# Safety and efficacy of continuous glucose monitoring devices in individuals with diabetes undergoing hyperbaric oxygen therapy: a scoping review

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# Keywords

Hyperbaric medicine; Hyperbaric research; Implantable devices

## Abstract

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**Introduction:** Continuous glucose monitoring devices (CGMs) have emerged as an effective approach to optimise glycaemic control for individuals living with diabetes mellitus. Despite CGMs offering improved patient satisfaction and quality of life, they have been primarily validated for outpatient and home use. This has posed a challenge for patients and providers who wish to incorporate CGMs into clinical settings such as hyperbaric oxygen therapy (HBOT). Those with advanced diabetes mellitus who have diabetic foot ulcers that are refractory to treatment are among the most prevalent users of HBOT. However, those who prefer to use their CGM during HBOT face uncertainty regarding the accuracy and safety of their device under hyperbaric conditions.

**Methods:** The product specifications of commonly used CGMs were collated. In addition, a scoping review of the literature was conducted where Medline, Embase, and Scopus were searched for reports that assess the accuracy or safety of CGMs in hyperbaric conditions.

**Results:** The product specifications of commonly used CGMs by Dexcom, Abbott, Medtronic, and Senseonics demonstrate a maximum validated pressure of approximately 106 kPa (1.06 atmospheres absolute). Our literature search identified five reports, of which four focused on accuracy and one focused on safety of CGMs in hyperbaric conditions. Treatments were conducted in multiplace chambers and cumulatively described 39 participants, of whom 12 have diabetes. Although heterogeneous in nature, the reports generally supported the safety and accuracy of CGMs in hyperbaric conditions.

**Conclusions:** The safety and accuracy of using CGMs during HBOT warrants further investigation. CGMs have not been validated for repeated exposure to hyperbaric conditions and should not be used in oxygen pressurised monoplace chambers until further safety data is available. We provide practical recommendations for use of CGMs in multiplace chambers.

#### Introduction

Diabetes mellitus (DM) and its related complications represent one of the most significant global health crises. In North America, there are currently 50.5 million people living with DM, reflecting an approximate prevalence of 14%.<sup>1</sup> Glucose monitoring is an essential management tool and has traditionally been accomplished with self-monitoring blood glucose (SMBG). However, advancements in diabetes care have made continuous glucose monitoring devices (CGMs) increasingly effective for both short- and long-term use. CGMs offer a user-friendly alternative to SMBG that

provides real-time glucose tracking and reliable reduction in glycated haemoglobin (HbA1c) levels and hypoglycaemic episodes. Indeed, the American Diabetes Association has issued clinical practice recommendations and guidelines ascribing benefits to CGM use for managing diabetes in individuals on daily insulin therapy.<sup>2</sup>

The peripheral neuropathy, small vessel vasculopathy, and impaired immune response that is characteristic of advanced DM often results in complex diabetic foot ulcers (DFUs).<sup>3,4</sup> When unresponsive to conventional approaches, hyperbaric oxygen therapy (HBOT) has been shown to accelerate the

healing of DFUs and improve quality of life.<sup>5-11</sup> CGMs are playing a growing role in managing DM, including among those referred for HBOT. However, little is known regarding how to best integrate CGMs in the hyperbaric oxygen environment.

# CGM DEVICES

The advent of CGMs represents a significant advancement in the field of diabetes, enhancing glycemic control and overall quality of life.<sup>12,13</sup> A CGM typically consists of a wearable sensor inserted into the subcutaneous tissue which automatically measures glucose levels in the interstitial fluid and transmits this information to a nearby receiver every 1-5 minutes for user interpretation. CGMs aid in glycemic control by tracking glucose fluctuations and providing alerts for rapidly changing glucose levels and hypo- and hyperglycaemic thresholds. These alerts not only help maintain glucose levels within a safe range but also encourage lifestyle modifications by highlighting deviations from individual glucose targets.<sup>14,15</sup> Glucose measurement methods vary depending on the sensor, with electrochemical methods being the most commonly used. Furthermore, one optical approach is currently in clinical use.<sup>16</sup> Presently available CGMs are developed by medical technology companies such as Dexcom, Abbott, Medtronic, and Senseonics.

Most modern CGM electrochemical sensors (Dexcom, Abbott, and Medtronic) work through a glucose oxidase enzymatic reaction.<sup>17</sup> Oxidation of glucose leads to a transfer of electrons to the sensor's electrode, producing an electrical current proportional to the glucose concentration in the interstitial fluid.<sup>17</sup> The electrical current is then converted to a glucose concentration that is displayed for the user. Current Dexcom, Abbott, and Medtronic CGM devices are factory calibrated, eliminating the need for daily calibration with SMBG.<sup>18</sup> However, electrochemical sensors have lifespans of 1–2 weeks beyond which their accuracy significantly deteriorates.<sup>18</sup>

Optical sensing is a novel means of glucose detection first brought to market by Senseonics. Their Eversense® E3 CGM device uses a fluorescence-based optical sensor to measure glucose concentrations. This surgically-implanted device consists of a microfluorometer within a capsule coated with proprietary material that produces fluorescence proportional to the glucose concentration in the interstitial fluid.<sup>19</sup> The degree of fluorescence is converted into a glucose concentration that is displayed for user interpretation. The Eversense E3 CGM is the only device that can be left in place for six months; however, it also requires calibration with a SMBG every 12 hours.

