ANETIC AID LTD
AT4™ ELECTRONIC TOURNIQUET
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

RECAST 3

REMOTE ISCHAEMIC CONDITIONING AFTER STROKE TRIAL 3

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
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PRODUCT TRAINING GUIDANCE
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FORM 995104

INTRODUCTION

Product training guidance documents are an outline of the devices intended use.

They are not detailed instructions and should not be used in replacement of and without a good working knowledge of the device's instructions for use.

Each section will be discussed and demonstrated during site training.

Study title

Remote Ischaemic Conditioning After Stroke 3 (RECAST-3):
A multicentre randomised controlled trial

Chief Investigator

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Coordinating Centre

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RECAST-3@nottingham.ac.uk

http://recast-3.ac.uk/

WARNINGS AND CAUTIONS

Various warnings and cautions are made throughout product training guidance.

⚠	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 device.

Each one must be demonstrated and discussed during product training to ensure they are observed once the device is in use.

Originator: M Lee	**Site Approval:** L Smith	**QA Approval:** I Divers
Issue Date: 11/10/23	**Issue No: 01**	

ANETIC AID LTD
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For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

EQUIPMENT CLASSIFICATION

The equipment referenced in this document is CE marked and has been classified as a Class IIa Medical Device under the scope of both the Medical Devices Directive 93/42/EEC and the Medical Device Regulation 2017/745.

INTENDED USE AND CONTRAINDICATIONS

This product is intended for the control of pneumatic tourniquet cuffs in use for the RECAST 3 trial.

The device will be used to deliver the Remote Ischaemic Conditioning (RIC) or sham intervention to adults with acute ischaemic stroke presenting within Emergency Departments and Stroke Units in the UK.

RECAST-3 participants will be randomised to receive either:

Intervention: RIC group: 4 cycles of intermittent upper limb ischaemia - alternating 5 minutes inflation (+20 mmHg above systolic BP) followed by 5 minutes deflation of bilateral upper arm blood pressure cuffs.

Comparator: Sham RIC. Bilateral upper arm blood pressure cuffs are inflated to 50 mmHg for 4 cycles (5 minutes inflation/5 minutes deflation).

Duration of treatment: twice daily for 14 days (28 doses). 1 dose=4 inflation/deflation cycles.

The device should only be operated by trained and competent members of the research team or ward staff who have been authorised onto the RECAST-3 delegation log.

CONTRAINDICATIONS:

A decision for the patient to take part in the trial will have been made through screening the eligibility criteria available in the trial protocol which ensures we select a particular population of patients with acute ischaemic stroke. The trial's eligibility criteria are also detailed below and are relevant at the time of randomisation and not once trial randomisation and treatment has started. Contraindications to the use of RIC, however, are few. We expect those applying RIC to routinely check the skin integrity of the limbs to which the cuff is applied and any concerns raised with the trial team.

Trial inclusion criteria at randomisation:

- Acute ischaemic stroke (≤24 hours post onset)
- Spontaneous intracerebral haemorrhage ruled out on baseline clinical neuroimaging
- NIHSS score 5-25 at randomisation
- Age ≥18 years

ANETIC AID LTD
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PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

Trial exclusion criteria at randomisation:

- Pre-morbid dependency (modified Rankin Scale, mRS>3)
- Spontaneous intracerebral haemorrhage
- Systolic blood pressure <80mmHg
- Haemorrhagic transformation of infarction PH2
- Pre-existing diagnosis of dementia
- Coma (GCS <8)
- Malignancy
- Significant co-morbidity (life expectancy <6 months)
- BM <3.0mmol/L
- Known pregnancy
- Taking part in another interventional trial, unless co-enrolment has been approved by Chief Investigators and Sponsors
- Seizure on presentation unless brain imaging identifies evidence of significant brain ischaemia
- Significant tissue injury of the upper limbs, which in the opinion of the investigator, will be exacerbated by remote ischaemic conditioning
- Expected repatriation of the participant to another hospital not participating in RECAST-3 where RIC or sham cannot continue.

