Chapter

# Operation of Implantable Cardiac Devices in Hyperbaric Conditions

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## Abstract

Implantable devices, including Implantable Cardiac Defibrillators (ICD) and Pacemakers (PM), are being seen with increasing frequency in patients wanting to conduct recreational diving or referred for Hyperbaric Oxygen Therapy (HBOT). Under hyperbaric conditions, these devices are at risk of malfunction, mostly by changes of ambient pressure. In some cases, manufacturers publish information on how their devices operate under increased pressure. Unfortunately, this is not always the case, and for other devices, someone must perform an individual risk-benefit analysis specific for single patient and his/her implanted device. In case of medical treatment, such analysis must take into account the patient's clinical condition, the indication for HBOT, and the capability of the HBOT facility for monitoring and intervention in the chamber.

**Keywords:** diving, hyperbaric medicine, oxygen, defibrillator

## 1. Introduction

The hyperbaric chamber is an active medical device, which is potentially hazardous taking into accounts its application and exposure of people inside to increased ambient pressure and increased partial pressure of oxygen. Typically, in most clinical indications, the internal pressure of 2.5 absolute atmosphere (ATA) (equivalent to 15 m of sea water [msw]) is used, with the range from 1.5 to 6.0 ATA (equivalent to 5–50 msw), for a period of 60 min, with the range from 30 to 120 min, as depending on the specific hyperbaric center [1]. Regardless of using the monoplace chamber, where patient is left alone within the pressure vessel, or in multiplace chamber, where patient is staying in the larger internal space together with medical attendant, as with other patients, if so organized, in all cases, any medical device, either external to the patients or implanted, including Implantable Cardiac Defibrillators (ICD) and Pacemakers (PM), is exposed to increased ambient pressure.

Use of other medical devices for therapeutic purpose in the hyperbaric chamber is also related with additional hazards due to increased pressure, oxygen-enriched atmosphere, electricity, and confined space. Therefore, every medical device introduced into the hyperbaric chamber should be designed in that way that its use in the hyperbaric chamber does not create significant risk of malfunction, damage, or ignition of fire in the hyperbaric environment; this should be certified by the manufacturer for specific conditions (working pressure, maximum allowable content of oxygen, temperature, and humidity). Unfortunately, until now only few medical devices are specifically designed for usage in hyperbaric chambers.

Therefore, medical providers often need to conduct themselves appropriate assessment of the medical equipment needed for continuation of intensive or general care during hyperbaric treatment.

## 2. Risk management process

In Europe, as well as in the rest of the world, the general risk management process applicable for all medical devices is described in the ISO EN 14971 [2]. This concerns also ICDs and PMs. Detailed recommendations for medical devices used specifically in hyperbaric chamber systems are presented in the Annex B of the European Norm CEN EN14931 [3]. This Annex includes a description of all potential hazards that can be created by the use of specific medical devices, as well as the risks induced by them inside medical hyperbaric chambers. Moreover, in order to ensure the highest possible level of safety of the patient treated with the Hyperbaric Oxygen Therapy (HBOT) and the attendants, recommendations are given to both manufacturers of such devices and medical users of hyperbaric installations [3].

Generally speaking, there are three hazards related to the use of medical devices in the hyperbaric chamber:

1. An increased ambient pressure and changes of pressure during compression and decompression can significantly affect mechanical parts of the item, leading to distortion of its structure or even damaged and/or performance deterioration of the medical devices, which have been designed and manufactured for use at normobaric pressure.

2. An increased fractional amount of oxygen, either locally, as so-called "oxygen clouds," or generally in mixed chamber atmosphere, creates risk for fire, especially if combined with a source of ignition, e.g., local overheating or sparks and combustible products (e.g., oil, grease)—see below.

3. The electricity used for medical devices in the hyperbaric environment creates a risk for fire as a potential source of ignition when sparking or overheating.

The preferred method of using medical devices inside hyperbaric chambers is having manufacturer's clearance for specific ambient conditions, confirmed by the appropriate certificated, e.g., "CE certificate" in European Union. However, there are some cases when the medical devices need to be introduced into the hyperbaric environment, but the manufacturer does not certify them for use in such conditions. In those cases, the user of the device (staff of hyperbaric centers) must conduct the safety evaluation before introducing it to the hyperbaric environment. This process includes at least checking the structure of the device, taking into account:

1. Increased ambient pressure and its changes to make sure that it is pressure-resistant or at least it does not have any sealed compartments, which could be mechanically damaged;

2. Increased oxygen fraction in the ambient atmosphere to ensure that it does not contain any material that is either non-compatible with oxygen or easily combustible;

3. Electrical power supply to ensure that it does not use high energy (both with voltage and current) inside the hyperbaric chamber.