It is important to note that interstitial electrochemical and optical sensors indirectly measure blood glucose, which makes them accurate only under steady state conditions.<sup>20</sup>

Capillary glucose is shuttled into the interstitial fluid through simple diffusion which creates a physiological lag time of 5.5 minutes between plasma and interstitial compartments in healthy individuals at rest.<sup>21</sup> This can lead to differences in glucose values between the two compartments which can be exacerbated during times of rapid glucose change, such as in postprandial, exercise, or certain disease states.<sup>22</sup> For instance, although there is significant inter-individual and exercise specific variability, individuals with type 1 diabetes have been reported to have a lag time of 12-35 minutes during moderate to vigorous aerobic exercise.22-25 The lag time may potentially impact the CGM's analytical performance, typically measured as the mean absolute relative difference (MARD) which represents the difference in measurement between the device and a reference standard. Several studies have reported an increased CGM MARD during various forms of activity, indicating a potential decline in accuracy.<sup>22,26-29</sup> Others have shown conflicting evidence regarding CGM performance during exercise.<sup>30,31</sup> As a result, guidelines and position statements have been developed to clarify how CGMs can be used safely and effectively during physical activity.<sup>25,32</sup> Importantly, stimuli that promote rapid glucose fluctuation can potentially have a similar deleterious impact on CGM accuracy, predispose patients to hypoglycaemia, and complicate carbohydrate replacement and insulin dosing decisions.

# USE OF CGMS IN HYPERBARIC OXYGEN CONDITIONS

Diabetic foot ulcers refractory to conventional therapy represent significant cohorts commonly referred for HBOT. However, HBOT presents a unique set of conditions that may impact the accuracy and safety of CGM devices. It is unknown whether increases in pressure or oxygen affect the function, reliability, and safety of CGMs. There are currently no technical or clinical guidelines outlining the appropriate use of CGMs among those undergoing HBOT. As a result, we reviewed the product specifications of commonly used CGMs and have conducted a scoping review of the literature to explore the accuracy and safety of CGMs for individuals undergoing HBOT. We have also provided practical considerations which was informed by a recently published expert consensus guideline regarding the adaptation of CGMs to the hospital setting.<sup>33</sup>

#### Methods

#### PRODUCT SPECIFICATIONS

As part of a comprehensive review, we collated information with respect to the product specification of commonly used CGMs currently on the market. This data was obtained from publicly available records from product monographs of respective manufacturers' websites. We have reviewed the available information on Dexcom, Abbott, Medtronic, and Senseonics websites.<sup>34–38</sup>

# PROTOCOL AND SEARCH STRATEGY

To supplement the product specifications of current CGMs, we mapped the available evidence regarding CGM use in HBOT through a scoping review that conforms to the PRISMA guidelines. The paucity of available literature that explores CGM use in the context of HBOT guided our decision to implement a scoping review approach. We have reviewed the available literature from MEDLINE (Ovid), Embase (Ovid), and Scopus (Elsevier) databases from inception to 19 October 2024. Our search strategy consisted of Medical Subject Headings (MeSH) and keywords related to hyperbaric oxygen therapy and glucose monitoring, with a complete version of the search strategy available in **\*Supplementary File 1** (GK). We have also performed a supplementary search of the literature by reviewing the bibliographies of all included studies and searching Google Scholar for any additional reports.

# INCLUSION CRITERIA

The inclusion criteria consisted of peer-reviewed original studies that reported on the safety or accuracy of CGMs under hyperbaric conditions. Only full length randomised controlled trials, cohort, cross-sectional, case-control, case reports, case-series, and technical reports were included, while commentaries, letters to the editor, editorials, abstracts, and reviews were excluded from this study. Studies that described at least one primary outcome were included in this review: (1) CGM accuracy in hyperbaric conditions or (2) safety of CGMs in hyperbaric conditions.

# SCREENING AND DATA EXTRACTION

The studies were initially screened through title and abstract by two independent reviewers (GK and RK). Thereafter, full texts were screened by two independent reviewers (GK and RK). Conflicts that arose were resolved by mutual agreement. Data extraction was similarly performed by two independent reviewers (GK and RK). The screening and data extraction for this study was conducted through the Covidence Systematic Review Tool (https://www.covidence.org/). Data extracted included study details (primary author and year of publication), patient characteristics (number of participants, presence of diabetes, CGM model), HBOT characteristics (treatment pressure, duration of treatment, type of chamber used), as well as variables related to the primary outcomes. A narrative data synthesis was done using a qualitative approach due to the limited number and heterogeneous nature of the reports identified.

#### Results

The product specifications of commonly used CGMs are available in Table 1. The operational temperatures for CGMs were from approximately 0°C to 45°C. The maximum approved pressure is approximately 106.4 kPa (1.05 atmospheres absolute [atm abs]) across all devices. The lifespan of the Metronic Guardian Connect is seven days, Dexcom G6 and G7 are 10 days, Freestyle Libre 2 and 3 are 14 days, and the Senseonics Eversense E3 is six months. The MARD of all devices ranged from 7.6% to 10.55%. The measurement frequency for Dexcom G6, Dexcom G7, Medtronic Guardian Connect, and Senseonics Eversense E3 CGMs is every five minutes, while the Abbott FreeStyle Libre 2 and 3 measure every minute.

After deduplication, our scoping review of the literature identified 378 total number of reports (Figure 1). After title and abstract screening, there were 15 studies remaining. Once full text screening had concluded, six reports were excluded because no CGM was used, one was excluded because of incorrect study design, and four were excluded because the full text was not accessible. One study was identified in the secondary search of the literature. Five studies ultimately underwent data extraction and are found in Table 2.

# STUDY CHARACTERISTICS

The five studies were published between 2012 and 2021 and involved a total of 39 participants. Twelve of the participants had a diagnosis of DM, while the remainder did not. The devices analysed include the Dexcom G4, Dexcom G6, Minimed Medtronic Guardian Connect, and the iPro Medtronic (with an Enlite sensor) CGMs. The treatment conditions of included studies had significant variability with respect to the pressure and duration of hyperbaric exposure. Four of the studies explored multiplace chambers, while one study did not report which chamber was used. Four studies discussed CGM accuracy, while only one study addressed the safety of CGMs during HBOT.

