Annex (49)

Whole-body cryochamber and cryosauna

1. Introduction:

Whole-body cryotherapy (WBC) devices are permitted to be available in the following facilities only:

- Medical centers.
- Medical spa centers.
- Hospitals.
- Physiotherapy and rehabilitation centers.
- A new group of users are professional sport clubs / centers where 3-minutes session of whole-body cryotherapy is post-training procedure to improve and speed up the recovery process.

- **There are 2 types:**
  - Classic cryochambers.
  - Cryosaunas.

Both constructions are supplied with liquid nitrogen. Low temperature inside **classic cryochamber** is produced by evaporating of liquid nitrogen in two or more heat exchangers. There is never a direct contact between user and cryogenic medium in any of system operation mode (closed supply system).

Cryosauna is cooled down by filling with cold vapor of liquid nitrogen. Supply system is considered open because it allows for direct contact between user and cryogenic medium.

Initially, cryogenic chambers were dedicated to medical applications only. Devices could be found exclusively in hospitals or rehabilitation centers. Cryotherapy sessions were always preceded by medical examination and proceeded under supervision of medical personnel.

2. Definition and categorization of the cryotherapy devices:

Cryotherapy devices are dedicated to perform low temperature treatment to cause natural defence reaction of human body. Temperature of cryotherapy treatment are in the range from -40 to -160°C depending on the indication.

- **Devices can be divided into two groups:**

- Whole-body cryotherapy (WBC)
- Partial-body cryotherapy (PBC).

Currently two terms: cryochamber and cryosauna are used interchangeable for the cryotherapy devices. This causes misleading users and disarrangement in the literature.

To distinguish both terms:

Cryochamber: is whole body cryotherapy device designed to provide low temperature surroundings to entire body including head whereas.

Cryosauna : allows to submerge body into low temperature atmosphere up to the shoulders only (head remains at the ambient temperature). These two terms never should be used in turns.

Hazard is defined as a group of characteristics which can potentially cause a loss whereas risk is a combination of the probability of the event leading to this loss and its consequence(s)

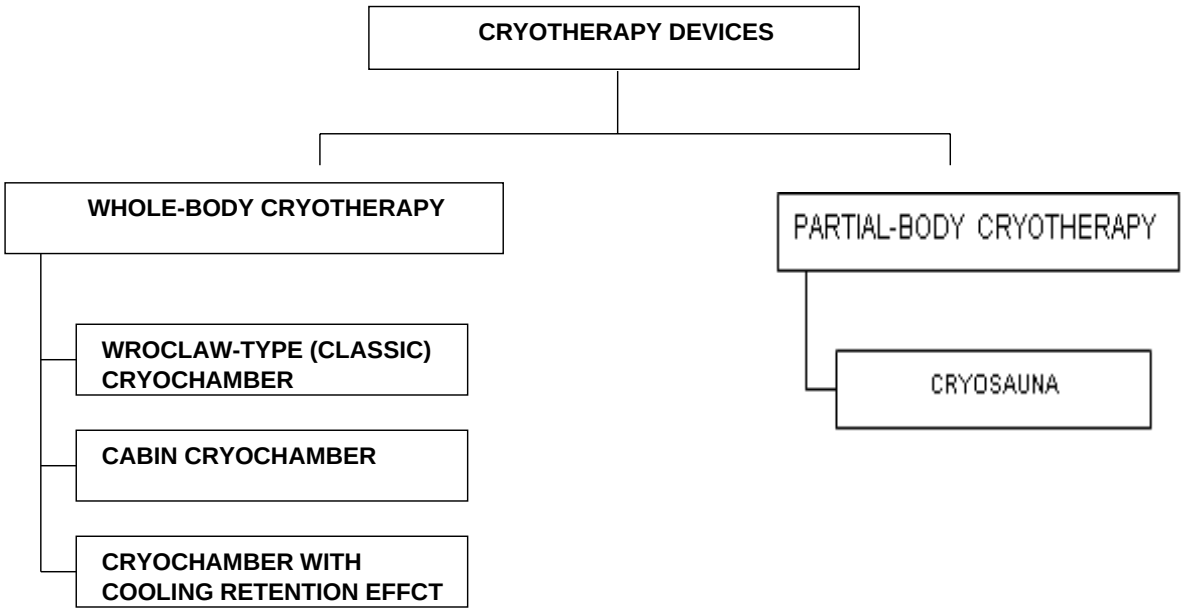

Figure 1. General categorization of the cryotherapy devices

There are four main types of cryotherapy devices (3 cryochambers and cryosauna) currently available on the global market. European and American markets are dominated by two of them: classic cryochambers (Wroclaw-type) and cryosaunas, respectively. Cabin cryochamber is relatively new product with not much information available and confirmed so far whereas cryochamber with cooling retention effect. Availability of this type of cryochamber is strongly limited by required cooling medium (liquid synthetic air).

