AT4 Tourniquet System
Operating Instructions

Rx ONLY

AT4 Pneumatic Tourniquet Reference No. 40070
AT4 Electronic Tourniquet Reference No. 40080
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1. Introduction
These instructions are intended to assist you with the operation of the AT4 Electrically powered and Pneumatically powered Tourniquets and it is important that the instructions are read thoroughly and understood before using the equipment.

It is also important to check the tourniquet before use to ensure there is no loss or change in performance; ensure that all functions operate correctly and to their full range. We recommend that the tourniquet is visually inspected for any damaged parts, or contamination before use.

In this manual items in green text relate exclusively to the pneumatic powered version of the AT4 while items in blue relate exclusively to the electrically powered version. Items in black apply to both versions

1.1. Warnings & Cautions
The European Medical Device Directive requires all manufacturers to include appropriate warnings and cautions and many of the warnings and cautions will apply to other similar devices.

To ensure that all users are well informed various warnings and cautions are made throughout these operating instructions.

A WARNING: is given when the personal safety of the patient or user may be affected and when disregarding this information could result in injury.

A CAUTION: is given when special instructions must be followed. Disregarding this information could result in permanent damage being caused to the tourniquet.

1.2. Scope of Use
This product is intended for the control of pneumatic tourniquet cuffs in operating theatres or similar environments.

1.3. Intended user
Tourniquets should only be operated by trained and competent clinical staff and used in accordance with your establishments approved clinical practice.

WARNING:
Intra Venous Regional Anaesthesia (IVRA) should only be administered by staff that have been trained and approved to carry out this procedure.

1.4. Equipment Classification
This tourniquet has been classified as a ‘Class IIa’ medical device in accordance with the European Medical Device Directive 93/42EEC as amended by 2007/47.
1.5. **Associated Devices**
The cuffs and gas cylinder (pneumatically powered version only) which may be used with this device are considered to be associated devices and will have their own instructions for use which should be read and understood. Any conflicts between the instructions should be resolved before use.

To ensure compatibility it is recommended that accessories and associated devices are supplied by Anetic Aid. Inappropriate bore size of the hose and compliance of the cuff can affect the stability of the pressure control.

Ensure that O rings on cuffs and associated hoses are in good condition before use.

1.6. **Serial Number Label**
The Serial and Reference Numbers are located on a label on the rear of the device. When requesting service ensure that both the Ref No and the Serial No are quoted.
2. Summary of Warnings, Cautions and Side-Effects

In common with all medical devices of this nature there are inherent risks and side-effects that the user should be made aware of. Whilst every effort has been taken to eliminate these risks, care should be taken when using the tourniquet. It is important that the user familiarises themselves with all of the warnings and cautions contained within this document.

**WARNING:**

The pressure and duration of application of a tourniquet cuff is a matter for clinical judgement. Application of a tourniquet cuff for excessive duration or at excessive pressures can result in tissue narcosis. The correct size and shape of cuff will allow cessation of blood flow at lower pressures and reduce the risk of tissue narcosis.

Intra Venous Regional Anaesthesia (IVRA) should only be administered by staff that have been trained and approved to carry out this procedure.

The castors are intended for positioning the tourniquet within the operating room they are not to be used for transportation over thresholds or steps.

The AT4 should always be moved by pulling the handle it should not be moved by pushing.

When the electrically powered AT4 is not in use it should be connected to the mains electrical supply to recharge the battery. See section 10.1 relating to charging.

Only Gas Cylinder Mounting kits and regulators supplied by the manufacturer may be used. Other equipment may make the unit unstable. When handling gas cylinders take appropriate precautions with respect to lifting and high pressure gas.

If a gas supply from a cylinder is being used check the contents before every procedure.

The cylinder should be removed if the AT4 is to be moved further than being repositioned within the operating room.

Disconnect the tourniquet from the cylinder or turn cylinder valve off when tourniquet is not in use as high precision regulators by the nature of their design vent a small amount of gas even when the pressure is set to zero and the cuff is deflated.

