

Performance of Infusion Pumps during Hyperbaric Conditions

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Background: Many hyperbaric facilities use infusion pumps inside the chamber. It is therefore important to ensure that this equipment will perform accurately during hyperbaric conditions. The authors tested the function and accuracy of the Imed 965 and Infutec 520 volumetric infusion pumps, the Easy-pump MZ-257 peristaltic infusion pump, and the Graseby 3100 syringe pump.

Methods: The authors calculated the deviations of infused volumes at low and high rates (12–18 and 60–100 ml/h) on three different hyperbaric protocols (up to 2.5, 2.8, and 6 atmospheres absolute [ATA]), resembling a standard hyperbaric oxygen treatment and US Navy treatment tables used for decompression illness and for arterial gas embolism. Two examples of each pump model were examined in every experiment.

Results: The Easy-pump MZ-257 failed to function completely beyond a chamber pressure of 1.4 ATA, making it unsuitable for use inside the hyperbaric chamber. The Graseby 3100 failed to respond to all keyboard functions at 2.5–2.8 ATA, making it unsuitable for use in most hyperbaric treatments. The Imed 965 performed within an acceptable volume deviation ($\leq 10\%$) during most hyperbaric conditions. During the compression phase of the profiles used, and for the low infusion rates only, exceptional volume deviations of 20–40% were monitored. The Infutec 520 demonstrated an acceptable deviation (within 10%) throughout all the hyperbaric profiles used, unaffected by changes in ambient pressure or infusion rate.

Conclusions: Commercially available infusion pumps operating during hyperbaric conditions demonstrate substantial variations in performance and accuracy. It is therefore important that the hyperbaric facility staff make a careful examination of such instruments to anticipate possible deviations in the accuracy of the equipment during use.

IN many hyperbaric facilities treating critically ill patients in a multiplace chamber, infusion pumps must be used inside the chamber, working under elevated and

repeatedly changing ambient pressures. As reported in the literature¹ and as we have found from our own personal experience, not all commercially available infusion pumps function well during such conditions. Furthermore, to the best of our knowledge, no such instrument has ever been specifically designed for the hyperbaric environment.

An alternative option is for the pump to be outside the chamber, where it would work against the pressure gradient between the chamber and atmospheric pressures. However, this method also has a number of inherent technical problems and inaccuracies.² We believe that, to achieve better control of treatment, the infusion pump should be inside the chamber within reach of the attending physician or paramedic.

The accuracy with which potent drugs such as inotropic agents must be administered to the hemodynamically compromised patient requires that the equipment perform with a high degree of precision, otherwise cardiovascular instability might ensue.

During hyperbaric conditions, this drug-induced instability might be additive to the hemodynamic changes secondary to hyperoxia, especially during the compression phase of the treatment.² A significant decrease in heart rate and cardiac output, and a significant increase in systemic vascular resistance, have also been reported in conscious dogs and rats during hyperbaric hyperoxia.^{3,4}

There are several factors that may affect the accurate performance of infusion pumps under high ambient pressure. One such factor is the volume of air-filled spaces in the tubing, which will be reduced in proportion to the increase in pressure. Another is the possible depression of electronic components and the control buttons whenever an air pocket is present.

Manufacturers do not design or test their equipment for hyperbaric use, and hence it is important to examine such instruments. However, we were unable to find more than a few reports in the literature investigating this issue.^{1,5–9}

In the current study, we examined the function and accuracy of the following infusion devices, which are in widespread use in our referring hospitals, some of them in our hyperbaric facility: the Imed 965 (Alaris Medical Systems, San Diego, CA) and the Infutec 520 (Infutec Medical Systems 2000 Ltd., Lod, Israel), which are volumetric infusion pumps; the Easy-pump MZ-257 (Lemi-Op Ltd., Bnei-Brak, Israel), a peristaltic infusion pump; and the Graseby 3100 syringe pump (SIMS Graseby, Watford, United Kingdom).

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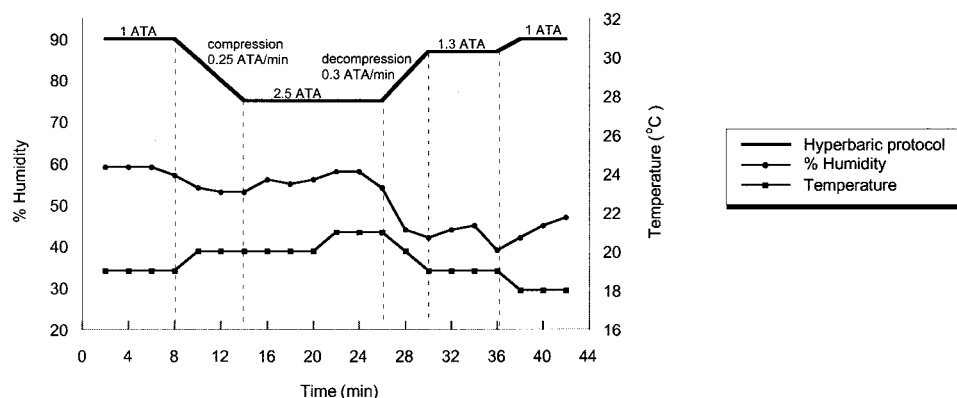


