1. Name & Address of Client/Requesting Authority ........................................................ 1
2. Introduction .................................................................................................................. 1
3. Test Product(s)/Sample(s) ........................................................................................ 2
  3.1 Departures/Abnormalities of Sample Condition .................................................. 2
4. Images of Sample Regulator Dials .......................................................................... 3
5. Date of Testing ............................................................................................................ 5
6. Test Method ................................................................................................................ 5
  6.1 Flow Rates .............................................................................................................. 5
  6.2 Plastic Creep ........................................................................................................... 6
  6.3 Standards relevant to the medical device ............................................................... 6
  6.4 Deviations/exclusions from, and additions to standard methods ....................... 6
  6.5 Sampling Details .................................................................................................... 7
  6.6 Sample Preparation ............................................................................................... 7
7. Results ........................................................................................................................ 8
  7.1 Flow rate ................................................................................................................ 8
  7.2 Plastic Creep .......................................................................................................... 11
8. Summary ..................................................................................................................... 14

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LIST OF FIGURES

Figure 1. Baxter Control A Flow ................................................................. 3
Figure 2. Braun Exadrop ......................................................................... 3
Figure 3. Bexen Easydrop ................................................................. 4
Figure 4. Plasti Medical Spa Tutodrop 3 ........................................ 4
Figure 5. Sarstedt Air G Regulator ............................................................. 5
Figure 6. Baxter Control-a-Flow Set (10ml/h) ....................................... 11
Figure 7. B Braun Exadrop (10ml/h) .................................................. 11
Figure 8. Bexen (UHS) Easydrop (5ml/h) ........................................... 12
Figure 9. Plasti Medical Spa (Alaris) Tutodrop 3 (5ml/h) ................. 12
Figure 10. Sarstedt Air G Drop Regulator (15ml/h) ............................ 13
Figure 11. UHS Mediflex Roller Clamp Set (10ml/h) ......................... 13
LIST OF TABLES

TABLE 1. Test Product(s)/Sample(s) tested by SMTL .......................................................... 2
TABLE 2. Flow Rates at 1 Metre Hydrostatic Head ................................................................. 8
TABLE 3. Flow Rates at 0.5 Metre Hydrostatic Head ............................................................... 9
TABLE 4. Plasti Medical Spa Tutodrop 3 Flow Rates at 0.8 Metre Hydrostatic Head .................. 10
TABLE 5. B Braun Exadrop Flow Rates at 0.76 Metre Hydrostatic Head ................................. 10
1. Name & Address of Client/Requesting Authority.

Chris Callander  
Consultant Anaesthetist  
Chair, All-Wales Commodity Advisory Group  
Email: Christopher.Callander@gwent.wales.nhs.uk

2. Introduction

The SMTL were requested by the All-Wales Commodity Advisory Group to investigate the accuracy of gravity feed intravenous administration sets with regulator dials. The regulator dials are in-line and take the place of the traditional roller clamps.

The International Standard BS EN ISO 8536-4:2007 - Infusion equipment for medical use. Infusion sets for single use, gravity feed\(^1\) lists a test method for determining the maximum flow rate of infusion sets, however, it does not take into account the control of flow rate via the roller clamps or any other flow regulator.

The efficacy of roller clamps to control/maintain a constant infusion fluid flow rate have previously been questioned due to the effect of plastic creep (Demourelle \textit{et al.}, \textit{Am J Hosp Pharm} 1975; \textbf{32}: 177-185 and Ziser \textit{et al.}, \textit{Am J Hosp Pharm} 1975; \textbf{36}: 1090-1094), and therefore, regulator dials are designed to overcome the issue of plastic creep and improve mechanical flow control.

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This report details the results of testing:

i. Various regulated administration sets for accuracy of flow rate when low (5-15ml/h), medium (100-125ml/h) and high (250ml/h) flow rate were applied.

ii. Testing for plastic creep of various regulated administration sets and standard roller clamp administration sets.

