Safety aspects of whole-body cryochamber and cryosauna operation

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Abstract. Interest in low temperature treatment is constantly increasing. Whole-body cryotherapy (WBC) devices are becoming available not only in medical centers but also in local gyms and spa centers. A new group of users are professional sport clubs where 3-minutes session of whole-body cryotherapy is post-training procedure to improve and speed up the recovery process. There are four different types of WBC devices available on the market and offered to commercial (non-medical) users. The American and European market is dominated by two of them: classic cryochambers and 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. Open supply system of cryosauna is primary and most questionable issue of its operational safety, particularly after tragic accident in October 2015. This paper presents the comparative analysis of classic cryochamber and cryosauna from safety point of view. Both devices have been analyzes and tested on existing systems in operation. Paper gives detailed analysis of constructions, supply systems and working parameters. Special attention has been focused to problem of oxygen deficiency hazard. Different failure or accident scenarios have been analyzed and discussed.

1. Introduction
Since 1978 when first cryochamber was constructed in Japan, their constructions and supply systems have been slowly evaluating into the current state and variety. Despite treating pain with cold is natural and well known for ages, there is no wide historical background for the medical cryogenic chambers. They are considered as relatively new devices. Cryochambers were out of the interest of most medical doctors and engineers in the 80s and 90s. Only few countries have been continuously developing, improving and testing cryogenic chambers from both technical and medical point of view.

First Polish cryochamber was constructed in 1989. Since then, cryotherapy has become appreciated method supporting treatment of movement disorders. Sessions are reimbursed by national health insurance (Polish National Health Fund). More than 230 of cryochambers in operation together with experience of several millions of cryotherapy sessions performed places Poland within the leaders in cryotherapy and cryochamber technology right now.

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. Significant change was
noticed few years ago. Athletes have pointed their attention to whole-body cryotherapy (WBC) as an alternative method of post training recovery. Growing interest of sport, spa & wellness industries have opened a new market for the manufacturers. Cryochambers have entered gyms, training and SPA centers becoming available for commercial (non-medical) users and supervised or operated by personnel without medical background.

First lethal accident in cryotherapy device was reported in the USA in October 2015. 24-years old manager of SPA center was found dead after she became trapped in the low temperature chamber overnight. She broke principal safety rule taking session without any supervision. Strong discussion concerning safety issues of the cryotherapy devices has been started resulting in the FDA statement (U.S. Food and Drug Administration) released on July 5th, 2016. Two-page document titled “Whole Body Cryotherapy (WBC), A Cool Trend that Lacks Evidence, Poses Risks” covers general information concerning WBC, available devices and potential risks for users. Content of this document proves that WBC technology requires alignment, introducing definitions and recommendations or standards for manufacturers.

2. Definition and categorization of the cryotherapy devices
Lack of clear definitions concerning cryotherapy both treatment and devices can’t be acceptable anymore. General definition states that 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) and partial-body cryotherapy (PBC) systems.

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.

Figure 1 shows proposed categorization of the cryotherapy devices.

![Figure 1. General categorization of the cryotherapy devices.](image)

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 is not widely used outside Poland. Availability of this type of cryochamber is strongly limited by required cooling medium (liquid synthetic air). Therefore, this paper has been focused exclusively on the comparison of classic (Wroclaw-type) cryochamber and cryosauna.

3. Comparative analysis of classic cryochamber and cryosauna constructions

3.1. Classic (Wroclaw-type) cryochamber

Classic cryochamber, also called Wroclaw-type (from the name of the city where first Polish cryochamber was constructed) 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 30 s 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.

![General scheme of classic cryochamber.](image1)

![Front view of classic cryochamber.](image2)

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.

Figure 4 presents general scheme of the cryosauna unit. 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 definitely distinguishes construction of cryosauna from classic cryochamber.

**Figure 4.** General scheme of cryosauna.

Table 1 gathers basic data concerning both classic cryochamber and cryosauna constructions and operational parameters.

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

### 4. Safety of classic cryochamber and cryosauna operation

Safety/reliability engineering distinguishes hazard from risk [4]. 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) [5]. 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: 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 analyzed constructions are supplied with liquid nitrogen, hazard for potential user of cryochamber and cryosauna is same. The more, this hazard can’t 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 analyzed 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. This paper has been focused exclusively on the risk of oxygen deficiency (ODH). ODH-related event is defined by decrease of oxygen concentration in breathable air below 18% (when first symptoms of anoxia occurs [3]). 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 analyzed because they are located outside the cryochamber enclosure.