3. Classic cryochamber and cryosauna constructions:

3-1 Classic (Wroclaw-type) cryochamber:

Classic cryochamber, also called Wroclaw-type consists of two separated rooms: pre- and main chamber. Operation temperatures of pre- and main chambers are -60 and -120°C, respectively.

Cryotherapy session should last max. 3.5 minutes. User spends 30s inside pre-chamber (to adapt to low temperature) and up to 3 minutes inside the main chamber (proper treatment). The entire body of the user including head is exposed to cold breathable air.

Supply system consists of external LN2 tank, transfer lines with set of valves to control flow stream, heat exchangers and silencers.

Required operating temperatures are achieved by evaporation of liquid nitrogen inside 2 or more heat exchangers (fed periodically) located in both chambers.

Waste stream of gaseous nitrogen is transferred directly to the environment.

Supply system is designed to limit any contact between user and liquid nitrogen during entire operation of the cryochamber (all modes incl. cool down, operation and regeneration).

General scheme and picture of classic cryochamber is presented in Figure 2 and Figure 3.

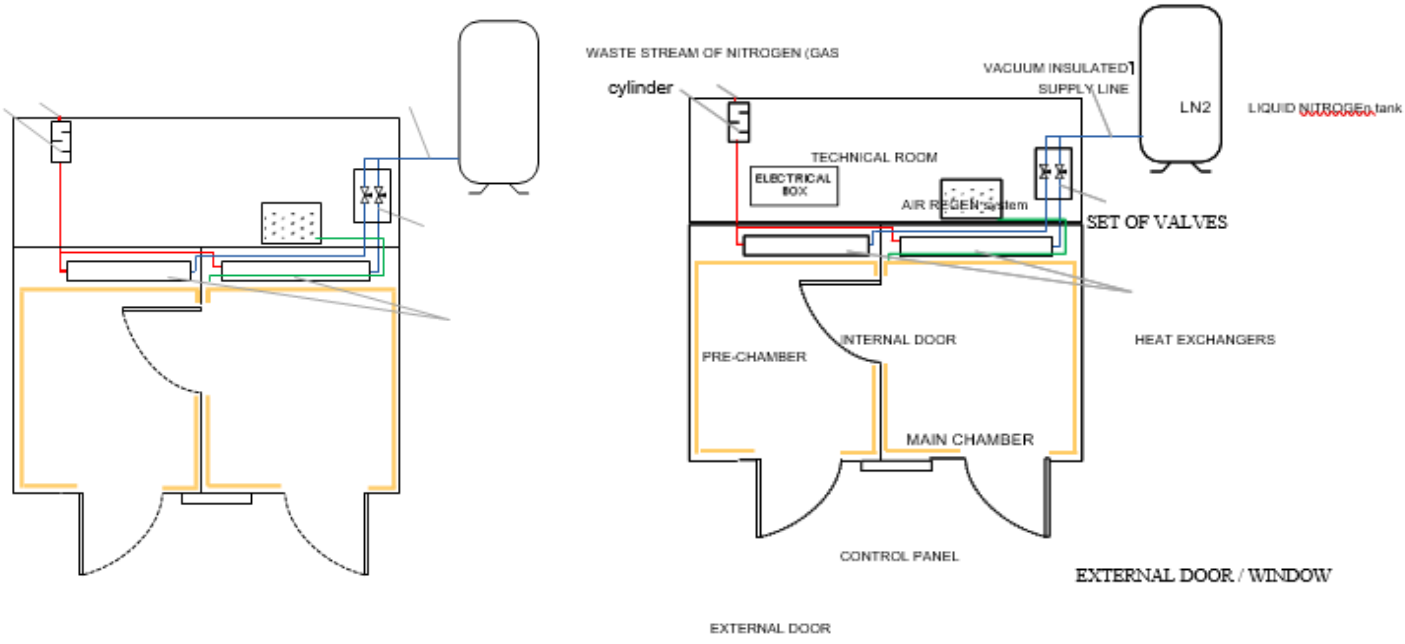

Figure 2. General scheme of classic cryochamber

Figure 3. Front view of classic cryochamber.

