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Dosin® – A New Pump Device. Its Construction and Function

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Abstract

The cyclic flow of the Dosin® is useful in interventional radiology since it prevents clotting and increases the mixing with the blood. The flow rate varies from 0.03 mL/s to 5 mL/s and it is recommended to use fluid with a viscosity lower than 3 mPa.s. The outlet pressure is recommended below 300 mm Hg. The Dosin® must be replaced after each patient, alternatively after maximum 24h continuous use.

Introduction

To the many pump inventions already in existence and circulation, we wish to add a whole new concept called *Dosin®* (Figure 1). This Dosin® is based on the principle of continuous flow, in this case with optional, controlled pulsation. The research and development of the Dosin® and the (medical) pump system, in which it is used (*Octapump® Injection System*) was initiated in response to a demand for a new and improved method of delivering fluids to patients. The key requirement was to make the use of refillable syringes obsolete in a cost-effective and user-friendly alternative.

Most syringes, despite their accurate delivery quotas, have a limited volume that necessitates frequent monitoring and filling or changing. This very act is time consuming and potentially dangerous in inexperienced hands.

The new principle, Dosin®, is capable of delivering (medical) fluids of various consistencies in extremely precise amounts regardless of the fluid viscosity. The outlet of the Dosin® goes through another innovation, the bubble detector, which detects any change in direction of a light beam that passes through the content of the outlet. Thus, should an air bubble enter the outflow of the Dosin® and hence be about to enter the blood stream of a patient, the flow of fluid will halt immediately and an alarm will notify the user of the problem.

Basically, the Dosin® is designed to allow adjustable flow rate, up to certain volumes. This pumping effect is achieved by utilizing the internal structure of the cylinder of the Dosin® so as to function as directional valves during the pumping cycle. At recommended flow rates the Dosin® construction is rigid enough to allow a continuous (or pulsed) and accurate (less than 5% deviation) flow rate per pump

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Figure 1. The Dosin®.

cycle. By controlling the rotation rate, together with the well defined pump volume at the operational range, one is able to maintain accurate volume delivery.

Design Inside the Dosin® cylinder (Figure 2), a piston rotates and thereby produces a continuous flow of, in the case of this report, a stroke volume of 3 mL/s. At the same time as the Dosin® rotates, it also reverses back and forth. The design parameters of the Dosin® allow it to achieve a flow rate of between 360 mL/h and 12000 mL/h depending on the application for which it has been programmed.

The Dosin® consists of 5 main parts, a shell, a plunger (above called piston), an axle, a steering notch and a closing lid. The shell, the plunger and the closing lid are together called the cylinder. The housing has connections for an inlet and an outlet. On the outlet is a long straight piece with flat parallel walls which slides into the bubble detector. Both the inlet and outlet have Luer Lock connections to fluid lines. The pumping action is achieved within two cavities that contain the plunger in its housing. The plunger has a semi-helical groove that forces the plunger back and forth as the plunger rotates. Simultaneously, there are two cut-outs on the plunger that are connected hydraulically to either end of the plunger. These cut-outs are situated so as to control the flow. When the volume of the cavity decreases, its cut

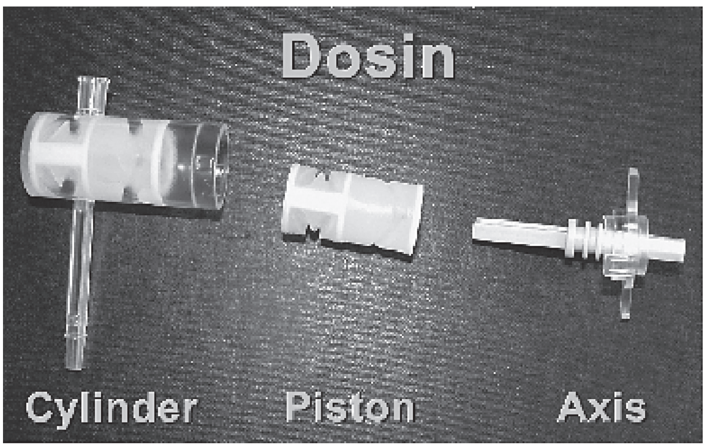

Figure 2. Three of the Dosin®'s 5 parts.

out is connected to the outlet and the other cut out (associated to the cavity that increases its volume) is connected to the inlet. When the axial motion reverses, the cut-outs move from inlet to outlet, respectively.