Only use the cells (Battery) specified and always replace all ten cells do not mix batteries or replace only some of them. Rechargeable Cells should not be used.

It is recommended that only CE marked cleaning products are used in the cleaning of the AT4. See section 8.

Dilute all disinfectants in accordance with the manufacturer’s guidelines. See section 8.
CAUTION:
Before use, ensure all device functions operate correctly. Also visually inspect the device for any loose or damaged parts. If the device's performance changes from that specified or required, the device should be taken out of service immediately.
Maintenance work should only be conducted by suitably trained personnel following the manufacturer's guidelines.
Do not use concentrated solutions of bleach or disinfectant, organic solvents, abrasive powders or expose any part of the tourniquet to excessive heat. For cleaning and disinfection methods, see section 8.
The AT4 pneumatically powered tourniquet should only be powered by compressed air. Oxygen or other medical gases must NOT be used.
Disinfectant products are corrosive in nature; failure to properly wash and dry the surfaces could leave a corrosive residue which may cause damage.
Do not steam clean or jet wash any areas of the device or its detachable hoses or cables.
Do not use concentrated bleaching disinfectant solutions, organic solvents, abrasive powders or expose any part of the device to excessive heat.

SIDE-EFFECTS:
Application of a tourniquet cuff for excessive duration or at excessive pressures can result in tissue narcosis. The correct size and shape of cuff will allow cessation of blood flow at lower pressures and reduce the risk of tissue narcosis.
Intra Venous Regional Anaesthesia (IVRA) if incorrectly performed can have catastrophic and even fatal side effects. The inclusion of a system to reduce the risk of errors should not be seen as mitigating or reducing the level of training and caution required when using IVRA. IVRA should only be administered by staff that have been trained and approved to carry out this procedure.
### 3. Symbols