3-2 Cryosauna:

Cryosauna is an individual-size can-like enclosure open at the top. User's torso and legs are enclosed in the device and exposed to cold vapor of liquid nitrogen while the head remains above the enclosure at room temperatures. Operation temperature can be regulated between -100 and -160°C.

Liquid nitrogen is transferred from tank, evaporating in the external heat exchanger to be injected as cold gas into the cryosauna enclosure. Fully filled with cold vapor enclosure creates near 0% of oxygen atmosphere surrounding user during entire session. Aspect of direct contact between user and cooling medium distinguishes construction of cryosauna from classic cryochamber.

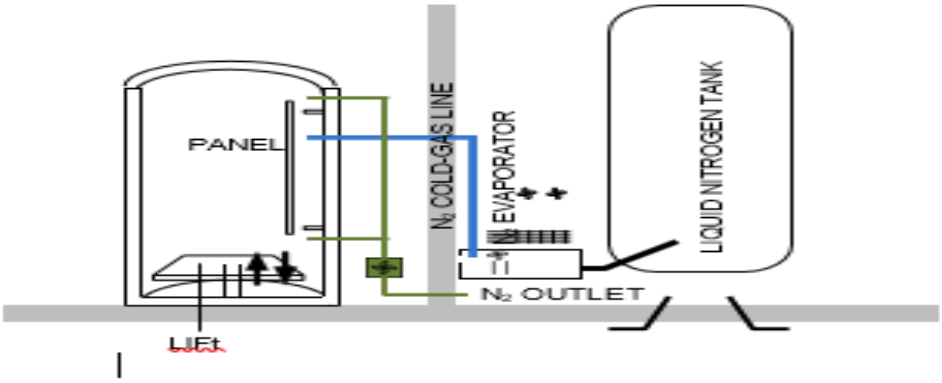

Figure 4. presents general scheme of the cryosauna unit.

Table 1. Basic exploitation data for classic cryochamber and cryosauna:

	Classic cryochamber	**Cryosauna**
Number of users	up to 6	1
Operational temperature	-60°C in pre-chamber -120 ÷ -160°C in main chamber	-100 ÷ -160°C
Cooling medium	liquid nitrogen	liquid nitrogen
Direct contact between users and medium	NO	YES
LN2 consumption	100 - 120 kg to cool down 8 – 10 kg/session	10 kg to cooldown 1.5 kg/session

4. Safety of classic cryochamber and cryosauna operation:

Safety/reliability engineering distinguishes hazard from risk. Both cryochamber and cryosauna are supplied with liquid nitrogen. Basing on fundamental concepts of safety engineering, two main hazards for users of cryotherapy devices can be identified:

a. low temperature which can lead to tissue damage or hypothermia and effect of significant change of volume during evaporation (in case of nitrogen 1 dm3 of liquid evaporates into approximately 700 dm3 of gas) which can result in decrease of oxygen concentration in confined space (Oxygen Deficiency Hazard, ODH).

Since both analysed constructions are supplied with liquid nitrogen, hazard for potential user of cryochamber and cryosauna is same. Furthermore, this hazard cannot be changed as long as liquid nitrogen is used as a cooling medium. Nevertheless, risk for user can be limited either by decreasing probability of the event (e.g. failure) or by introducing actions to mitigate the consequences. Temperature-related risk has been not analysed because one: low temperature is required to perform cryotherapy session and two: several actions are introduced to limit this risk, e.g. wood panels covering all low temperature surfaces, limited time of the session (up to 3 min recommended) with constant supervision of the operating personnel or proper outfit for the users.

b. ODH-related event is defined by decrease of oxygen concentration in breathable air below 18% (when first symptoms of anoxia occur). Potential causes of the ODH event for both cryochamber and cryosauna have been recognized and their probabilities assessed and compared.

4-1 Classic (Wroclaw-type) cryochamber:

Liquid nitrogen flows inside set of heat exchangers located in both pre- and main chambers. There is no direct contact between user and cooling medium in any operation mode (neither during cool down, nor standard operation mode). Decrease of oxygen below safe limit (ODH event) can be caused only by nitrogen release directly inside cryochamber due to the defect of the system

components (supply line or heat exchanger). ODH-related event for classic cryochamber is always caused by the failure mode of the device.

