Instructions for use
1. Copyright and Trademarks

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

The manufacturer reserves the right to make changes to specifications and other information contained in this document without prior notice.

Pulsair Desktop™ is a registered Trademark of Keeler Limited 2007.

Copyright © Keeler Limited 2007.

Published in the UK 2009.

Description of the product

The Pulsair Desktop Tonometer is indicated for measuring intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.

It is an “air puff” Tonometer designed to accurately measure Intra Ocular Pressure (IOP) without making contact with the surface of the eye.

Air impulse tonometry is a variant of the general applanation tonometry in which a portion of the cornea is flexed by mechanical stimuli in which the force/pressure required to produce the flexing effect is related to the intraocular pressure.

The air puff technique requires directing a calibrated quantized packet of air towards the central portion of the cornea, and the detection of the pre-defined deformation of the cornea through optical means and reflections from the corneal surface.

Please read and follow these instructions carefully.
2. Introduction

Thank you for purchasing the Keeler Pulsair Desktop.

The product has been designed and manufactured to ensure that you will enjoy many years of trouble free and safe use.

Please follow the User Instructions to ensure optimum performance.
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

- Double insulated

- Type BF protections against shock

- Consult instructions for use

- Manufacturers name and address

- Keep dry

- USB transfer port

- **Power input port**

- On/Off

- Colour adjustment

- Brightness adjustment

- Contrast adjustment

- Fragile

- This way up

- Material suitable for recycling
4. Safety

4.1 Device Classification
CE Regulation 93/42 EEC: Class 2a
FDA: Class II

4.2 Warnings and cautions

⚠️ Warning
- 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.
- This product should not be immersed in fluids.
- 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.
- This equipment should only be used by trained personnel. USA Federal law restricts this device to sale by or order of a physician.
- Only use approved Keeler power supply EP29-32777 or instrument may malfunction.

⚠️ Caution
- 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.
- Accuracy of IOP measurements is known to be affected by variations and changes in corneal rigidity due to differences in corneal thickness, intrinsic structural factors or corneal refractive surgery. It is recommended that these factors are considered during IOP measurement.
- Keeler recommends the use of disposable hygienic chinrest tissues on the chin rest before the patients place their chin on it.
- This product should be used in a room with subdued lighting.
- Before using the Pulsair Desktop, press the ‘Clear/Demo’ button for 1 second to dispel any minute particles of dust or moisture which may have settled whilst the instrument was not in use.
5. Cleaning instructions

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.
6. Power supply assembly

Set Plug

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

Your Pulsair Desktop is designed to be used on a sturdy flat surface, for example a medical instrument table or a purpose designed refraction system table top.

Choose carefully the intended location for your Pulsair Desktop with particular consideration to health and safety aspects, for example the routing of the power lead, and it’s position in regard to the user and the patient.

Your Pulsair Desktop has four anti slip rubber feet, ensure these are located well within the edge of your intended flat surface to ensure there is no possibility of the Pulsair becoming dislodged and causing injury to a user or patient.

Your Pulsair Desktop has an adjustable chinrest, however we recommend that to ensure maximum patient comfort you use it on a height adjustable table that allows wheelchair access for any wheelchair bound patients.
8. Tonometry, pressure variations in the human eye

The Keeler Pulsair Desktop measures intra-ocular pressure by automatically releasing a gentle puff of air onto the cornea. This is known as an event.

A single reading can sometimes be misleading as the IOP will vary 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.

Up to 4 readings may be required in order to reduce the impact of these variants to a constant IOP.

Pulsair Desktop software will recognise the readings and give a sound notification when two consecutive readings are +/- 1mmHg of each other indicating that further measurements may not be required.
9. Names of controls and components

1. Travelling lock
The Pulsair Desktop is fitted with a travelling lock to protect the moving parts from damage when in transit or when the device may be subject to sudden movement or shock.
To release the travelling lock rotate it counter clockwise until the joystick assembly is free to move.

To lock the moving section in place, align the moving upper section with the base unit and carefully screw the travelling lock clockwise until it is firmly located.
Note – do not over tighten the travelling lock.

2. Chinrest and chinrest height adjuster
Rotate the chinrest adjuster to increase or decrease the height of the chinrest until the patients outer canthus is in line with the indicator line on the chinrest vertical bar.