This pumping construction has a number of benefits, primarily in pumping large liquid quantities as it pumps from a reservoir unrestricted by volume. Since the walls that make up the cavities are solid, the volume is absolutely constant for one revolution. There is no risk of back flow and the motor unit within the pump does not have the capability of revering. The pump does not have parts that travel from the free air thereby eliminating paths for contaminants or other infectious agents to enter the internals of the pump. A rotary motion of the axle drives the plunger around, the steering notch in the semi-helical groove causes the back and forth motion. The axle is run through a rubber O-ring as a seal. All parts of the Dosin® are lubricated at assembly with high viscosity silicon oil. This oil is the standard lubrication method for medical equipment, and does not cause any harm if injected into human tissues. The sealing on the plunger is made in a second injection mould creating a molecular bond to the plastic in the plunger.

Materials

The Dosin® is made of various thermoplastics:

–#Isoplast is used for housing and the closing lid
–#Reinforced PEEK is used for the axle and steering notch
–#Polypropylene is used for the plunger.
–#The seals on the plunger are made in a second injection mould process with thermoplastic rubber (Santoprene).

All parts are injection moulded in a clean room ISO Class 8 and according to the quality standard ISO 13485.

The Dosin® is assembled and tested under laminar flow benches before packing and sterilisation by E-beam.

Procedure to evaluate the fluid mechanical aspects of the Dosin®. The operation of the Dosin® has been studied both experimentally and theoretically. These studies have been used to enhance the understanding of the details of the flow and the operational possibilities, and possible limitations, of the Dosin®.

The theoretical work is based on computing the time dependent flow in the Dosin® geometry. We assume that the liquid is Newtonian; that is, the shear-stress is proportional to the deformation-rate and the proportionality constant is property of the fluid only. This constant is known as the viscosity coefficient of the fluid. The volume occupied by the liquid is divided into small volume elements. Within each of these elements the balance equations for the conservation of mass and momentum must be satisfied. Thus, the flux of mass and momentum through the boundaries of each volume element has to be balanced by the sources within the

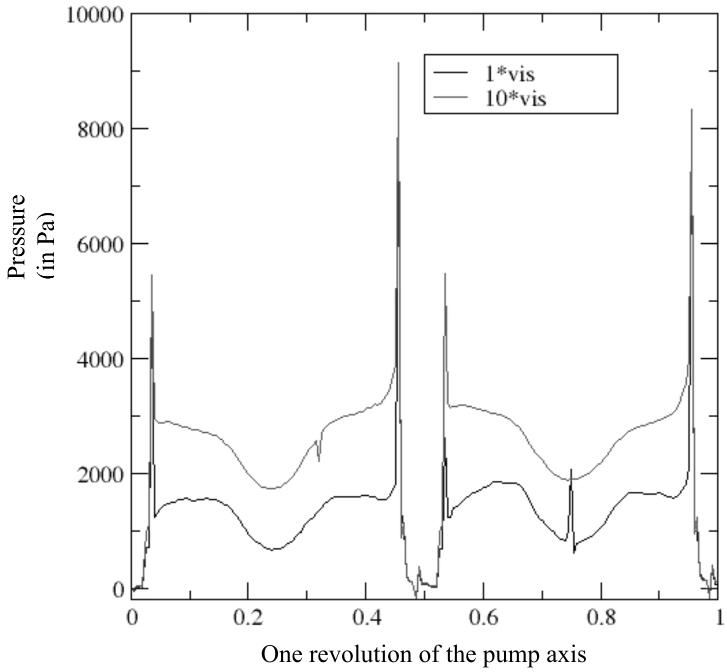

Figure 3. The pressure drop (in Pa) across the Dosin® over the pumping cycle (one revolution of the pump axis). The curves are related to two liquids: the low viscosity liquid is water whereas the other is a liquid with ten time larger viscosity.