#### ACCURACY

In an unblinded study of 10 participants with DM undergoing HBOT for two hours in a multiplace chamber (at unspecified pressures), Baines et al.<sup>39</sup> found that venous serum samples, capillary samples drawn with finger pricking, and the glucose oxidase-based Minimed<sup>TM</sup> Medtronic Guardian<sup>TM</sup> CGM sensor demonstrated average glucose readings within 1 mmol·L<sup>-1</sup> of one another. This accuracy was maintained throughout the two hours which enabled real-time glucose trends. In another study, Huang et al.<sup>40</sup> assessed 26 participants without DM who were undergoing HBOT at 243 kPa (2.4 atm abs) in a multiplace chamber for 90 minutes with five-minute air breaks every 30 minutes. They found that the glucose oxidase-based Dexcom G6<sup>TM</sup> CGM device slightly overestimated glucose readings when compared to both glucose oxidase and dehydrogenase-based self-monitoring devices. While the dehydrogenase-based glucometer had

\*Footnote: Supplementary File 1 is available to download from https://www.dhmjournal.com/index.php/journals?id=356

Table 1 Product specifications of commonly used continuous glucose monitors; <sup>a</sup> mean absolute relative difference (MARD) values for CGMs were determined based on heterogeneous studies with
dissimilar populations. In order to maximise consistency, where multiple MARD values were provided by manufacturers, we reported the one corresponding to the population of adults aged 18
and older. Where unique MARD values were provided based on sensor site (arm, abdomen, buttocks, etc.), we reported the overall MARD provided by the manufacturer. If no overall MARD was
documented, we provided the MARD corresponding to each sensor site. <sup>b</sup> Maximum pressure was converted from meters below sea level minimum altitude, where temperature = 21°C and sea level
= 101.3 kPa (1 atm abs). <sup>c</sup> Information not found in user manual, instead obtained from study by Bliss et al. <sup>45</sup> dMARD values provided corresponds with calibration every 12 hours. Calibration 3-4
times per day yields a MARD of 9.64% for the abdomen site and 8.68% for the arm site. atm abs – atmospheres absolute; NR – not reported

Sensor/transmitter	Temperature range	Humidity range	Maximum pressure	Maximum altitude	Power source	Duration	Accuracy (MARD) <sup>a</sup>	Measurement frequency
Dexcom G6	10-42°C	10%-95%	106.1 kPa 1.047 atm abs <sup>b</sup>	4,206 meters	Lithium-ion <sup>c</sup> battery	10 days	9.8%	5 min
Dexcom G7	10-42°C	10%-90%	105.9 kPa 1.045 atm abs <sup>b</sup>	5,000 meters	NR	10 days	8.7%	5 min
Abbott FreeStyle Libre 3	10-45°C	10%-90%	105.9 kPa 1.045 atm abs <sup>b</sup>	3,048 meters	Silver oxide battery	14 days	7.6%	1 min
Abbott FreeStyle Libre 2	10-45°C	10%-90%	105.9 kPa 1.045 atm abs <sup>b</sup>	3,048 meters	Silver oxide battery	14 days	9.2%	1 min
Medtronic Guardian Connect	0-45°C	10%-95%	105.9 kPa 1.048 atm abs	NR	NR	7 days	Abdomen-10.55% Arm-9.09% <sup>d</sup>	5 min
Senseonics Eversense E3	5-40°C	15%-90%	106 kPa 1.046 atm abs	3,048 meters	Lithium polvmer	6 months	8.5%	5 min

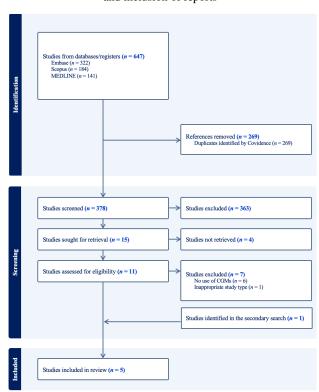


Figure 1 PRISMA flow diagram illustrating the identification, screening, and inclusion of reports

no significant difference in glucose values when comparing normobaric conditions and hyperbaric oxygen conditions (5.05 mmol·L<sup>-1</sup> to 4.98 mmol·L<sup>-1</sup>, P = 0.841), glucose values measured by CGMs significantly increased from 5.607 mmol·L<sup>-1</sup> in normobaric conditions to 5.816 mmol·L<sup>-1</sup> (P < 0.001) in hyperbaric oxygen conditions. Although there was statistical significance, 0.2 mmol·L<sup>-1</sup> is not clinically significant. As part of their study, Huang et al.<sup>40</sup> reproduced findings that are consistent with previous studies involving SMBG devices that show glucose oxidase-based test strips underestimating glucose values when exposed to HBOT, whereas glucose dehydrogenase-based strips do not.<sup>41,42</sup>

The effect of ambient pressure on the accuracy of CMGs is described by Adolfsson et al.43 They showed that the Medtronic Enlite<sup>™</sup> sensor performed adequately under both hypobaric and hyperbaric conditions in a healthy individual who was exposed to a variety of pressures in a multiplace chamber pressurised with room air  $(21\% O_2)$ . The hypobaric test consisted of exposure to 101.3 kPa (1.0 atm abs) for 30 minutes, followed by 50.5 kPa (0.5 atm abs) for 20 minutes, 76 kPa (0.75 atm abs) for 10 minutes, and 101.3 kPa (1.0 atm abs) again for 30 minutes. On the subsequent day, with a new set of sensors, the hyperbaric conditions consisted of 30 minutes at 101.3 kPa (1.0 atm abs), 20 minutes at 405 kPa (4.0 atm abs), 10 minutes at 132 kPa (1.3 atm abs), and 30 minutes at 101.3 kPa (1.0 atm abs). Interestingly, the sensor sensitivity was slightly diminished in hypobaric conditions, but remained unchanged in hyperbaric