3. On/Off push button
On pressing the On/Off button, the instrument will be switched on and ready for use. The display will progress quickly through the following stages during system initialisation.
9. Names of controls and components

When the system is ready to use, the display will read L: Ready or R: Ready depending on whether the tonometer is in position to test the left eye or the right eye.

R indicates it is in the right eye position – the display could also read L: Ready.

4. Start/Stop button
Pressing this button while the Pulsair Desktop is running will stop the pump and put the system into standby mode, the display will show Standby. The Start/Stop button will reset the memory buffer, clearing all readings stored. Pressing this button while the unit is on standby, the Pulsair Desktop will start with the pump running and the system is initialised ready for use. The instrument will go through all the displays as per section 3.

5. Motion sensitive wakeup mechanism
The Pulsair Desktop is equipped with a motion sensor. Upon moving the platform from left to right or vice versa, the motion sensitive switch is activated to start the pump and the rest of the system from Standby mode so that it is ready for measurement use. The instrument will go through all the displays as per section 3. After two minutes of inactivity the system automatically switches off to save energy.

6. Clear/Demo button
Pressing the Clear/Demo button momentarily clears all records of previous readings and the instrument is set to its default setting. If this button is pressed and held for more than a second, the instrument initialises and puffs a demo puff in order to demonstrate to the patient the softness of the air puff.
9. Names of controls and components

7. Print/Menu button
Pressing the Print/Menu button momentarily will print the results on the integrated printer and send the data to the USB data port. If this button is pressed and held for more than a second, a user selectable menu option is entered.

8. Easy Pulse Button
Pressing and holding this button for over a second activates the ‘Easy Pulse’ mode. This enables the instrument to fire in the event of difficulties in firing, for example, with a damaged or scarred cornea. This action is accompanied by sound and an additional momentary indication on the display. On pressing any other button or changing the eye, the instrument resets to normal mode.

9. USB transfer port
This is used for transferring IOP data to an external device such as a personal computer and for use by a qualified technician when calibrating the Pulsair Desktop or performing a software revision.

10. Power input connection/disconnection
To connect, insert the low voltage power lead into the power input socket. To disconnect, remove the low voltage power lead from the power input socket.

11. Joystick
The rotating joystick controls the elevation of the measurement head and back front movements of the moving upper section of the Pulsair Desktop.
9. Names of controls and components

12. Printer cover
   Access to the printer paper is via this cover, use your finger in the lip on the top of the cover and gently pull towards you to open the printer cover.

13. Alignment screen
   The alignment screen allows the user to visualise the patient’s eyes in order to correctly align the instrument with the centre of the cornea prior to measurement. Alignment is performed using the moving part of the Pulsair Desktop and the joystick for final alignment. The Pulsair Desktop will fire automatically when correctly positioned and aligned. See section 10 for detailed instructions on the alignment process.

14. Alignment screen adjustment control wheels
   Refer to Section 3 for information on the function of these three control wheels.
9. Names of controls and components

15. Measurement display screen

Measurement display screen – This screen will display the Eye measured, the average reading and individual readings from either the left (L) and right (R) eyes. Left and right detection is automatic.

After the first reading is taken the display shows the measured IOP. After each of the consecutive readings are taken the display shows the individual reading and the average of up to the last four 4 readings per eye.

In addition to IOP readings, the Pulsair Desktop also displays a number of messages on the character display when a measurement is not detected for a number of reasons. In such cases, the display may read as follows:

a) < 5: This is shown when the reading is lower than 5mmHg, in which case no valid reading is displayed. (Signified by long sound)

b) >25: This is shown when applanation is detected with soft-puff and the reading is greater than 25mmHg, in this case the instrument displays >25 and switched to hard puff. The instrument shall stay in hard puff until two consecutive readings are less than 20mmHg.

c) >50: This is shown when the reading is greater than 50mmHg, in which case no valid reading is displayed. (Signified by long sound)

Note: The displayed dummy average is rounded to the nearest whole number or displayed to one decimal place depending on the user setting accessed via the menu.

The displayed running 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, or 16 depending on user settings. Please note independent readings are displayed as whole numbers.

When all the required readings have been taken the figure displayed is the IOP that is recorded for the patient. When two consecutive readings are within 1mmHg an audible sound will be heard indicating that sufficient readings may have been taken.
10. Measurement procedures

10.1 Preparing the device

1. Plug in the power supply cord to the instrument. The power socket is located on the right hand side of the instrument.