The following Symbols have been used on the AT4 tourniquet control panel:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="ON / OFF" /></td>
<td>ON / OFF</td>
<td>Press to turn ON, Green indicator. To turn OFF press and hold until pressure displays are blank.</td>
</tr>
<tr>
<td><img src="image" alt="AUDIBLE ALARM PAUSE" /></td>
<td>AUDIBLE ALARM PAUSE</td>
<td>Press once to pause audible alarms for 3 minutes; Amber Indicator. (Except Low Battery)</td>
</tr>
<tr>
<td><img src="image" alt="AUDIBLE ALARM OFF" /></td>
<td>AUDIBLE ALARM OFF</td>
<td>Press second time to cancel audible alarms (Except Low Battery) Red Flashing Indicator</td>
</tr>
<tr>
<td><img src="image" alt="INFLATE PRESSURE CONTROL" /></td>
<td>INFLATE PRESSURE CONTROL</td>
<td>Turn to set inflation pressure blue channel Turn to set inflation pressure red channel</td>
</tr>
<tr>
<td><img src="image" alt="PRESSURE SET OR APPLIED" /></td>
<td>PRESSURE SET OR APPLIED</td>
<td>Indicates the set and applied pressures</td>
</tr>
<tr>
<td><img src="image" alt="INFLATE" /></td>
<td>INFLATE</td>
<td>Inflates blue and red channels respectively</td>
</tr>
<tr>
<td><img src="image" alt="DEFLATE" /></td>
<td>DEFLATE</td>
<td>Deflates blue and red channels respectively.</td>
</tr>
<tr>
<td><img src="image" alt="IVRA" /></td>
<td>IVRA</td>
<td>Selects IVRA control mode interlocking the controls of both channels. Amber indicates ready but not operational, green indicates operational, Red indicates incorrect action.</td>
</tr>
<tr>
<td><img src="image" alt="TIMER REMINDER" /></td>
<td>TIMER REMINDER</td>
<td>Prior to inflation of cuff this button sets the reminder start time and repeater frequency. This function is cancelled after the cuff has been inflated. Audible Reminder is supported by amber visual indicator and flashing of the timer LCD and is cancelled by pressing the timer button</td>
</tr>
<tr>
<td><img src="image" alt="TIME" /></td>
<td>TIME</td>
<td>Indicates the timer display for blue and red channels respectively.</td>
</tr>
<tr>
<td><img src="image" alt="BATTERY LEVEL" /></td>
<td>BATTERY LEVEL</td>
<td>Green: represents acceptable battery level Amber: connect to mains as soon as soon as practical Green/Amber: Charging Red: connect to mains immediately Amber: Replace batteries as soon as practical Red: Replace batteries</td>
</tr>
<tr>
<td><img src="image" alt="MAIN- TENANCE INDICATOR" /></td>
<td>MAIN- TENANCE INDICATOR</td>
<td>Amber: Service required Red: stop using and request immediate service</td>
</tr>
</tbody>
</table>
The following symbols are used on the AT4 tourniquets:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE MARK</td>
<td>Indicates compliance with the European Medical Device Directive 93/42 and amendments thereto. Symbol is associated with a number indicating the Notified Body.</td>
<td></td>
</tr>
<tr>
<td>READ INSTRUCTIONS</td>
<td>Read Instructions For Use</td>
<td></td>
</tr>
<tr>
<td>CAUTION</td>
<td>Indicates the need for the user to consult the instructions for use for important cautionary information</td>
<td></td>
</tr>
<tr>
<td>FUSE</td>
<td>Location and value of fuses</td>
<td></td>
</tr>
<tr>
<td>CELL</td>
<td>Location and type of cells</td>
<td></td>
</tr>
<tr>
<td>BATTERY</td>
<td>Location and type of battery used</td>
<td></td>
</tr>
<tr>
<td>WEEE</td>
<td>Do NOT dispose of in domestic waste see section 13</td>
<td></td>
</tr>
<tr>
<td>AIR CONNECTION</td>
<td>Location of compressed air supply connector</td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Supply voltage of mains inlet</td>
<td></td>
</tr>
<tr>
<td>~ Hz</td>
<td>Frequency of AC mains supply</td>
<td></td>
</tr>
<tr>
<td>W Max</td>
<td>Maximum power consumption in watts</td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>Unique serial number used for traceability</td>
<td></td>
</tr>
<tr>
<td>REF</td>
<td>Reference or model number indicating the type of unit</td>
<td></td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td>Date of manufacture as YYYY:MM</td>
<td></td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>Name and address of manufacturer is adjacent</td>
<td></td>
</tr>
<tr>
<td>Do not push</td>
<td>The AT4 should not be pushed as it is more stable when pulled by the handle.</td>
<td></td>
</tr>
</tbody>
</table>
4. Getting Started

Packaging can be fully recycled or reused.

During manufacture the base moulding and front panel are protected by a thin plastic film. The film, indicated with the symbol illustrated, shall be removed during commissioning.

On receipt or after periods of storage the AT4, must be cleaned and disinfected before being put into clinical use.

For safety the AT4s are shipped without the batteries being operational. The fuse requires to be fitted connecting the battery of the electrically powered version and the D size cells require to be fitted to the pneumatically powered version as detailed in section 9. The D size cells should be removed if the AT4 is going to be stored for more than 8 weeks.

The AT4 electrically powered version will have been supplied with a T3.15A fuse which requires to be fitted during commissioning. Lay the AT4 on its back and fit the fuse in the fuse holder indicated by the fuse symbol on the underside of the AT4.

On receipt the electrically powered AT4, or after periods of storage, it must be connected to the mains electricity supply with the cable provided for 24 hours to allow the battery to be charged.

When fully charged the AT4 may be disconnected from the mains and operated from the battery avoiding the requirements for mains cable in the surgical area. The AT4 may also be operated while connected to the mains if the battery is low.

When not in use it is recommended that the AT4 be left connected to the mains to ensure that the battery is fully charged and ready for Use.

On receipt of the pneumatically powered AT4, must be connected to the piped medical air supply before use with the hose provided. The hose should be attached by hand to the DISS connector on the rear of the AT4 indicated by the air symbol illustrated. The use of tools should not be required to achieve a gas tight seal and over-tightening may result in damage. The pneumatically powered AT4 has optional cylinder mount and regulator which requires to be fitted before delivery from the manufacturer, as part of the commissioning or by a competent service engineer.

