CryoTechnoMed

Power of cold

Therapeutic Hypothermia Equipment «THE-01»

Reduce mortality	Reduce period of rehabilitation	Return patients to fulfilling life

АГЕНТСТВО СТРАТЕГИЧЕСКИХ ИНИЦИАТИВ Sk Сколково Baikal

Problem Identification: Destruction of neurons

Cerebrovascular diseases (and cardiovascular diseases):

17 million people die yearly

Brain injuries

98 out of 100

prize winning sportsmen get severe injuries

Addictions

Russia is among leaders in heroin consumption for years

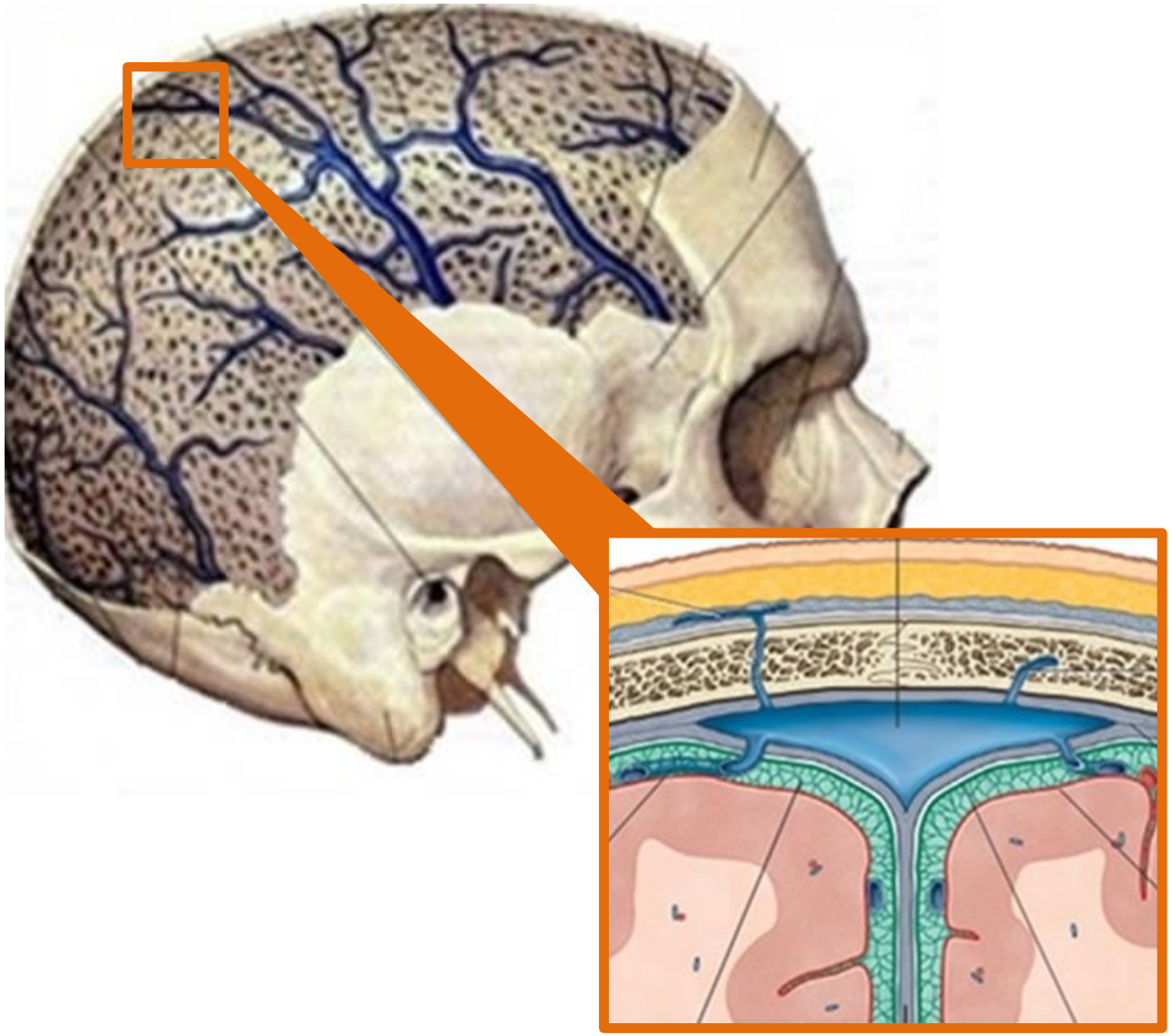
Solution: Controlled cooling of brain

Craniocerebral hypothermia using equipment «THE-01»

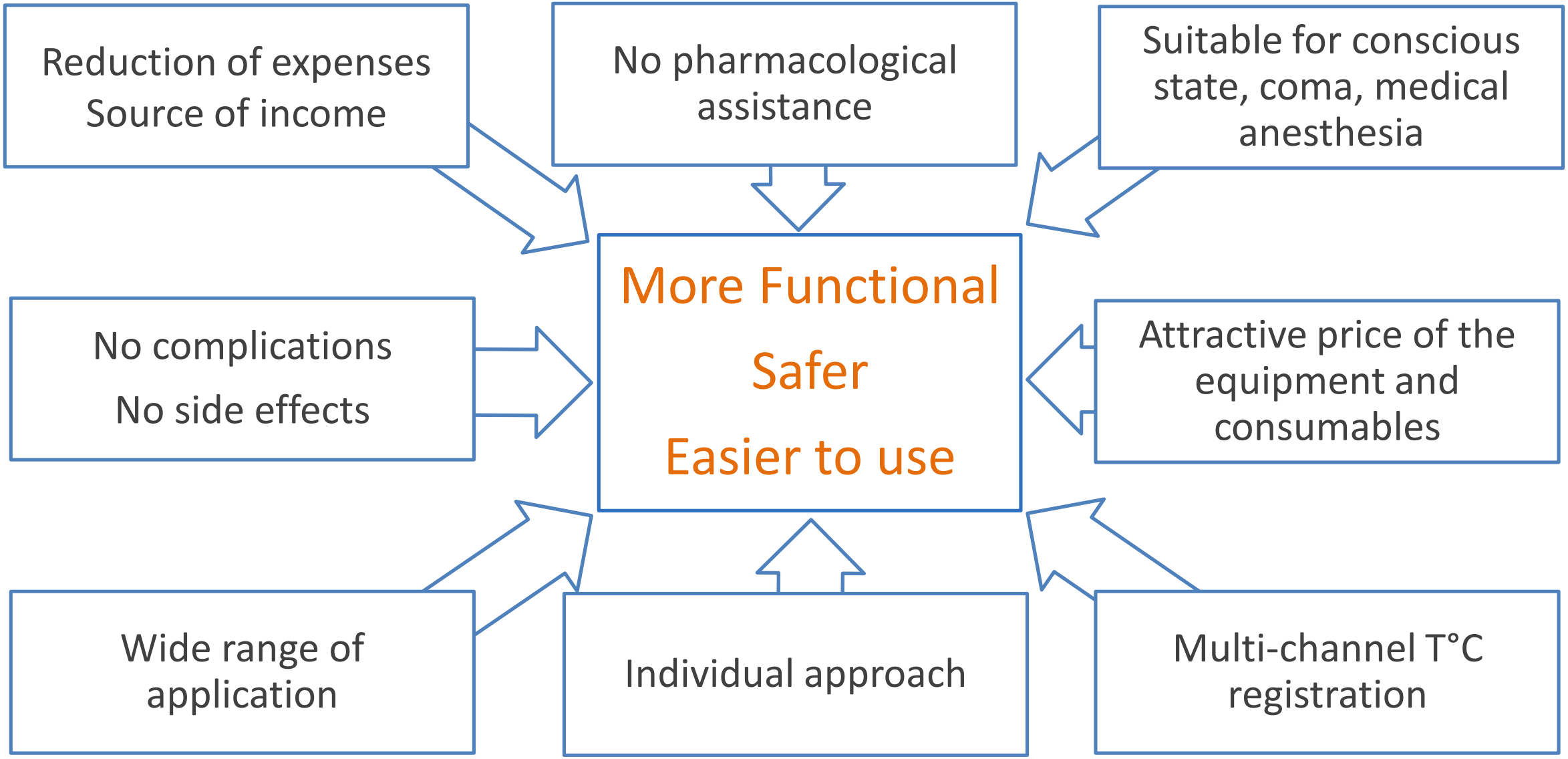
- ✓ Can form local cerebral hypothermia
- ✓ Can also induce general hypothermia (cool the whole body)
- ✓ No complications
- ✓ No requirement for sedation and myorelaxation
- ✓ Applicable in various states of consciousness

