RESEARCH ARTICLE

Safety of a continuous glucose monitoring device during hyperbaric exposure

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ABSTRACT

Background: Hyperbaric oxygen therapy has been demonstrated to lower blood glucose levels in patients with diabetes. Continuous glucose monitoring (CGM) allows glucose monitoring in real time. Battery-operated CGM transmitters have yet to be formally tested and given safety approval for use in a hyperbaric environment.

Materials and Methods: We evaluated and tested commercially available Dexcom® G6 CGM transmitters under hyperbaric conditions. Each transmitter contains a 3V, 130-mAh (0.39 Wh) lithium manganese dioxide battery (IEC CR1632) and circuit board that are fully encapsulated in epoxy. Each transmitter is pressurized to 90 pounds per square inch (psi) in an autoclave at 40°C for up to 72 hours during manufacturing to ensure that all enclosed air spaces are eliminated from the epoxy. We compared the CGM components against section 14.2.9.3.17.5 of the 2018 National Fire Protection Association 99 (NFPA 99) Health Care Facilities Code requirements. Six CGM transmitters attached to estimated glucose value generators (EGVGs) underwent 11 pressurization cycles to 45 feet of seawater (fsw). All transmitters were returned to the manufacturer to assess post-exposure structural integrity. G6 sensors, which contain no electrical components or compressible air spaces, do not pose a risk in the hyperbaric environment.

Results: There was no observed change in preset EGVG readings during hyperbaric exposures. Post-exposure testing revealed no structural compromise after repeated hyperbaric exposures.

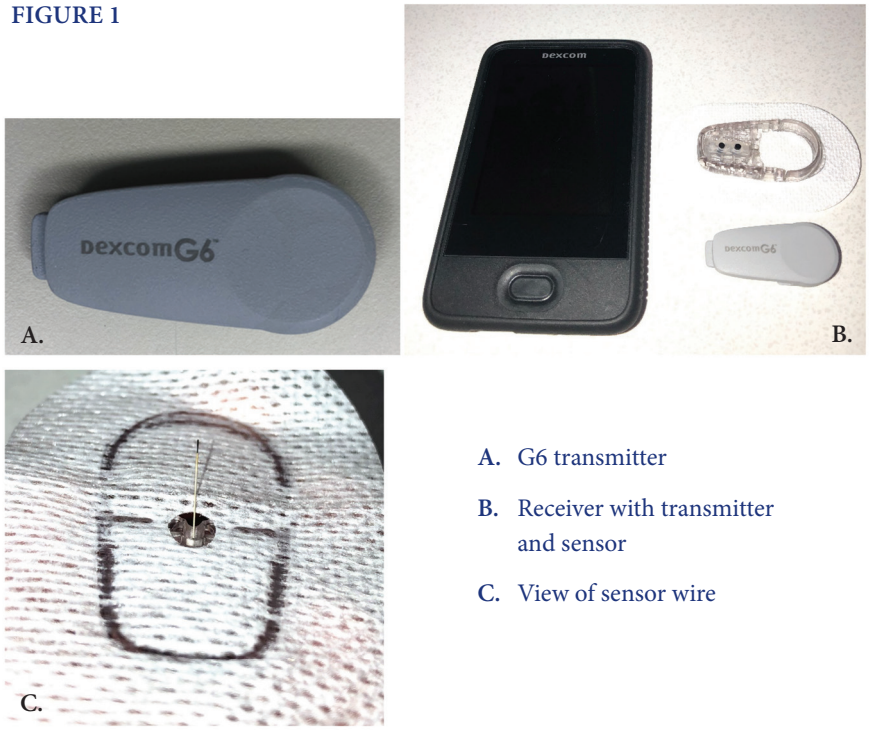
Conclusions: The CGM transmitter meets section 14.2.9.3.17.5 of the 2018 NFPA 99 requirements for battery-operated devices allowed for use in a hyperbaric environment. This analysis revealed no significant safety concerns with subjecting Dexcom G6 CGM transmitters to hyperbaric environments. ∎