Warning:

Only Gas Cylinder Mounting kits and regulators supplied by the manufacturer may be used. Other equipment may make the unit unstable. When handling gas cylinders take appropriate precautions with respect to lifting and high pressure gas.
The D-Cells will have been supplied separately for safety. Lay the unit on its back and fit the D-Cells as indicated in the installation of battery section 9 and indicated by the labels on the underside ensuring correct orientation as indicated by the + symbol on the lid of the battery holder.

The AT4 will have been supplied with Red and Blue cuff hoses. These should be connected to the connections in the front of the AT4 and below the appropriate red or blue segment of the front panel. There are two connections to pressurise the cuff and two which are for stowage of the cuff end of the hose when not in use.

1. Control Panel
2. Pulling Handle
3. Main Air Supply DISS connection (AT4 Pneumatic Only)
4. Cuff Supply Hose Connectors
5. Cuff Supply Hose Storage Connectors
6. Cuff Supply Hose
7. Storage Facility
8. Cuff Hooks
9. Additional Storage Facility Locating Pins
10. IEC Socket (AT4 Electronic Only)
5. Controls and Operation

Both versions of the AT4 have identical control panels and operate in similar manner.

*IVRA stands for Intravenous Regional Anaesthesia.

5.1. Preparation

If a gas cylinder is being used to power the device ensure that the contents gauge indicates there is sufficient gas to complete the procedure, that the cylinder valve is turned on and that the supply hose is connected to the regulator outlet socket.

If pipeline gas is being used to power the device ensure that the supply hose is connected to the wall or pendant outlet socket.

If the AT4 is electrically powered ensure that the battery has been charged and the battery indicator is green, if not it must be used connected to the mains supply.

The red and blue cuff hoses should be connected to the connectors in the front of the AT4 ready for use below the appropriate red or blue segment of the front panel. There are two connections to pressurise the cuff and two which are for stowage of the cuff end of the hose when not in use.

Select the appropriate size and type of cuff(s) and apply to the patient’s limb(s). The correct size and shape of cuff will allow cessation of blood flow at lower pressures and reduce the risk of tissue narcosis.
Caution:
Before use, ensure all device functions operate correctly. Also visually inspect the device for any loose or damaged parts. If the device's performance changes from that specified or required, the device should be taken out of service immediately.

Ensure that O rings on cuffs and associated hoses are in good condition before use.
5.2. General operation

The AT4 requires to be turned by depressing the ON button. The green light will be displayed.

By default the Timer Reminder is set to commence at 90 minutes (1.30) and repeat at 15 minute intervals. Before a cuff is inflated the Timer Reminder option may be set by repeatedly depressing the button until the required option is obtained. The option is momentarily displayed in the lower displays the left display being the time to the first reminder and the right display setting the frequency that the reminder repeats.

Set the required pressure on the desired channel by rotating the control clockwise to increase and anticlockwise to decrease. The selected pressure in mmHg is displayed in the window above the rotary control. Application of a tourniquet cuff at excessive pressures can result in tissue narcosis.

To inflate the cuff depress the inflate button associated with the pressure set in the previous step.

The Timer Reminder will sound at pre-set intervals and can be cancelled until the next scheduled reminder by depressing the Timer button.

To deflate the cuff depress the deflate button associated with the cuff a single push initiates a slow deflate a second depression initiates a fast deflate. During deflation the screen will flash.

If bilateral operation is required the second cuff can be inflated at any time without affecting the first channel.

When the procedure is finished press the off button to turn the AT4 off as this will conserve battery life.

If the AT4 is not turned off it will automatically shut down if the cuffs have not been inflated for 15 minutes.

When not in use it is recommended that the electrically powered AT4 be left connected to the mains to ensure that the battery is fully charged and ready for use.

Caution:
When not in use it is essential that the tourniquet is disconnect from the cylinder or that the cylinder valve is turned off. High precision regulators by the nature of their design vent a small amount of gas even when not in use and this can deplete the cylinder contents even when the tourniquet is not in use.
5.3. IVRA Operation

**Warning:**
Intra Venous Regional Anaesthesia (IVRA) should only be administered by staff that have been trained and approved to carry out this procedure.