Fig. 1. The hyperbaric oxygen profile.

Materials and Methods

All of the infusion pumps were prepared with a 500-ml solution of D5W (5% dextrose in water; Teva Medical Ltd., Ashdod, Israel) connected to a standard infusion set (Migada, Kiryat-Shmona, Israel) and then to a low-volume high-pressure polyethylene extension tube (Lectro-Cath 1155.05, Vygon, France), which was placed with its free edge in a preweighed plastic test tube. The Imed 965 was connected to this extension tube *via* its original 9260 Microset, and the Graseby 3100 was prepared with a 20- or 60-ml syringe (Terumo, Leuven, Belgium) filled with the same solution and connected to the aforementioned extension tube.

The batteries of all pumps were fully charged before commencing the hyperbaric chamber experiments. We used two examples of each pump model in every experiment to test possible variance between individual instruments. The pumps were placed in the main compartment (16,000 l) of a multiplace, three-lock, mobile hyperbaric chamber (Dräger, Lübeck, Germany). All experiments were conducted by members of our hyperbaric facility staff who had daily experience with similar hyperbaric conditions and were medically fit for diving. Each examiner was assigned to a single infusion pump to ensure accuracy of measurement. Three hyperbaric profiles were examined (figs. 1–3). The first resembled a standard hyperbaric oxygen (HBO) treatment protocol at 2.5 atmospheres absolute (ATA)¹⁰ (HBO profile), and the second resembled US Navy treatment tables for decompression illness at 2.8 and 1.9 ATA¹¹ (USNt profile). These profiles were based on a no-decompression-limit dive and included the accepted safety period of oxygen breathing, to avoid exposing the examiners to the risk of decompression illness. The third protocol, designed to examine the instruments' performance at 6 ATA, resembled US Navy table 6A for the treatment of arterial gas embolism¹¹ (the 6-ATA experiment). The examiners breathed a 50%–50% nitrogen–oxygen mixture from the beginning of the compression phase to the 1.3 ATA decompression stop, when the gas was switched to 100% oxygen. This safety measure was taken to minimize the risk of decompression illness and cerebral

oxygen toxicity. While inside the chamber and operating on batteries, the pumps were primed during normobaric conditions according to the manufacturer's instructions. After being primed, they were allowed to run at the initial experimental rate for 10 min to maximally stabilize initial accuracy. Volume measurements were then taken every 2 min throughout the experiment. The first three measurements were taken at normobaric pressure. This was followed by pressure elevation while the pump rate was not changed. At maximum pressure, the flow rate was increased to test whether a rate change is possible under pressure. Three final measurements were taken on returning to normobaric pressure. The HBO and USNt profiles were examined twice, first with low infusion rates (an initial rate of 12 ml/h increased to 18 ml/h during maximal pressure: HBO-low and USNt-low experiments) and then with high infusion rates (60 ml/h increased to 100 ml/h: HBO-high and USNt-high experiments). The 6-ATA experiment was conducted once, combining low and high rates of 18 and 80 ml/h. Hence, five different experiments were performed. Chamber temperature and humidity were recorded throughout each experiment.

Volume measurements were performed by passing the free edge of the extension tube from one test tube to the other. At the end of each experiment the tubes were reweighed. All weights were taken using analytical scales (Mettler H-10, Zurich, Switzerland, and Mettler-Toledo B154-S, Greifensee, Switzerland). The actual volume infused was calculated by dividing the net weight by 1.05 (the specific density of D5W).

Data Analysis

The main parameter taken as a measure of pump accuracy was the percent deviation of the volume infused, calculated from the difference between the expected and the actual volume infused. A generally accepted criterion for proper accuracy of infusion pumps, as stated in the pumps' manuals, is a maximal volume deviation of 5–10% during normobaric conditions. We believe that up to 10% volume deviation might represent acceptable performance from the clinical point of view.

