

Medical device

CB240\_Aurora



## SELECTIVE AND PORTABLE CEREBRAL TARGETED TEMPERATURE MANAGEMENT

CB240\_Aurora is manufactured by Neuron Guard S.r.l., P.IVA/C.F. 03521100366

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# Medical device

## CB240\_Aurora



CB240\_Aurora is a **targeted temperature management system** composed by a **therapeutic collar** powered by a **smart control unit**. The disposable collar transforms the neck into a natural heat exchanger exploiting several physiological and anatomical characteristics of the human body. It is quicker to act on brain tissue but can also function as total body temperature adjusting device if required. The collar acts as a thermal interface between the device and the patient ensuring optimal heat exchange and comfort. The control unit collects all the data of the treatment.



- **Miniaturization and portability** avoid dangerous fluctuations in temperature during transfer to diagnostics and surgery or transport
- **Precise temperature control** to adapts to the needs of the patient
- **Brain targeted** (selective brain cooling) to reduce systemic complications (i.e. pneumonia)
- **Easy to use** reduces the nursing workload covering a smaller area of the body
- **Affordable** - financial sustainability, usable on ambulances

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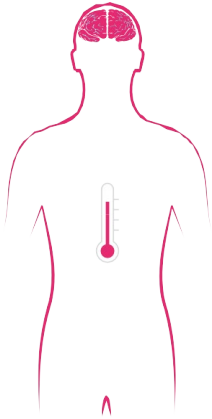
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# Hyperthermia in the critical patient

## - a frequent problem

### Hyperthermia



Hyperthermia is a frequent complication (> 50%) in patients with brain damage, such as acute ischemic stroke, subarachnoid haemorrhage and intracerebral haemorrhage, and is related to secondary brain injury and increased morbidity and mortality [1].

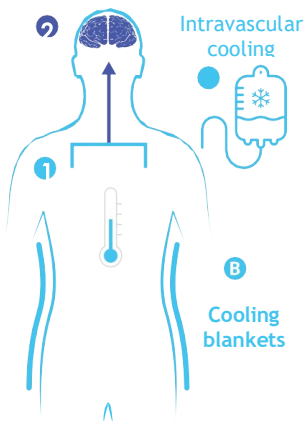
Hyperthermia increases the metabolic needs of the brain, thereby aggravating ischemic damage and leading to vasodilation of cerebral vessels, resulting in worsening intracranial pressure.

Harmful effects of hyperthermia in patients with brain damage:

- increased brain metabolism
- increased intracranial pressure
- increased inflammatory response of brain tissue

## Targeted Temperature Management (TTM)

### "Total body" cooling



Targeted Temperature Management (TTM) is the process of controlling body temperature which can be adjusted to a desired value [2].

As part of standard clinical practice in several acquired brain injury protocols, pre-clinical evidence shows that temperature management has a strong neuroprotective action, such as:

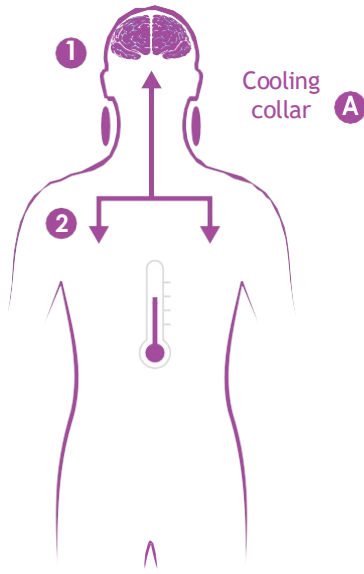
- reduction of brain metabolism
- lowering of intracranial pressure
- reduction of the inflammatory response of brain tissue

The two most common systems available today are intravascular cooling (A) and cooling blankets (B). They work by reducing body temperature (1) and consequently brain temperature (2). This means that the body must be cooled more than the brain in order to achieve the desired brain temperature.