There are two elements which defect can potentially result in ODH: damage of either heat exchanger or LN2 supply/gN2 discharge pipes, schematically shown in Figure 5. Instrumentation (pressure sensors) and valves have not been analysed because they are located outside the cryochamber enclosure.

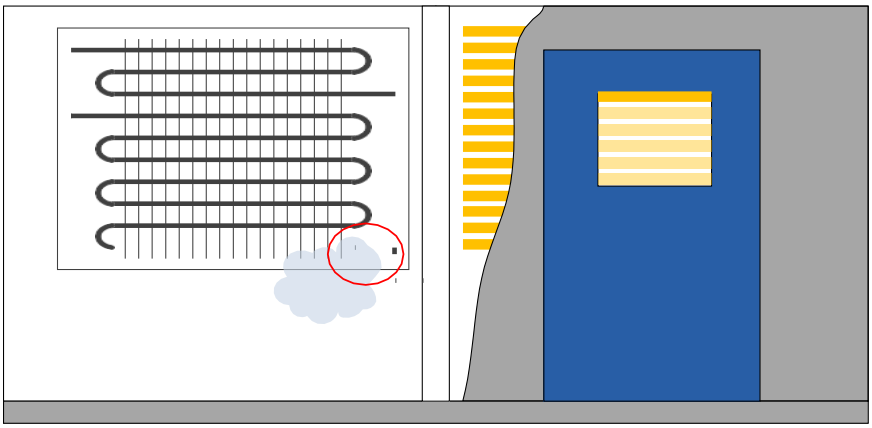

Figure 5. Scheme of supply system inside cryochamber enclosure.

The following data have been taken:

-Total volume of heat exchanger and pipes located in the main chamber: 0.022 m3

-Maximum filling level of liquid in heat exchangers during standard operation mode: 30%

-Volume of main chamber: 7 m3

-Total mass of nitrogen released inside main chamber: 5.7 kg

-Occupation rate of the main chamber (Or): 0.1

-Density of nitrogen at 300 K and 1 bar (pN2@300K): 1.12 kg/m3.

Final O2 concentration is expected to be 11.5%. Users exposed to reduced-oxygen atmosphere may suffer a variety of harmful effect, including very poor coordination, very poor judgment or loose of consciousness (for O2 level below 12%). To mitigate potential consequences of this failure mode, classic cryochamber is equipped with O2 monitoring system activated (laud alarm and shutdown of LN2 valves) in case of oxygen concentration decrease below 18.5 %.

4.2 Cryosauna:

As it was mentioned before, specific construction of cryosauna creates near 0% atmosphere surrounding user during the entire session. In this case, direct contact between user and cooling medium is essential to perform cryotherapy session. Therefore, ODH event can be expected even in standard operation mode (in opposite to classic cryochamber). Human error has been identified as potential cause. Extremely low temperature affecting human body together with lethal atmosphere surrounding user can be considered as unnatural and stressful situation. Possible human errors leading to ODH event include unaware breath in of nitrogen (resulting in immediate loss of conscious), submerge into cold vapours e.g. to pick up something, lack or insufficient instructions provided by operating staff or human ignorance.

Cryotherapy session (both in cryochamber and cryosauna) must be supervised by trained staff (recommendation of the manufacturer). Therefore, it can be assumed that serious consequence for user, like loss of conscious due to lack of oxygen, would be followed by human error of both user and operating staff (caused by lack or too slow reaction for potentially dangerous situation, routine of tasks, fatigue, etc.).

The probability of the event can be decreased to 1·10-6 per session (once in million sessions human error of user and personnel can lead to serious consequences for user). With assumption of 36 sessions/users per working day (3 h of device operation), ODH-related event can be expected every 105 years of cryosauna operation. The probability is much higher in comparison to classic cryochamber (1 event per 800 years).

Due to near 0% of oxygen atmosphere created within the enclosure, cryosauna units are specially designed to avoid user being trapped inside. In case of emergency situation, like loss of consciousness, the enclosure can be immediately opened because of weight of body leaning against the door. Indeed, enclosure can be easily opened both from inside and outside. However, keeping door opened (even for more than 10 minutes) does not stop the flow of cold N2. To keep set temperature, the following operational procedure has been introduced:

-1.5 min of gas delivery and 1min of shutdown.

-Implemented procedure results in release of 18 kg/h of gas.

-The more, opened enclosure allows to spread nitrogen around cryosauna.