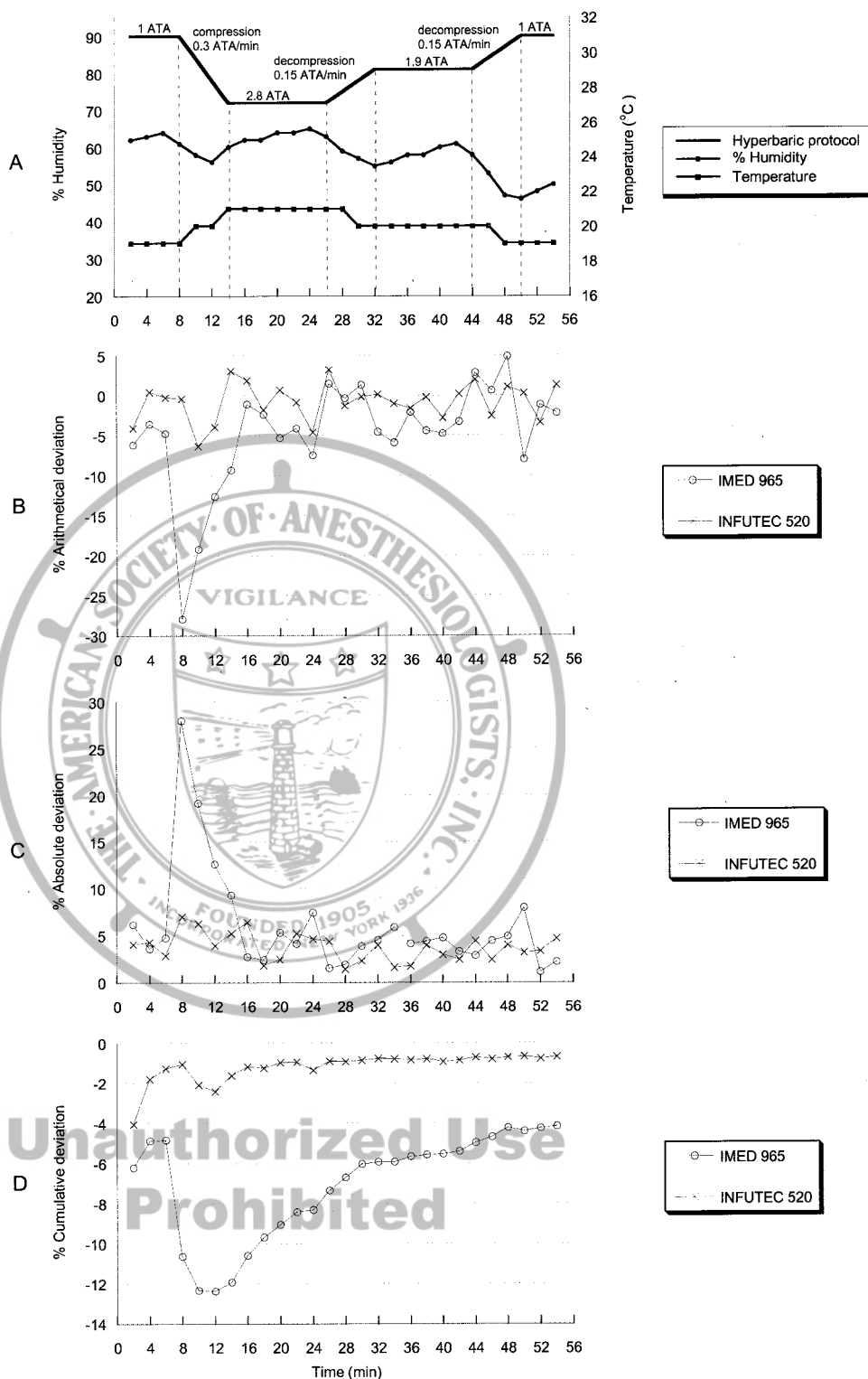


Fig. 2. The United States Navy treatment tables (USNt)-low experiment, demonstrating (A) the USNt hyperbaric profile. (B–D) The deviations of the two pump models that functioned well technically during hyperbaric conditions, expressed as the average value of two different examples of each pump model. % Arithmetical deviation = percent deviation from expected volumes measured every 2 min; % Absolute deviation = percent deviation from expected volumes expressed in absolute values; % Cumulative deviation = percent deviation from the expected cumulative volume.