Characteristics of included studies; "ISO guideline 15197: at least 95% of the values compared must have a maximum difference of 20% for glucose levels > 75 mg·dL<sup>-1</sup>  $(4.2 \text{ mmol} \cdot \text{L}^{-1})$  and within 15 mg dL<sup>-1</sup> (0.83 mmol \cdot \text{L}^{-1}) for values that are < 75 mg dL<sup>-1</sup> (4.2 mmol \cdot \text{L}^{-1}); HBO<sub>3</sub> - Hyperbaric oxygen; MARD - Mean absolute relative difference; NA - Not applicable; NFPA – National Fire Protection Association; NR – Not reported; T1D – Type 1 diabetes; T2D – Type 2 diabetes

Table 2

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Ref	u	Diabetes Status	CGM Model	Treatment Pressure	Chamber	<b>Treatment</b> duration	Safety	Accuracy
43		Healthy	iPro Medtronic (Enlite sensor)	50.5–405 kPa 0.5–4.0 atm abs	Multiplace	105 minutes	NR	-Hypobaric: accuracy reduced (MARD 14.9 $\pm$ 9.1%) -Hyperbaric: accuracy maintained (MARD 6.7 $\pm$ 7.9%)
44	2	TID	Dexcom G4	NR	NR	45 minutes	NR	2/26 measurements inaccurate, thereby narrowly failing ISO guideline 15197 <sup>a</sup>
45	0	NA	Dexcom G6	138 kPa 1.36 atm abs	Multiplace	11 cycles of 120 minutes	Met NFPA 99 code	NR
40	26	26 Healthy	Dexcom G6	243 kPa 2.4 atm abs	Multiplace	90 minutes	NR	-CGM slightly overestimated glucose relative to glucometers 0.2 mmol·L <sup>-1</sup> glucose change in HBO <sub>2</sub> vs. normobaric air with CGM ( $P < 0.001$ )
39	10	3 T1D 7 T2D	Minimed Medtronic Guardian Connect	NR	Multiplace	120 minutes	NR	-CGM within 1 mmol·L <sup>-1</sup> of capillary and venous samples

conditions. Lastly, although not explicitly stated in their report, Pieri et al's<sup>44</sup> study was likely similarly conducted in a multiplace chamber with hyperbaric air since the purpose of the exposure was to validate the CGM device prior to scuba diving. They found that in two participants with DM, the Dexcom G4<sup>™</sup> CGM was largely accurate with the exception of two of 26 measurements which significantly deviated from the reference standard. Besides having a treatment exposure of 45 minutes, there was otherwise limited information provided regarding the specific hyperbaric conditions.

# SAFETY

One study explored the safety of CGM use in the hyperbaric environment.<sup>45</sup> They found that the lithium-ion batteries in the Dexcom G6 CGM device met the standards of section 14.2.9.3.17.5 of the 2018 National Fire Protection Association 99, and were deemed safe to use. However, this safety assessment was done primarily through an evaluation of the manufacturer's design specifications, while formal testing of this device was limited to a multiplace chamber with maximum oxygen concentrations of 23.5%.<sup>45</sup>

# Discussion

Evidently, the safety and accuracy of CGM use in the context of HBOT warrants further investigation. The reports identified in this review were heterogeneous with respect to the sensor used, treatment conditions, and reported outcomes. None of the studies explored CGM use in monoplace chambers, nor did they consider repeated daily exposures consistent with accepted HBOT clinical protocols. However, the studies that assessed CGM accuracy generally supported their use in the hyperbaric environment. The only study assessing CGM safety in hyperbaric conditions deemed it safe, but testing was limited to a multiplace chamber pressurised with air. CGMs are only approved by manufacturers for clinical use at pressures of approximately 106 kPa (1.05 atm abs), far below typical pressures during HBOT. Furthermore, CGM safety and efficacy studies have conventionally been conducted at room air (21% oxygen).

The questionable accuracy of CGM during HBOT may be partially explained by the physiological changes that occur during treatment. HBOT is known to acutely decrease blood glucose concentrations, particularly in those with DM.<sup>46-48</sup> Although the exact mechanism is poorly understood, the implications are significant considering the decreased accuracy of CGM devices under conditions of rapid glucose flux. However, some studies have reported inconsistencies regarding the effect of HBOT on glycaemia likely owing to methodological differences. For instance, the type of chamber, the pressure and duration of exposure, the glucose detection approach, and the health status of participants were variable across studies, which potentially confounded the results.<sup>49–51</sup> Nonetheless, concerns about intra-chamber hypoglycaemic crises have rightfully prompted many hyperbaric units to require minimum plasma glucose levels for HBOT users.

Several studies have explored the accuracy of CGMs in the context of recreational diving, a hyperbaric environment in which a hypoglycaemic event could be life-threatening. These results are limited to pre/post dive analytical performance due to a lack of a feasible reference standard during the dive itself.<sup>52–56</sup> Despite this limitation, there is a general consensus that CGMs provide potentially valuable information for risk reduction pre and post dive. However, CGMs are only water resistant to a depth of around 2.5–3.5 meters which precludes their use during deeper dives.<sup>57</sup>

The primary safety concern associated with using CGMs during HBOT is the risk of fire. This risk is particularly salient in monoplace hyperbaric chambers which are pressurised with 100% oxygen. Battery powered devices, especially those that are lithium-based, may present a source of ignition in the chamber. In monoplace chambers, a fire would have catastrophic consequences, endangering the life of any occupant within the chamber and any medical personnel in the area. Although a CGM was not used, Tsouras<sup>58</sup> conducted a study where the lithium batterypowered Abbott Optium FreeStyle glucometer was found to be safe in hyperbaric conditions at 23.5% oxygen or less. Despite both Tsouras<sup>58</sup> and Bliss et al.<sup>45</sup> supporting the safety of lithium batteries in hyperbaric conditions, it is critical to conduct appropriate testing in monoplace chambers due to the increased risk that pressurised high fraction oxygen may pose. Furthermore, patients may require up to 60 hyperbaric treatments, which is why it is also necessary to test the effects of repeated pressure cycling on the structural integrity and safety of CGMs.<sup>59</sup> This assessment is of particular importance for devices that are of longer lifespan, such as the implantable Senseonics Eversense E3, which has a lifespan of six months.