2. Turn the instrument on using the on/off push switch located on the front of the instrument. To initialise the instrument ready for use.

3. Remove the protective dust cap from the puff tube.

4. Unscrew the transit lock if secured.

5. Using the joystick bring the moving part of the Pulsair Desktop back towards you and across to the left (to measure the right eye first).

6. Before using the Pulsair Desktop, press the 'Clear/Demo' button for 1 second to dispel any minute particles of dust or moisture which may have settled whilst the instrument was not in use.
10. Measurement procedures

10.2 Preparing the patient

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

1. Ensure that the patient is comfortable and in a relaxed position.

2. Ask the patient to remove their contact lenses or spectacles if worn and to blink and breathe normally.

3. In order to reassure the patient, you can demonstrate the procedure, using the Demo button, on the back of the patient’s hand prior to taking a reading.

4. Place disposable chinrest tissue on the chin rest. Ask the patient to place their head on the chinrest.

5. Adjust the chinrest height so that the outer canthus is aligned with the marker on the chin rest vertical support.

Before taking a reading you should:

1. Ask the patient to blink to ensure a good and reflective tear film.

2. Ensure the patient and instrument optics are not positioned under direct lighting (i.e. spot lights or sunlight).

3. Ensure the patient’s eyes are fully opened. This helps to prevent squeezing, where the patient unconsciously tenses their eyelids and increases IOP.

4. Throughout the reading process, you should:
   Allow the patient to blink at intervals in order to maintain the corneal tear film.
10. Measurement procedures

10.3 Taking the reading

1. Holding the joystick, move with the other hand the moving part of the Pulsair Desktop until the patient’s eye to be measured is visible and central on the alignment video screen. Height adjustment is obtained by rotating the joystick. If there is insufficient travel re-check the patient’s head height in the chinrest and try again using the joystick.

2. Carefully move the tonometer towards the patient until the external eye image becomes the cross hairs alignment target.

3. Using the joystick, focus the cross hair alignment target until the correct focused position triggers the tonometer to fire automatically.

4. Remain in the firing position until the Pulsair stops reading, after four readings per eye are taken. The Pulsair Desktop will indicate with a short beep when sufficient readings may have been taken i.e. when two successive readings are within +/- 1mmHg of each other.

5. If a reading is recorded as a non event or bad event, a bad event long tone will be heard.

6. The first reading will be the measured value; successive readings will display the running average IOP. Outlying or spurious readings will automatically be excluded from the calculation.
11. Display examples

The unit will display ‘STANDBY’ when the power is on.

The unit will display ‘STARTING’ while the system initialises.

Individual readings, along with the running average (on the left hand side of the display) of measurements taken so far will be displayed. The decimal point in the running average is selectable by the user. i.e. ‘16.5’: if the xx.x setting is selected in the SET IOP Format or 16 is displayed if xx is selected through the menu system (refer to section 14). Outlying or spurious readings will automatically be excluded from the calculation.

When a pressure (IOP) of less than 5mmHg is detected, the unit will display ‘<5 READ AGAIN’.

When a pressure (IOP) of greater than 25mmHg is detected, the unit will display >25. When a pressure (IOP) of greater than 50mmHg is detected, the unit will display >50. In each case, the puff intensity will automatically be increased from the soft puff to the normal puff level for subsequent measurements. In these cases the user does not need to reset the instrument.

A self test program can be run for diagnostic purpose by selecting the Menu Option. The display will show run self test. By pressing the Clear/Demo button self test is entered and the display will show self test running, and this will run for 45 seconds. At the end of the test the resulting data is sent to the printer and the display is cleared.
12. Printing

The results can be printed by pressing the print button at any time. Printing the results does not clear the print memory buffer.

**USB data out**
Pressing the print button sends a flat file to the usb port in the following format:

[R] : xx, xx, xx, xx, [xx.x]
[L] : xx, xx, xx, xx, [xx.x]

This data may be able to be imported into other applications, for details of how to perform this please consult your third party program support team.
13. Replacing the printer paper

1. Access to the printer paper is via the printer cover, use your finger in the lip on the top of the cover and gently pull towards you to open the printer cover.