INTRODUCTION

Hyperbaric oxygen therapy has been demonstrated to lower blood glucose levels in patients with diabetes [1]. Continuous glucose monitoring (CGM) allows for the monitoring of blood glucose values of patients in real time, providing users with detailed information about their glucose homeostasis. The Dexcom® G6 CGM system (Dexcom, Inc., San Diego, California) provides a glucose measurement every five minutes (up to 288 glucose measurements per day) along with user-defined alerts, alarms and information regarding rate of change. The G6 system includes a sensor, a transmitter, and a receiver (Figure 1). The sensor is inserted into the subcutaneous space and is replaced every 10 days by the patient. The transmitter is attached to the sensor and typically lasts for three months and contains a battery. The receiver may be designated as either the stock medical device receiver provided by Dexcom, or a compatible smartphone with a downloadable application that may be used as an alternative. The transmitter is equipped to store and backfill up to three hours of data to the receiver in the event of temporary loss of connection with the receiver. Currently, no CGM systems are approved for use in hyperbaric environments. The CGM is not intended to be removed daily, and reapplication would be costly for the patient. Very few items are manufactured specifically for the hyperbaric environment; therefore, hyperbaric medicine departments follow a certain set of protocols for device assessment and approval for use in a hyperbaric environment. As described by Burman, et al. [2], several steps are necessary to assess medical equipment for hyperbaric use:

KEYWORDS: CGM; continuous glucose monitoring; diabetes; glucometer; HBO; hyperbaric device clearance; hyperbaric oxygen therapy; hyperbaric safety

FIGURE 1



A. G6 transmitter

B. Receiver with transmitter and sensor

C. View of sensor wire

1. Determine if it is necessary to be used in a hyperbaric environment.
2. Research the history of the device and determine if it has already been tested and approved for use in a hyperbaric environment.
3. Analyze the risks and areas of concern with using the equipment in the hyperbaric environment (i.e. fire, pressure, any toxic and/or physical issues).
4. Test the function of the device under hyperbaric conditions.
5. Document the research and decision processes used as a primary resource for endorsement of use of the device in a hyperbaric environment.

Here we sought to analyze G6 CGM transmitters with respect to their functionality and structural integrity during and after hyperbaric exposure.

METHODS

G6 system components were obtained from the manufacturer. We evaluated the sensor, transmitter and receiver against the NFPA 99 code. Methodology for this research was broken down into three phases – pre-hyperbaric exposure safety assessment, in-chamber testing of the device, and post-hyperbaric exposure evaluation.

Pre-hyperbaric exposure safety assessment and testing

We performed a point-by-point evaluation of the individual CGM components against Chapter 14, Section 14.2.9.3.17.5 of the NFPA 99 code requirements for Battery-Operated Devices.[3] We ensured there were no design aspects that would be affected or compromised by exposure to a hyperbaric oxygen environment. Two members of our team requested and were granted access to the manufacturing process for the CGM. We spoke with engineers and visually inspected the equipment used to produce and test the G6 sensors and transmitters. The manufacturer utilizes estimated glucose value generators (EGVGs) to provide the transmitters with electrical currents that correspond to the glucose-related signals obtained during in vivo use. EGVGs can determine whether the transmitters are functioning properly. We performed identical pre-hyperbaric exposure safety evaluation of the EGVGs before testing.

In-chamber testing

Once the safety assessment was complete we tested the ability of the transmitters to function while in a hyperbaric environment. Testing took place in a multiplace hyperbaric chamber (Oxyheal Medical Systems, Inc., San

Diego, California). The oxygen concentration during each test was monitored and kept below 23.5%. The two functions of the CGM tested were: 1) whether the CGM was accurately recording EGVG signals; and 2) whether the CGM could transmit a Bluetooth signal through a multiplace chamber hull to corresponding receivers located outside the chamber. All transmitters were placed on the far end of the multiplace hyperbaric chamber, approximately 20 feet away from the door. The receivers were placed just outside the vicinity of the hyperbaric chamber door. Six transmitters attached to EGVGs underwent a total of 11 serial two-hour pressurizations to 45 fsw. Simulated glucose values were recorded during hyperbaric exposures. Two EGVGs were set to report values within a hypoglycemic range (<70 mg/dL), two within a euglycemic range (80-140 mg/dL), and two within a hyperglycemic range (>180 mg/dL).

Post-hyperbaric exposure evaluation

The transmitters were then returned to the manufacturer, where they underwent X-ray and further structural and functional analytical testing to make sure the units had sustained no damage.

RESULTS

The first phase of our results summarizes our analyses of the medical necessity, existing literature, and risk analysis of using the Dexcom CGM in the hyperbaric environment.