3. Test Product(s)/Sample(s)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Item</th>
<th>Batch/Lot No</th>
<th>Quantity</th>
<th>Date Received</th>
<th>SMTL Sample I.D. Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baxter</td>
<td>Control-a-flow Infusion set with flow-rate regulator (Catalogue number 04113V756G)</td>
<td>04113V756G</td>
<td>21</td>
<td>15/4/05</td>
<td>20847</td>
</tr>
<tr>
<td>B Braun</td>
<td>Exadrop Intralite Air G with Exadrop regulated flow IV Set (Catalogue number 4061284)</td>
<td>4061284</td>
<td>50</td>
<td>17/5/05</td>
<td>20892</td>
</tr>
<tr>
<td>Bexen</td>
<td>Easydrop Regulated flow control set (Catalogue number 129.01)</td>
<td>X-099</td>
<td>12</td>
<td>19/4/05</td>
<td>20855</td>
</tr>
<tr>
<td>Plasti Medical Spa</td>
<td>Tutodrop 3 IV flow control set (Catalogue number 03508040)</td>
<td>210504</td>
<td>20</td>
<td>20/4/05</td>
<td>20856</td>
</tr>
<tr>
<td>Sorstedt</td>
<td>Air G Drop Regulator Infusion system with precision drop control (Catalogue number 74.4103)</td>
<td>5050901</td>
<td>20</td>
<td>03/5/06</td>
<td>20870</td>
</tr>
<tr>
<td>Universal Hospital Supplies (UHS)</td>
<td>Mediflex Infusion Set (Catalogue number UN998606)</td>
<td>X-354</td>
<td>20</td>
<td>02/8/05</td>
<td>21209</td>
</tr>
</tbody>
</table>

Note:
- The test results in this report relate only to the test sample(s) analysed.
- The Universal Hospital Supplies Mediflex Infusion Set was a traditional roller clamp infusion set that was included in the study as a comparison for the assessment of plastic creep.

3.1 Departures/Abnormalities of Sample Condition

None
4. Images of Sample Regulator Dials

**Figure 1.** Baxter Control A Flow

![Baxter Control A Flow](image1)

**Figure 2.** Braun Exadrop

![Braun Exadrop](image2)
Figure 3. Bexen Easydrop

Figure 4. Plasti Medical Spa Tutodrop 3
5. Date of Testing
July - October 2005

6. Test Method
6.1 Flow Rates
A 20 gauge intra-venous cannula was secured to a 500ml beaker that contained a layer of oil on water and covered with film. The purpose of the oil and film is to prevent evaporation from the beaker over the duration of the experiment. The initial weight of the beaker was then recorded via a calibrated balance.

The male Luer connection patient end of the administration set under test was connected to the cannula and the closure piercing tip of the set inserted into a 1 litre bag of saline (0.9% sodium chloride). The bag was then suspended on a drip stand (set at 1 metre, 0.5 metre or a height recommended by the manufacturer) and the system primed to remove entrained air. A specific high flow rate of 250ml/hour was set via the flow regulator on the administration set and the system allowed to run for 30 minutes. The beaker was then re-weighed and the actual flow rate calculated from the fluid dispensed.

The test was repeated with flow regulators set at medium (100-125ml/h) and low (5-15ml/h) flow rates. Unfortunately, as the scale and markings of the regulator dials vary between company designs, different rates had to be chosen for medium and low flows. The duration of the experiment for medium and low flow rates was increased to 1 and 2 hours respectively.
Additional tests were performed on certain regulated administration sets, as some manufacturers provided specific conditions to verify the accuracy of their flow regulators. BBraun Exadrop (76cm hydrostatic head with an 18 gauge cannula) and Plasti Medical Tutodrop 3 (distributed by Alaris 80cm hydrostatic head)) regulated sets were assembled as per the manufacturers recommendations and the sets assessed at high, medium and low flow rates.

6.2 Plastic Creep

A 500ml beaker containing a layer of oil on water to prevent evaporation of test solution was placed on a calibrated top pan balance. An electronic data-logger was connected to the balance in order to record the balance reading during the course of the experiment. In order to prevent balance fluctuation due to air current the balance was covered by a box. A cannula was then positioned into the top of the box directly above the beaker.

The patient end of the administration set under test was then assembled to the cannula, and the closure pieceing tip of the set inserted into a 1 litre bag of saline (0.9% sodium chloride). The bag was then suspended on a drip stand set at 1M and the system primed to remove entrained air. A low flow rate (5-15ml/h, depending on the marking of the regulator scale) was set via the flow regulator on the administration set and the system allowed to run overnight. Following the infusion, the data-logger was downloaded, and a graph of weight change against time plotted.

The test was repeated on a variety of flow regulated administration sets and one roller clamp non-regulated IV set currently on contract with Welsh Health Supplies (Universal Hospital Supplies, Mediflex Infusion Set). The Mediflex roller clamp was positioned so that a flow rate of approximately 10-12ml/h was achieved.

6.3 Standards relevant to the medical device

— BS EN ISO 8536-4:2007 - Infusion equipment for medical use. Infusion sets for single use, gravity feed, with amendments to include assessment of flow control and clinical practise.

