

# **LITRE Assessment of Ambulatory Pumps for Parenteral Nutrition**

Results of a LITRE Assessment Panel

15<sup>th</sup> May 2011



# **LITRE – Looking Into The Requirements for Equipment**

## **What is LITRE?**

This committee is a multi-professional group led by patients. It is a standing committee of PINNT (Patients on Intravenous and Naso gastric Nutrition Therapy).

## **Our Mission**

LITRE – is a multi-disciplinary group that aims to improve the quality of life for patients on nutritional support at home. We do this by:

- ❖ Investing and responding to the needs and concerns raised by patients, carers and healthcare professionals with regard to equipment and services.
- ❖ Forging links between patients and industry.
- ❖ Acting as a forum for users to help in product and service development and market research.

## **Representation on the Committee**

The LITRE committee will always be predominantly patients and carers. LITRE meet to address individual projects and the most appropriate team of experts are assembled based on the nature of each project. LITRE will invite additional experts to join them with the clear intention of ensuring each additional person will bring knowledge and expertise to the project in hand.

## **Previous Projects**

### **LITRE Stand**

Developed in 1994, updated at various intervals, last update 2002 in response to user comment.

### **Equipment Survey**

Over the period 1990/1995 and was presented at BAPEN 1995.

### **LITREVIEW**

A publication outlining committee work in the early years. Once BAPEN was established LITRE transferred to working under the BAPEN umbrella. Publication ceased once funds were re distributed.

### **Home TPN Check List**

Produced in response to hospital and companies asking what patients needed as minimum requirements. This is no longer required due to improved homecare provision.

### **Gastrostomy Survey 1995**

Extensive research into types and items included, looking for the ideal pack. Conclusion – a final result was not achievable due to variations in practice; it was felt it was not LITRE's roll to dictate practice.

### **X-ray Safety at Airports**

Concerns were raised regarding the safety of feeds and pumps passing through x-ray machines. Advice was sought from manufacturers and a University Professor who specialised in x-ray effects. Patients were advised to seek specific details for their products but in general advice received was that they were safe.

### **Universal Clamps**

Patients reported problems with cleaning small areas on their clamps. Industry acknowledged the problem but the cost of changing the design was too expensive. Advice given was to use a soft make-up brush to clean them but nothing sharp and to seek out hospital advice.

### **Skin Tone Dressings**

Patients reported social discomfort when stared at with obvious white dressings. Manufacturers were contacted to establish whether they could be skin toned like stoma products. They felt there was insufficient demand and it would be a costly exercise to undertake.

### **Sharps Containers**

Patients reported issues regarding travelling and sharps containers. Patients were informed that they came in various sizes and they could request these from their homecare company, depending on their personal needs and durations of travel. It was advised to always bring containers home for disposal.

### **TPN Feed Containers**

Frequent reports were received from patients regarding air, gassing out of the champagne effect in the bag. Temperature and storage are related to such issues. Talks with manufacturers prompted research into improvements. Miramed bags were popular with patients as they appeared to reduce problems.

### **Snapped CVC Line Clamps**

Patients reported snapped line clamps and the problem to have them replaced. Advice was that they should have blue plastic clamps for back up in such situations. One patient informed us of a replacement clamp which did not require a repair thus reducing problems.

### **Travelling**

Patients regularly ask questions in relation to travelling; LITRE has assisted PINNT with the compilation of their Holiday Guidelines, free to existing members and £5 to all others. Contact PINNT on [info@pinnt.com](mailto:info@pinnt.com) for a copy.

### **Enteral Syringes**

LITRE was approached for comment on the prototype for a new reusable syringe designed for longer life than the standard ones. This is now in use and can be seen by the purple syringes.

### **TPN Line Occlusion**

A common issue reported to LITRE, so an in depth survey was undertaken in June 2003 to look at extensive parameters of incidence. The survey produced 103 returns which have been published.

### **Leaking Gastrostomy Survey**

A common issue for LITRE, this new study is with specialist centres and is presently under review.

### **Rucksack Design**

We regularly meet with industry to re-design and improve different types of rucksacks used for intravenous feeding.

### **Giving Set Designs**

Offering advice to establish giving sets that are more user-friendly which are still safe and effective to deliver feeds. Positioning of key components needed amending to make them comfortable for the users.

