# Neur@Safe

How can technology of local brain cooling assist World Healthcare

### What is craniocerebral hypothermia?

Craniocerebral hypothermia is controlled cooling of the brain, which reduces metabolism of neurons, enhances strength of cell membranes, decreases their requirement in oxygen, and as a result makes them more viable

# When is craniocerebral hypothermia necessary?

In case of diseases which are accompanied by overheating of the brain and result in destruction of the neurons, causing death and disability

#### Wide range of application







### Why is craniocerebral hypothermia necessary?





## The solution

### NeuroSafe

Compact, portable model: beta testing, registration process is progress

#### Compressor

- Cooling of one patient
- Weight (with coolant) 12 кг
- Cooling of the brain TO no lower than 29°C
- Speed of cooling 1 <sup>о</sup>С за 45 минут
- Time of cooling of coolant from +25°C to 0°C: **20 min**.
- Display with user-friendly interface
  Easy transportation
  Automatic protocol of the procedure
  Engineering ENCATA
  Prototype June 2021
  Registration September 2021



#### **THE-01** MVP (Original model)

Registered: РУ ФСР 2011/11788 от 12.12.2017, Declaration of compliance РОСС RU Д-RU.ИМ25.В.00024/18 (30.10.2018)

Serial Production phase: «Izhevsk Mechanical Factory» Concern «Kalashnikov»

10 Patents

#### Cooling of the brain TO no lower than 290C

- Cooling of body T<sup>o</sup> 36,6 ... 33<sup>o</sup>C
- Time of cooling of coolant from to 0°C 30 min
- Speed of cooling 1 °C per 45 minutes
- Cooling of two patients simultaneously
- Automatic protocol of the procedure

3 channels of monitoring of patients body T<sup>o</sup>
 Display with user-friendly interface
 Automatic procedure control
 Size 94x45x52 cm
 Weight (with coolant) 70 kg
 Reusable cryoapplicators



## The effect

Improves pharmacoeconomical characteristics of the medical care

Improves cognitive abilities and reduces fatigue

Reduces time in the resuscitation units by 1,5 times

Halves neurological deficit

More than 5 0000 people have been treated in Russia, Kazakhstan and Uzbekistan clinics with defined

and Uzbekistan clinics with defined therapeutic effect and without side effects and complications

Halves death rate among patients in critical conditions

## How does it work?

«When craniocerebral hypothermia initiates neuroprotection, one can benefit from it long after cooling»\*

\* Nina M. Rzechorzek et al (2016) Hypothermic Preconditioning Reverses Tau Ontogenesis in Human Cortical Neurons and is Mimicked by Protein Phosphatase 2A Inhibition



Temperature monitoring in the ear canal © controls parameters of cooling of the brain

Neuroprotection is initiated – resistance of neurons to hypoxia and ischemia and to lack of substratum, stable cytoprotective phenotype is formed for 24 hours and more

Cryoapplicator in the form of helmet cools scalp (A) and tissues under the skull (B) cools down venous blood of the head which gradually spreads all over the brain (F), including core area of lesion (E): this reduces edema, reduces intracranial pressure, limits neurogenic inflammation, volume of necrosis and development of apoptosis, cerebral hyperthermia is terminated

#### Brain T<sup>o</sup>C in case of stroke before using «THE-O1»



Brain T<sup>o</sup>C after using «THE-O1» after 4 hours of the procedure

In the area of lesion (E) edema is formed, which in combination with central heat inflows (D) does not allow cold blood flow to reach core of hyperthermia area, Temperature rises up to 41°C, which leads to damage and destruction of neurons

#### Software

Allows to control the procedure	Prepari When T THE is re
Allows to monitor temperature of the patient and coolant during the procedure	Th: +2
Tc - coolant T <sup>o</sup> C Th - helmet (cryoapplicator) T <sup>o</sup> C Tt - tympanic T <sup>o</sup> C (measured in the ear area) Ta - axillary T <sup>o</sup> C (measured in the armpit)	Tt: +2:
Allows to protocol the procedure	<b>Length</b> Th: 05,0 Tt: 15,0°
Allows to adjust settings for different nosologies	Prote