![Figure 5. Scheme of supply system inside cryochamber enclosure.](image)

Table 2 presents results of probability calculation for the failure mode: nitrogen released inside main chamber. Total length of the pipes and solder joint have been assessed on the basis of commercially available classic cryochamber (equipped with 2 heat exchangers).

| Defect                | Total length of the element | Failure rate   | Probability of the defect |
|-----------------------|-----------------------------|----------------|---------------------------|
| Solder joint non-tight| 37 m                        | 5.07·10^{-6} m^-1 year^-1 | 1.88·10^{-3} year^-1 | |
| Cold pipe leakage     | 260 m                       | 8.45·10^{-6} m^-1 year^-1 | 2.20·10^{-3} year^-1 | |
| **Total:**            |                             | **4.08·10^{-3}** year^-1 |                           |

Total probability of ODH-related event caused by either solder joint non-tight or pipe break, has been assessed of 4.08·10^{-3} year^-1. Statistically, it can be expected once in more than 200 years of the device operation.
To assess consequence of the failure mode caused by defect of the supply line, expected concentration of oxygen has been calculated. Lumped parameter isochoric non-adiabatic model of air-nitrogen mixture was used, see equation (1)

\[
c_{O2} = \frac{21\% \cdot (1-O_T) \cdot V_C}{(1-O_T) \cdot V_C + \frac{m_{N2}}{\rho_{N2@300K}}}
\]  

(1)

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 (\(\rho_{N2@300K}\)): 1.12 kg/m³.

Based on the calculation, 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 shut-down 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 vapors e.g. to pick up something, lack or insufficient instructions provided by operating staff or human ignorance. One of the probable scenarios of the lethal accident in 2015 was assuming that victim was trying to pick up her mobile dropped inside the cryosauna.

Based on data derived from nuclear power industry, estimated human error rate per demand can be taken from the range of 1·10⁻³ to 3·10⁻¹ for very stressful incident. For the purpose of this analysis human error rate of 1·10⁻³ per session has been accepted. It assumes that statistically user can make a mistake once per 1,000 sessions. 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 lack of consciousness, the enclosure can be immediately opened because of weight of body leaning against the door. For the purpose of this paper, standard cryosauna has been tested. Indeed, enclosure can be easily opened both from inside and outside. However, keeping door opened (even for more than 10 minutes) doesn’t stop the flow of cold N₂. To keep set temperature, the following operational procedure has been introduced: 1.5 min of gas delivery and 1 min of shut-down. Implemented procedure results in release of
approximately 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.

4.3. Prediction of the ODH-related events for future market of cryotherapy devices

Despite installation of the cryotherapy device is always supervised by both manufacturer and company supplying cryogenic gas, there are no clear standards regulating this technology from production, through commissioning to the standard operation phase. Cryotherapy device installed in the hospitals or rehabilitation centers requires certification according to Medical Directive 93/42/EWG which is focused mainly on the electrical aspect. Pressure Directive PED 2014/68/EU locates system like cryochamber or cryosauna in the lowest category with recommendation of good engineering practice implemented to product design and manufacturing. Monitoring market of new devices dedicated to WBC or PBC, the following conclusion can be stated: lack of safety-related standards allows manufacturers to introduce to the market devices which seems to be designed with belief in high standards of safety guaranteed while the operational risk is obvious and the consequences of defect or human error easy to predict. With new trend of using WBC / PBC devices as a way of improving post training recovery, assuring safety to commercial users becomes primary problem to be solved as soon as possible. Manufacturers predict escalation of the interest (particularly from sport and wellness industries) within next 3 years resulting in significant increase of number of units in operation. Probability of the ODH-related event for classic cryochamber and cryosauna have been assessed of 1.21·10⁻³ year⁻¹ (defect of either pipe or heat exchanger) and 9.54·10⁻³ year⁻¹ (human error of both user and operating staff and assumption of 36 sessions per day for 1 cryosauna), respectively. Despite the probability seems to be very low for a single unit, it increases together with the number of units. Figure 6 presents profiles of number of probable ODH events corresponding to the number of cryochamber and cryosauna operation (10 years of operation assumed). Profiles shows that construction assuring lack of direct contact between user and cooling medium decreases the probability of the ODH event by 5 in comparison to open supply systems.

![Figure 6. Prediction of ODH-related events within 10 years of operation of cryotherapy devices.](image-url)
5. Conclusions
Industrial cryogenic systems are operated and supervised by engineers and well-trained technical personnel with special safety procedures introduced. Cryotherapy devices as cryochambers or cryosaunas are supplied with liquid nitrogen, should be then considered as cryogenic pressure machines characterized by same hazards as industrial, complex systems. Entering cryochambers and cryosaunas into commercial markets requires introducing special approach which assures maximum possible level of operational safety. General analysis of human and non-human (defect of the component) failures proves that safety of the cryogenic devices shouldn’t rely mostly on operator. It must be assured primary by the construction and supported by the operator. Therefore, closed supply systems should be recommended to be used in commercial units.

6. References
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