#### PRACTICAL CONSIDERATIONS

As CGMs continue to become more prevalent, hyperbaric units should consider establishing clear guidelines that communicate their policies on these devices. Many patients are hesitant to revert to SMBG using finger pricking, underscoring the need for detailed explanations. These guidelines should highlight that none of the current CGMs have been appropriately tested at clinically relevant pressures during repeated hyperbaric sessions, and the accuracy of these devices has not been appropriately validated after single or serial exposures to pressure. CGMs contain batteries that should not be allowed in the enriched oxygen environment of monoplace chambers due to the increased fire hazard they pose. Furthermore, surgically implanted CGMs which have extended lifespans may pose greater safety risks due to the unknown effects of pressure cycling on the device structure and performance. As a result, their use in hyperbaric conditions should be discouraged until

#### Figure 2

Sample informed consent agreement form for clinical HBOT use of CGM devices

I \_\_\_\_\_\_\_\_\_ currently have a continuous glucose monitor (CGM) in place and wish to maintain this device during my hyperbaric oxygen therapy (HBOT) sessions. I understand and agree to the following:

- 1. My CGM device will only be permitted to be used in a multiplace chamber (not monoplace)
- I have a self administered CGM (not a surgically implanted CGM).
  I may continue to wear my CGM during my HBOT session, but my blood glucose will also be monitored using a hospital-approved blood glucose meter and treatment decisions will be based on these results.
- I will keep a back-up supply of all CGM supplies including sensors and dressings in the event a change is required.
- I will change the CGM sensor in keeping with the device instructions, making sure that the
- sensor is replaced prior to the maximum lifespan is reached. 6. I will notify a hyperbaric provider immediately if my CGM indicates my glucose reading is trendine out of tareet (too hieh or low) so that my blood elucose can be tested to confirm
- trending out of target (too high or low) so that my blood glucose can be tested to confirm the trend and appropriate treatment can be initiated according to the prescriber's order. 7. I will allow my hyperbaric provider to assess the sensor during every appointment, including before and after the HBOT session.
- Any of my CGM supplies stored by hyperbaric staff will be returned to me prior to my discharge from the clinic.

By signing below, I acknowledge that I have read, understood, and agreed to the above and that all of my questions have been answered.

Patient signature:
Health care provider name:
Health care provider signature:
Unit/service:
Date:
Time:

more data on their accuracy and safety becomes available. If patients wish to use their self-administered CGM in a multiplace chamber pressurised with air, then a detailed risk-benefit discussion should be documented both verbally and in writing. A sample written consent form, provided as a template, is shown in Figure 2.

Care must be taken to avoid inadvertent wearing of CGMs during monoplace treatment. Patients may sometimes forget they are wearing one particularly if it is surgically implanted or if it is a skin colored self-administered CGM. Adding a CGM assessment as part of a pre-treatment checklist is recommended. The hyperbaric team may want to review the history of the CGM readings to determine the glucose control of each patient, including daily variations, and carefully monitor higher risk patients for early hypoglycaemic symptoms during treatment.

Device manufacturers should be encouraged to perform tests of their devices in hyperbaric environments, similar to what has been done by some manufacturers for implantable pacemakers.<sup>60</sup> These tests are relevant for both hyperbaric oxygen therapy and for recreational diving, with the latter requiring additional evaluation of water resistance.

#### Conclusions

This report highlights the need for more high-quality studies and consensus guidelines to define the reliability, safety, and logistics of CGM use during HBOT. Based on current data, the accuracy of CGMs has not been validated under hyperbaric conditions during repeated HBOT sessions. Furthermore, CGMs should not be allowed in monoplace chambers pressurised with oxygen due to potential fire hazard. The risks and benefits of CGMs in multiplace chambers should be discussed with patients who have an interest in using their CGM during HBOT. Regardless, CGMs should complement but not replace routine glucose monitoring applied for individuals with DM undergoing HBOT.

#### References

- Sun H, Saeedi P, Karuranga S, Pinkepank M, Ogurtsova K, Duncan BB, et al. IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045. Diabetes Res Clin Pract. 2022;183:109119. doi: 10.1016/j.diabres.2023.110945. PMID: 34879977. PMCID: PMC11057359.
- 2 American Diabetes Association Professional Practice Committee. 7. Diabetes technology: standards of care in diabetes–2024. Diabetes Care. 2024;47(Suppl 1):S126–44. doi: 10.2337/dc24-S007. PMID: 38078575. PMCID: PMC10725813.
- 3 Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. N Engl J Med. 2017;376:2367–75. doi: 10.1056/NEJMra1615439. PMID: 28614678.
- 4 Armstrong DG, Tan T-W, Boulton AJM, Bus SA. Diabetic foot ulcers: a review. JAMA. 2023;330:62–75. doi: 10.1001/ jama.2023.10578. PMID: 37395769. PMCID: PMC10723802.
- 5 Chen P, Vilorio NC, Dhatariya K, Jeffcoate W, Lobmann R, McIntosh C, et al. Guidelines on interventions to enhance healing of foot ulcers in people with diabetes (IWGDF 2023 update). Diabetes Metab Res Rev. 2024;40(3):e3644. doi: 10.1002/DMRR.3644. PMID: 37232034.
- 6 Löndahl M, Katzman P, Nilsson A, Hammarlund C. Hyperbaric oxygen therapy facilitates healing of chronic foot ulcers in patients with diabetes. Diabetes Care. 2010;33:998– 1003. doi: 10.2337/dc09-1754. PMID: 20427683. PMCID: PMC2858204.
- 7 Abidia A, Laden G, Kuhan G, Johnson BF, Wilkinson AR, Renwick PM, et al. The role of hyperbaric oxygen therapy in ischaemic diabetic lower extremity ulcers: a double-blind randomised-controlled trial. Eur J Vasc Endovasc Surg. 2003;25:513–8. PMID: 12787692.
- 8 Sharma R, Sharma SK, Mudgal SK, Jelly P, Thakur K. Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials. Sci Rep. 2021;11(1):2189. doi: 10.1038/s41598-021-81886-1. PMID: 33500533. PMCID: PMC7838311.
- 9 Baroni G, Porro T, Faglia E, Pizzi G, Mastropasqua A, Oriani G, et al. Hyperbaric oxygen in diabetic gangrene treatment. Diabetes Care. 1987;10:81–6. doi: 10.2337/diacare.10.1.81. PMID: 3568965.
- 10 Löndahl M, Landin-Olsson M, Katzman P. Hyperbaric oxygen therapy improves health-related quality of life in patients with diabetes and chronic foot ulcer. Diabet Med. 2011;28:186–90. doi: 10.1111/j.1464-5491.2010.03185.x. PMID: 21219427.
- 11 Zhang Z, Zhang W, Xu Y, Liu D. Efficacy of hyperbaric oxygen therapy for diabetic foot ulcers: an updated systematic review and meta-analysis. Asian J Surg. 2022;45:68–78. doi: 10.1016/j.asjsur.2021.07.047. PMID: 34376365.
- 12 Adolfsson P, Rentoul D, Klinkenbijl B, Parkin CG. Hypoglycaemia remains the key obstacle to optimal glycaemic control – continuous glucose monitoring is the solution. Eur Endocrinol. 2018;14:50–6. doi: 10.17925/EE.2018.14.2.50.