element (so called finite-volume method). A major source in the Dosin® is related to the viscous forces within the liquid and near the walls wetted by the liquid. The rotational and linear motion of the piston is taken into account. The computations give quantitative information about the instantaneous liquid velocity and the pressure within each volume element. The computations provide also information about the forces on the walls of the device and the power required to drive Dosin®. Additionally, from the local pressure, it is possible to estimate the risks for cavitation or leakage. Figure 3 depicts the pressure drop across Dosin® for two liquids over the pumping cycle. The peaks are related to the opening and closing of the inflow and outflow openings as the piston is moving within the device. The limitations on flow rate are related to these pressure peaks, and are dependent on the particular liquid that is used.

Evaluation of the new pump device

Flow and volume meters, including dosing and batching instruments tend to have the same properties regardless of application. Therefore, one can see many similarities between the Dosin® and a chemical batch meter or a fuel dispenser. With this in mind a number of tests was selected to verify the capacities and limitations of the Dosin®. Of course, the user application must be held in focus while doing this selection. However, reasonable tolerances for volume uncertainty in different medical therapies are not discussed here.

The Dosin® is used together with either a small pump (Octapump Injection System 1, OIS-1) or a bigger pump (Octapump Injection System 2, OIS-2). The pump, the Dosin®, the liquid container and tubes/catheters are together called the *injection system*.

For the Dosin® some measurement properties are particularly interesting;

1. Within what speeds can the pump work (maximum and minimum flow rate)?
2. How small is the minimum dose (pulse)?
3. Are there any limitations regarding type of liquid (viscosity) to be used?
4. Are there any influences from pressure (long and/or small tubes/catheters)?
5. What are the tolerances/differences between different Dosin® individuals?
6. What is the life time of the Dosin®'s sealing and plastic components?

Air and gas. In most applications of liquid volume and flow measurements, entrained air or gas causes accuracy problems. In a medical device like the Dosin® air and gas bubbles not only limit the measuring accuracy, they are also a risk for the patient since too much air/gas can cause air emboli. This gives two important reasons to carefully remove all bubbles from the injection system before starting an injection.

As the Dosin® uses a volumetric principle (repeated filling and emptying of a measuring chamber) entrained air or gas in this chamber would have a direct impact on the measuring error. However, it has been observed several times that a small amount of gas remains in the measuring chamber. It is important to keep this amount as small as possible. The Dosin® is provided with a "flushing" mode, which is intended to be used before injection to remove air from the injection system. During this process it must be observed that the flushing flow rate is not too high with regard to dimension and length of used tubes. At too high a flow rate, the pressure at some location may be reduced to a level below the vapour pressure of the liquid at the given temperature. Under these conditions, cavitation may occur whereby bubbles containing vapour of the liquid are formed. These bubbles, in contrast to air bubbles, disappear once the causes for cavitation are removed.

Accuracy tests. In the graphs below the measurement error of the Dosin® under various conditions is presented. In all diagrams the specified measurement error in percent (E) is defined by

$$E = \frac{indicated \quad volume - delivered \quad volume}{delivered \quad volume} \text{ x } 100$$

where indicated volume is displayed on the pump display and the really delivered volume is measured by weighing. This means that a "positive" error indicates too small a dose!