Medical necessity

While the use of a CGM is not mandatory, there are many operational advantages of utilizing CGMs during hyperbaric treatment. Current protocols for patients with diabetes involve multiple finger-sticks before, during and after treatment. Use of a CGM could improve quality of life for hyperbaric patients in the form of fewer traumatic finger sticks for glucose measurement, as well as providing real-time information to the hyperbaric care team on the patient's glucose values prior to, throughout, and at the end of their hyperbaric treatment. The G6 system is already approved for non-adjunctive use, allowing it to be used for routine diabetes treatment decisions without the need for confirmatory blood glucose tests [4]. By utilizing CGM for glucose measurement, hypoglycemic events during hyperbaric treatment may be mitigated or avoided by providing glucose trend information prior to their arrival as well as during the treatment itself. This is in contrast with finger-stick-only measures that provide a single point in time without any information on the positive or negative trend in rate of glucose change. Blood glucose checks during a hyperbaric oxygen therapy treatment require patient accessibility and are not feasible in a monoplace environment. Therefore, CGM use would allow providers to monitor blood glucose throughout a treatment.

Literature search

The manufacturer did not have any internal studies to use in making a recommendation on the safety or accuracy of using G6 sensors and transmitters in a hyperbaric environment. We found one published report of a single volunteer who wore 48 non-Dexcom sensors and transmitters over the course of two days [5]. This volunteer was exposed to a hypobaric environment (0.5 ATA) on day 1 and a hyperbaric environment (4 ATA) on day 2 while breathing air. This study showed that 90% of the devices functioned during their tests and were more accurate in the hyperbaric environment than in the hypobaric environment.

Areas of concern

Sensor: The sensor was assessed by walking through the manufacturing process and was determined to have no electrical components or enclosed air spaces that could be affected by the hyperbaric environment.

Transmitter: The transmitter contains a circuit board and battery that presented concerns for fire risk; however, the transmitter circuitry and battery are fully encapsulated in epoxy and are pressurized to 90 psi for up to 72 hours at 40°C during manufacturing (Figure 2). This encapsulation would prevent exposure of any potential electrical arc or heat generation to the surrounding hyperbaric environment. The lithium manganese coin battery was assessed against section 14.2.9.3.17.5 of the 2018 NFPA 99 standard on battery-operated devices requirements [3].

1. The lithium manganese dioxide coin battery is 3 volts and 0.39 watts, which is less than the 12 volts and 48-watt maximum limits for Class A (air-filled, multiplace) chambers.
2. The battery is fully enclosed within the epoxy.
3. The battery is one-time use and unable to be changed or recharged.

Bluetooth communication protocols should pose no risk for fire; however, the concern raised was the ability to transmit signal through the multiplace hyperbaric chamber hull.

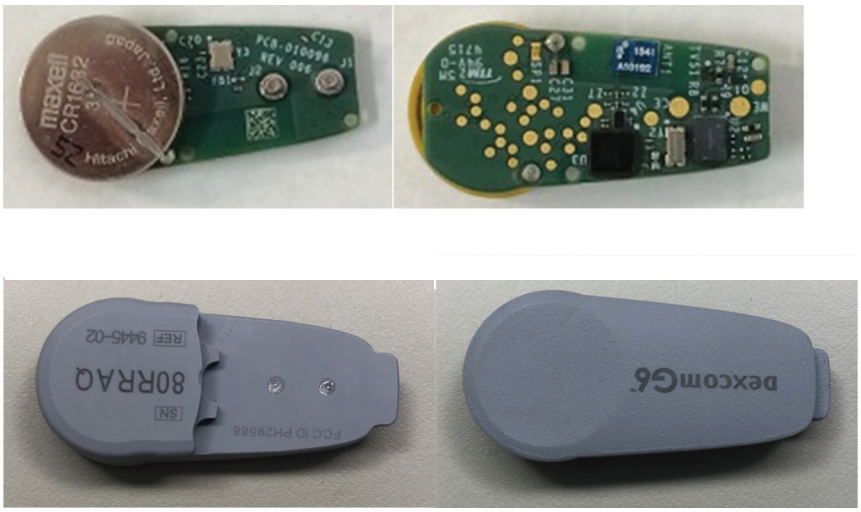


FIGURE 2

Circuit board and battery of transmitter before being encapsulated in epoxy.

The only exposed metal is in the two posts, which are then filed down until flush with the epoxy case.

Receiver: The CGM receivers have rechargeable lithium-ion batteries that have previously been prohibited in a hyperbaric oxygen environment [3]. Modern smartphones contain the same type of batteries and are similarly prohibited. The receivers were maintained outside of the hyperbaric environment during testing.