## **Interim review of PN pumps**

A minor review of pumps was carried out in October 2009

### **LITRE Panel Members**

PINNT advertised the proposed assessment in Online and requested volunteers to complete a simple questionnaire (appendix 1). The questionnaire asked salient questions in relation to age, duration of feeding, the number of nights per week feeding took place as well as the volume infused and the duration of each feed. PINNT were keen to ensure the LITRE panel covered the diverse feeding regimes as well as the various lifestyles in which home parenteral feeding was carried out. Once the patient/carer members of the panel were selected additional relevant panel members were invited; an independent buyer, a paediatric nutrition nurse and an adult nutrition nurse.

LITRE also required each patient/carer member of the panel to sign a disclaimer which made it abundantly clear that at no point during the assessment period should any giving set, which formed part of the assessment, be connected to a patient.

The panel consisted of the following members:-

Roger Baldwin – HPN patient  
Jasmine Cheesman – Carer of HPN paediatric patient  
Jane Cherry – GP/HPN patient  
Adam Duncombe – HPN patient  
Winnie Magambo – Adult Nutrition Nurse  
Emma Norman – Independent Buyer  
Mark Rooney – HPN patient  
Lauren Sainty – Interested party  
Elaine Sexton – Paediatric Nurse  
Richard Shawyer – HPN patient  
Carolyn Wheatley – HPN patient

This report is a collective summary based on opinion of the group as a whole. No individual, other than those named at the end of the report should be contacted in relation to this report.

### **Pump Testing**

To strengthen the patient and carers perspective the assessment of the pumps started in the patients' own homes which was a first for LITRE. Each company were asked to provide a typical TPN package to enable the pump to be fully tested by the individual committee members.

Each pump was tested with the giving sets provided by the company and normal saline was used to prime the sets.

The testing of all the pumps took place over a 4 week period and each personal assessment had to be completed prior to the committee meeting on 7<sup>th</sup> May 2011.

Each panel member completed an assessment form for each pump. The form used was the same as the one previously used by LITRE.

LITRE wish to thank each of the companies for arranging delivery and collection of the equipment.

LITRE also requested a test by the companies which was to run the pump with 3500ml bag of fluid at 350ml per hour for a fortnight with the same battery. We were keen to know the battery life and consistency over this period. The panel felt that this was a much more realistic running rate than 150ml per hour, used as the normal marker, for a home patient. All companies agreed to complete the test. The results, as received from each company, are shown at the end of the individual pump review.

## Pump Review

This pump review has been based on testing of equipment at home and the final presentations received by LITRE on 7<sup>th</sup> May 2011.

We have based our advice and comments on the knowledge that we hold as a panel. Through PINNT we have contact with patients and end users who have been vocal about their preferences and these have been extremely useful in providing an insight into patient expectations from a pump. As a patient advocates we endorse the quality of life issues related to home feeding.

LITRE was also keen to consider the whole package, not just related to the full range of accessories. For us this included the corporate approach, their ability to view the people for whom this product will be life-changing, how it could be made to enhance their feeding experience as well as making life less stressful.

LITRE and PINNT acknowledges that we are **not** in a position to make recommendations for individual patients.

Our findings have been based on:

- ❖ Initial impressions of the pump
- ❖ Programming, ease of use and giving set
- ❖ How the pump is powered and the options available to the patient
- ❖ The complete package
- ❖ Reviewing the manufacturer's response to recommended changes and how they have demonstrated an understanding of the issues affecting parenteral nutrition at home.

All pumps have been rated out of 10 in the following categories:

- Noise level
- Ease of use
- Manufacturer's response to recommended changes
- Size and weight
- Backpack
- Giving set
- Battery life/options

LITRE would like to stress that this is a non technical test. It is based on user feedback with independent feedback on battery life. It is therefore end user report. We do not look at line pressures or safety margins.

