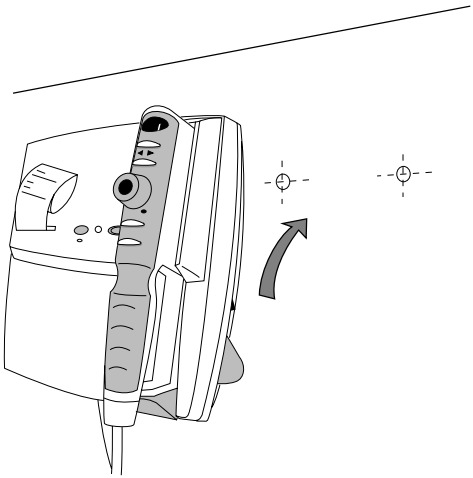
Mounting the Unit

The Pulsair EasyEye can be either desk top or wall mounted. The unit is delivered in **Desk Top** mode. If you want to mount the unit on the Wall, you need to use the Wall Mounting kit supplied:

1. Turn the Pulsair EasyEye over and undo the two screws on the bottom of the unit, remove the blue support foot.
2. Turn the blue support foot through 180° and then screw it back on to the base unit at the opposite end.



3. Position the supplied template on the wall and drill two holes. Remove the template and fit the wall mounts using the screws (x2) provided.
4. Hook the keyhole openings on the back of the Pulsair EasyEye onto the screws to mount the unit on the wall.



Patient Preparation

Before using the Pulsair EasyEye you should make your patient feel at ease and ensure they are located in an optimum reading location. This is because apprehension and nervousness may adversely affect the readings obtained. Follow the points outlined below to achieve this:

- Ask the patient to switch their mobile telephone off if they have one.
- Ensure that the patient is comfortable and in a relaxed position.
- Ask the patient to remove their contact lenses or spectacles if worn and to blink normally.

In order to reassure the patient, you can demonstrate the procedure on the back of the patient's hand prior to taking a reading:

- Position the hand unit above the patient's hand and press **Demo**. The patient experiences a gentle puff of air.

Before taking a reading you should:

- Ensure the patient and instrument optics are not positioned under direct lighting (i.e. spot lights or sunlight).
- Ensure the patient's eyes are fully opened. This helps to prevent *squeezing*, where the patient unconsciously tenses their eyelids and increases IOP.

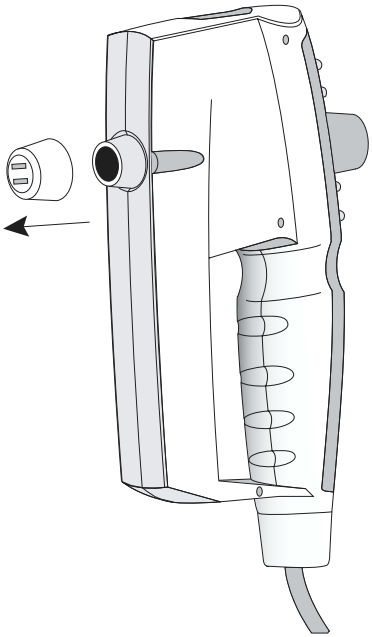
Throughout the reading process, you should:

- Allow the patient to blink at intervals in order to maintain the corneal tear film.

Instrument Preparation

1. Plug the power supply in to the Pulsair EasyEye unit.
2. Turn the On/Off switch to **I**, the status indicator on the front of the unit luminates green. The display on the hand unit initially shows **8.8**, this demonstrates that all segments of the display are functioning. After a pause the display shows **0**, this indicates that the unit is ready for use.
3. Lift the hand unit from the holster. The unit is supplied with an orange dust cover which protects the puff tube lens from dust and scratching whilst in transit. Remove the cover before using the unit.

Note: *When the unit is not in use you should replace the dust cover to protect the puff tube lens.*



When the hand unit is removed from the holster the two green LED's on the front illuminate, and the pump starts (an audible tone is emitted). The pump takes 2 seconds to prime before the unit is operational.