"Total body" cooling can cause complications including cardiac arrhythmias, coagulopathy, hypokalemia and infections, of which pneumonia is the most frequently found. It can also cause chills which in turn lead to a significant increase in energy expenditure, thus slowing down the cooling process and increasing intracranial pressure.

# Innovation: CB240\_AURORA

## Selective cooling



CB240\_Aurora is an innovative system for the control of brain temperature able to selectively regulate the temperature of the blood flow.

Thanks to a collar equipped with active elements, a high and efficient heat exchange with the large arterial vessels of the neck (A) is guaranteed, reducing the temperature of the brain (1) and consequently that of the body (2).

The selective cooling system allows to avoid the side effects of conventional cooling methods, optimizing the therapeutic strategy in the management of both brain and body temperature.

In a first feasibility study based on an animal model, the effectiveness of the device equipped with a cooling collar was demonstrated, which was able to create and maintain separate temperature zones for the head and body, with the potential to limit the negative effects of "total body" cooling while optimizing its therapeutic effect [3].

## Potential clinical applications

Current TTM guidelines suggest undertaking this strategy in patients with cardiac arrest, severe head injury, stroke, intracerebral and subarachnoid haemorrhage in order to control and reduce intracranial pressure, improve survival and neurological outcome [4, 5, 6].

### Cardiac arrest

Unresponsive cardiac arrest patients despite spontaneous circulation restoration (ROSC)

### Trauma

Patients with severe head injury, refractory intracranial hypertension and/or hyperthermia

### Intracerebral haemorrhage

Patients with intracerebral or subarachnoid haemorrhage, refractory intracranial hypertension and/or hyperthermia

### Acute ischemic stroke

Patients with acute ischemic stroke and hyperthermia

# Targeted temperature management in patients with intracerebral haemorrhage, subarachnoid haemorrhage, or acute ischaemic stroke: updated consensus guideline recommendations by the Neuroprotective Therapy Consensus Review (NTCR) group

Lavinio A et al. *British Journal of Anaesthesia*, doi: 10.1016/j.bja.2023.04.030 [5]

## Background

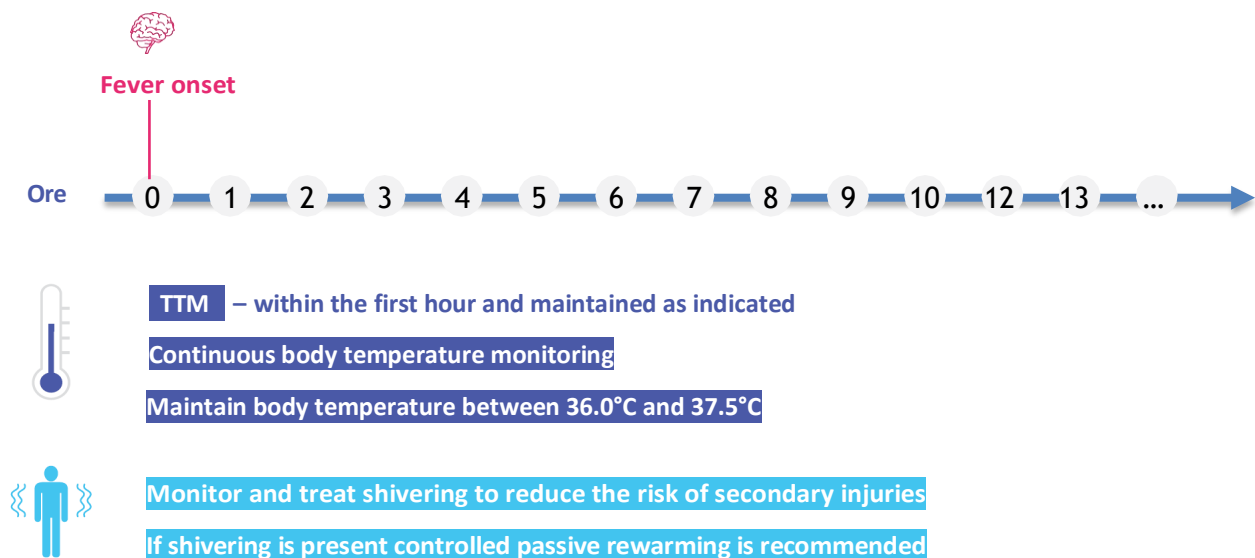
Stroke is a pathological condition caused by a disruption of cerebral blood flow, which can cause a lasting loss of neurological function and tissue damage. It is considered one of the main causes of disability and has a significant social-economic impact. There are two main types of stroke: haemorrhagic and ischaemic stroke. Haemorrhagic stroke can be further divided into subarachnoid haemorrhage and intracerebral haemorrhage.