Brain T°C < Body T°C

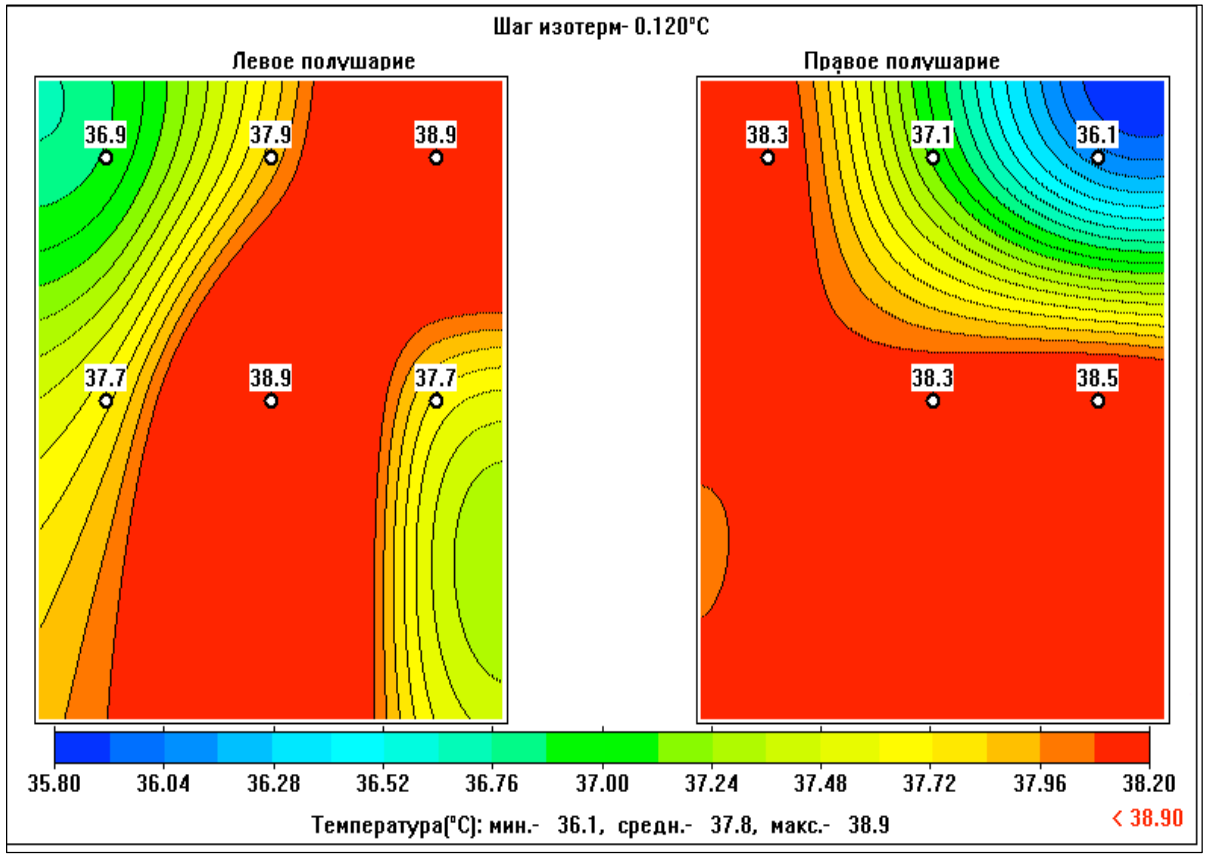
Technology



Competitive advantage

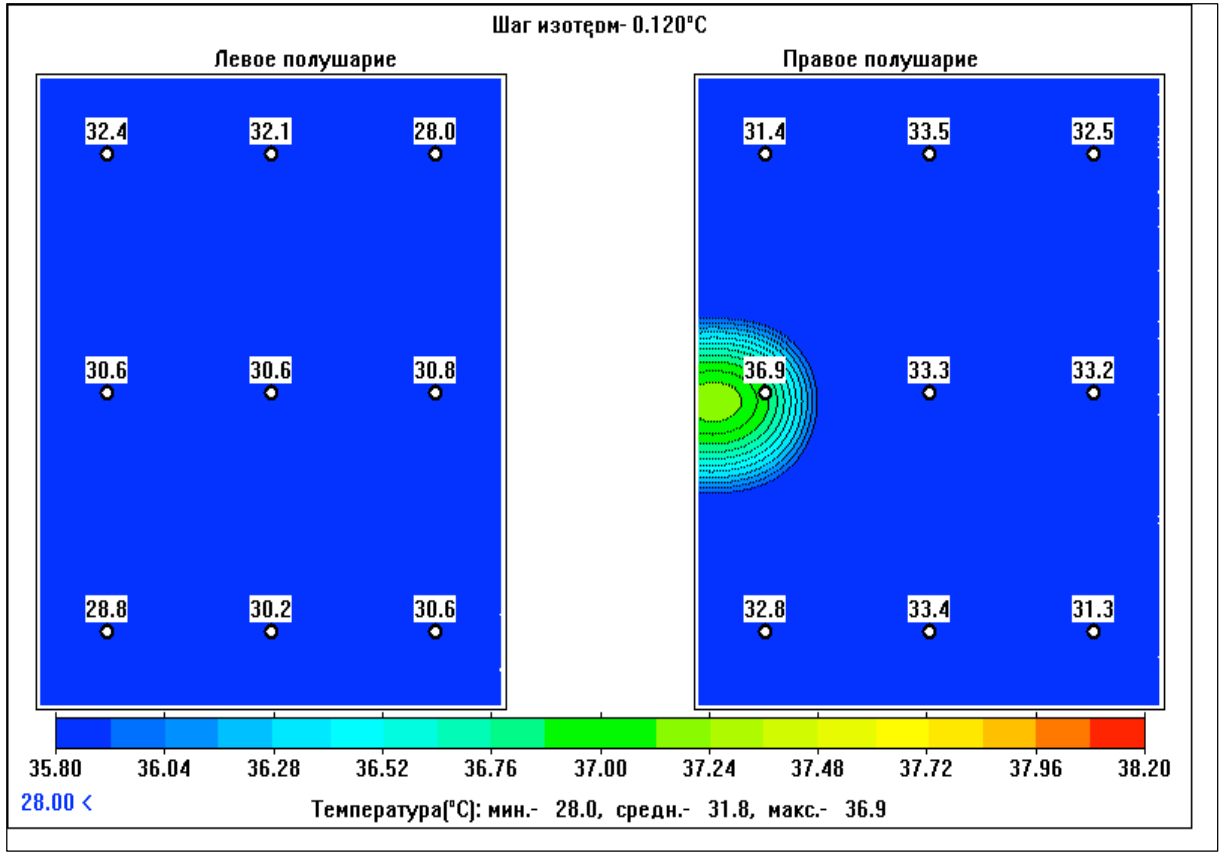


Technology



Brain T°C of patient after ischemic stroke

Before application of THE



Brain T°C of patient after ischemic stroke

After application of THE

Application of THE

Purpose:

- To reduce neurological deficit
- To stabilize hemodynamics (blood flow)
- To effectively manage fever
- To decrease complications

Effect:

«THE-01» saves lives:

- ↓ of death rate among patients in critical condition by 35 – 40%
- ↓ of complications by 35-40%
- ↓ of time in the resuscitation units by 1,5 times
- ↓ of rehabilitation period by 2-3 times
- ↑ of pharmacological and economic characteristics of the medical care

Product line

THE-01

THE-02 (prototype)

THE-02 Portable (prototype)

Cryoapplicator (prototype)

Radio thermometer

7 Patents

Product line

Characteristics:	Original model «THE-01»	Stationary model «THE-02»	Portable model «THE-02P»
Current status:	Completed and registered	R&D	
Weight (kg):	65	45	30
Size (mm)	940x450x520	885x450x450	500x450x450
Type of equipment:	compressor	compressor	Thermoelectric Cooler Peltier
Wattage (W):	450	350	250
Cooling area:	1: cryoapplicator «helmet»	2: «helmet» + «collar»	1: «helmet»
Body T°C monitoring:	3 channels	4 channels	
Procedure programming:	No	Yes	
Parameter setting:	Manual	Automatic	
Express diagnostics:	No	Yes	
Mobility:	No	No	Yes

IP

No	Name	Document	Status	Author
1	Hypothermia applicator	RF Patent no. 74563 dd. 15.02.2008	valid	Usyshkin I.M. Shevelev O.A.
2	Device for human body local cooling/heading	RF Patent no. 94149 dd. 20.03.2010	valid	Usyshkin I.M. Shevelev O.A.
3	Device for human scalp and brain cord cooling	RF Patent no. 96762 dd. 20.08.2010	valid	Usyshkin I.M. Shevelev O.A.
4	Heat exchanger for human body local cooling systems	RF Patent no. 97504 dd.10.09.2010	valid	Galkin I.I., Agishev S.A., Kostenko A.Yu., Rostovtsev V.I., Chernetsov V.A., Usyshkin I.M., Shevelev O.A.
5	Device for human body local cooling	RF Patent (industrial model) no. 83369 dd.16.10.2012	valid	Usyshkin I.M. Shevelev O.A.
6	Device for therapeutic hypothermia induction	RF Patent no. 126262, 2013	valid	Shevelev O.A.
7	Device for correction of cerebral hyperthermia	RF Patent no. 2615283 04.04.2017	valid	Shevelev O.A., Balaboshko N.G., Gapeev U.A., Syrchenko N.V., Rostovcev V.I.