Before using the Pulsair EasyEye press the **Demo** button to dispel any minute particles of dust or moisture which may have settled whilst the Pulsair EasyEye was not in use.

Taking Readings

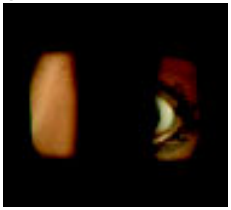
For quick reference, please refer to the pull out short form instructions located underneath the Pulsair EasyEye unit.

Once the Pulsair EasyEye and the patient are prepared, you are ready to take a reading.

1. The Pulsair EasyEye is set to automatically select the right eye. If you wish to select the left eye, press the **Change Eye** button on the hand unit.

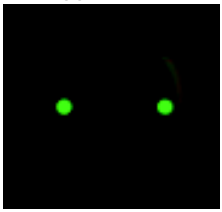
2. Lift the hand unit, the pump starts and the two green LED's illuminate.

3. From a distance of about 25 cms (10 inches), look through the eyepiece and locate the patients eye.

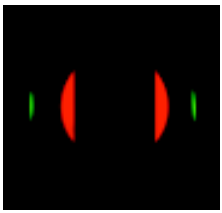


4. Slowly move closer to the patient, maintaining alignment. Support the Pulsair EasyEye against your free hand, and rest the hand against the patient's forehead.

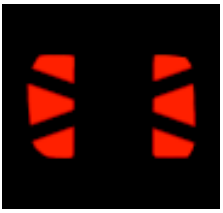
5. Continue to move in slowly towards the patient, two green dots appear.



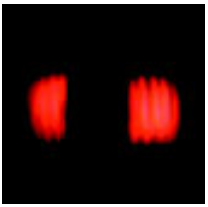
6. Continue to move closer, a red reflex appears.



7. Move closer. At a distance of approximately 15mm, a *bow tie* image appears. Centralise this image (on the central bar) and the Pulsair EasyEye fires.



8. If you see filaments you are too close. Move back and repeat.



9. Once you have taken a reading, remain in the operating position, wait a few seconds for the air chamber to refill. When the *bow tie* image appears Pulsair EasyEye takes a subsequent reading. Keeler recommends you take four readings.

10. If the reading is recorded as a non event or bad event the 30+ indicator illuminates. 30+ mode is automatically activated, wait for a few seconds and try again.

11. If the unit does not fire, repeat step 4-8. ***See Troubleshooting on page 28 for more details***.

12. After each reading is taken, the display shows the average of all the readings taken on the eye. When four or more readings have been taken the average displayed is the IOP recorded for the patient.

13. You can review the readings taken using the **Review** button. If a non event or bad event has been detected *ER* appears in the display when reviewing.

Note: *Each measurement is taken to 1 decimal place but is displayed to the nearest whole number; 0.5 would be rounded up to 1 mm Hg.*

The Next Eye

Once a satisfactory number of readings have been taken on the right eye press the **Change Eye** button, the left arrow above the Change Eye button illuminates. Readings can now be taken on the left eye. ***See the Change Eye Indicators and the Change Eye Button on page 13 for more details***.

Printing the Results

The Pulsair EasyEye has a built in printer which prints a patient's record once all the readings have been taken.

When the hand unit is returned to the holster the results are automatically printed if the printer is turned on.

If the printer is turned off when the hand unit is returned to the holster, press the **Printer** on/off switch to turn the printer on, then press the Change Eye button on the hand unit (do NOT remove the hand unit from the holster). The last recorded readings are then printed.

The Pulsair EasyEye memory is cleared when the hand unit is removed from the holster for use on another patient, therefore if a printout is required you must turn the printer on before removing the hand unit from the holster for use on another patient.

To print off another copy of the report press the **Change Eye** button whilst the hand unit is in the holster.

If you want to review the patients' readings you must do this before the hand unit is removed from the holster for use on another patient.

