

## LITRE MEETING – MONDAY 16<sup>TH</sup> JANUARY 2006

**Subject:** To receive presentations on three portable PN pumps – Gemstar, IVantage, CADD Prism. The presentations would form the basis for a report which would provide the companies with feedback and would be posted on the LITRE website.

In November 2005 it became apparent that the Baxter 6060 multi-infusion therapy ambulatory pump was to be withdrawn from the market. Both PINNT and LITRE had discussions with Baxter to determine how this withdrawal would be managed. An assurance was given that patients would not have their 6060 pump withdrawn from them until healthcare professionals had identified a suitable replacement for the pump. Baxter have stated that they will continue full service of the pump along with providing the necessary ancillaries, but the new giving sets and re-designed rucksack will not be available for use. PINNT has subsequently issued a statement which appears on their website ([www.pinnt.co.uk](http://www.pinnt.co.uk)) and has promised to keep members updated with information about alternative pumps.

LITRE's scheduled meeting for 16<sup>th</sup> January 2006 provided the ideal forum for reviewing ambulatory pumps that were either already available in the market place or which are being offered as suitable for parenteral nutrition infusions. Baxter 6060 users have been in touch with both PINNT and LITRE as the information they are receiving from hospitals and homecare companies is inconsistent and worrying for them.

To ensure an effective panel, LITRE invited two HPN patients, two carers and an adult nutrition nurse specialist in addition to those experts already on the committee.

Invitations were sent out to three companies: Fresenius/Calea, Hospira and Smiths Medical to request that they do a 30-minute presentation about the pump and its ancillaries. Fresenius/Calea and Hospira accepted the invitation to attend the meeting.

LITRE wish to state that they fully appreciated that given the limited time allocated for presentations it would not be possible to fully evaluate individual pumps on full functionality, but it was hoped a better insight into the products would be gained.

One of LITRE's previous projects was to work with BIME (Bath Institute of Medical Engineering) to design and use a 'User Assessment Questionnaire for Enteral and Parenteral Feeding Pumps'. This formed the basis of the panel's thought process for the meeting, with additional aspects added to take into account aspects of pump use that had changed since the first questionnaire was designed. The following headings relate to those on the questionnaire.

### **Section 1 – General:**

***Appearance, weight, size, operating manual, moving about whilst pump is on stand, length of battery life, charging time for battery, total time to set up feed, carrying pack. Additional questions on this section: Is there an external power pack/battery, is there a dry cell battery support option?***

**IVantage** – General appearance was good. It is a small size and was a light weight. We did not have an opportunity to study the manual but one was available. We did not see the pump attached to a dripstand although its pole attachment was demonstrated. The stated battery life of the pump was good once fully charged via the mains supply, although it is not known how long the battery will power the pump for the higher rates of mls/hr for PN. Charge time was also good, stated to be 4 hours. We did not focus on the setting-up of feeds in any detail. The carrying pack was not available to us at the time. The IVantage does not have an external power supply nor dry-cell battery back-up. Once the internal battery is depleted it needs to be recharged.

**Gemstar** – General appearance was good, slightly larger than other portable pumps and although heavier was deemed as satisfactory. We did not have an opportunity to study the manual although we were assured one was available. We did not see the pump attached to a dripstand although its pole attachment/‘docking station’ was demonstrated. The stated battery life of the pump was felt to be good once fully charged via the mains supply. Charge time was 8 hours. We did not focus on the setting up of feeds in any detail. The rucksack comes in 3-litre and 1-litre sizes; the 3-litre was not available to us, but the 1-litre was shown and is a ‘bum-bag’ style. The Gemstar does have an external power supply and also has the back-up of dry-cell batteries. The ‘docking station’ for the pump can also be used to charge the internal battery with the external power supply fitted to the pump.

## **Section 2 – Use of Pump:**

### ***Reliability, accuracy, noise of pump, lights on pump, vibration of pump, pump stability whilst in use***

Given the nature of the presentations, none of the above aspects were fully investigated on either of the pumps, although noise, lights and accuracy were discussed. Accuracy is reported to be  $\pm 5\%$  nominal for the both pumps.

### ***To set the rate and/or volume, to fill/prime set, to load the giving set into the pump, using pump whilst walking around, attaching pump to the drip stand, cleaning the pump***

**IVantage** – There are minimal numbers of function buttons. Function buttons were small and some had multiple actions. It was felt this may cause problems with patients who are not technically minded. The giving set could be primed either by gravity or via the pump. The cassette loaded easily into the pump and was secured via a lock. The set had a safety lock to prevent free-flow of fluid. There is a program lock to prevent unauthorised changes of infusion therapy. The pump has a dedicated pole attachment although during this meeting this was not demonstrated therefore we are unable to comment on ease of walking around.