PMID: 30349594. PMCID: PMC6182923.

- 13 Johnston AR, Poll JB, Hays EM, Jones CW. Perceived impact of continuous glucose monitor use on quality of life and selfcare for patients with type 2 diabetes. Diabetes Epidemiol Manag. 2022;6:100068. doi: 10.1016/j.deman.2022.100068.
- 14 Jendle J, Agvall B, Galozy A, Adolfsson P. Patterns and predictors associated with long-term glycemic control in pediatric and young adult patients with Type 1 diabetes. J Diabetes Sci Technol. 2023;17:1243–51. doi: 10.1177/19322968221096423. PMID: 35549729. PMCID: PMC10563547.
- 15 Pratley RE, Kanapka LG, Rickels MR, Ahmann A, Aleppo G, Beck R, et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with Type 1 diabetes: a randomized clinical trial. JAMA. 2020;323:2397–406. doi: 10.1001/jama.2020.6928. PMID: 32543682. PMCID: PMC7298607.
- 16 Mihai DA, Stefan DS, Stegaru D, Bernea GE, Vacaroiu IA, Papacocea T, et al. Continuous glucose monitoring devices: a brief presentation (Review). Exp Ther Med. 2022;23(2):174. doi: 10.3892/ETM.2021.11097. PMID: 35069855. PMCID: PMC8764584.
- 17 Nguyen A, White JR. FreeStyle Libre 3. Clin Diabetes 2022;41:127–8. doi: 10.2337/cd22-0102. PMID: 36714257. PMCID: PMC9845075.
- 18 Forlenza GP, Kushner T, Messer LH, Wadwa RP, Sankaranarayanan S. Factory-calibrated continuous glucose monitoring: how and why it works, and the dangers of reuse beyond approved duration of wear. Diabetes Technol Ther. 2019;21:222–9. doi: 10.1089/dia.2018.0401. PMID: 30817171. PMCID: PMC6477582.
- 19 Joseph JI. Review of the Long-term implantable senseonics continuous glucose monitoring system and other continuous glucose monitoring systems. J Diabetes Sci Technol. 2021;15:167–73. doi: 10.1177/19322968211065392. PMID: 32345047. PMCID: PMC7783000.
- 20 Cengiz E, Tamborlane WV. A tale of two compartments: interstitial versus blood glucose monitoring. Diabetes Technol Ther. 2009;11 Suppl 1:S11–6. doi: 10.1089/dia.2009.0002. PMID: 19469670. PMCID: PMC2903977.
- 21 Basu A, Dube S, Slama M, Errazuriz I, Amezcua JC, Kudva YC, et al. Time lag of glucose from intravascular to interstitial compartment in humans. Diabetes. 2013;62:4083–7. doi: 10.2337/db13-1132. PMID: 24009261. PMCID: PMC3837059.
- 22 Zaharieva DP, Turksoy K, McGaugh SM, Pooni R, Vienneau T, Ly T, et al. Lag time remains with newer real-time continuous glucose monitoring technology during aerobic exercise in adults living with Type 1 diabetes. Diabetes Technol Ther. 2019;21:313–21. doi: 10.1089/dia.2018.0364. PMID: 31059282. PMCID: PMC6551983.
- 23 Li A, Riddell MC, Potashner D, Brown RE, Aronson R. Time lag and accuracy of continuous glucose monitoring during high intensity interval training in adults with Type 1 diabetes. Diabetes Technol Ther. 2019;21:286–94. doi: 10.1089/ dia.2018.0387. PMID: 31017497.
- 24 Guillot FH, Jacobs PG, Wilson LM, El Youssef J, Gabo VB, Branigan DL, et al. Accuracy of the Dexcom G6 glucose sensor during aerobic, resistance, and interval exercise in adults with Type 1 diabetes. Biosensors (Basel). 2020;10:138. doi: 10.3390/bios10100138. PMID: 33003524. PMCID: PMC7600074.
- 25 Moser O, Riddell MC, Eckstein ML, Adolfsson P, Rabasa-Lhoret R, van den Boom L, et al. Glucose management for

exercise using continuous glucose monitoring (CGM) and intermittently scanned CGM (isCGM) systems in type 1 diabetes: position statement of the European Association for the Study of Diabetes (EASD) and of the International Society for Pediatric and Adolescent Diabetes (ISPAD) endorsed by JDRF and supported by the American Diabetes Association (ADA). Pediatr Diabetes. 2020;21:1375–93. doi: 10.1111/ pedi.13105. PMID: 33047481. PMCID: PMC7702152.