### Software Settings

Allows to set temperature of the coolant

Allows to set length of the procedure

Allows to set goal temperature of the patient and coolant during the procedure Th - helmet (cryoapplicator) T<sup>o</sup>C Tt - tympanic T<sup>o</sup>C (measured in the ear area)



### Protocol of the procedure

Patients medical details

Details of CHH procedure and patient's parameters before the treatment

Length of the Procedure

#### Preparing equipment for the procedure

When Tc (coolant T°) reaches + 5°C, THE is ready for the procedure

Nev	w patient	Cancel	Save
Name of Patient №	1		
Date: Gender: Age: Diagnosis:			
Criteria of the inclu	sion:		
Start of CCH:			
Finish of CCH:			
Artificial ventillation	6		
Sedation/therapy:			
NIHSS:			
Glasgo:		1	
Body I:	Tympanic (e	ear) I:	
Blood pressure:	Heart rate:		
0,5 hour			
1 hour			
2 hours			
4 hours			
8 hours			
16 hours			
20 hours			
24 hours			

# Data Analysis Visual representation of temperature of the patient and helmet during the procedure

Th – helmet (cryoapplicator) T<sup>o</sup>C Tt – tympanic T<sup>o</sup>C (measured in the ear area) Ta – axillary T<sup>o</sup>C (measured in the armpit)







	Document	Date of publication	Expiry date
Device for human body local cooling	RF Patent no. 83369	16.10.2012	30.03.2026
Device for therapeutic hypothermia induction	RF Patent no. 126262	27.03.2013	28.08.2022
Device for correction of cerebral hyperthermia	RF Patent no. 2615283	04.04.2017	12.11.2035
«Method of diagnostics and management of cerebral hypothermia syndrome»	RF Patent no. 2645927	15.06.2017	15.06.2037
«Device for conduction of controlled therapeutic hypothermia of the brain»	RF Patent no. 2653794	14.05.2018	25.08.2037
Application for «Device for induction of controlled hypothermia of the brain»	PCT/RU2017/000633	In progress	In progress
Application for «Method of therapy of knee joints using deep local hypothermia»	RF Patent no. 2653794	14.05.2018	25.08.2037

# Why us?

Individual approach and widest range of application: suitable for conscious state, coma, medical anesthesia

Safest and most convenient method: no pharmacological assistance required, no complications, no side effects

Reduction of expenses to hospitals

The most effective hypothermia device on the market, which has the widest range of application

The most attractive price for equipment and consumables on the market

#### **in the world** Price/Quality ratio parameter

#### Reasons to consider us

#### Healthcare problems in EU

- Stroke is the leading cause of death in EU
- Europe has highest proportion of heavy episodic drinking in the World
- Over 66 million people have chronic depression (7% of population)
- Almost 74 million people suffer from migraines (10% of population)
- Market volume in USA, Canada, EU, Japan 250 000 units
- Export potential: annual market growth in developed countries (USA, Canada, EU, Japan) 7-10%

## €5 Billion EUR

Market volume in USA, Canada, EU, Japan



Of French ICUs are equipped with general hypothermia equipment



### NeuroSafe



What we do:

Development и production of craniocerebral therapeutic hypothermia equipment line

Introduction of craniocerebral hypothermia into medical practice

Development of methodologies of craniocerebral hypothermia

Scientific research of craniocerebral hypothermia



#### Mission statement:

Development of effective and economically efficient hypothermia technologies with aim to improve resuscitation and rehabilitation outcomes:

- ••• reduction of mortality
- •••• reduction of rehabilitation period
- o protection of health and preventive healthcare أسلم
- improvement of quality of life

Support:

Agency of Strategic Initiatives (RUS)

Skolkovo Innovation Centre (RUS)

### We are ready for cooperation!

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