**Gemstar** – There are numeric and command buttons. Function buttons were single action. The giving set will only be sold with the integral anti-syphon valve in the UK under an agreement with the MHRA, due to past adverse incidents where free flow had occurred. It is not possible to gravity prime with integral anti-syphon valve. The cassette loaded easily into the pump and was secured via a lock. The set also had a safety lock to prevent free flow of fluid but there were concerns about its size and how easily this could be removed. There was a function to lock the pump via a 4 digit number to ensure it was not accidentally turned off or the rate altered unintentionally. The pump has a dedicated pole attachment although during this meeting this was not demonstrated therefore we are unable to comment on ease of walking around.

The giving set for both pumps would benefit from some modifications:

- The length of each sector of the sets should be reviewed; both feedbag to pump and pump to patient
- Removal of the ‘Y’ ports
- Additional safety clip on the air in line filter for security purposes
- Roller clamps
- Removal of the air inlet valve on the IVantage set
- Ensure sets are not sterilised with gamma irradiation
- Consider light protective sets
- Various filter sizes to cover the range of feeds given and necessary filtration required
- Able to prime set manually as well as via pump
- Plasticizer free

### **Section 3 – Display:**

#### ***Is display panel clear to read, brightness of display, dimmer (if available)***

**IVantage** – The display panel is small. All the information required is given, ease of reading will vary from patient to patient, it has a light which illuminates when the key pad is in use. The light switches off when no actions are taken on the function keys. A dimmer facility is not present.

**Gemstar** – The display panel was a good size. All the information required is given, and appeared easy to read. The light switches off when no actions are taken on the function keys. An on/off facility for the light is present.

### **Section 4 – Controls**

**IVantage** – Once an infusion has commenced it is possible to alter parameters with ease. It has an indicator to show the pump is running and the flow rate is displayed whilst the pump is running. The pump allows tapering up and down.

**Gemstar** - Once an infusion has commenced it is possible to alter parameters but the system must be unlocked unless the pump is in ‘full freedom’ mode which allows changes. It has an indicator to show the pump is running and the flow rate is displayed whilst the pump is running. The pump allows tapering up and down.

### **Section 5 – Alarms; Can you hear the alarms easily? Is the alarm volume adjustable? Can the alarm be silenced for a short period? If yes, if the period of silence long enough?**

**IVantage** – The pump has air-in-line, occlusion (but not upstream occlusion), battery nearly empty, end of infusion and pump error alarms. There is no facility to adjust the volume of the alarms. You can silence the alarm for a short period to attend to the alert warning and restart the pump. The air-in-line protection is 100 microlitres.

**Gemstar** - The pump has the full compliment of alarms. There is a facility to adjust the volume of the alarms. You can silence the alarm for a short period to attend to the alert warning and restart the pump. The air-in-line protection is 500 microlitres, which is five times the amount deemed as acceptable by the MHRA.

### **Section 6 – Labels on Pump:**

#### ***Are there clear instructions on the pump?***

Both pumps have step by step guidance during the programming of the pump. Function buttons are clearly labelled but neither pump has any set up or error information on the actual pump, due to the size.

### **Section 7**

**Charging time:** Information provided on both pumps indicated acceptable charging times.

### **What improvements would you like to see?**

#### **IVantage**

***Additional power options.*** We are aware that the battery life within the pump is being extended. An external power supply would be ideal, also with the additional support to use dry cell batteries when all other power sources have been exhausted.

**Giving set** – changes in line with previous suggestions in section 2.

### **Gemstar**

**Air in line** - protection needs altering as per section 5.

**Giving set** – changes in line with previous suggestion in section 2.

We may have suggestions for both of the carrying packs once we have seen them.

### **In conclusion**

It is not our place to put the pumps through the technical tests and therefore leave such matters to experts in this field.

People at home on PN have become familiar with a pump that answers the purpose for them and many will be reluctant to change; however there are some patients who have experienced problems with their previous pump and will welcome the change.

We ask that consideration be given to the benefits of each pump for each patient. Some patients will broach technology with open arms, the smaller the better. Others will prefer the more traditional style which they feel provides continuity.

We recognise that despite the common factor of being fed parenterally there are still differences in the styles and preferences of centres. The facility of 'gravity priming' raised various ways in which this is done and how this impacted on the length of the giving set.

We feel we must strongly comment in relation to two issues; power sources and battery options and air-in-line protection. Many patients benefit from having an ambulatory system because of the freedom to feed on the move; this is not just governed by feeding outside the home but within the home too – this appears to be restricted by the power options of the Ivantage. The current air-in-line protection for the Gemstar is seriously below that recommended by the MHRA and needs to be addressed, as does the ability to gravity-prime.

Our aim is not to discredit any pump on the market, merely identify aspects that would enhance the use of the pump and hopefully make it capable of allowing people on PN to live their lives in their own way, each free to fulfil their personal beliefs and determine their quality of life with the assistance of technology.

LITRE committee  
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