In case of any doubt, the use of this medical device in hyperbaric chamber should be abandoned.

## 3. The practice

The number of patients with implanted pacemakers (PM) and automatic implanted cardiac defibrillators (AICD) treated inside hyperbaric chambers for other medical reasons is growing.

Internal cardiac pacemaker cans are semi-rigid pieces of equipment, providing to some degree both water tightness to the internal circuits and protection against external pressure. It seems logical that due to different compressibility, use of a resin-filled ICD/PM should be safer than a gas-filled model [4]. According to general opinion, internal cardiac pacemakers are unaffected by the hyperbaric environment [5]. However—obviously—the pressure resistance can be true only for limited range of pressures. During the ISO-compatible ETO-standard sterilization process, the pressure is from 1.7 up to 2.5 ATA (7–15 msw); therefore, all the devices sterilized by this method are unintentionally tested for at least such overpressure [6]. Some implanted devices were used to at least 2.4 ATA (14 msw) [7, 8]. There are also reports that all pacemakers tested by the authors were adequate to treatment pressure below 3 ATA (20 msw), and some even to 7 ATA (60 msw) [9].

One of the ICD/PM manufacturers officially reported that their devices "should operate normally up to 49.5 feet of seawater (2.5 ATA, 15 msw) and will begin to significantly deform at pressures near 132 feet of seawater (5 ATA, 40 msw)" and that "No loss or degradation of output operation was observed in any of the devices tested; however, rate responsive pacing began to diminish at pressures in excess of 66 feet of seawater (3 ATA, 20 msw), which caused the devices to pace at the programmed lower rate. The loss of rate responsive pacing was observed to be temporary; activity pacing returned at lesser pressures." [10].

There was a suspicion that if ICD leads are damaged, ignition could occur if the ICD discharges, so some experts advised that defibrillation mode of the ICDs should be deactivated before HBOT [11].

Indeed, the question whether dangerous electrical arcing harmful for either patient or any medical attendant touching him/her can occur in case of implanted device malfunction during resuscitation in the hyperbaric chamber is a vital one.

In the literature, there are some reported events concerning skin burns due to faulty automatic ICDs at normobaric conditions [12]. There are also some reports of electric shocks passed to the rescuer doing chest compressions while performing cardiopulmonary resuscitation (CPR) out of the hyperbaric chamber [13–15]. In the statement from the one ICD manufacturer, there is a note that "Although we are not aware of any reported incidences of ICD shock triggered ignition, and do not believe this to be of significant risk, it may be advisable to disable defibrillation therapies, pending further study to the contrary, while patients are undergoing hyperbaric treatments." [10].

Based on results of experiments performed on dogs using energy of 30 joules by the internal defibrillator [16] as well as the analysis of the worst-case scenario (Dr. Jake Freiberger, Duke University, USA, personal communication), the energy released from the malfunctioned ICD should not exceed 0.374 W, which is well below NFPA equipment guideline limit of 0.5 W for any medical devices entering the hyperbaric chamber [17]. In summary, the risk of fire caused by the electric arc initiated by the malfunction ICD/PM can be made negligible, even if the defibrillation option is left ON during hyperbaric session. But, in fact, ICD defibrillation during HBOT has not been reported, nor tested.

In the largest study concerning independent testing of commercially available cardiac pacemakers [18], 40 separate pacemakers supplied by four different manufacturers were exposed to liquid pressurization in a small hyperbaric chamber up to 4 ATA (30 msw) and 7 ATA (60 msw). Throughout the testing, no recording of arrhythmia, reprogramming, or any other electronic dysfunction was noted. During the pressurization period, a transient (<90 s duration) increase of the pacing rate of some rate-responsive pacemakers was noted. This pacing rate increase, which was sometimes large (up to +40 beats per minute), slowed down spontaneously. The mechanical results related to the can's deformation showed that all casings were reversibly distorted during pressurizations. No permanent deformation was observed at pressures up to 4 ATA (30 msw). However, after the 7 ATA test (60 msw), 65% of the devices tested were significantly deformed in the electronic part of the device (**Figure 1**), whereas the battery part was not significantly altered. No connector deformation or damage was noted.

The authors concluded that there was good electronic tolerance for all devices both during and after hyperbaric tests. Also, there was a good tolerance of all the devices studied to a liquid environment with a good water tightness up to 7 ATA (60 msw). So, the risk of dysfunction of a device related to penetration of liquids into the can appears to be very low. And this was in accordance with the data published also on other implantable devices [19].