Fine titration of the drug concentration would then be tailored according to the patient's monitored physiologic response. Because both positive and negative deviations in the volume infused are undesirable from the clinical point of view, the absolute values for volume deviation were also calculated. Another clinically important parameter obtained was the cumulative volume de-

viation in the course of the treatment, since deviations above and below the expected values may balance out. In addition to these accuracy parameters, other performance criteria tested were the ability to change volume and rate parameters during all hyperbaric profiles and the repeatability of the results between different examples of the same pump model. Individual examples of

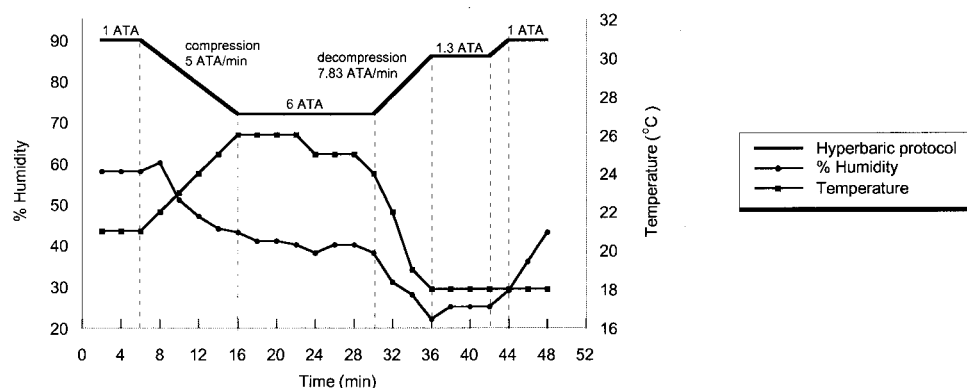


Fig. 3. The 6-ATA hyperbaric profile.

the same pump model were considered to have similar performance if at no point during the experimental profiles the cumulated volume infused by each differed by more than 10%.

Results

The Easy-pump MZ-257 peristaltic infusion pump failed to function completely beyond a chamber pressure of 1.4 ATA. The Graseby 3100 syringe pump failed to respond to a desired change in the infusion rate on two of four examinations at 2.5 ATA and on all four examinations at 2.8 ATA. The instrument did not respond to any of the control buttons, continuing to infuse the previously set rate. It was also impossible to switch the pump off or to reload a new syringe and then reoperate it. The Imed 965 and the Infutec 520 volumetric infusion pumps did not show any operating problems.

Satisfactory performance similarity could be demonstrated for the two examples of the Imed 965 and Infutec 520 models. Although the cumulative volume deviation curves were not strictly overlapping, at no point did the difference between the two Imed 965 pumps exceed 10%. The Infutec 520 pumps fulfilled this criterion in four of five experiments. Specifically, differences greater than 10% (up to 18%) between the two examples of the Infutec 520 were documented in the HBO-low experiment. In that trial, differences of 16–18% were already

identified during normobaric conditions but did not increase further during the hyperbaric profile. Thus, we consider that even on this trial, the two Infutec 520 pumps functioned similarly. An example of the differences in cumulative volume deviation between two examples of the same pump model is shown in figure 4 for the USNt-low experiment.

The Infutec 520 pump showed less than 10% volume deviation for all profiles and rates examined. The Imed 965 met this criterion for the 60-ml/h rate but failed during the compression phase when it was set at the 12- and 18-ml/h rates, when deviations of 20–40% were found. Figure 2, describing the USNt-low experiment, provides an example of the average deviations of the Imed 965 and Infutec 520 pumps, which performed well technically during hyperbaric conditions.

Chamber temperature during the HBO, USNt, and 6-ATA experiments was 18–25°C, 19–26°C, and 18–26°C, respectively. These changes were in accordance with the alterations in pressure. The humidity was 32–67%, 32–65% and 22–60%, respectively, influenced by the external humidity, pressure changes, and ventilation of the chamber (figs. 1, 2A, and 3).

Discussion

Commercially available infusion pumps are not specifically designed or tested by the manufacturers with re-

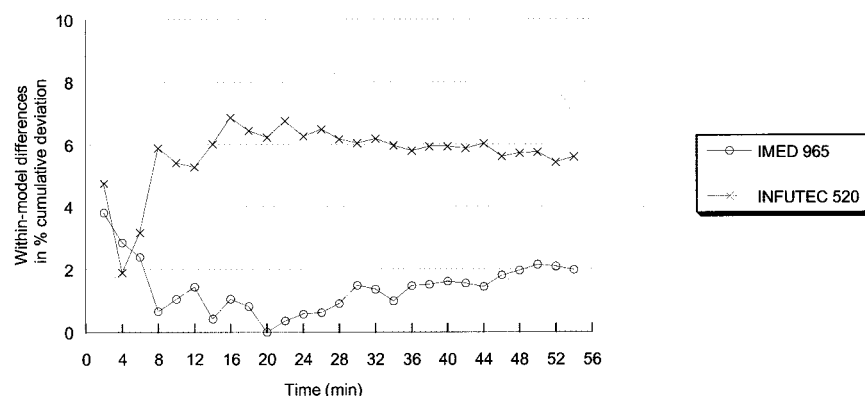


Fig. 4. Variance between two examples of the same pump model expressed as the difference in the percent cumulative volume deviation, during the United States Navy treatment tables (USNt)-low experiment.

gard to their performance during hyperbaric conditions. Some pumps are unable to operate during hyperbaric conditions at all. Those that do function may have technical problems affecting their accuracy, which is of particular importance in the hemodynamically compromised patient.