REGISTRATION DOCUMENTS AND CERTIFICATES

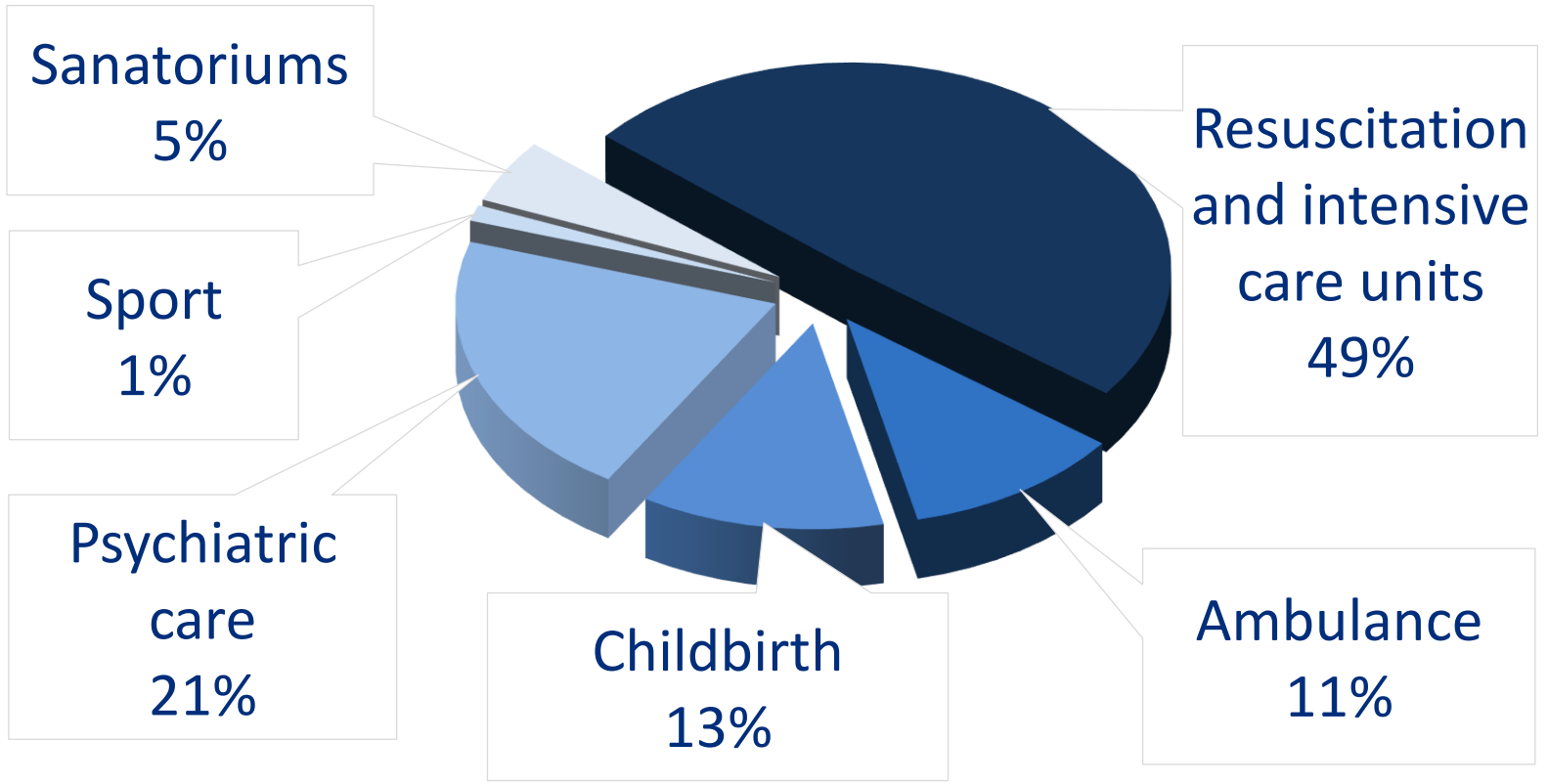
- Registration certificate
- Certificate of compliance
- Performance specifications
- Engineering documentation.
- Application methodology.