Targeted Temperature Management (TTM) is a complex treatment that aims to minimize brain injury and improve outcome in certain types of stroke, such as intracerebral haemorrhage, aneurysmal subarachnoid haemorrhage and acute ischemic stroke. Such an approach involves controlling body temperature to prevent fever, maintain normothermia or induce hypothermia.

The following guidelines aim to improve temperature management standards for critically ill patients following intracerebral haemorrhage, aneurysmal subarachnoid haemorrhage and acute ischaemic stroke, based on currently available scientific and clinical evidence.

## Recommendations

Following an intracerebral haemorrhage, aneurysmal subarachnoid haemorrhage or acute ischemic stroke requiring admission to intensive care:



## Seletherm study - preliminary data

- First-in-human study at the Cambridge University Hospital NCCU
- Case - control (5 targeted cooling vs. 5 total body cooling)
- Protocol
  - TBI patients with indication of TTM to lower ICP
  - Brain temperature invasive monitoring
  - Core body temperature continuous monitoring (oesophageal)
  - Total body cooling group - Arctic Sun 5000
  - Targeted cooling group - CB240\_Aurora

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# CB240\_AURORA

Technical features	Specifications
<b>CB240A - Control Unit</b>	
Maximum cooling power per element	120 watts (Printing)
Battery power	150 Wh
Battery voltage	14 V
Weight	7 kg
Tank capacity	120 mL
Operating ambient temperature	+10°C - +35°C
Operating ambient humidity	10% - 50% non-condensing
Storage conditions	Temperature from +5°C to +35°C, pressure from 101 kPa to 75 kPa, humidity from 10% to 70%, protect from rain
<b>Functional features</b>	
Minimum treatment temperature	+5°C
Maximum treatment temperature	+42°C
<b>Batteries</b>	
Deliverable power of each battery	75 Wh
Estimated autonomy with fully charged battery	45' (indicative estimate, which may vary significantly depending on the patient's temperature, the environment and the level of treatment required for the patient)
<b>CB240C - Disposable collar (for use with CB240A only)</b>	
Non-sterile	Polyurethan
Material bags	35-50 cm
Neck	40-120 mL
Filling volume of each bag	60 months
Shelf life	60 months
Storage conditions	Temperature from +5°C to +40°C, pressure from 101 kPa to 75kPa, humidity from 10% to 70%, protect from rain
<b>CB240AP - Power supply Protek PMP400-14-S</b>	
Input voltage	100-240 V
Frequency	50-60 Hz
Output voltage	24 V
Maximum absorbed current	4,6-2,3 A
Maximum power output	400 W
Operating temperature	-10°C - +60°C
Operating humidity	5% - 95% non-condensing

The product is CE marked.

## References

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2. Madden, L.K., et al., The Implementation of Targeted Temperature Management: An Evidence-Based Guideline from the Neurocritical Care Society. Neurocrit Care, 2017. 27(3): p. 468-487
3. Giuliani E, Magnoni S, Fei M, Addis A, Zanasi R, Stocchetti N, Barbieri A. A Novel Cooling Device for Targeted Brain Temperature Control and Therapeutic Hypothermia: Feasibility Study in an Animal Model. Neurocritical Care. 2016 Dec;25(3):464-472
4. Nolan JP, Sandroni C, Andersen LW et al., ERC-ESICM guidelines on temperature control after cardiac arrest in adults, Resuscitation 2022
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