The AT4 requires to be turned by depressing the ON button. The green indicator will be illuminated.

By default the Timer Reminder is set to commence at 90 minutes (1.30) and repeat at 15 minute intervals. Before a cuff is inflated the Timer Reminder option may be set by repeatedly depressing the button until the required option is obtained. The option is momentarily displayed in the lower displays the left display being the first reminder and the right display setting the frequency that the reminder repeats. With default of 1:30 for first reminder and 15 for repeat

To implement the IVRA mode depress the IVRA button. The green indicator will be illuminated.

Set the required pressure on the first channel (Upper cuff) by rotating the control clockwise to increase and anticlockwise to decrease. The selected pressure in mmHg is displayed in the window above the rotary control. Application of a tourniquet cuff at excessive pressures can result in tissue narcosis.

To inflate the cuff depress the inflate button associated with the pressure set in the previous step. If this button is depressed prior to setting the pressure levels above, the device will lock out. To reset turn the IVRA button off and then back on to start the process again.

Set the required pressure on the second channel (Lower cuff) by rotating the control clockwise to increase and anticlockwise to decrease. The selected pressure in mmHg is displayed in the window above the rotary control. Application of a tourniquet cuff at excessive pressures can result in tissue narcosis.

To inflate the cuff depress the inflate button associated with the pressure set in the previous step.

The first cuff can be deflated when the second cuff has been inflated

The Timer Reminder will sound at pre-set intervals and can be cancelled until the next scheduled reminder by depressing the Timer button.
To deflate the cuff depress the deflate button associated with the cuff a single push initiates a slow deflate.

When the procedure is finished, to turn the AT4 off, press the off button and hold down until the pressure displays turn blank then release the button.

Turning off after use will conserve battery life. If the AT4 is not turned off it will automatically shut down after both cuffs have been deflated for 15 minutes.

When not in use it is recommended that the electrically powered AT4 be left connected to the mains to ensure that the battery is fully charged and ready for use.

**Caution:**
When not in use it is essential that the tourniquet is disconnected from the cylinder or that the cylinder valve is turned off. High precision regulators by the nature of their design vent a small amount of gas even when not in use and this can deplete the cylinder contents even when the tourniquet is not in use.
5.4. Alarms and Warning Indicators

Caution:
A number of Alarm and Indicator functions have been included and due note and actions should be taken.

Maintenance:
The spanner symbol with a red indicator requires investigation. If the indicator is not cleared by replacing leaking cuffs hoses and O-rings and then restarting the AT4 a service should be requested. The AT4 has integral calibration and leak detection monitoring and an alarm which is not cleared by the above procedure may indicate failure of a pressure sensor or a leak in the internal pneumatic circuit.

Battery Level:
The battery level alarm indicates:

When the Electrically powered unit is being used while NOT connected to the mains supply the following indications apply:

Amber: Low battery connect to mains as soon as practical
Red: Extremely low battery, connect to mains immediately
Green: Normal operation condition

When the electronic unit is connected to the mains supply but NOT in use:

Amber: Indicates connection to the mains. This is NOT an indication of battery level (See Battery Charging Section 9)

When the electronic unit is being used while connected to the mains supply:

Green/Amber: Alternating Green/Amber indicating connection to the mains while in use

Note: The amber indicator will take approximately 30 seconds to extinguish after disconnection from the mains

The Pneumatically powered unit has the following indications:

Amber: Low Battery, replace batteries as soon as practical
Red: Extremely low battery, Replace batteries before further use
Green: Normal operating condition

Timer Indicator:
The timer indicator can be set as preferred see section 5.2 and 5.3 but will as a default commence at 90 (1.30) minutes and repeat at 15 minute intervals. Application of a tourniquet cuff for excessive duration can result in tissue narcosis.
**Excessive Pressure Indicator:**
When pressures above those normally applied are selected an audible indicator will sound. Application of a tourniquet cuff at excessive pressures can result in tissue narcosis.