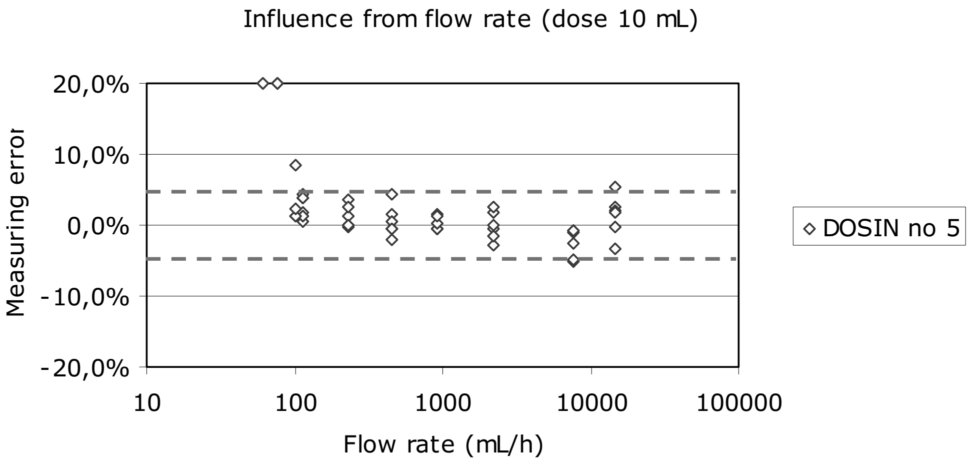

Figure 4. The measurement error for varying flow rates in a logarithmic scale. The test was repeated several times at different flow rates indicating that with a 95 % confidence the error is less than 5 %. Below 100 mL/h the error increases rapidly exceeding 20 %.

Only individual pulses (volume doses) from the Dosin® have been evaluated. The uncertainty in the measurement procedure, i.e. the determination of the measurement error, is in all tests smaller than ƒ0.5 % of the specified value. All tests except the "viscosity test" were performed using distilled water with a temperature of 22ºC.

The results presented here only refer to the individual Dosin® units undergoing the specific test. The components of the injection system during the tests were:

–#An OIS-1 (serial.no. 19-4-002)
–#10 units of Dosin®s (batch 18-8)
–#Tubes of length 150 cm and diameter 3 mm
–#BD Neoflon™-infusion canula.Yellow. OD 0.7 mm, ID 0.6 mm.Length 19 mm. Attached to the distal end of the tube.

Flow speed. With different therapies and injection sequences in mind it was decided to test the Dosin® at different flow rates up to 18 000 mL/h (i.e. 5 mL/s). At flow rates below 100 mL/h the measuring errors exceed 20% and these are therefore not included in Fig. 1.

Minimum pulse volume. The measuring chamber of the Dosin® has a volume of approximately 3 mL. If the pulse volume is smaller than 3 mL, the Dosin® will move only parts of a complete cycle (the axis will move only parts of a complete revolution) during each pulse. This will cause a measuring error larger than 5%. This cyclic error only affects volumes smaller than 3 mL.

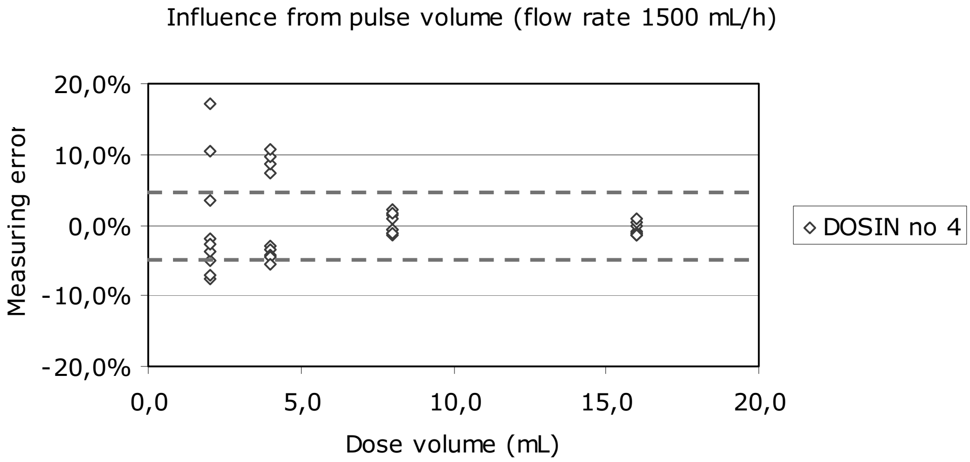

Figure 5. The measurement error for varying dose volumes. As expected, repeated measurements show that the error and its variation increase with decreasing dose volume. An important contribution to this is the volumetric working principle of the Dosin®, and the fact that its cyclic volume affects the error at small volumes.