EGV Generators: The EGVGs do not contain a battery, and the circuitry is fully enclosed in a plastic box which allows a simulated glucose value to be set and sent to the G6 transmitters. (Figure 3)

In-chamber testing

There was no issue with Bluetooth connectivity through the chamber hull/port windows, and the values recorded remained unchanged for a series of 11 two-hour hyperbaric exposures to a pressure of 2.4 ATA.

Post-hyperbaric evaluation

Analytical testing with two-dimensional X-ray and digital caliper measurements showed no change in transmitter size for transmitters that underwent hyperbaric exposure, compared to those that did not [6] (Figure 4). The analytical testing also measured the battery voltage during hyperbaric treatments which showed stability within anticipated parameters through the entire assessment period.[7]

DISCUSSION

The use of non-verified electrical devices in a hyperbaric chamber may pose risks to patients, staff and equipment. By following the safety approval process laid out by Burman et al.[2] we were able to evaluate and test the Dexcom G6 transmitters for use inside a hyperbaric environment.

The biggest concern when using this type of electronic equipment in a hyperbaric oxygen environment is the risk of fire. Fires require a triad of oxygen, a fuel source, and an ignition source. Multiplace hyperbaric operations limit the amount of oxygen by pressurizing the chamber with air, unlike monoplace hyperbaric operations that often pressurize the chamber with near-100% oxygen. Fuel sources such as blankets, sheets, and the patients themselves are plentiful in the hyperbaric chamber, so departments have implemented protocols that limit extraneous and unnecessary items being brought into the chamber. Ignition sources are therefore the most controllable element of the triad. Controlling ignition sources is possible by following the NFPA 99 (Chapter 14) requirements on battery-powered devices, which preclude battery-powered devices from use in monoplace chambers filled with oxygen [6]. Our results show that the G6 transmitter met the NFPA 99 standard for battery-operated devices. Therefore, there was no plausible risk of fire. The NFPA code allows physiological patient monitoring leads in monoplace chambers. Some may be concerned that this CGM may be considered to be

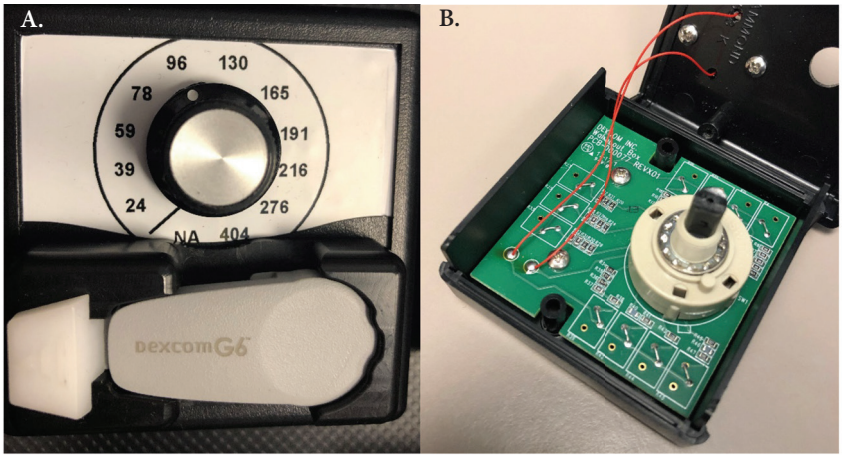


FIGURE 3

A. A transmitter is attached to an EGVG set to simulate an EGV of 96 mg/dL.

B. The internal circuitry and hardware of the EGV posed no risk of fire or implosion during hyperbaric exposure.

C. Receivers located outside of the hyperbaric chamber monitor EGVGs inside the hyperbaric chamber.

more than a lead because it contains a power source with transmission circuitry; however, the battery and power circuit are hermetically sealed and hence isolated from the chamber environment, eliminating any concern for acting as a source of ignition.

The CGM receiver and personal phones use rechargeable lithium-ion batteries, which have previously been prohibited for use inside a hyperbaric chamber [6]. The 2015 and 2018 editions of NFPA 99 (Chapter 14) have different recommendations regarding battery-operated devices [3,6]. The 2015 edition states:

"lithium or lithium ion batteries shall be prohibited in the chamber, unless it has been accepted for hyperbaric conditions or tested by a nationally recognized testing agency."

The 2018 edition makes no mention of lithium-ion batteries in section 14.2.9.3.17.5, but does go on to state that while this allows a limited quantity of lithium and lithium-ion batteries for essential medical equipment, section 14.3.1.6.1.2 of NFPA 99 (Chapter 14) remains in place prohibiting cell phones and personal electronic devices [3].