**Low Pressure**
When the cuff pressure is reduced below those normally applied an audible indicator will sound. In the event that there is a catastrophic loss of pressure such as the disconnection of a cuff hose the alarm will sound and will be cancelled when the pressure is re-established or the deflate button is pressed.

**IVRA**
If the IVRA option has been activated pressing an incorrect inflate or deflate button will generate an audible indication that the function is not appropriate and has not been implemented.
6. Handling

**Warning:**
The AT4 should not be pushed as equipment is more stable and controllable when pulled by the handle.

The castors are intended for repositioning the AT4 within the operating room environment or on other smooth level surfaces and slopes up to 10°. They are not intended for negotiating steps, thresholds or other obstacles such as cables or hoses.

If a cylinder is fitted it shall be removed before transporting the AT4 pneumatic version further than repositioning it within the operating room.

If required to be lifted up a step or over a threshold the AT4 should be lifted by the cuff hooks on the side of the unit. Do not lift the AT4 by the control panel as this may result in damage.
7. Performance and Technical Specification

Accuracy and resolution:
- Pressure is measured to an accuracy of +/- 2.5 mmHg and displayed with a resolution of 5 mmHg

Maximum cuff pressure:
- The maximum cuff pressure is set to 600mmHg
- The maximum cuff pressure is set between 550-600mmHg

Input Electrical:
- Mains Electricity supply factory set to either:
  - 230V 50-60 Hz
  - 110-120V 50-60HZ
  See label beside mains inlet for voltage your unit has been set to.

Input Pneumatic:
- 4-7 bar Air
- DISS Connection

Battery:
- Ten Energiser Industrial D Size Alkaline Cells
  EN95-LR20-AM1-1.5V
- Sonnenschein A512/6.5 S NGA51206D5HS0SA

Fuse:
- Battery T3.15A 250V 20mm
- 230V supply 2 X Mains fuse T630mA 250V 20mm
- 110-120 V Supply 2 X Mains fuse T1A 120-250V 20mm
- Battery Fuse T1A 250V 20mm

Safety:
- Earth connection as per EN IEC 60601-1 class 1

Weight:
- Excluding accessories but with batteries fitted:
  - 17.3 Kg Electrical powered
  - 15.5 Kg Pneumatic Powered

Standards Applied:
- EN IEC 60601-1
- EN IEC 60601-1-2
Environment:

Operating
- Temperature of 15°C to 35°C
- Humidity of 20% to 80% non-condensing
- Height above sea level to be less than 2000m

Movement and storage between use
- Temperature of 5°C to 40°C
- Humidity of ≤ 80% non-condensing
- Atmospheric Pressure 50kPa - 106kPa
- Floor to be level to within 10° of horizontal when being moved
- Not suitable for negotiating steps or thresholds

Initial Transport and Storage in original packaging
- Temperature of 0°C to 40°C
- Humidity of ≤ 80% non-condensing
- Atmospheric Pressure 50kPa - 106kPa

Dimensions
EMC Data:
Note items relating to conducted immunity or emissions do not apply to the Pneumatic version

<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>IEC 61000-4-6</td>
<td>10 Vrms 150 kHz to 80 MHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the AT4 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance ( d = 1.2\ P )</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>10 V/m 80 MHz to 2,5 GHz</td>
<td>( d = 1.2\ P ) 80 MHz to 800 MHz ( d = 2.3\ P ) 800 MHz to 2,5 GHz</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, (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (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 AT4 is used exceeds the applicable RF compliance level above, the AT4 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AT4.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Guidance and manufacturer's declaration – electromagnetic immunity