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
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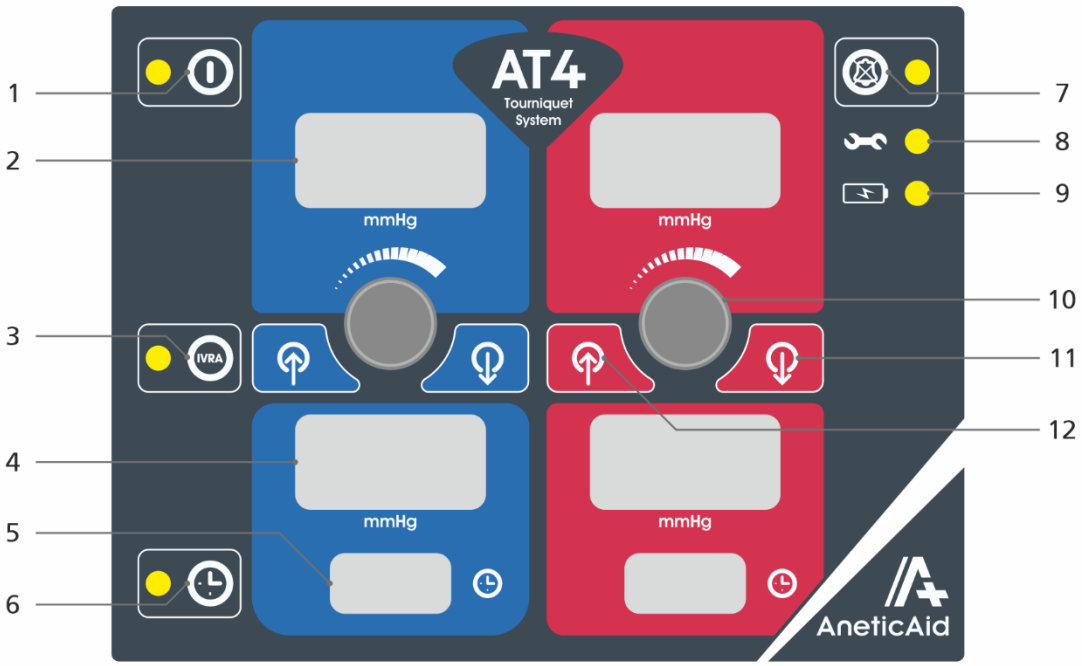
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

PRODUCT FUNCTIONS

1. Control Panel
2. Cuff Supply Hose Storage Connectors
3. Cuff Supply Hose Connectors
4. Cuff Supply Hose
5. Pulling Handle
6. Cuff Hooks
7. Storage Facility
8. Additional Storage Facility Locating Pins
9. IEC Socket

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
AT4™ ELECTRONIC TOURNIQUET
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104



1. ON/OFF
2. Set Pressure display
3. IVRA (Intravenous Regional Anaesthesia) **NOT APPLICABLE FOR RECAST-3**
4. Applied Pressure display
5. Elapsed Time H:MM
6. Reminder control **NOT APPLICABLE FOR RECAST-3**
7. Audible Alarm, pause and indicator
8. Maintenance indicator
9. Battery Level indicator
10. Pressure controller
11. Deflate button
12. Inflate button

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
AT4™ ELECTRONIC TOURNIQUET
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

INITIAL USE

PACKAGING

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, should be removed during commissioning.

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

FUSE FITTING AND INITIAL BATTERY MANAGEMENT

For safety, the AT4™ is shipped without the batteries being operational; the fuse is removed during final inspection. The unit will have been supplied with a T3.15A fuse in a clear plastic bag with the operating instructions; this needs 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, or after periods of storage, the AT4™ 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 clinical 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.

CUFF SUPPLY HOSE CONNECTION

The AT4™ will have been supplied with Red and Blue cuff hoses. These should be connected to the connections on 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 connections which are for stowage of the cuff end of the hose when not in use.

EQUIPMENT CHECK

Ensure that the battery has been charged and the battery indicator is green, if not it must be used connected to the mains supply.

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

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 participant's upper arms. The correct size and shape of cuff will allow cessation of blood flow at lower pressures and reduce the risk of harm to the tissue.

⚠ **CAUTION:** Before use, ensure all device functions operate correctly. Also visually inspect the device for any loose or damaged parts. If the devices 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.

RECAST-3 INTERVENTION

NOTE: RECAST-3 intervention is undertaken bilaterally on the upper arms. Before each 'dose' of the RIC or sham intervention, the investigator will inspect the participant's arms and skin condition, and make a note of any skin changes or damage.

NOTE: The elapsed inflation time reminder and IVRA features will not be used.