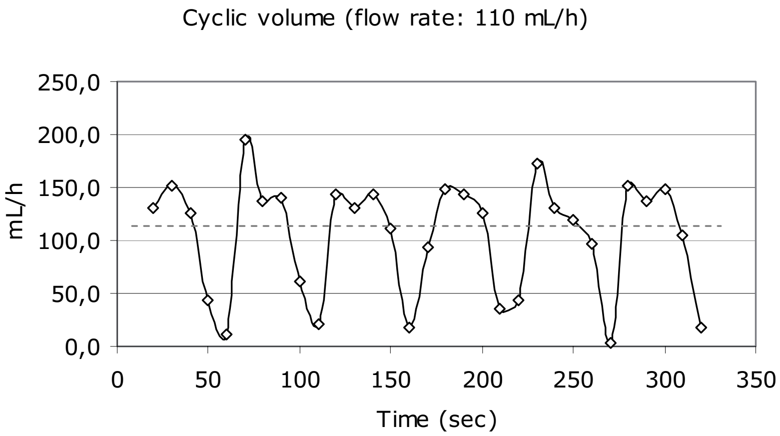

Figure 6. The figure shows the flow variations during full cycles of the Dosin®, observed every 10 second.

If a series of small pulses is used, with a total volume larger than 3 mL, the measuring error of the total injected volume is still within 5%.

Viscosity. The accuracy of the Dosin® was tested with 3 different liquids, simulating 3 different medical fluids:

–#Water (1 mPa·s and 0,998 kg/L) simulating salt solution
–#Ethyleneglycol (3 mPa·s and 1,056 kg/L) simulating blood
–#Glycerol (12 mPa·s and 1,161 kg/L) simulating contrast media

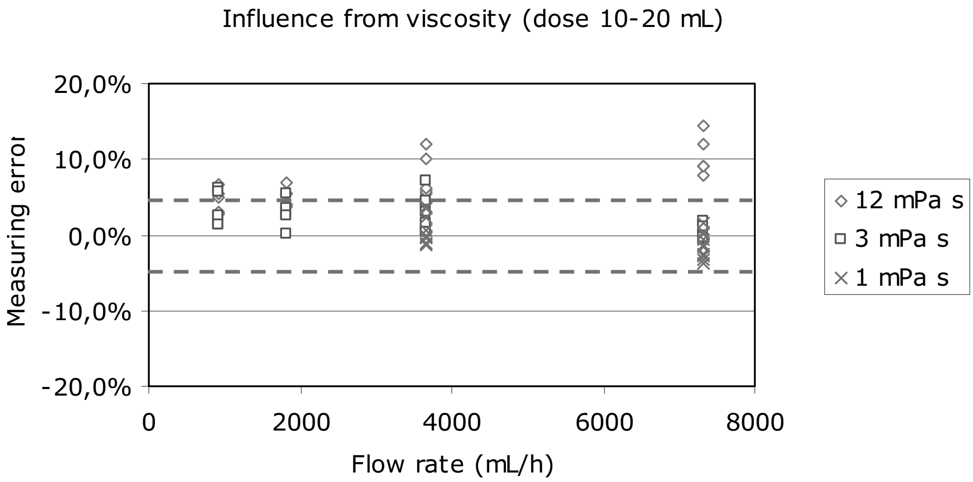

Figure 7. The test of three liquids of different viscosities at varying flow rates shows that the measurement error increases with flow rate and predominantly for the high viscosity. This result is due to the effect of viscosity on the pressure drop (as shown by theoretical computations, Figure 3).