The AT4 is intended for use in the electromagnetic environment specified below. The customer or the user of the AT4 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) ± 2 kV line(s) to earth</td>
<td>± 1 kV differential mode ± 2 kV common mode</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 lines IEC 61000-4-11</td>
<td>&lt;5 % 240 (&gt;95 % dip in 240) for 0.5 cycle 40 % 240 (60 % dip in 240) for 5 cycles 70 % 240 (30 % dip in 240) for 25 cycles &lt;5 % 240 (&gt;95 % dip in 240) for 5 s</td>
<td>&lt;5 % 240 (&gt;95 % dip in 240) for 0.5 cycle 40 % 240 (60 % dip in 240) for 5 cycles 70 % 240 (30 % dip in 240) for 25 cycles &lt;5 % 240 (&gt;95 % dip in 240) for 5 s</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the AT4 requires continued operation during power mains interruptions, it is recommended that the AT4 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>If there is a reduction in delivery performance it may be necessary to position AT4 further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.</td>
</tr>
</tbody>
</table>

NOTE 240 is the a.c. mains voltage prior to application of the test level.
8. Cleaning and Disinfecting

The AT4, and its detachable hoses/cables must NOT be immersed in water or other liquids during cleaning or disinfection. Do NOT use solvents or abrasive cleaners.

Cleansers and disinfectants must be CE marked indicating an intended purpose of medical devices & specified for use on plastics and metal surfaces. Suitable disinfectants include: quaternary ammonium compounds, isopropyl alcohol, chlorine or chlorine dioxide 0.5% and phenolics.

![Caution:]
Before cleaning, disconnect from the mains electrical supply.

Wipe the AT4 and its detachable hoses/cables using a cloth dampened with detergent diluted with water as per the manufacturer’s instructions. Apply the liquid to the cloth and squeeze out surplus liquid. Do not apply liquid directly to the AT4 or its detachable parts.

After cleaning disinfect the AT4 and its detachable hoses and cables using a cloth dampened with disinfectant which is indicated for use on plastic and metal and is diluted as per the manufacturer’s instructions. Apply the liquid to the cloth and squeeze out surplus liquid. Do not apply liquid to the device. After the specified contact time wipe dry with a clean dry cloth.

![Warning:]
It is recommended that only CE marked cleansers and disinfectants are used to clean the AT4.

Dilute all disinfectants in accordance with the manufacturer’s guidelines.

![CAUTION:]
Disinfectant products are corrosive in nature; failure to properly wipe and dry the surfaces could leave a corrosive residue which may cause damage.

Do not steam clean or jet wash any areas.

Do not use concentrated bleaching disinfectant solutions, organic solvents, abrasive powders or expose any part of the device to excessive heat.
9. Installation of Battery

**Pneumatic Powered Unit**
The Pneumatically powered AT4 requires the D size cells to be inserted during commissioning and periodically at the annual service or earlier if indicated by the battery indicator.

Amber indicates that the Cells (Battery) should be replaced at the earliest opportunity and red indicates that they must be replaced immediately.

To replace the Cells lay the AT4 on its back and from the underside remove the battery holder caps by rotating them anticlockwise. Lift the top of the AT4 to incline it slightly, the 10 cells will slide out.

Ensuring correct orientation insert 10 new:

Energiser Industrial D Size Alkaline Cells EN95-LR20-AM1 1.5V

Replace the battery holder caps rotating them clockwise to secure.

**Warning:**
Only use Energiser Industrial D Size Alkaline Cells EN95-LR20-AM1 1.5V. Do not use other types of battery and always replace all ten cells do not mix batteries or replace only some of them. Rechargeable Cells should not be used.
**Electronically Powered Unit**

The battery of the electrically powered AT4 is recharged from the mains and requires to be replaced every two years during scheduled service.

It is recommended that when not in use the device is connected to the mains electrical supply to recharge the battery. The battery will not be damaged by leaving it connected to the mains when fully charged.

To determine the battery status:

- Disconnected from the mains,
- Turn on
- Wait for 30 seconds until the battery indicator ceases alternating colours and obtains a single stable colour
- Red or Amber the device can only be used while remaining connected to the mains supply
- Green can be used on battery power without connection to the mains.