| <b>Features</b> |                                | <b>Ambix</b>      | <b>CADD Solis VIP</b>        | <b>Bodyguard 323</b>            | <b>Gemstar</b>                                                                                                                                                                                                                                   | <b>Rythmic</b>                                                                                                                                                            | <b>Bodyguard 2 Channel</b> |
|-----------------|--------------------------------|-------------------|------------------------------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| <b>Weight:</b>  | <b>Pump with battery alone</b> | 550g              | 423g                         | 390g                            | 482g                                                                                                                                                                                                                                             | 300g                                                                                                                                                                      | 538g                       |
|                 | <b>Pump with charger</b>       | 1070g             | 487g                         | Docking station - 765g combined | With rechargeable battery - 526g                                                                                                                                                                                                                 | 300g + 120g                                                                                                                                                               | 538g + 483g                |
| <b>Size:</b>    | <b>Pump alone</b>              | 132 x 120 x 45mm  | 41 x 102 x 127mm             | 112 x 89 x 32mm                 | 140 x 96 x 51                                                                                                                                                                                                                                    | 80 x 130 x 46mm                                                                                                                                                           | 89 x 112 x 32              |
|                 | <b>Pump with charger</b>       | 152 x 162 x 135mm | Charger fits within the pump | Docking station 165 x 94 x 79mm | Not applicable                                                                                                                                                                                                                                   | 106 x 144 x 46mm                                                                                                                                                          | 125 x 155 x 55             |
| <b>Battery:</b> | <b>Charging times</b>          | 5 hours           | 4 hours                      | 6-8 hours                       | 8 hours                                                                                                                                                                                                                                          | 2½ hours external battery pack from flat to fully charged.                                                                                                                | 6 hours                    |
|                 | <b>Dry cell capacity</b>       | No                | 4 AA batteries               | 2 x 9v option                   | 2 x AA                                                                                                                                                                                                                                           | 9v battery                                                                                                                                                                | No dry cell                |
|                 |                                |                   |                              |                                 | Using two fresh AA batteries of a charged battery pack the pump is capable of delivering the following:<br>96 hrs @ rates below 5ml/hr but below 25ml/hr. 24 hrs @ rates above 25ml/hr but below 125ml/hr. 3000ml @ a rate of 125ml/hr or higher | Battery pack - 9v 30 hours @ 125ml/h, 9 hours @ 400 ml/h 12 hrs 12 hours at 300ml/h dry cell battery<br><br>Internal battery is standard alkaline dry cell PP3 Battery 9V |                            |
| <b>Charger:</b> | <b>Size</b>                    | Docking station   | 120 x 762 x 48mm             | Docking station - 165 x 94 41mm | Not applicable - battery pack is directly charged from the mains                                                                                                                                                                                 | Mobile phone size charger with integral 2-pin plus for continental use                                                                                                    | Docking Station            |
|                 | <b>Weight</b>                  | Not provided      | 354g                         | 375g                            | Not provided                                                                                                                                                                                                                                     | 120g                                                                                                                                                                      | Not provided               |

|                                                         |                                                                                 |                                                                                 |                                                                   |                                                             |                                                                                                                |                                                                     |                                                                        |
|---------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|------------------------------------------------------------------------|
|                                                         |                                                                                 |                                                                                 |                                                                   | There is a plug in wall charger with standard charging time |                                                                                                                |                                                                     |                                                                        |
| <b>Accuracy:</b>                                        | <b>+/-5%</b>                                                                    | +/-5%                                                                           | +/-6%                                                             | +/-5% (normal)                                              | +/-5%                                                                                                          | +/-5%                                                               | +/-5%                                                                  |
| <b>Noise when running:</b>                              | <b>Low rate</b>                                                                 | Quiet                                                                           | Acceptable                                                        | Quite noisy                                                 | Extremely quiet at both rates                                                                                  | Quiet in operation                                                  | Quite noisy due to 2 channels                                          |
|                                                         | <b>High rate</b>                                                                | Quiet                                                                           | Quite noisy                                                       | Quite noisy                                                 | Extremley quiet                                                                                                | Quiet in operation                                                  | Quite noisy due to 2 channels                                          |
| <b>Lights:</b>                                          | <b>Ability to turn back light off:</b>                                          | Yes, on touching key                                                            | Yes, on touching key – backlight intensity is programmable        | Yes                                                         | Not lit at night                                                                                               | Yes, has a time-out, after key press or alarm                       | Yes                                                                    |
| <b>Display panel:</b>                                   | <b>Easy to read?</b>                                                            | Yes, it uses symbols to demonstrate a problem and correct functioning           | Yes , acts like a mobile phone                                    | Yes, keypad volume can be turned off                        | Yes, keypad - the audible alarm is user-adjustable from the maximum volume down to silent                      | Yes, keypad volume can be turned off                                | Yes, keypad volume can be turned off                                   |
| <b>Ease of programming:</b>                             |                                                                                 | Very easy and it remembers the last profile                                     | Complicated when changing bag size otherwise simple               | Very easy with logical steps                                | Simple, different infusion protocols can be stored for ease of programming                                     | Very easy with logical steps                                        | Easy with logical steps, slightly more complicated with the 2 channels |
| <b>Size of keys: Numeric keypad/multi-function keys</b> |                                                                                 | Keys are easy to press with a noticeable click                                  | Same size as a mobile phone                                       | Buttons quite small but raised. Numeric keypad              | Numeric keypad with sizeable buttons                                                                           | Large, multi-function keys                                          | Buttons quite small but raised – with a numeric keypad                 |
| <b>Alarms:</b>                                          | <b>Are they adjustable? Is there a warning when the infusion is due to end?</b> | Yes<br>Standardly at 20% infusion left, however this can be altered to no alarm | Yes<br>programmable reservoir low trip point (0-999ml)<br><br>Yes | Yes<br><br>No                                               | Alarms can be silenced. 'Help' screen will inform the user of the steps needed to address and correct an alarm | Adjustable volume level<br><br>Yes – configurable on time or volume | Yes<br><br>No                                                          |
| <b>Is it a multi-therapy pump?</b>                      |                                                                                 | Yes                                                                             | Yes                                                               | Yes                                                         | Yes                                                                                                            | No                                                                  | Yes                                                                    |