6.4 Deviations/exclusions from, and additions to standard methods

— The dials of the regulated administration sets were adjusted to specific flow rates instead of setting the regulator to maximum flow as stated in BS EN ISO 8536-4:2007.

— Bags of 0.9% saline (sodium chloride) were used as the test solution rather than distilled water stated in BS EN ISO 8536-4:2007.

— A 20 gauge cannula was connected to the outlet of the administration set.

— A pressure equivalent of 500cm head of water, and any height a manufacturer recommended in their literature/instructions for use were also assessed as well as the stated 1 metre head of water in the BS EN ISO 8536-4:2007.
6.5 Sampling Details
All samples were selected and supplied by the manufacturers.

6.6 Sample Preparation
Not applicable.
7. Results

7.1 Flow rate

Results from flow rate experiments are presented in Tables 2, 3, with the manufacturers recommended height being displayed in Tables 4 and 5.

**TABLE 2.** Flow Rates at 1 Metre Hydrostatic Head

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Flow Rates</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>250ml/h</td>
<td>125ml/h</td>
<td>100ml/h</td>
<td>15ml/h</td>
</tr>
<tr>
<td>Baxter Control-a-Flow</td>
<td>267.30 (29.53)</td>
<td>132.68 (11.79)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>+7%</td>
<td>+6%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>B Braun Exadrop</td>
<td>274.37 (14.20)</td>
<td>-</td>
<td>126.77 (6.33)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>+10%</td>
<td>+27%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bexen Easydrop (UHS)</td>
<td>264.46 (63.63)</td>
<td>139.95 (28.49)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>+6%</td>
<td>+12%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Plasti Medical Spa</td>
<td>413.10 (35.56)</td>
<td>211.10 (14.84)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tutodrop 3 (Alaris)</td>
<td>+65%</td>
<td>+69%</td>
<td>+275%</td>
<td></td>
</tr>
<tr>
<td>Sarstedt Air G Drop Regulator</td>
<td>291.79 (26.63)</td>
<td>108.73 (11.12)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>+17%</td>
<td>-13%</td>
<td>-11%</td>
<td></td>
</tr>
</tbody>
</table>

Note:
- The results are the mean of 10 determinations
- Figures in brackets denote standard deviations
- Figures in italics denote percentage difference from the regulator setting.
### TABLE 3. Flow Rates at 0.5 Metre Hydrostatic Head

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Flow Rates</th>
<th>Flow Rates</th>
<th>Flow Rates</th>
<th>Flow Rates</th>
<th>Flow Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High 250ml/h</td>
<td>Medium 125ml/h</td>
<td>Medium 100ml/h</td>
<td>Low 15ml/h</td>
<td>Low 10ml/h</td>
</tr>
<tr>
<td>Baxter Control-a-Flow</td>
<td>268.65 (30.62)</td>
<td>131.74 (9.56)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>+7%</td>
<td>+5%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>B Braun Exadrop</td>
<td>179.57 (16.92)</td>
<td>-</td>
<td>75.94 (12.63)</td>
<td>-</td>
<td>6.25 (0.98)</td>
</tr>
<tr>
<td></td>
<td>-28%</td>
<td>-24%</td>
<td>-</td>
<td>-</td>
<td>-38%</td>
</tr>
<tr>
<td>Bexen Easydrop (UHS)</td>
<td>182.19 (46.27)</td>
<td>91.39 (13.63)</td>
<td>-</td>
<td>-</td>
<td>5.37 (2.64)</td>
</tr>
<tr>
<td></td>
<td>-27%</td>
<td>-27%</td>
<td>-</td>
<td>-</td>
<td>+7%</td>
</tr>
<tr>
<td>Plasti Medical Spa Tutodrop 3 (Alaris)</td>
<td>278.13 (45.44)</td>
<td>130.76 (10.93)</td>
<td>-</td>
<td>-</td>
<td>11.21 (3.46)</td>
</tr>
<tr>
<td></td>
<td>+11%</td>
<td>+5%</td>
<td>-</td>
<td>-</td>
<td>+124%</td>
</tr>
<tr>
<td>Sarstedt Air G Drop Regulator</td>
<td>201.87 (27.62)</td>
<td>63.80 (6.97)</td>
<td>-</td>
<td>6.44 (2.29)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>-19%</td>
<td>-49%</td>
<td>-</td>
<td>-57%</td>
<td>-</td>
</tr>
</tbody>
</table>