Russian Market

Availability in Russia is petty **0,4%**

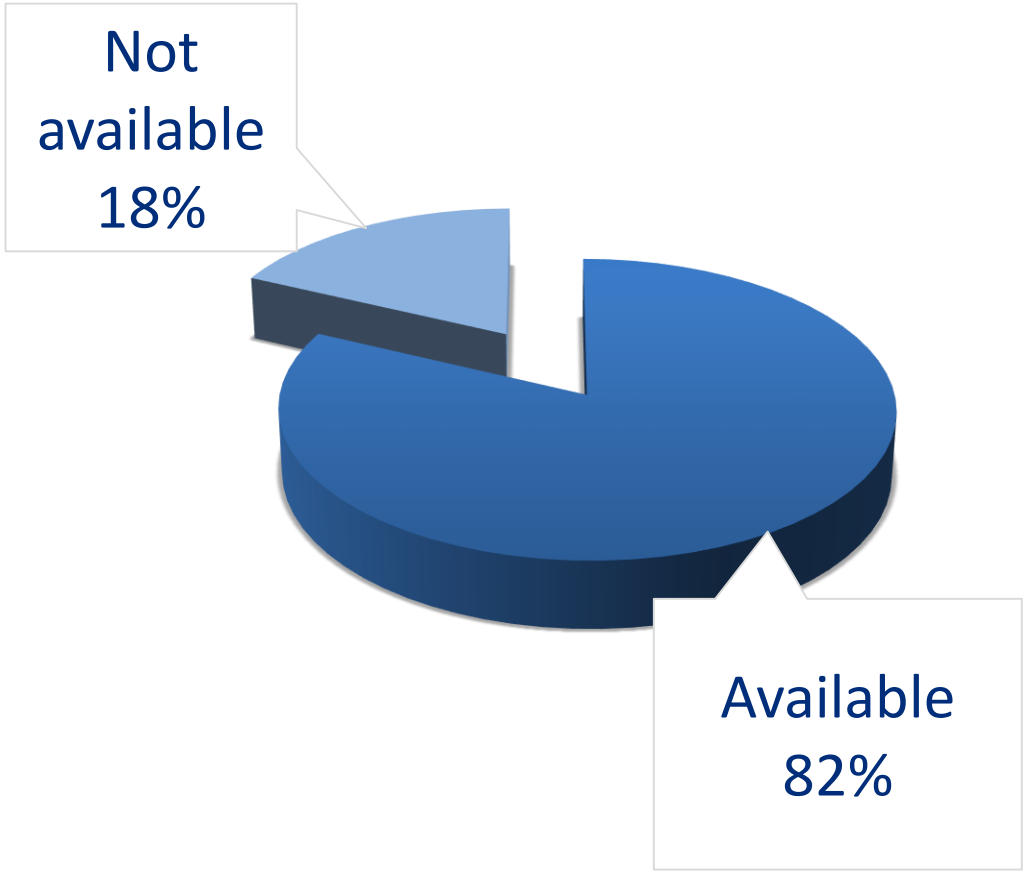
Total therapeutic hypothermia market (Russia):

- 16 197 clinics
- 32 559 «THE»
- $0,77 billion USD



Export potential: annual market growth 7-10%

Availability in Germany (emergency dpt.)



Country	Market volume	
	thousand units	million $ USD
USA, Canada, EU, Japan	275 000	6 132
Kazakhstan	3 464	78
Belarus	9 427	218
China	277 286	6 183
India	253 263	5 645

«THE» market coverage (Russia)

NO.	HEALTH CARE FACILITIES	QTY	FOCUS
1	Neurosurgical Institute named after L.A.Polenov, St-Petersburg	1	Patients after neurosurgical repair of arterial aneurysms rupture
2	Peoples' Friendship University of Russia, Anesthesiology and Emergency Department, clinical site of city clinical hospital No.64, Moscow	2	Patients after cardio-pulmonary resuscitation, with acute ischemic stroke
3	Moscow Scientific-Research Institute of emergency pediatric and traumatic surgery, Emergency Department	1	Children's craniocerebral injury
4	Scientific-Research Institute of Surgery named after Vishnevsky	1	Patients after cardio-pulmonary resuscitation
5	Hospital No.1, Department of Presidential Affairs (Volynskaya hospital), Moscow	1	Patients with acute ischemic stroke
6	Moscow arthrology center	1	Patients with rheumatoid arthritis and degenerative-dystrophic diseases of large-size joints
7	Scientific-Research Institute of sports medicine	1	Orthopedic traumas, athletic craniocerebral injuries
8	Nizhnevartovsk Central Regional Hospital, Emergency Department of Psychoneurological dispensary	1	Patients after cardio-pulmonary resuscitation, neuro-intoxications, intractable fever, abstinence syndrome
9	Yaroslavl Central Clinical Hospital, Emergency Department of Psychoneurological dispensary	2	
10	Saransk Regional Psychoneurological dispensary, Emergency Department	1	
11	Central Clinical Hospital in Kursk city, Emergency Department	1	Patients after cardio-pulmonary resuscitation, with acute ischemic stroke
12	First-aid station in Ufa city	1	
13	Regional Clinical Hospital No.2 in Tyumen city, Emergency Department	2	
14	1st Regional Clinical Hospital (Izhevsk), Emergency Department	1	Patients after cardio-pulmonary resuscitation
	Total:	17	