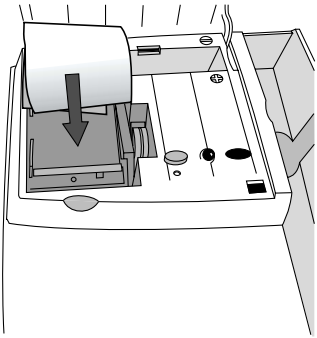
Closing Down the Instrument

Having performed the required readings for a patient return the hand unit to the holster and turn the **On/Off** switch to **O**. If the instrument is to remain unused for any length of time, it should be switched off at the mains.

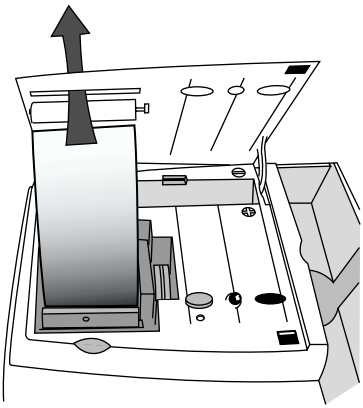
To Change the Printer Paper

To change the printer paper:

1. Lift the cover of the Pulsair EasyEye and remove the empty printer roll.
2. Place the new roll of paper into the paper holder, making sure the free end is loose at the top of the roll.



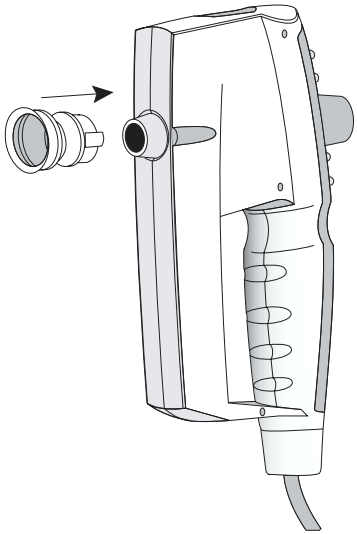
3. Feed the free end of paper through the gap in the cover.



4. Clip the cover back into position.

Eyecaps

The Pulsair EasyEye is supplied with two eyecaps. An eye cap can help when training new users, by assisting them in maintaining the correct positioning and distance from the cornea. To use the eyecap place it around the puff tube lens. The eyecap can remain on the hand unit when it is placed in the holster. Eyecaps should only be used during training, and not when recording patients IOPs. Eyecaps are disposable and must only be used once.



The Rechargeable Battery

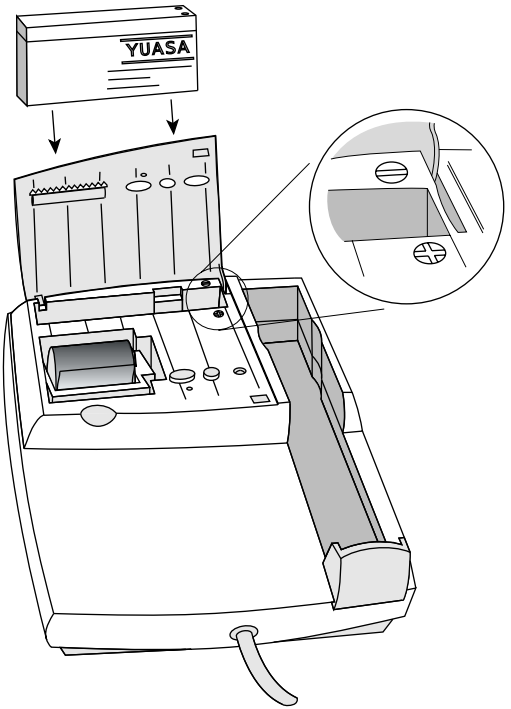
The Pulsair EasyEye can be used with a rechargeable battery instead of the mains. The rechargeable battery is an optional extra and can be requested at the time of purchase. If you don't currently have a rechargeable battery and you require one, please contact your local distributer.

The rechargeable battery must be charged for 12 - 14 hours before it is used for the first time.

To fit the battery:

1. Lift the front cover of the Pulsair EasyEye and insert the rechargeable battery into the back of the compartment as shown below, ensure the battery strap fits under the new battery. Make sure the battery orientation is correct (+ to +, and - to -) as shown on the top of the moulding.