In the literature, one can find also summary list of ICD/PM, which have been used under different pressures showing no obvious malfunction [20], as well as lists of devices from different manufacturers, which were permitted by the manufacturer to be exposed in real HBOT sessions based on individual requests from referring physicians [21]. These cover different pressures from 1 ATA to 7 ATA (from 0 msw to 60 msw) in most cases.

The list of implanted devices, which have been already exposed to some degree for the hyperbaric conditions, will never be exhaustive, as every year some new devices are showing on the market, and some patients with new devices are referred to the hyperbaric facilities. Moreover, the fact that in some patients, implanted devices works fine, does not mean that it concerns all the items from the series.

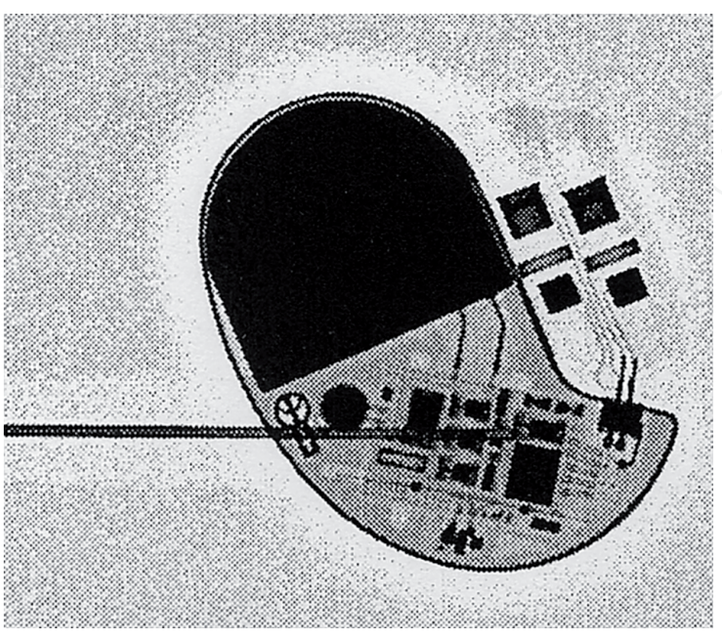

**Figure 1.**
*X-ray picture of a pacemaker. Note maximal deformation, which is located at the tip of the needle (from [18], with copyrights).*

There are several options on how to manage those implanted devices, which are not yet officially approved for hyperbaric conditions [22]. First option is to request manufacturer to support the hyperbaric facility staff with the written opinion about the compatibility of the ICD with the specific hyperbaric conditions (absolute pressure, time of exposure, and number of planned hyperbaric sessions). This can be applicable, if the clinical indication is not acute one, but chronic, when the start of HBOT can be safely delayed. For such approach, it is necessary to have direct contact with the ICD manufacturer's representative in the country, as for international use, there is no communication channel available.

The other option, used also in our hyperbaric center, is to perform the risk assessment by the hyperbaric medicine specialist, which will consider the fact that most modern compact ICD are internally pressure resistant, at least due to the sterilization process (see above). So, the residual risk for ICD failure is low and should be accepted by most patients having obvious clinical indications for using HBOT [23]. Such approach seems valid at least until the pressure of 4 ATA (30 msw of depth). In most reports, the extension of the limit to 7 ATA (60 msw) results in mechanical reversible distortion of the device can with functional disturbances, but without any reported permanent failures in most of modern devices.

Nevertheless, it is highly advisable to constantly monitor ECG of patients with implanted pacemakers and cardiac defibrillators during every HBO session [22]. Every hyperbaric facility should have implemented the protocol for clinical management in case of ICD failure during the hyperbaric treatment. This should cover either switching off the internal device not working properly or external pacing if necessary for life threating situations.

## 4. Conclusions

Implantable devices, including Implantable Cardiac Defibrillators (ICD) and Pacemakers (PM), are being seen with increasing frequency in patients wanting to conduct recreational diving or referred for Hyperbaric Oxygen Therapy (HBOT). Considering the intrinsic properties of the modern implantable devices, it seems that the residual risk for malfunction while being exposed to maximum pressure of 4 ATA, equivalent to the depth of 30 msw, is extremely low. Greater pressures up to 7 ATA (equivalent to the depth of 60 msw) increase the risk of temporarily deterioration with degradation of the performance. Higher pressures, unlikely to be used either in modern HBOT or in recreational conservative diving, can cause permanent damage of the device; unless specifically tested and confirmed by the manufacturer, such exposures should be avoided.

## Conflict of interest

I declare no conflict of interest.

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