Competition analysis

Analogues	Stage	Price million RUB	Method	Functionality	Safety	Mobility
«THE-02»	Development	1,6 (consumables 0,01)	Craniocerebral hypothermia Mild general hypothermia	Different states of consciousness Sedation, artificial ventilation (AV) and mio-relaxation is not needed SHF registration of brain T°C. Automated thermoregulation (T°C in 4 areas of the body).	No complications, automated feedback.	No
«THE-02P»	Development	1,6 (consumables 0,01)	Craniocerebral hypothermia	Sedation, artificial ventilation (AV) and mio-relaxation is not needed Automated thermoregulation (T°C in 4 areas of the body).	No complications, automated feedback.	Yes
«HCU 40»	On the market	4,288	General hypothermia	Sedation, artificial ventilation (AV) and mio-relaxation is needed. Only one channel of temperature registration.	Complications associated with general hypothermia.	No
«Arctic-Sun 5000»	On the market	4,002	General hypothermia			No
«3T Heater-Cooler System»	On the market	3,757	General hypothermia			No
«Blanketrol-III»	On the market	3,757	General hypothermia			No
CoolCard 3000	On the market	2,127 (consumables 0,076)	General hypothermia Invasive			No
The RhinoChill®	On the market	0,691 (consumables 0,131)	Craniocerebral hypothermia Intranasal			Yes

Additional areas of application

❖ Areas of application:	➢ Addiction medicine. ➢ Neurology. ➢ Rheumatology. ➢ Sport medicine.
❖ Hypothermia method specifications:	➢ As part of integrated therapy as the main method. ➢ As a subsidiary method which enhances therapy (for instance pharmacological support).
❖ Recommended service parameters:	➢ Service duration: 60 - 120 minutes. ➢ Quantity of the procedures in the treatment: 8 - 10 ➢ Periodicity of procedures: daily – once in two days.
❖ Type of license:	➢ Licensed as a physiotherapy (service)
❖ Classification of the service:	➢ Physiotherapy as part of medical healthcare in the following specialties: ▪ neurology, ▪ Orthopedic/trauma (arthrology), ▪ Psychiatry/narcology, ▪ Sport medicine.

Implementation stage

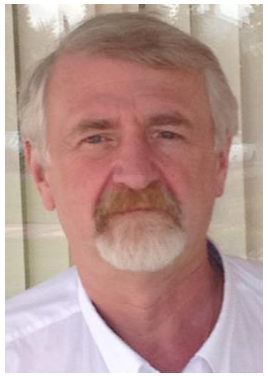
- Clinical base for R&D is established
- Equipment is registered and certified RF, Kazakhstan and Belorussia
- Hypothermia application in resuscitation and intensive care has been mastered
- «THE-01» equipment is operating in emergency medicine (14 hospitals, 4 000 patients)
- Prototypes of THE-02 AND THE-02P have been created.
- Russian Ministry of Healthcare established working group to include therapeutic hypothermia into standards and guidelines of medical care provision.
- «Therapeutic hypothermia research center» has been established
- Agreement for serial production of «THE-01» has been signed

Team:

Oleg Shevelev

Leader/Director of the Project

- Developer of therapeutic hypothermia method and equipment
- M.D. Professor. 3 monographs, 240 published articles
- Over 20 years of experience in production of medical equipment business management



Andrey Butrov

Key specialist/clinician

- Developer of therapeutic hypothermia method and it's clinical application in emergency care
- M.D. Professor. Over 300 published articles, 20 textbooks and methodical manuals
- Laureate of USSR Government award
- Member of European anesthesiology and resuscitation communities and parenteral and enteric nutrition

Galina Repina

Key Specialist/Marketing/Management

- 5 years of experience as Project Manager
- MSc Management/Marketing CASS Business School, City University, London, UK