|                     |                        |                                                                                                                                                                              |                                                      |                                                          |                            |                                                                                                                                                                                                                                                                                      |                                                          |
|---------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------------|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| <b>Giving set:</b>  | <b>Length</b>          | 275cm                                                                                                                                                                        | 234, 300 and 305cm                                   | 300cm                                                    | 244cm                      | 2½m, Bag to pump<br>85m, pump to patient<br>1.5m (rest of the set is in the pump)                                                                                                                                                                                                    | 300cm                                                    |
|                     | <b>Filter position</b> | Filter is positioned nearer to the pump than the patient which makes it more comfortable                                                                                     | Filter located between the pump and patient          | Filter is positioned 30cm from the patient access device |                            | Filter fits into the pump                                                                                                                                                                                                                                                            | Filter is positioned 30cm from the patient access device |
|                     | <b>Ease of spiking</b> | Easy to spike                                                                                                                                                                | Easy to spike                                        | Very easy to spike                                       | Easy to spike              | Easy to spike. The spike has an air-inlet valve which will remain integral to the set                                                                                                                                                                                                | Very easy to spike                                       |
|                     |                        | The filter has a part which easily breaks on the exit point, however Fresenius confirmed that they are re-designing the filter and exit points to exclude the breaking parts |                                                      | The filter has air exhaust ports                         |                            | Set made of microbore tubing which means it is almost impossible to kink. Filter has 2 exhaust ports to expel air, one at each end of the filter so it can expel air when the filter is in any position. The air filter is placed before the air sensor to eliminate nuisance alarms | The filter has air exhaust ports                         |
| <b>Filter size:</b> |                        | 1.2 micron                                                                                                                                                                   | 1.2 and 0.2 micron; manual or pump priming available | 1.2 micron. 0.2 micron must be primed through the pump   | 0.22 micron and 1.2 micron | 1.2 micron. 0.22 micron. Air filter is placed before the air sensor to eliminate nuisance alarms                                                                                                                                                                                     | 1.2 micron or 0.22 micron.                               |