When the Electrically powered unit is being used while NOT connected to the mains supply the following battery indications status applies:

- **Amber:** Low battery connect to mains as soon as soon as practical
- **Red:** Extremely low battery, connect to mains immediately
- **Green:** Normal operation condition

When the electronic unit is connected to the mains supply but NOT in use:

- **Amber:** Indicates connection to the mains. This is NOT an indication of battery level

When the electronic unit is being used while connected to the mains supply:

- **Green/Amber:** Alternating Green/Amber indicating connection to the mains while in use

Note: the amber indicator will take approximately 30 seconds to extinguish after disconnection from the mains

**10. Expected battery life:**

When running on DC power only, a fully charged AT4E unit should be able to perform the following number of bi-lateral 30 minute procedures at 300mmHg:

- 35* times with battery indicator displaying green
- A further 15* times with battery indicator displaying amber

Once the battery indicator begins displaying red the device should only be used while remaining connected to the mains supply.

* Based on well-maintained battery.
11. Maintenance

11.1. Daily

Ensure that O rings, cuffs and associated hoses are in good condition before use. Those that are damaged or worn should be replaced.

Caution:
Before use, ensure the device's functions operate correctly. Also visually inspect the device for any loose or damaged parts. If the device's performance or mode of operation changes from that specified or required the device should be taken out of service immediately. If after checking O rings, cuffs and associated hoses are in good condition the AT4 is still not operating as expected then request maintenance before returning the device to clinical use.

If there is any sign of damage or a change in performance the device should be taken out of clinical use and maintenance requested.

If the battery indicator of the electrically powered AT4 shows amber connect it to the mains electrical supply as soon as possible. If the indicator shows red connect to the mains electrical supply immediately. Green shows normal operating conditions.

If the battery indicator of the pneumatically powered AT4 shows amber replace the D size cells (Battery) as soon as possible as per section 9. If the indicator shows red replace the D size cells (Battery) immediately. Green shows normal operating conditions.

The spanner symbol with a yellow or red indicator requires investigation. If the indicator is not cleared by replacing leaking cuffs hoses and O rings and then restarting the AT4 a service should be requested.

11.2. Recurrent (Periodic) Testing

CAUTION:
In line with the MHRA Device Bulletin DB2006(5), maintenance work should only be conducted by suitably trained personnel following manufacturer's guidelines and approved parts.

It is recommended that the device is serviced, electrically safety tested and the performance and accuracy confirmed on an annual basis in accordance with the manufacturer's service schedule and EN IEC 62353:2007.

The electrically powered AT4 contains a lead acid battery pack which will require to be replaced every two years. The device is class I electrical safety with a protective earth, it is NOT classified as an applied part.
The pneumatically powered AT4 contains alkaline cells which will require to be replaced annually.

The main air supply hose should be replaced every 3 to 4 years in line with MDA-2003-007.

When requesting service ensure that both the Ref No and the Serial No are quoted. The Serial and Reference Numbers are located on a label on the rear of the device.
12. Product Warranty

The product, when new, is guaranteed to be free from defects in materials and workmanship and to perform in accordance with the manufacturer’s specification for a period of one year from the date of purchase from Anetic Aid Ltd or their approved Distributor. Anetic Aid Ltd will repair or replace, at their discretion, any components found to be defective or at variance with the manufacturer’s specification within this time at no cost to the purchaser. The warranty will take effect from the date of purchase, subject to the purchaser registering the product with Anetic Aid to confirm its receipt, installation date and product details.

The warranty does not provide cover for breakage or failure due to tampering, misuse, neglect, accidents, modifications or shipping. The warranty is also void if the product is not used in accordance with the manufacturer’s instructions or is repaired during the warranty period by any persons other than Anetic Aid or its appointed agent. No other expressed or implied warranty is given.

For details of our extended warranty packages please contact Anetic Aid or your authorised dealer.

13. Disposal of Waste Electrical & Electronic Equipment

This symbol on the products and/or accompanying documents means that used electrical and electronic products should not be mixed with general waste.

disposing of this product correctly will save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling. If you are unsure of your national requirements with respect to disposal please contact your local authority, dealer or supplier for further information.

Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

The above information is based on the European waste electrical and electronic equipment directive 2002/96/EC

Please note the electrically powered AT4 contains a lead acid battery pack which will require to be replaced every two years.

Please note the pneumatically powered AT4 contains alkaline cells which will require to be replaced annually.