RECAST-3 intervention is bilateral inflation of tourniquet cuffs on the upper arm for a period of 5-minutes for 4 cycles with a 5-minute interval between cuff deflation and reinflation (40 minutes in total).

SWITCHING ON

The AT4 is switched on by depressing the ON button. The LED will be lit green.

If the internal air reservoir requires it, the internal compressor may be heard for a brief period.

CONNECTING THE TOURNIQUET CUFFS

After applying the tourniquet cuffs to both upper arms:

At the end of the cuff supply hose connected to the intended channel of use, depress the metal connector clip before fully inserting the tourniquet cuff connector.

Ensure the connector is fully inserted and secure.

ELAPSED INFLATION TIME

It will be necessary to use a standalone timer to ensure that the cuffs are inflated and deflated at 5-minute intervals for the duration of the intervention (4 cycles: 40 minutes total).

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
AT4™ ELECTRONIC TOURNIQUET
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

PRESSURE SELECTION

A blood pressure measurement must be taken immediately prior to pressure selection.

Set the required pressure on both channels 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.

The following values should be used according to whether the participant has been randomised to receive RIC or Sham:

RIC: +20 mmHg above systolic blood pressure.

Sham: 50 mmHg.

NOTE: At 450mmHg and above, an audible beep will be heard to draw the user's attention to the pressure selection.

Application of a tourniquet cuff at excessive pressures can result in tissue necrosis.

INFLATING A TOURNIQUET CUFF

To inflate the cuffs, depress the inflate buttons on both channels in turn.

The applied pressure displays will now illuminate and display the applied pressure.

The cuffs should remain inflated for a period of 5-minutes before being deflated.

NOTE: Once inflated, reducing the pressure below 250mmHg an audible beep will be heard to draw the user's attention to the pressure selection.

DEFLATING A TOURNIQUET CUFF

To deflate the cuffs, depress the deflate buttons on both channels in turn.

A single push initiates a slow deflate a second depression initiates a fast deflate.

During deflation the screen will flash.

The cuffs should remain deflated for a period of 5-minutes prior to reinflation (until the 4th cycle has been completed).

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

POST INTERVENTION

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

DEFAULT SETTINGS

When switching on an AT4 it will always revert to its default settings: -

- Selected pressure 000mmHg.

These default values are non-amendable and will have to be reset if the unit is switched off between interventions.

BATTERY MANAGEMENT

The AT4 is intended to be used from battery and placed on charged when not in use.

Under normal working conditions, when not connected to mains, the battery LED should be lit green.

If, when not connected to mains, the battery LED changes from green, the following applies: -

Orange: Low battery – connect to mains as soon as it is practical to do so.

Red: Very Low Battery – connect to mains immediately.

When connected to mains, whether switch on or off, the battery LED should be lit green with flashing orange LED.

NOTE: Whilst connected to mains the battery LED will remain in this status, regardless of the battery charge level (i.e. it will not change from this status to indicate a fully charged battery, even though trickle charging has commenced).

NOTE: Once disconnected from mains the battery LED will remain in this status for approximately 30 seconds before reverting to being lit green, amber or red.

NOTE: If an AT4 is allowed to reach very low battery status (red battery LED) it will require up to 48 hours in a charge cycle to recover capacity.

NOTE: Battery capacity will diminish as a result of an AT4 being allowed to reach very low battery status (red battery LED).

An AT4 should be placed on charge when not in use or as a minimum, overnight, every night.

An AT4 battery should be replaced every six years.

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FORM 995104

BATTERY LIFE

When running from battery, a fully charged 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.

BATTERY CONSERVATION MODE

An AT4 will automatically switch itself off after a 15-minute period of idle activity with neither channel inflated.

This default value is non-amendable.

ALARMS AND INDICATORS

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

BATTERY

If an AT4 is allowed to reach very low battery status the battery & audible alarm LED with be lit red and flash.

An audible alarm will sound, which will cancel once the AT4 has been connected to mains.

LOW PRESSURE ALARM

If whilst inflating a channel the applied pressure does not meet 80% of the selected pressure within 6 seconds the low-pressure alarm will be triggered.

The audible alarm LED will be lit red and flashing and the relevant channel applied pressure display digits will flash.

Once the applied pressure is within 80% of the selected pressure the alarm can be cancelled by pressing the audible alarm button.