- 26 Biagi L, Bertachi A, Quirós C, Giménez M, Conget I, Bondia J, et al. Accuracy of continuous glucose monitoring before, during, and after aerobic and anaerobic exercise in patients with Type 1 diabetes mellitus. Biosensors (Basel). 2018;8(1):22. doi: 10.3390/bios8010022. PMID: 29522429. PMCID: PMC5872070.
- 27 Moser O, Pandis M, Aberer F, Kojzar H, Hochfellner D, Elsayed H, et al. A head-to-head comparison of personal and professional continuous glucose monitoring systems in people with type 1 diabetes: hypoglycaemia remains the weak spot. Diabetes Obes Metab. 2018;21:1043–8. doi: 10.1111/ dom.13598. PMID: 30484947. PMCID: PMC6590188.
- 28 Da Prato G, Pasquini S, Rinaldi E, Lucianer T, Donà S, Santi L, et al. Accuracy of CGM systems during continuous and interval exercise in adults with Type 1 diabetes. J Diabetes Sci Technol. 2021;16:1436–43. doi: 10.1177/19322968211023522. PMID: 34111989. PMCID: PMC9631517.
- 29 Dyess RJ, McKay T, Feygin Y, Wintergerst K, Thrasher BJ. Factory-calibrated continuous glucose monitoring system accuracy during exercise in adolescents with type 1 diabetes mellitus. J Diabetes Sci Technol. 2022;18:584–91. doi: 10.1177/19322968221120433. PMID: 36047647. PMCID: PMC11089875.
- 30 Maytham K, Hagelqvist PG, Engberg S, Forman JL, Pedersen-Bjergaard U, Knop FK, et al. Accuracy of continuous glucose monitoring during exercise-related hypoglycemia in individuals with type 1 diabetes. Front Endocrinol (Lausanne). 2024;15:1352829. doi: 10.3389/fendo.2024.1352829. PMID: 38686202. PMCID: PMC11057372.
- 31 Giani E, Macedoni M, Barilli A, Petitti A, Mameli C, Bosetti A, et al. Performance of the flash glucose monitoring system during exercise in youth with Type 1 diabetes. Diabetes Res Clin Pract. 2018;146:321–9. doi: 10.1016/j. diabres.2018.10.001. PMID: 30312715.
- 32 Adolfsson P, Taplin CE, Zaharieva DP, Pemberton J, Davis EA, Riddell MC, et al. ISPAD clinical practice consensus guidelines 2022: exercise in children and adolescents with diabetes. Pediatr Diabetes. 2022;23:1341–72. doi: 10.1111/pedi.13452. PMID: 36537529. PMCID: PMC10107219.
- 33 Galindo RJ, Umpierrez GE, Rushakoff RJ, Basu A, Lohnes S, Nichols JH, et al. Continuous glucose monitors and automated insulin dosing systems in the hospital consensus guideline. J Diabetes Sci Technol. 2020;14:1035–64. doi: 10.1177/1932296820954163. PMID: 32985262. PMCID: PMC7645140.
- 34 Downloads and Guides. Dexcom. [cited 2024Nov 4]. Available from: <u>https://www.dexcom.com/en-CA/downloadsandguides/ search</u>.
- 35 My FreeStyle resources. Abbott; Canada. [cited 2024 Nov 4]. Available from: <u>https://www.freestyle.abbott/ca-en/support/</u><u>myfreestyle-resources.html?srsltid=AfmBOoqOH3FJ</u><u>uSDNuFysgqahy70o3F90WC\_rfogtzq99Vj1Y3SZ\_DMx.</u>
- 36 Freestyle Server. [cited 2024 Nov 4]. Available from: <u>https://</u> <u>freestyleserver.com/payloads/ifu/2023/q3/ART41641-001</u> <u>rev-A-web.pdf</u>. (accessed 4 Nov2024).
- 37 Senseonics Eversense CGM patient user guides. [cited 2024

Nov 4]. Available from: <u>https://www.eversensecgm.com/</u>user-guides/.