|                                    |                                                               |                                                                                                                       |                                                 |                                                                   |                                                                                                                                                                  |                                                                                     |                                                           |
|------------------------------------|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>Air detector:</b>               |                                                               | 0.15 ml                                                                                                               | Integral to pump – low or high sensitivity      | 0.1-2.0 ml (0.1-0.5 suggested)                                    | On: pump alarms at approx. 0.5ml of air. Alarms for any bubble greater than 500 micro-litres with a tolerance of 200 microlitres. more info available on request | 0.1, 0.5 or 2ml                                                                     | 0.1ml – 2.0ml. 0.1-0.5ml suggested                        |
| <b>Ability to manually prime:</b>  |                                                               | Yes, very easy                                                                                                        | Yes                                             | Yes, anti-syphon valve manual override push button system         | The giving set cassette has a rocker switch that can be turned on to allow priming                                                                               | Yes, anti-syphon valve manual override push button system is ergonomically designed | Yes, anti-syphon valve manual override push button system |
| <b>Integral anti-syphon valve:</b> |                                                               | The anti free-flow valve is incorporated in the giving set as standard at the point where it connects the patient     | Yes                                             | Yes                                                               | No                                                                                                                                                               | The anti free-flow valve is incorporated in the giving set as standard              | Yes                                                       |
| <b>Cradle for dripstand:</b>       |                                                               | The charger serves as the cradle. A pole clamp is standard                                                            | Pole clamp available                            | The charger serves as the cradle. A pole clamp will be considered | Yes                                                                                                                                                              | A pole clamp is available                                                           | Large clinical style pole clamp                           |
| <b>Instruction manual:</b>         | <b>Patient-friendly UK version</b>                            | Full manual, under development as well as quick reference guides                                                      | Full manual for patient and clinician available | Full manual and quick guides                                      | Full manual and quick guides. This can be adapted to suit the patient                                                                                            | Full manual with new easy to read patient guide in development                      | Full manual and quick guides                              |
|                                    | <b>Quick reference cards/information</b>                      | Yes                                                                                                                   | Yes                                             | Yes                                                               | Yes                                                                                                                                                              | Three types – setup, alarms and troubleshooting                                     | Yes                                                       |
| <b>Travel information</b>          | <b>Is there access to guidances for X-raying at airports?</b> | Pump function will not be affected by X-ray machines                                                                  | Yes                                             | Available on request                                              | Guidance under development                                                                                                                                       | Yes, information supplied as standard                                               | Available on request                                      |
|                                    | <b>Foreign adaptors available?</b>                            | No adaptors, however from LITRE panel review it is noted that the pump will charge at lower voltages but takes longer | Yes for Europe, US, Australia and Japan         |                                                                   | Uses a standard travel adaptor, US power lead can be provided                                                                                                    | Micrel can provide a 2 pin charger                                                  |                                                           |

## Anti-free flow devices

It is well documented that all administration sets for volumetric infusion pumps *must* be fitted with an anti-free flow device.

Interpretation of 'anti-free flow' led to the introduction of 'anti-syphon valves' being added to some of the administration sets for portable infusion pumps. These components, while adding an extra dimension to safety, have not been popular with users of the administration sets, indeed they have actually be problematic in relation to leaking and malfunction of the sets. Numerous recalls of specific batches of sets have caused major issues for suppliers, distributors and patients alike.

Moving forward with clarification on the required components for 'anti-free flow' some administration sets are being modified to remove anti-syphon valves. LITRE welcome these changes providing all modifications are in line with current guidelines. Where there are fewer complications for the end user without any safety aspect compromised we welcome these modifications.

## Review of individual pumps

### Bodyguard 323

The panel agreed that the pump is compact and lightweight and reliable. There is a rechargeable battery and the pump can be powered via the mains while infusing. The panel would like to see the giving set made easier to load into the pump, as some panel members felt that the 'key' was of a soft material that could benefit from being a little more rigid to aid loading.

The panel noted that CME Medical UK Limited was still replacing rucksacks every 12 months upon request via homecare suppliers.

The panel thought that the laminated 'Quick user guide' was excellent and hoped that these would be distributed to all existing users of the pump.

The panel requested that the A5 leaflet – 'Directions for use of the Infusion Set' be produced in the same format as the Quick user guide both for continuity and for ease of use.

LITRE and PINNT acknowledge that extensive talks have taken place with regards to the giving set however the panel would like to note that patients may have difficulty with the priming of the set with the button. LITRE also acknowledge that the filter position has moved since the last assessment.

The noise of the pump was slightly disappointing both in the lower and upper rates. LITRE would like to see a reduction in the noise levels across the infusion ranges.

The panel liked the fact that the pump was self correcting.

### Battery test result:

After the meeting CME Medical UK Limited reported that the Bodyguard pump will run for an average of 11.3 hours at 350mls which would complete a feed of 3955mls before the need to recharge.



## **Gemstar – Series 7**

The panel were disappointed not to have the full accessory range available on the day.

The panel felt that the pump was slightly large but this did not detract from its functionality.

The charger base unit is extremely large and very clinical looking for a home environment. There was confusion as to exactly which accessories came as standard and over time various options had been demonstrated to LITRE. Hospira have subsequently confirmed that the Gemstar has the flexibility to be used with or without the docking station.

The pump can be powered via the power lead, AA batteries or the rechargeable battery option. LITRE has been informed that a mobile phone style charger is currently in testing.

Previous suggestions offered by LITRE regarding the giving set had not taken place but assurances were given that these are currently being addressed. LITRE suggested that once these has been made, Hospira would be welcomed back to show changes to the panel.