We did demonstrate that the transmitters could successfully pair and transmit data over a distance of 20 feet through the metal hull of our multiplace hyperbaric chamber. Failing such signal transmission, the three-hour data buffer within the G6 transmitter allows backfilling of data and eventual synchronization of this data with the receiver once the treatment is complete. While this infrequent event would negate the benefit of real-time monitoring, it does not compromise the safe use of this device for patients receiving hyperbaric oxygen therapy.

Another concern elicited is the effect of pressure on devices used within a hyperbaric chamber. Boyle's law states that in an enclosed system, the pressure and volume of an ideal gas are inversely proportional, as long as

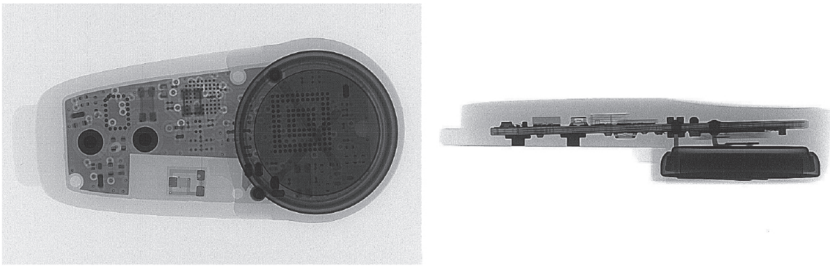


FIGURE 4. X-ray view of one transmitter after going through 11 hyperbaric compressions.

temperature and mass remain constant. In a hyperbaric environment, any enclosed air space will decrease in volume as ambient pressure increases. Therefore, we needed to determine whether there were any enclosed air spaces present in the sensor or transmitter during the manufacturing process that would be subject to such volume changes when exposed to a hyperbaric environment.

During the manufacturing process it was demonstrated that all G6 transmitters are pressurized to 90 psi for up to 72 hours in order to cure the epoxy and eliminate air spaces during manufacturing. This pressure is well above our routine treatment pressure of 45 fsw (35.28 psia) and even above our maximum clinical treatment pressure of 165 fsw (88.2 psia). This is significant, as it means that G6 transmitters would not be at any risk of implosion during our routine wound healing treatments or even our deeper clinical treatment pressures. Additionally, we verified that the CGM would function at the temperature range of typical hyperbaric oxygen therapy operations of 18°C–32°C (65°F–90°F) as the operational conditions for the transmitter are 10°C–42°C (50°F–107.6°F) with humidity of 10%–95%. Post-hyperbaric exposure testing also verified that there was no compromise of structural integrity of the transmitter caused by any potential swelling of the battery or effects of pressure.

We were able to demonstrate that the CGM transmitters functioned as designed by verifying that the EGVG data was accurately recorded throughout 11 serial hyperbaric exposures to 45 fsw. The data logs on the receivers for each transmitter showed no deviation from the preset EGVG value and no data loss from extended disconnection. An occasional signal loss would occur from transmitter to receiver, but the transmitter buffer would act as a safeguard and backfill any data that had not been logged in real time, once it re-paired with the receiver.

Damage to hyperbaric equipment and patient safety are obvious concerns, but it is also important to verify that exposure to hyperbaric environments does not damage medical equipment that is brought into the hyperbaric chamber. Based on X-ray analysis, digital caliper measurements and voltage testing of the transmitter batteries, we are confident there was no damage to the transmitters as a result of the hyperbaric exposures.

The transmitters are replaced every 90 days, so the event of battery swelling from pressure changes are highly unlikely. We are confident there was no damage to the transmitters after reviewing the analytical test results.

LIMITATIONS

The Dexcom G6 transmitters were not formally tested in a monoplace environment as we did not have monoplace chambers available to us. Our safety evaluation, however, did assure us that there would be no increased risk of fire (in the form of an ignition source) for patients inside a monoplace near-100% hyperbaric oxygen environment. Another limitation is that we report only values derived from EGVGs rather than from actual patients undergoing hyperbaric oxygen therapy. In vivo testing has been completed and is being reported separately.

CONCLUSION

This analysis showed that there were no significant safety concerns with subjecting Dexcom G6 CGM transmitters to hyperbaric exposure, and it was shown to be safe for hyperbaric use. Other CGM brands were not tested in this study.

Conflict of interest statement

The authors have declared that no conflict of interest exists with this submission.