Remove the empty paper 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, otherwise it won’t print.

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

4. Close the cover.
14. User menu options

1. With the unit switched on, press and hold the ‘print/menu’ button for > 3 second to enter the user menu.

2. The display will show the first Menu Option (Buzzer Control) and the current selection (ie. [BUZZER ON] or [BUZZER OFF])

3. Pressing the ‘clear/demo’ button for < 1 second, cycles through the user Change Options (shown in table.)

4. Pressing the ‘print/menu’ button for < 1 second moves you forward to the next Menu Option (shown in table), in this case the Desktop Level.

5. Use the ‘clear/demo’ button to make your preferred selection.

6. Continue to repeat steps 4 and 5 until ‘OK’ is displayed. Your Pulsair Desktop is now ready to use with your preferred settings.

Menu option | Display | Change options
--- | --- | ---
Buzzer Control | BUZZER ON | ON/OFF
IOP Format | DISPLAY XX | XX / XX.X
Display Screen | CONTRAST 0 | 0 - 20
Full Self Test | RUN SELF TEST? | RUNNING SELF TEST
15. Calibration, maintenance and inspection

Clean the puff tube lens on a weekly basis:
1. Moisten a cotton bud with Isopropyl Alcohol.
2. Move the tip of the bud around the lens in a circular motion.
3. After one circle the bud should be discarded to avoid smearing on the lens.
4. 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.

*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.

External cleaning
Keep the unit free of dust.

Keep the chinrest and forehead rest clean.

Regular inspection
Inspect your power supply unit and cable for damage regularly.

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

If the outer insulation of the cable appears to be damaged, discontinue use immediately. Contact your local dealer for a replacement.
15. Calibration, maintenance and inspection

General

Keep the instrument free from dust.

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

Servicing and calibration

Keeler recommends an annual calibration for the Tonometer. Do not modify this equipment without authorisation of the manufacturer.

This must be performed by an authorised Pulsair service centre or distributor. The unit performs a self function check when switched on and will indicate if a fault is found.

There are no user serviceable parts in this instrument. Service manuals will be available to authorised Keeler service centres and Keeler trained service personnel.
# 16. Specifications and electrical ratings

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dimensions</strong></td>
<td>450 x 435 x 245mm (H x D x W)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>16kg</td>
</tr>
<tr>
<td><strong>Calibrated range</strong></td>
<td>5mmHg to 50mmHg</td>
</tr>
<tr>
<td><strong>Repeatability</strong></td>
<td>&lt;5% (Average coefficient of variation)</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>+/-5mmHg (95% confidence level)*</td>
</tr>
<tr>
<td><strong>Working distance</strong></td>
<td>20mm from surface of patient’s cornea to front surface of first lens.</td>
</tr>
<tr>
<td></td>
<td>This equates to a nominal distance of</td>
</tr>
<tr>
<td></td>
<td>15mm from the front of the puff tube shroud to the front surface of the</td>
</tr>
<tr>
<td></td>
<td>patient’s cornea</td>
</tr>
<tr>
<td><strong>Displayed scale</strong></td>
<td>Single line 16 character alphanumeric display</td>
</tr>
<tr>
<td><strong>Illumination system</strong></td>
<td>LED infra red</td>
</tr>
<tr>
<td><strong>Complies with</strong></td>
<td>Electrical Safety (Medical) BS EN 60601-1:2006. Electromagnetic</td>
</tr>
<tr>
<td></td>
<td>compatibility EN 60601-1-2:2007</td>
</tr>
<tr>
<td></td>
<td>Ophthalmic instruments - fundamental requirements and test methods</td>
</tr>
<tr>
<td></td>
<td>ISO 15004-1:2006</td>
</tr>
<tr>
<td><strong>Power Supply Unit</strong></td>
<td>Switch mode, (110 – 240V)+/- 10% multi plug type compliant to EN</td>
</tr>
<tr>
<td></td>
<td>60601-1, EN 61000-6-2, EN 61000-6-3</td>
</tr>
<tr>
<td><strong>Power supply output</strong></td>
<td>30 VA (12V DC 2.5A)</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>50/60 Hz</td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td>Use: +10°C to +35°C, 0% to 75% relative humidity, 700hPa to 1060hPa</td>
</tr>
<tr>
<td></td>
<td>atmospheric pressure</td>
</tr>
<tr>
<td></td>
<td>Storage: -10°C to +55°C, 10% to 95% relative humidity, 700hPa to</td>
</tr>
<tr>
<td></td>
<td>1060hPa atmospheric pressure</td>
</tr>
<tr>
<td></td>
<td>Transport: -10°C to +60°C, 10% to 95% relative humidity, 500hPa to</td>
</tr>
<tr>
<td></td>
<td>1060hPa atmospheric pressure</td>
</tr>
</tbody>
</table>

*In house trial carried out on 20 participants*
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 light levels on the Pulsair have been set at the lowest level possible.