We tested four models of infusion pumps that are in frequent use in our institute and local referring medical centers to examine their ability to function under increased ambient pressure and decide whether their level of accuracy meets our clinical standards. The pumps were tested first at low infusion rates (12 and 18 ml/h), for which inaccuracies have previously been reported.² The clinical use of inotropic drugs commonly required for the HBO-treated critically ill patient dictates similar infusion rates. High infusion rates (60, 80, and 100 ml/h) were also tested, because other clinical circumstances, such as fluid maintenance therapy, may require these rate levels. Greater accuracy has been reported for high infusion rates compared with low rates during hyperbaric conditions for a different pump model.⁹ We also tested the instruments' ability to change the infusion rate during hyperbaric treatment. This is important to titrate intravenous treatment and react promptly to changes in the patient's condition.

We found that the Easy-pump MZ-257, a peristaltic pump controlled by a drip chamber, did not function at all during hyperbaric conditions. When the drip chamber filled with fluid under increased pressure, the instrument stopped working. The same phenomenon has been described previously in connection with a different instrument that works on the same principle.¹ One may assume that this would occur with any pump controlled by a drip chamber alone; therefore, its use during hyperbaric conditions is not recommended.

The Graseby 3100 syringe pump did not meet the performance criterion, since at chamber pressures of 2.5 ATA and higher the infusion rate could not be changed, and no response could be elicited to any of the other control panel keys. Pressures of 2.5 ATA and higher are used in the treatment of crush injury and acute peripheral traumatic ischemia, decompression illness, carbon monoxide intoxication, gas gangrene, and arterial gas embolism.¹²

In our study, the Infutec 520 and the Imed 965 volumetric infusion pumps demonstrated, for the most part, a deviation within 10%. When we examine the deviations measurement by measurement, in all the experiments the Infutec 520 demonstrated a similar performance pattern irrespective of the pressure phase or the infusion rate; every 2–4 min, it made a partial self-correction of the volume infused (figs. 2B and C). This characteristic might be of advantage, because it may enable the maintenance of better control over drug administration, thus achieving improved hemodynamic stability.

The Imed 965 also demonstrated similar performance patterns in all the experiments, but these were pressure phase-dependent. The deviation increased with the change in chamber pressure, being at its highest during compression, then gradually returning to minimal values as the ambient pressure stabilized. A similar pressure phase-dependent performance pattern has been reported for other types of infusion pumps.^{5,6,9}

During the compression phase of the three experiments when low infusion rates were used, the deviation level of the Imed 965 reached 20–40%. The clinical outcome of such a deviation might be unfavorable to the patient's condition, especially when combined with the hemodynamic instability caused by hyperoxia, which is also reported to be greatest during the compression phase.² However, in the two experiments using a high infusion rate of 60 ml/h, the volume deviation during compression reached only 9%, an observation that supports the results of a previous study reporting satisfactory performance of the Imed 965 when it was set to high infusion rates in the hyperbaric chamber.¹ One possible conclusion regarding the use of the Imed 965 pump is that the required drug could be diluted and delivered at a proportionally higher rate to minimize the delivery deviation, provided fluid overload will not occur.

In summary, our results indicate that the Easy-pump MZ-257 is unsuitable for use inside the hyperbaric chamber. We assume this would be the case with all peristaltic pumps controlled by a drip chamber. The Graseby 3100 is not recommended for use in hyperbaric treatments because of its technical failure on pressure profiles used for most hyperbaric treatment indications. The Imed 965 was found suitable for use during hyperbaric conditions, but special attention should be paid to the patient's physiologic responses during the vulnerable phase of compression. When all of the parameters tested are taken into consideration, of the instruments we examined, the Infutec 520 is the most suitable infusion pump for use inside the hyperbaric chamber.

We conclude that commercially available infusion pumps operating during hyperbaric conditions demonstrate substantial variations in performance. It is therefore important that the hyperbaric facility staff make a careful examination of such instruments to anticipate possible deviations in the accuracy of the equipment during use.

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