- 38 Guardian<sup>™</sup> Connect CGM System user guides and manuals | Medtronic. [cited 2024 Nov 4]. Available from: <u>https://www.medtronicdiabetes.com/download-library/guardian-connect</u>.
- 39 Baines C, Vicendese D, Cooper D, McGuiness W, Miller C. Comparison of venous, capillary and interstitial blood glucose data measured during hyperbaric oxygen treatment from patients with diabetes mellitus. Diving Hyperb Med. 2021;51:240–7. doi: 10.28920/dhm51.3.240-247. PMID: 34547774. PMCID: PMC8608443.
- 40 Huang E, Demirel S, Bliss C, Savaser D, Castle JR. Reliability of the Dexcom G6 continuous glucose monitor during hyperbaric oxygen exposure. Diabetes Technol Ther. 2020;22:360–6. doi: 10.1089/dia.2019.0390. PMID: 31916854. PMCID: PMC7196364.
- 41 Vote DA, Doar O, Moon RE, Toffaletti JG. Blood glucose meter performance under hyperbaric oxygen conditions. Clin Chim Acta. 2001;305:81–7. <u>doi: 10.1016/s0009-8981(00)00418-6</u>. <u>PMID: 11249926</u>.
- 42 Tang Z, Louie RF, Lee JH, Lee DM, Miller EE, Kost GJ. Oxygen effects on glucose meter measurements with glucose dehydrogenase- and oxidase-based test strips for point-of-care testing. Crit Care Med. 2001;29:1062–70. doi: 10.1097/00003246-200105000-00038. PMID: 11378622.
- 43 Adolfsson P, Örnhagen H, Eriksson BM, Cooper K, Jendle J. Continuous glucose monitoring-a study of the Enlite sensor during hypo- and hyperbaric conditions. Diabetes Technol Ther. 2012;14:527–32. doi: 10.1089/dia.2011.0284. PMID: 22428621.
- 44 Pieri M, Cialoni D, Marroni A. Continuous real-time monitoring and recording of glycemia during scuba diving: pilot study. Undersea Hyperb Med. 2016;43:265–72. <u>PMID:</u> 27416695.
- 45 Bliss C, Huang E, Savaser D. Safety of a continuous glucose monitoring device during hyperbaric exposure. Undersea Hyperb Med. 2020;47:13–9. doi: 10.22462/01.03.2020.2. PMID: 32176942.
- 46 Trytko B, Bennett M. Blood sugar changes in diabetic patients undergoing hyperbaric oxygen therapy. SPUMS Journal. 2003;33:62–69. [cited 2024 Nov 4]. Available from: <u>https://dhmjournal.com/images/IndividArticles/33June/</u> <u>Trytko\_dhm.33.2.62-69.pdf</u>.
- 47 Ekanayake L, Doolette D. Effects of hyperbaric oxygen treatment on blood sugar levels and insulin levels in diabetics. SPUMS Journal. 2001;31:16–20. [cited 2024 Nov 4]. Available from: <u>https://dhmjournal.com/images/ IndividArticles/31March/Ekanayake\_SPUMSJ.31.1.16-20.</u> <u>pdf</u>.
- 48 Al-Waili NS, Butler GJ, Beale J, Abdullah MS, Finkelstein M, Merrow M, et al. Influences of hyperbaric oxygen on blood pressure, heart rate and blood glucose levels in patients with diabetes mellitus and hypertension. Arch Med Res. 2006;37:991–7. doi: 10.1016/j.arcmed.2006.05.009. PMID: 17045116.
- 49 Peleg RK, Fishlev G, Bechor Y, Bergan J, Friedman M, Koren S, et al. Effects of hyperbaric oxygen on blood glucose levels in patients with diabetes mellitus, stroke or traumatic brain injury and healthy volunteers: a prospective, crossover, controlled trial. Diving Hyperb Med. 2013;43:218–21. <u>PMID: 24510327</u>. [cited 2024 Nov 4]. Available from: <u>https://dhmjournal.com/images/IndividArticles/43Dec/Peleg\_dhm.43.4.218-221.pdf</u>.
- 50 Stevens SL, Narr AJ, Claus PL, Millman MP, Steinkraus LW, Shields RC, et al. The incidence of hypoglycemia during

HBO<sub>2</sub> therapy: A retrospective review. Undersea Hyperb Med. 2015;42:191–6. <u>PMID: 26152103</u>.

- 51 Heyboer Iii M, Wojcik SM, Swaby J, Boes T. Blood glucose levels in diabetic patients undergoing hyperbaric oxygen therapy. Undersea Hyperb Med. 2019;46:437–45. <u>PMID:</u> <u>31509900</u>.
- 52 Adolfsson P, Örnhagen H, Jendle J. Accuracy and reliability of continuous glucose monitoring in individuals with type 1 diabetes during recreational diving. Diabetes Technol Ther. 2009;11:493–7. doi: 10.1089/dia.2009.0017. PMID: 19698062.
- 53 Adolfsson P, Örnhagen H, Jendle J. The benefits of continuous glucose monitoring and a glucose monitoring schedule in individuals with type 1 diabetes during recreational diving. J Diabetes Sci Technol. 2008;2:778–84. doi: 10.1177/193229680800200505. PMID: 19885260. PMCID: PMC2769802.
- 54 Bonomo M, Cairoli R, Verde G, Morelli L, Moreo A, Grottaglie MD, et al. Safety of recreational scuba diving in type 1 diabetic patients: the Deep Monitoring programme. Diabetes Metab. 2009;35:101–7. doi: 10.1016/j.diabet.2008.08.007. PMID: 19251448.
- 55 Lormeau B, Pichat S, Dufaitre L, Chamouine A, Gataa M, Rastami J, et al. Impact of a sports project centered on scuba diving for adolescents with type 1 diabetes mellitus: New guidelines for adolescent recreational diving, a modification of the French regulations. Arch Pediatr. 2019;26:161–7. doi: 10.1016/j.arcped.2018.12.006. PMID: 30885605.
- 56 Gamarra E, Careddu G, Fazi A, Turra V, Morelli A, Camponovo C, et al. Continuous glucose monitoring and recreational scuba diving in Type 1 diabetes: head-to-head comparison between

free style Libre 3 and Dexcom G7 performance. Diabetes Technol Ther. 2024;26:829–41. doi: 10.1089/dia.2024.0126. PMID: 38768416.

- 57 Jendle JH, Adolfsson P, Pollock NW. Recreational diving in persons with type 1 and type 2 diabetes: advancing capabilities and recommendations. Diving Hyperb Med. 2020;50:135–43. doi: 10.28920/dhm50.2.135-143. PMID: 32557415. PMCID: PMC7481121.
- 58 Tsouras T. Test results for the evaluation of a glucometer for use under hyperbaric conditions: Technical report. Undersea Hyperb Med. 2017;44:27–32. <u>doi: 10.22462/1.2.2017.5</u>. <u>PMID: 28768082</u>.
- 59 Millar IL. Hyperbaric intensive care technology and equipment. Diving Hyperb Med. 2015;45:50–6. <u>PMID: 25964040</u>. [cited 2024 Nov 4]. Available from: <u>https://dhmjournal.com/images/ IndividArticles/45March/Millar\_dhm.45.1.50-56.pdf</u>.
- 60 Medtronic. Answers to questions about implantable cardiac devices Electromagnetic compatibility guide. [cited 2024 Nov 4]. Available from: <u>https://www.medtronic.com/content/dam/ medtronic-com/products/cardiac-rhythm/pacemakers/files/ electromagnetic-compatibility-patient-guide.pdf</u>.

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