**Note:**
- The results are the mean of 10 determinations.
- Figures in brackets denote standard deviations.
- Figures in *italics* denote percentage difference from the regulator setting.
### TABLE 4. Plasti Medical Spa Tutodrop 3 Flow Rates at 0.8 Metre Hydrostatic Head

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Flow Rates</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High 250ml/h</td>
<td>Medium 125ml/h</td>
<td>Low 5ml/h</td>
<td></td>
</tr>
<tr>
<td>Plasti Medical Spa Tutodrop 3 (Alaris)</td>
<td>348.94 (6.51)</td>
<td>175.27 (13.56)</td>
<td>11.22 (4.56)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>+39%</td>
<td>+40%</td>
<td>+124%</td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
- The results are the mean of 3 determinations.
- Figures in brackets denote standard deviations
- Figures in *italics* denote percentage difference from the regulator setting

### TABLE 5. B Braun Exadrop Flow Rates at 0.76 Metre Hydrostatic Head

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Flow Rates</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High 250ml/h</td>
<td>Medium 100ml/h</td>
<td>Low 10ml/h</td>
</tr>
<tr>
<td>B Braun Exadrop</td>
<td>223.41 (10.42)</td>
<td>105.51 (9.50)</td>
<td>10.30 (0.92)</td>
</tr>
<tr>
<td></td>
<td>-11%</td>
<td>6%</td>
<td>3%</td>
</tr>
</tbody>
</table>

**Note:**
- The results are the mean of 3 determinations
- Figures in brackets denote standard deviations
- Figures in *italics* denote percentage difference from the regulator setting
- The Exadrop administration set was connected to a size 18G cannula as per manufacturers instructions
7.2 Plastic Creep

The results of the creep test over 16 hours are expressed graphically in Figures 6 to 11.

**Figure 6.** Baxter Control-a-Flow Set (10ml/h)

**Figure 7.** B Braun Exadrop (10ml/h)
Figure 8. Bexen (UHS) Easydrop (5ml/h)

![Graph showing change in balance weight over time for Bexen (UHS) Easydrop (5ml/h).](image)

Figure 9. Plasti Medical Spa (Alaris) Tutodrop 3 (5ml/h)

![Graph showing change in balance weight over time for Plasti Medical Spa (Alaris) Tutodrop 3 (5ml/h).](image)

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Figure 10. Sarstedt Air G Drop Regulator (15ml/h)

Figure 11. UHS Mediflex Roller Clamp Set (10ml/h)
8. Summary

Intravenous fluids when regulated to flow according to the physicians instructions have positive therapeutic effects for the patient such as rehydration, restoration of electrolyte balance, restoration of acid-base balance, replacement of vitamins, proteins, and calories, and safe rapid medication administration. Potential issues with traditional roller clamp infusion sets include plastic creep leading to a reduced infusion, and difficulty in selecting a specific flow rate for infusion, and therefore regulated infusion sets were designed to overcome such issues.

The test results generated in this report indicate that there is a large difference in the accuracy of the regulated infusion sets between manufacturers. When tested at 1 metre hydrostatic head the Plasti Medical Spa Tutoplus 3 regulated infusion sets distributed by Alaris were shown to be the most inaccurate with significant over administration of test fluid. Fluid overload (fluids infused at a higher rate or in a larger volume than the system can absorb or excrete) could potentially lead to patient consequences such as hypertension, heart failure, and pulmonary oedema, however the SMTL cannot confirm whether the fluid overload shown with the Tutoplus 3 set would lead to such clinical complications.

Most of the sets tested produced a significant reduction in their flow rate when the hydrostatic head was lowered, and thus the height at which the infusion fluid is held above the patient would also have a significant effect on the rate of fluid administration. The exception to this was the Baxter Control-a-Flow regulated administration set that produced almost identical flows at both pressures tested.

Discrepancies in flow rate were more exaggerated when the intended flow was at the lower end of the regulation range, and therefore for critical low rate flow rate infusions it will be advisable to use a calibrated infusion pump.

No significant evidence of plastic creep (reduction of flow rate) was observed with any of the regulated infusion sets tested. It is interesting to note that the UHS Mediflex roller clamp infusion set also did not exhibit a significant reduction of flow rate over the testing period.

The instructions for use of all the regulated administration sets tested state that the drip rate should be assessed at regular intervals as with roller clamp infusion sets. However after consulting with potential users, most of the clinicians stated that they would have confidence in the accuracy of the regulator and would therefore be less inclined to check the drip/flow rate. It is important that clinical staff are aware of the variability of accuracy between manufacturers regulated infusion sets.

APPROVED:

Peter Phillips, Acting Director, SMTL. Date

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References