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RECAST 3

REMOTE ISCHAEMIC CONDITIONING AFTER STROKE TRIAL 3

RECAST-3: A multicentre randomised controlled trial

Chief Investigator: Professor Tim England

Professor of Stroke Medicine, University of Nottingham

Honorary Consultant Stroke Physician, Royal Derby Hospital

Email: recast-3@nottingham.ac.uk

Website: https://stroke.nottingham.ac.uk/recast-3/

Twitter: @recast3trial

Telephone: 0115 823 1770

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These training slides are designed to assist site investigators with becoming competent in delivering the RECAST-3 intervention using the AT4 Electronic Tourniquet System.

This will complement, not replace, the requirement to review the formal device training document entitled:

'Product Training Guidance - AT4 Electronic Tourniquet - RECAST-3'

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The AT4 system

The AT4 system will be used to deliver the RECAST-3 intervention. It is a CE marked device being used under indication

Participants will be randomised to the active remote ischaemic conditioning or sham group:

- **<u>Active: RIC group</u>**
  - **4 cycles of intermittent bilateral limb ischaemia - alternating 5 minutes inflation (+20 mmHg above systolic BP) followed by 5 minutes deflation of bilateral upper arm BP cuffs.**
- **<u>Control: Sham RIC</u>**
  - **Bilateral upper arm BP cuffs inflated to 50 mmHg for 4 cycles**

- **<u>Duration</u>**
  - **First 'dose' (4 cycles) ≤24 hours of onset.**
  - **Second dose >4 hours after the first dose.**
  - **Twice daily (am/pm) for 14 days**
  - **Total 28 doses**

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Power supply & battery

- When not in use, please connect the device to mains supply to ensure fully charged and ready for use.
- When plugged in, there will be a green and flashing amber light displayed on the interface next to the battery symbol.
- The AT4 must be left on charge overnight, every night.

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Checks before use

- Prior to use ensure that all functions operate correctly
- Visually inspect the device, hoses and cuffs for any loose or damaged parts.
- Check that the O rings on the cuffs and hoses are in good condition
- Ensure you have the study treatment log
- Ensure you have a timer to measure the inflation and rest intervals

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Pre-intervention BP/HR

- Confirm the participant is in the RECAST-3 study and which treatment arm they have been randomised to. Blood pressure (BP) is taken once from each arm.
- Participants Heart Rate (HR) should also be measured and recorded.
- For participants randomised to RIC the pressure applied will be 20mmHg above systolic pressure. The pressure can be set in 5mmHg increments so for systolic pressure of 140mmHg 160mmHg would be used, for systolic pressure between 141-145mmHg 165mmHg would be used.
- For participants randomised to SHAM 50mmHg pressure will be applied.

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Positioning and connecting the tourniquet cuffs

- Check the participants arms
- Make sure the participant is comfortable, using pillows if required
- The cuffs are positioned on the upper arm, as with a BP cuff
- The two hoses are colour coded blue and red to indicate which controls apply to them
- Attach the hose to the cuff, ensure the connector is fully inserted and secure, you will hear a click. Either cuff can be connected to either hose

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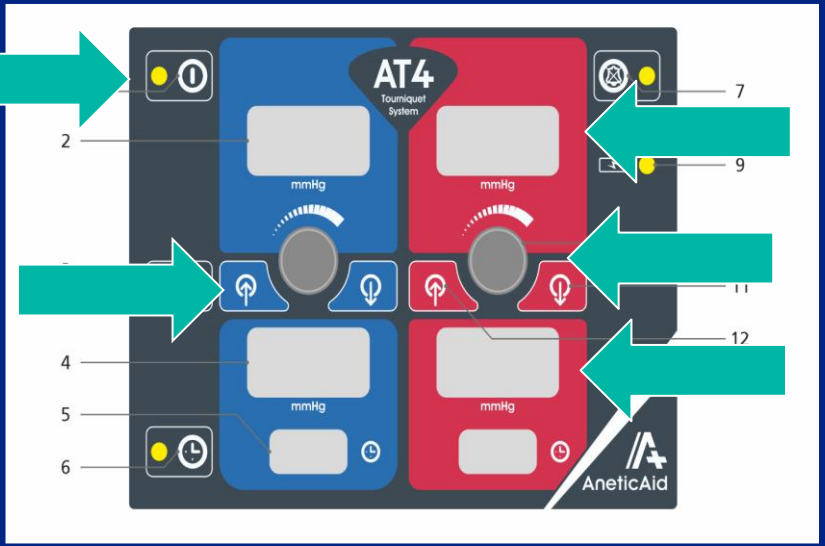
How to use

Switch on

Press the up arrow to inflate and the down arrow to deflate



Selected pressure

Select the pressure using the dials

Actual pressure

A separate timer will be required to time the inflation and deflation periods

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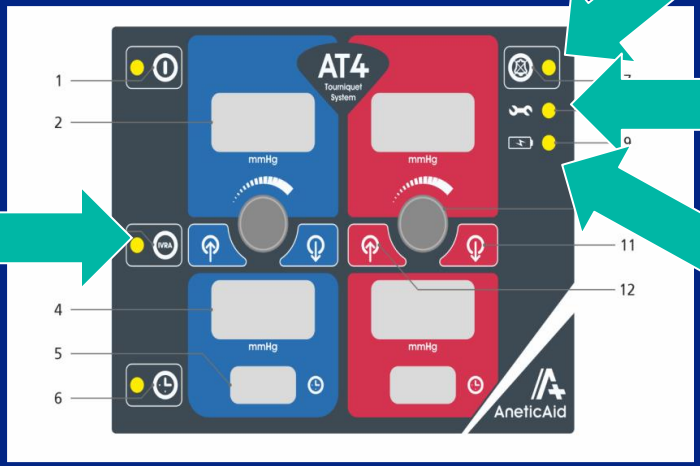
Troubleshooting

The alarm will sound if there is an issue with the pressure. The alarm is silenced by pressing the button

The spanner light indicates a fault

Battery warning light

Do NOT press the IVRA button. If pressed in error press again to turn off



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(Cleaning)

- After use wipe the AT4, the cuffs and tubes with Clinell wipes or similar CE marked disinfectants suitable for cleaning medical devices. DO NOT immerse the cuffs or cables in water or any other liquids.
- Detach the cuffs and store on the hooks
- Attach the hoses to the storage connectors.
- Check the black O ring seals on the cuffs and hoses periodically for signs of wear and replace if required.

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ANY QUESTIONS?

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