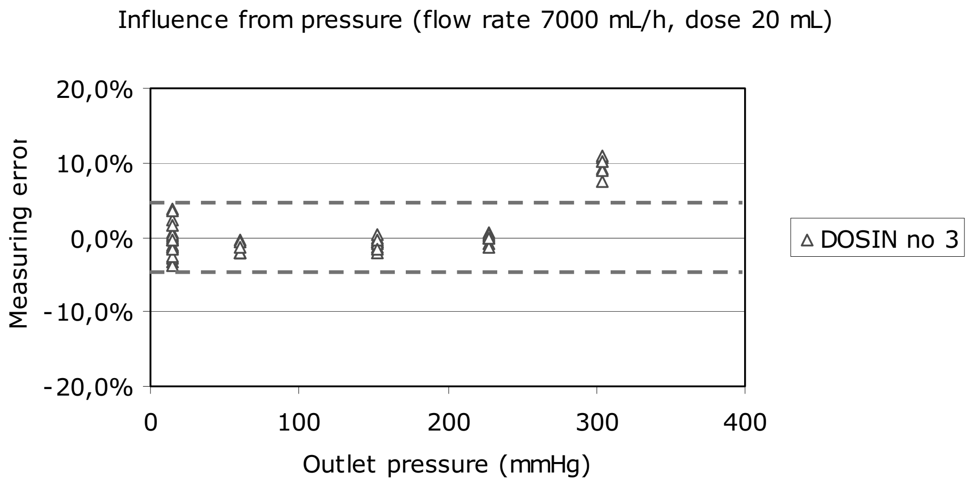

Figure 8. The results of increasing pressure at given dose and flow rate shows the same pattern as in Fig. 4. If the outflow of low viscous water is strangled, a part of it will be pressed backwards between walls and sealing inside the Dosin® and will therefore not be delivered. The sealing works well with water up to a pressure of 250 mm Hg, but with increasing pressure the delivered volume will successively get smaller than the indicated volume.

The main difference between these fluids is the viscosity, but also the densities are somewhat different. High viscosity and high flow rate result in high pressure in the injection system.

Pressure. To simulate different injection set-ups (lengths and dimensions of tubes) a reducer was installed downstream of the Dosin®. With this reducer it was possible

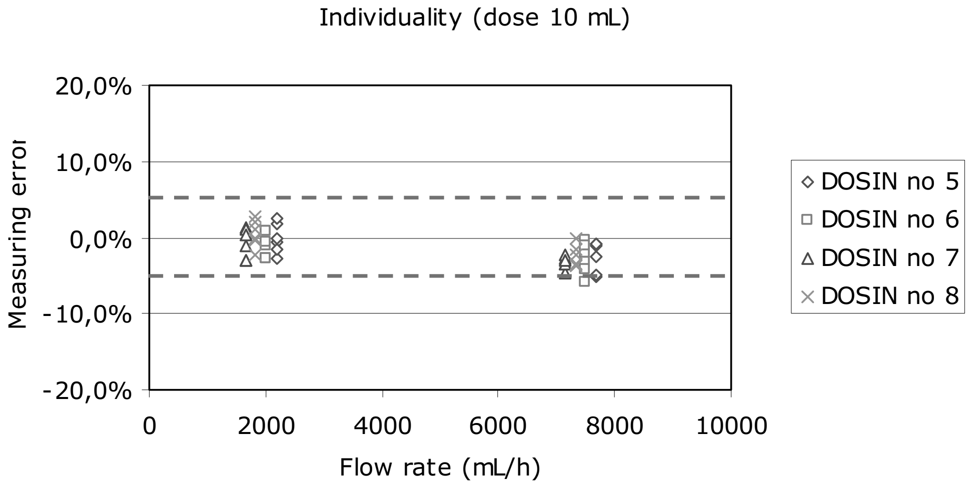

Figure 9. The 4 individual units exhibit comparable variation at 2 tested flow rates. The error is with a high degree of confidence within the tolerance of ±5 %.

to create different backpressures and to see the influence on the injection system. It should be noted that the pressure drop over the Dosin® is not constant (cf.: Figure 4). In the Figure below the average pressure values over a cycle are given.
(1 mmHg= 133 Pa)

Manufacturing variability. The limited test presented here is based only on 4 Dosin® units, giving an indication of the variation and tolerances among individual Dosin®s. Table 1 shows the average results of 6 individual measurements on each sample.