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

BURST ALARM

If following inflation of a channel that has met with 80% of the selected pressure, the applied drops by 10% without a button press or turn of the rotary controls, the burst will be triggered.

The audible alarm LED will be lit red and flashing and the relevant channel applied pressure display digits will flash.

Once the applied pressure is back within 80% of the selected pressure the alarm can be cancelled by pressing the audible alarm button.

MAINTENANCE

If the maintenance LED is lit orange or red then this indicates a maintenance issue which needs attention.

Orange: Internal compressor is producing a diminished rate of air flow to the internal reservoir

Red: An internal leak has been noted, the internal can no longer pressurize the internal reservoir (continuously running) or the unit requires calibration.

If switching the unit off and on does not clear the maintenance LED, or it does but it reoccurs shortly afterwards, the unit should be withdrawn from use and maintenance assistance sought.

HANDLING

CAUTION:

- 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 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.

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
AT4™ ELECTRONIC TOURNIQUET
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

CLEANING AND DISINFECTION

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.

⚠ **CAUTIONS:**
- 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.

⚠ **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.

MAINTENANCE

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.

Originator: M Lee	Site Approval: L Smith	QA Approval: I Divers
Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
AT4™ ELECTRONIC TOURNIQUET
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

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 six years. The device is class I electrical safety with a protective earth, it is NOT classified as an applied part.

CAUTION: In line with the MHRA document, Managing Medical Devices, maintenance work should only be conducted by suitably trained personnel following manufacturer's guidelines.

DEVICE LABELLING

Symbol:	Title:	Description:
	ON / OFF	Press to turn ON, Green indicator. To turn OFF press and hold until pressure displays are blank.
	AUDIBLE ALARM PAUSE	Press once to pause audible alarms for 3 minutes; Amber Indicator (except Low Battery).
	AUDIBLE ALARM OFF	Press second time to cancel audible alarms (except Low Battery). Red Flashing Indicator.
	INFLATE PRESSURE CONTROL	Turn to set inflation pressure blue channel. Turn to set inflation pressure red channel.
	PRESSURE SET OR APPLIED	Indicates the set and applied pressures.
	INFLATE	Inflates blue and red channels respectively.
	DEFLATE	Deflates blue and red channels respectively.
	TIME	Indicates the timer display for blue and red channels respectively.
	BATTERY LEVEL	Green: represents acceptable battery level Amber: connect to mains as soon as soon as practical. Green/Amber: Charging. Red: connect to mains immediately.
	MAINTENANCE INDICATOR	Amber: Service required. Red: Stop using and request immediate service.

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Issue Date: 11/10/23	Issue No: 01	

ANETIC AID LTD
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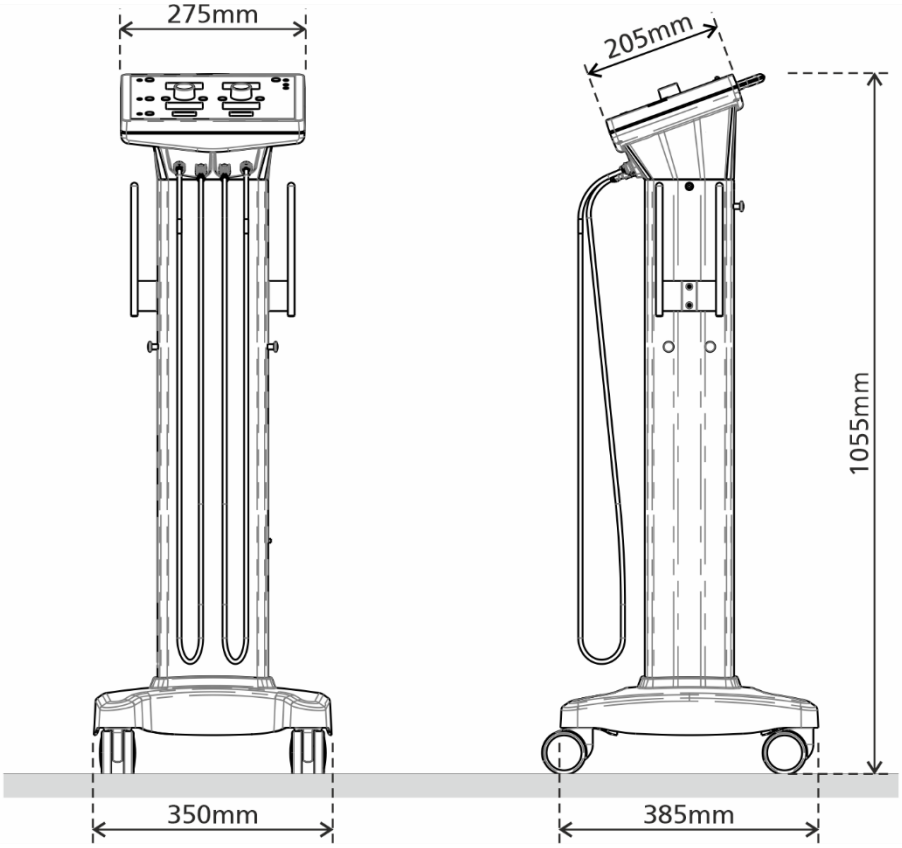
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