-Manufacturer recommends 37.5 m3 as a minimum volume of space available for cryosauna construction.

Assuming 30% of space occupancy by the cryosauna construction, final oxygen content in the confined space would be 13% which is comparable to consequences of failure mode of the classic cryochamber unit. To decrease risk, manufacturer requires mechanical ventilation system and oxygen sensor installed in the cryosauna room.

5. The physiological effects of cryotherapy are:

a. Vasoconstriction
b. Decreased temperature
c. Tissue destruction
d. Increased or decreased inflammation
e. Decreased metabolism
f. Decreased or increased pain
g. Decreased nerve conduction
h. Decreased blood flow
i. Decreased muscle spasm
j. Increased tissue stiffness
k. Decreased arthrogenic muscle inhibition
l. Decreased circulation

6. Benefits of cryosauna:

Specific effects attributed to the cryosauna are:

a. Pain relief
b. Decreased inflammation
c. Increased metabolism
d. Endorphin release
e. Healing
f. Relief of arthritic conditions
g. Relief of acute and chronic injuries
h. Increased venous pressure
i. Exercise recovery
j. Burning of about 300 calories
k. Preventing muscle soreness
l. Improved parasympathetic activity
m. Increased stroke volume
n. Enhanced running performance
o. Decreased core body temperature

7. Contraindications of Classic (Wroclaw-type) cryochamber& cryosauna:

Contraindications for WBC:

- cryoglobulinaemia, cold intolerance, Raynaud disease
- hypothyroidism, acute respiratory system disorders, cardiovascular
- system diseases (unstable angina pectoris, cardiac failure in III and IV stage according to NYHA)
- purulent-gangrenous cutaneous lesions
- sympathetic nervous system neuropathies
- local blood flow disorders, cachexia, and hypothermia
- as claustrophobia and mental disorders hindering cooperation with patients during the treatment.

Contraindications for cryosauna:

- Pregnancy
- Untreated hypothyroidism
- Chronic respiratory disease
- Severe hypertension
- Cardiovascular disease
- Recent stroke
- Uncontrolled seizure
- Fever
- Bleeding disorders
- Infection
- Claustrophobia
- Intolerance to cold

8. Specific Engineering requirements:

- The room size should not be less than (9 m2). However, a room can be (6 m2) if the Nitrogen Dewar's are stored in a separate room and connected through the wall.
- An optional layout can have the Dewar's in a separate room, routing the hose through the wall.

1. a single cryotherapy chamber to be used in a single room to keep the privacy.
2. The room where the Dewar's are stored would need a separate oxygen sensor.
3. Only one sensor is necessary. There is also an oxygen sensor built into the chamber. Therefore, no additional oxygen sensors are needed if the Dewar is in the same room.
4. Strong Wi-Fi. You may need a "Wi-Fi extender" if the router is far away from the chamber.
5. A normal 220v, 10-amp outlet.
6. Tile or linoleum is best for flooring although any hard/smooth surface and easy to clean will be okay.
7. The base of the chamber will need to be level, and this is accomplished with adjustable height caster-wheels.

- Air Circulation specifications: Important points:
  - If a fan is required, it will need to exhaust to the outside. A common bathroom-style exhaust fan is often sufficient.
  - Fan Size: The size should not less than 30x30 cm^2.
  - It is not recommended to install the fan directly above the cryo-chamber. If it is directly above the chamber, it will pull nitrogen out of the top of the chamber and into the patient face. A better setup is to have the fan on a wall or ceiling area away from the chamber.

9. Policies and procedures:

- Provide documented policies and procedures, but not limited to the following:
- Informed Consent policy: the consent form shall contain the following but not limited to: (refer to National Informed Consent Policy)
  - Organization name
  - Patient name, age and gender
  - Treating therapist and supervisor name
  - Precautions
  - Pre and post treatment management
  - Possible complications
  - Name and signature of patient, professional and witness.

- Date of the procedure.

- Care regulation
- Patient health record/ Medical Record
- Infection control policy
- Fire safety and evacuation
- Patient safety manual
- Response to emergencies
- Treatment complications and treatment termination
- Staff documentation
- Incident Reporting
- These documents shall be read and signed off by all staff at the facility.
- The facility shall maintain contracts with, but not limited to:
    - Nearby hospital to accept patients in case of any complication or emergency.
    - Ambulance service
    - Annual preventive maintenance of the chambers with the manufacturing company or an authorized dealer

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