No visible retinal lesions have been identified as a result of using Pulsair tonometers, however, young children and persons with diseased eyes may be at a higher risk. The risk may also be slightly increased if the person being examined has had any exposure with the same instrument or an other ophthalmic instrument using an intense visible light source during the previous 24 hours. This will apply particularly if the eye has been subjected to retinal photography.

### Red LED

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Wavelength (nm)</th>
<th>Value Measured</th>
<th>Limit</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>$E_{S-CL}$</td>
<td>250-400</td>
<td>8.98E-4</td>
<td>0.4</td>
<td>$\mu W \text{ cm}^2$</td>
</tr>
<tr>
<td>$E_{UV-CL}$</td>
<td>360-400</td>
<td>8.11E-7</td>
<td>1</td>
<td>mW cm$^2$</td>
</tr>
<tr>
<td>$E_{A-R}$</td>
<td>305-700</td>
<td>3.52E-2</td>
<td>220</td>
<td>$\mu W \text{ cm}^2$</td>
</tr>
<tr>
<td>$E_{IR-CL}$</td>
<td>770-2500</td>
<td>8.42E-3</td>
<td>20</td>
<td>mW cm$^2$</td>
</tr>
<tr>
<td>$E_{VIR-R}$</td>
<td>380-1400</td>
<td>1.23E-1</td>
<td>0.7</td>
<td>W cm$^2$</td>
</tr>
</tbody>
</table>

### White LEDs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Wavelength (nm)</th>
<th>Value Measured</th>
<th>Limit</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>$E_{S-CL}$</td>
<td>250-400</td>
<td>4.53E-5</td>
<td>0.4</td>
<td>$\mu W \text{ cm}^2$</td>
</tr>
<tr>
<td>$E_{UV-CL}$</td>
<td>360-400</td>
<td>4.85E-8</td>
<td>1</td>
<td>mW cm$^2$</td>
</tr>
<tr>
<td>$E_{A-R}$</td>
<td>305-700</td>
<td>0.24</td>
<td>220</td>
<td>$\mu W \text{ cm}^2$</td>
</tr>
<tr>
<td>$E_{IR-CL}$</td>
<td>770-2500</td>
<td>1.78E-4</td>
<td>20</td>
<td>mW cm$^2$</td>
</tr>
<tr>
<td>$E_{VIR-R}$</td>
<td>380-1400</td>
<td>2.69E-5</td>
<td>0.7</td>
<td>W cm$^2$</td>
</tr>
</tbody>
</table>

*Figure 2: Absolute spectral irradiance measured at the corneal plane of both sources*
16. Specifications and electrical ratings

The Keeler Desktop tonometer is a medical electrical instrument. The instrument requires special care concerning electromagnetic compatibility (EMC). This Section describes its suitability in terms of electromagnetic compatibility of this instrument. When installing or using this instrument, please read carefully and observe what is described here.

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

<table>
<thead>
<tr>
<th>Guidance and manufacturer’s declaration – electromagnetic emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Keeler Desktop is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The Keeler Desktop uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The Keeler Desktop is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and manufacturer’s declaration – electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD). IEC 61000-4-2</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst. IEC 61000-4-4</td>
<td>± 2 kV for power supply lines ± 1 kV for input/output lines</td>
<td>± 2 kV for power supply lines ± 1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge. IEC 61000-4-5</td>
<td>± 1 kV line(s) to line(s) ± 1 kV line(s) for line to earth</td>
<td>± 1 kV line(s) to line(s) ± 1 kV line(s) for line to earth</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11</td>
<td>&lt;5% $U_T$ (&gt; 95% dip in $U_T$) 40% $U_T$ (60% dip in $U_T$) for 5 cycles 70% $U_T$ (30% dip in $U_T$) for 25 cycles &lt;5% $U_T$ (&gt;95% dip in $U_T$) for 5 s</td>
<td>&lt;5% $U_T$ (&gt; 95% dip in $U_T$) 40% $U_T$ (60% dip in $U_T$) for 5 cycles 70% $U_T$ (30% dip in $U_T$) for 25 cycles &lt;5% $U_T$ (&gt;95% dip in $U_T$) for 5 s</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Keeler Desktop requires continued operation during power mains interruptions, it is recommended that the instrument be powered from an uninterruptible power supply.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Note $U_T$ is the a. c. mains voltage prior to application of the test level.
16. Specifications and electrical ratings