CE	CE MARK	Indicates compliance with the European Medical Device Directive 93/42 and amendments thereto. Symbol is associated with a number indicating the Notified Body.
	READ INSTRUCTIONS	Read Instructions For Use.
	CAUTION	Indicates the need for the user to consult the instructions for use for important cautionary information.
	FUSE	Location and value of fuses.
	BATTERY	Location and type of battery used.
	WEEE	Do NOT dispose of in domestic waste see Section **Error! Reference source not f ound.**.
V	SUPPLY VOLTAGE	Supply voltage of mains inlet.
~ Hz	SUPPLY FREQUENCY	Frequency of AC mains supply.
W Max	MAX POWER CONSUMPTION	Maximum power consumption in watts.
SN	SERIAL NUMBER	Unique serial number used for traceability.
REF	REFERENCE NUMBER	Reference or model number indicating the type of unit.
	DATE OF MANUFACTURE MANUFACTURER	Date of manufacture as YYYY:MM Name and address of manufacturer is adjacent.
	Do Not Push	The AT4 should not be pushed as it is more stable when pulled by the handle.
Rx ONLY	Rx ONLY	CAUTION: Within the USA Federal law restricts this device to sale by or on the order of a physician.

NOTE: The following label will be added to the devices to demonstrate that they are for research use only:

Originator: **M Lee**	**Site Approval:** **L Smith**	**QA Approval:** **I Divers**
Issue Date: 11/10/23	**Issue No: 01**	

SPECIFICATIONS



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

Weight:	Excluding accessories but with batteries fitted, 17.3 Kg.
IP Rating:	IP41
Standards Applied:	EN IEC 60601-1 and EN IEC 60601-1-2.
Environmental Conditions:	
Operating Conditions:	
– 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 - 113kPa. – 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 -20˚C to 40˚C. – Humidity of 20% - 90% non-condensing. – Atmospheric Pressure 50kPa - 113kPa.	

EMC Data:

Electromagnetic Disturbances;

The AT4 Tourniquet is compliant to EN IEC 60601-1-2:2015 the "Collateral standard for Electromagnetic disturbances - Requirements and tests" and is accordingly classified as a Class A device for professional use.

To reduce the risks of electromagnetic interference best practice as detailed below should be observed.

- If it is necessary to use the AT4 Tourniquet in close proximity to other electrical equipment, observe the performance of both the AT4 Tourniquet and the other equipment to make sure that they are operating normally. Ensure cables are not coiled or bundled in close proximity to each other and are separated from other cables where possible.
- The AT4 Tourniquet is suitable for use in hospital operating rooms and other clinical areas with antistatic flooring. The emissions characteristics of this equipment make it suitable for use in hospitals, it is not intended for use in a residential environment.
- To reduce risks of interference electromedical equipment should not be placed in close proximity to radio frequency communication equipment or electrosurgical equipment. Interference may occur in the vicinity of equipment marked with the symbol indicated.

- If interference occurs the user may need to take mitigation measures, such as moving or reorienting the equipment or separating cables.

ANETIC AID LTD
AT4™ ELECTRONIC TOURNIQUET
PRODUCT TRAINING GUIDANCE
For Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
FORM 995104

Date of Change	Issue No.	Brief Description of Change	Change Reference
11/10/23	01	Initial release of this document across the Havant and Baildon sites.	280

Originator: **M Lee**	**Site Approval:** **L Smith**	**QA Approval:** **I Divers**
Issue Date: 11/10/23	**Issue No: 01**	