2. Close the cover.



To charge the battery:

1. Plug the power supply in to the Pulsair EasyEye.
2. The **Status Indicator** lights yellow, this indicates that the battery is charging.
3. When the yellow LED extinguishes the battery is fully charged and ready for use.

Maintenance and Cleaning

Clean the puff tube lens on a weekly basis:

1. Unscrew the white plastic shroud fitted over the puff tube lens assembly.
2. Moisten a cotton bud with Isopropyl Alcohol.
3. Move the tip of the bud around the lens in a circular motion.
4. After one circle the bud should be discarded to avoid smearing on the lens.
5. Look at the puff tube lens from the patient's side, if traces of tear film can still be seen, repeat above steps until clear.
6. Replace the white plastic shroud, and ensure the trim ring position is correct before tightening.

Note: *Care should be taken not to damage the Puff Tube assembly during cleaning.*

Caution

Never use a dry cotton bud or tissue to clean the puff tube lens. Never use a silicone impregnated cloth or tissue to clean the puff tube lens.

Bulb Change

The bulb (Part No. 1024-P-7156) is located at the top of the hand unit. To replace, pull the old bulb out and insert replacement .

Power Supply Unit

Inspect your power supply unit and cable for damage regularly.

Before inspecting, disconnect the power supply from the Pulsair EasyEye and the mains.

If the outer insulation of the cable appears to be damaged discontinue use immediately. Contact your local dealer for a replacement.

General

Keep the instrument free from dust.

If the unit is to remain unused for any length of time, turn the **On/Off** switch to **O** and remove the power supply. Use the dust cover to protect the unit.

Before using the Pulsair EasyEye again, press the **Demo** button to dispel any minute particles of dust or moisture which may have settled on the instrument between readings.

Optional Accessories and Spares

Also available for the Pulsair EasyEye as optional extras:

- A carrying bag (Part No. 2414-P-7003)
- Rechargeable battery (Part No. 2414-P-7000)
- Eyecaps (Part No. 2414-P-7002)
- Printer paper (Part No. 2208-L-7008)
- Bulbs (Part No. 1024-P-7156)

Troubleshooting

Difficulty firing

Clean the puff tube lens, see page 25, if this does not solve the problem call your local distributer.

No audible sound when the hand unit is lifted

Ensure the unit is connected to the power supply or that the battery is fully charged, if this does not solve the problem call your local distributer.

No red light visible through the puff tube when the unit is on

Replace the bulb.

Paper jam

Remove the paper reel and re insert as described on page 22.

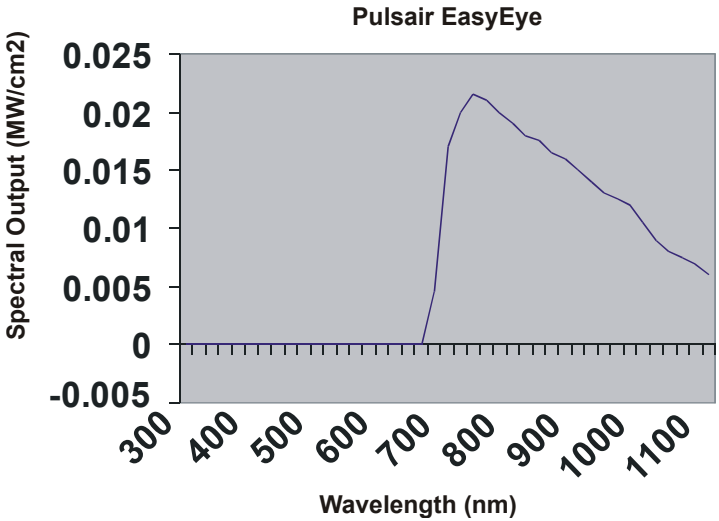
No power

Check that the mains plug is switched on, the power supply cable is inserted fully and that the **On/Off** switch is turned to **I**. If you are using a rechargeable battery check it is fully inserted and that the orientation is correct, see page 24 for more details.