### Guidance and manufacturer’s declaration – electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>3 V</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Keeler Desktop, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>3 V/m 80MHz to 2.5GHz</td>
<td></td>
<td><strong>Recommended separation distance</strong></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80MHz to 2.5GHz</td>
<td>3 V/m</td>
<td>[ d = 1.2 \sqrt{p} ]</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td></td>
<td>80MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[ d = 2.3 \sqrt{p} ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>800MHz to 2.5GHz</td>
</tr>
</tbody>
</table>

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 the following symbol:

\[ \text{Note 1} \] At 80MHz and 800MHz, the higher frequency range applies.
\[ \text{Note 2} \] These guide lines 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 Keeler Desktop is used exceeds the applicable RF compliance level above, the Keeler Desktop should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Keeler Desktop.

\(^2\) Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.
16. Specifications and electrical ratings

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 kHz to 80MHz</td>
<td>80MHz to 800MHz</td>
</tr>
<tr>
<td>d = 1.2√p</td>
<td>d = 1.2√p</td>
</tr>
<tr>
<td>800MHz to 2.5GHz</td>
<td></td>
</tr>
<tr>
<td>d = 2.3√p</td>
<td></td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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 separation distance for the higher frequency applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
17. Accessories and warranty

Accessories supplied
Dust cover Part Number EP39-70435
Chinrest paper pins (2) Part Number 2417-P-7006
Puff tube dust cap Part Number EP39-70433

Consumables
Chinrest papers Part Number 3104-L-8201
Printer Paper Part Number 2208-L-7008

Pulsair Warranty
The Pulsair Desktop and its components are covered by warranty that they meet their performance standards and are free from any defects in materials or workmanship. Within 2 years from delivery by Keeler, the manufacturer shall at no charge to the customer, upon written notice from the customer, repair or replace any components which are defective in material or workmanship.

The customer agrees that it shall have no remedy in the event of any breach of the foregoing warranty other than as provided above. This warranty is exclusive and in lieu of all other warranties, expressed or implied, and all implied warranties of merchantability or fitness for a particular purpose are expressly disclaimed.

The obligations of the manufacturer as set forth in this warranty are expressly conditioned on the following:-
(i) No alterations or repairs of any malfunction of the system shall be made to the system except by the manufacturer or his authorized representative, without the prior written approval of the manufacturer or his authorized representative (and in no case will the manufacturer assume responsibility for repairs or alterations made by those other than the manufacturer or his authorized representative).

And (ii) The customer shall give notice to the manufacturer or their authorized representative of any malfunction of the system and shall not use the system for any diagnostic purpose thereafter.
18. Contact, packaging and disposal information

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>USA Sales Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keeler Limited</td>
<td>Keeler Instruments Inc</td>
</tr>
<tr>
<td>Clewer Hill Road</td>
<td>3222 Phoenixville Pike</td>
</tr>
<tr>
<td>Windsor</td>
<td>Building #50</td>
</tr>
<tr>
<td>Berkshire</td>
<td>Malvern, PA 19355</td>
</tr>
<tr>
<td>SL4 4AA</td>
<td>USA</td>
</tr>
<tr>
<td>Freephone: 0800 521251</td>
<td>Toll Free: 1 800 523 5620</td>
</tr>
<tr>
<td>Tel: +44 (0) 1753 857177</td>
<td>Tel: 1 610 353 4350</td>
</tr>
<tr>
<td>Fax: +44 (0) 1753 827145</td>
<td>Fax: 1 610 353 7814</td>
</tr>
</tbody>
</table>

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).