Measuring error	Sample no 5	Sample no 6	Sample no 7	Sample no 8	*Average*
... at 2.0 L/h (0.6 mL/s)	–0,1 %	–0,9 %	–0,7 %	+0,5 %	*–0,3 %*
... at 7.5 L/h (2.0 mL/s)	–2,5 %	–2,8 %	–3,2 %	–2,4 %	*–2,7 %*

Durability. Only a few injection therapies require very long time use of the Dosin®. Sealing and materials will wear according to number of rotations rather than time in use. It is therefore reasonable to believe that both flow rate and time (equal to total volume) set the limit. To make a simple endurance test, 1 Dosin® was set to pump a total volume of 7000 mL during approximately 20 h. The figure below show measuring errors before and after these 20 h of operation.

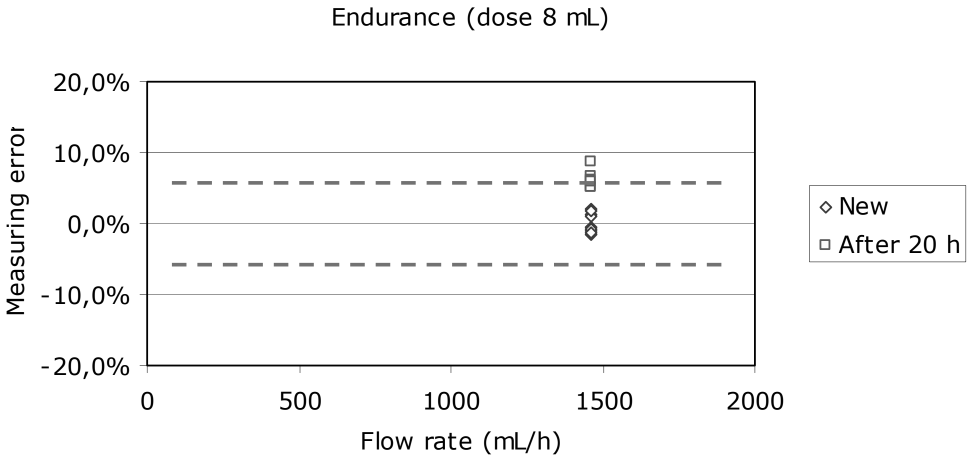

Figure 10. The result of a simplified endurance test shows that the error is increasing with time. A higher wear after many cycles may increase the risk for wear of sealing and thereby leakage, resulting in lower volume delivery than indicated. The result variation seems, however to be unchanged. However, one would expect this aging effect to increase with flow rate and indirectly due to an increase of pressure.

Concluding remarks

The newly designed Dosin® can be used for pumping both medical liquids and gases. The most common used so far in medical practice is liquids and therefore the detection of air within the liquid is important, since it hinders air from being injected into the patient. E.g. when CO_2 is used, the integrated bubble detector must be shut down. In the theoretical and experimental evaluations that have been made, different liquids have been used.

For the medical purposes we found that the volume inaccuracy is within 5% deviation limit. For flow rates between 100 mL/h (approx. 0.03 mL/s) and 18 000 mL/h (approx. 5 mL/s), the error is less than 5%, with 95% confidence.

The minimum pulse volume of doses less than 3 mL shows a cyclic error larger than 5%, but if the small doses are repeated in a series, whose total volume is larger than 3 mL, the error is less but still within the 5% deviation.

A common pulse of 2 mL/s, repeated every 60 seconds, gives after 90 min a total dose of 180 mL with a high accuracy. The fluids used in trombolysis or other medical treatments have a viscosity of 1 mPa.s and blood has a viscosity of 3 mPa.s, which also indicates the possible use of the Dosin® for blood transfusions.

At higher flow rates there may be larger variations in the flow rate, hence multiple Dosin®s are proposed as an integrated solution. Very low flow rates can be obtained by using a gear box (also a proposition for an integrated solution). The pulsatile flow is of value for improved mixing of the injected liquid with the blood and also for reducing the clotting risk in the catheters.

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