Spectral Radiance

It is well established that exposure of the eye to intense light for extended periods poses a risk of retinal photic injury. Many ophthalmic instruments illuminate the eye with intense light. The clinician must make a risk benefit judgement about the light intensity to be used in any procedure. The use of insufficient illumination to examine patients may result in adverse effects more serious than a retinal photic injury. Further, despite all efforts taken to minimise the risk of retinal damage, damage may still occur. While no visible retinal photic lesions have been identified for ophthalmic instruments, illumination levels have been set to the minimum necessary to perform the diagnostic function in the Pulsair EasyEye. Young children and persons with diseased eyes may be at 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.

The time to reach a potential optical radiation hazard for this device is 120 minutes. This time is for cumulative exposure in a day. It should be noted that there is a safety factor of about 10 built into the safety guidelines. Hence for a source with continuous light output, if the exposure time is 120 min, photoretinitis might be expected for an exposure time of 10 x 120 min = 1200 mins (about 20 hours).



Ophthalmic Instruments - Fundamental Requirements and Test Methods

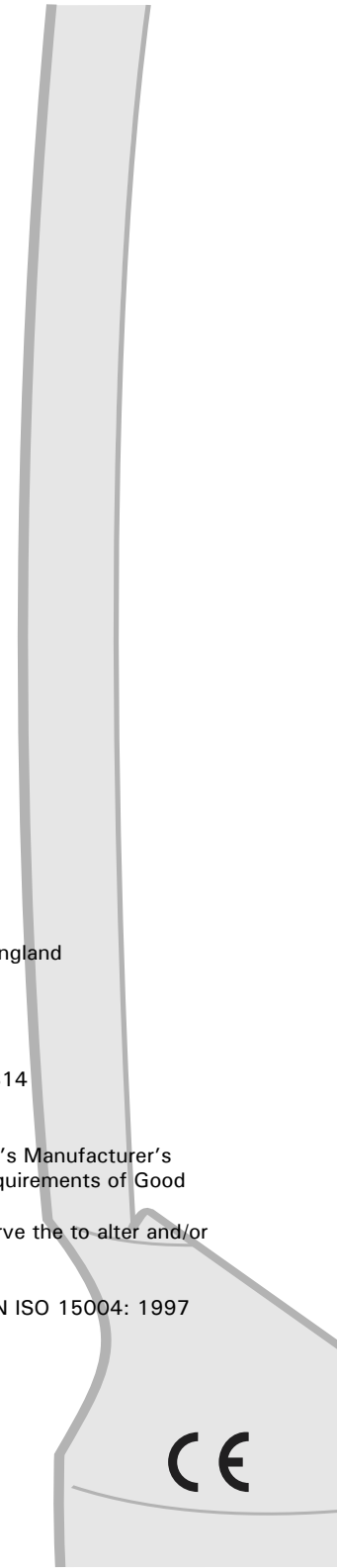
Pulsair EasyEye Technical Data

Console dimensions	355 x 305 x 205 mm (14 x 12 x 8 inches)
Hand Unit dimensions	265 x 115 x 40 mm (10.5 x 4.5 x 1.5 inches)
Console weight	3.18kg (7lb), 4.0kg inc. battery (8.8lb)
Hand Unit weight	0.887 kg (1.95 lb.)
Calibrated range	7 to 50 mm Hg
Displayed accuracy	± 1 mm Hg
Displayed scale	Direct in mm Hg
Length of umbilical cord	2.0 m / 6'6"
Complies with	EN 60601 class II, type BF. (Type BF definition as type B but with isolated or floating applied parts)

Power Supply Unit

Power input	30 VA
Input voltage	100, 110, 120, 220, 240 V - Note: ± 10%
Input frequency	50/60 Hz

Notes



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Keeler Limited is registered under the UK Medical Device Agency's Manufacturer's Registration scheme as meeting the UK Department of Health requirements of Good Manufacturing Practice.
As part of our policy of continued product improvement we reserve the to alter and/or amend specifications at any time without prior notice.

Approvals; EN 60601-1, EN 60601-1-2, UL 2601-1, EN8612, EN ISO 15004: 1997
Patent Pending

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