The noise levels of the pump were very acceptable both in the lower and high rates.

The panel noted that the pump can be quite complicated to setup and it “tweets” for no apparent reason, this could be frustrating for a patient given most feeding is carried out overnight. The panel were told that this alarm can be silenced.

It was also suggested that wording is made more user friendly with ‘upstream’ and ‘downstream’ rather than ‘distal’ and ‘proximal’. The panel note that Hospira have plans to change this.

Clinicians have reported to LITRE that a USB port would be useful to gather reporting data rather than the old style serial port.

### **Battery test result:**

After the meeting Hospira reported that the Gemstar pump will run at 350mls per hour for in excess of 24 hours which would cover 2 full 3500ml feeds without the need to charge the battery pack.



## Rythmic

Inspiration Healthcare represented the Rythmic manufactured by Micrel. It was noted that Inspiration Healthcare had not presented to LITRE prior to this meeting although key members of the team were familiar to LITRE.

The panel agreed that the new Rythmic pump was small and lightweight and ascetically similar to the previous Rythmic.

LITRE was pleased to see that Micrel had taken on board the previous LITRE comments and actioned them to further improve the patient's experience. This has included:-

- Extended life on dry cell battery option this applies to the rechargeable battery as well
- Improved connectors on charger and external battery packs
- Operating instructions now on a DVD
- Rucksack in different colours
- Click to confirm on the giving set

The battery was extremely small and appears to be able to deliver at a reasonable rate for an acceptable time; and now has better built connector port with a longer connecting lead.

Whilst the noise of the pump had been greatly reduced, the panel did not agree with the literature statement that it was “near silent”, and thought this was more of a users perspective.

LITRE appreciated the advancements made by Micrel including a remote buzzer which enhances the volume and enables carers or parents to hear alarms.

The panel would like to see back lit buttons for easy access during the hours of darkness.

### Battery test result:

After the meeting Inspiration Healthcare reported that the Rythmic pump will run for in excess of two 3500ml feeds running at 350mls an hour which would infuse over 7000ml.



## FK Ambix

This is the first full review of the FK Ambix by LITRE as the last report was an interim report.

The panel like the style of pump and found the giving set easy to load. However the panel thought the charging cradle was excessively large, especially when a patient is travelling, and thought an external battery pack or dry cells were needed to enhance the features that would enable this to be a full ambulatory pump.

As per our previous report LITRE would like to see the pole clamp redesigned so that a patient can easily remove this if the wish.

It was agreed that the noise of the pump during infusion was very acceptable. The alarming of the pump and clearing of errors was easy and manageable – however if they could self correct that would advantageous to patients more so for the downstream occlusion

The software on the pump only allows you to program minutes up to 9:55 minutes. Once you reach 10 hours you can only increase in 1 hour increments. It was felt that the ability to set the infusion rate other than hourly above 10 hours would enhance the use of the pump for the patients.

Patient feedback included that the door can get loose which in turn means the pump doesn't recognise the door is shut – LITRE asked if the quality be improved or the sensor changed.

Fresenius Kabi informed the panel that they are releasing a new giving set to market which will correct current problems with the filter. PINNT and LITRE hope that communication of the release is free flowing and circulated in an appropriate and timely manner.

### Battery test result:

After the meeting Fresenius Kabi reported that the Ambix pump will run for in excess of two 3500ml feeds running at 350mls an hour which would infuse over 7000ml.



## BodyGuard 2CH

The panel were pleased to see a single 2 channel device.

This device looks very clinical and is quite large.

The docking station is also large with a very obvious display at the top with red running figures – this could be very off putting for a patient although the panel accepted it would be a benefit for certain patients. The panel noted that a docking station is available without the red digits which would be preferable for home patients.

The panel thought the device was quite noisy when both channels were operating.

The panel would like to see the giving set made easier to load into the pump, as some panel members felt the 'key' was of a soft material that could benefit from being a little more rigid to aid loading.

### Battery test result:

The infusion performance tests carried out have confirmed that the average infusion duration possible with a BodyGuard 2 Channel pump; operating at a rate of 350ml/hr (powered solely from the fully charged battery) is 7 hours 19 minutes.



## CADD SOLIS VIP

The panel noted that it was a brand new design from previous pumps shown by Smiths Medical and as promised it was being shown to LITRE as soon as it was available which was very much appreciated.

The screen is colour and based around a mobile phone to try and make the patient experience easier. Whilst this is nice the panel were concerned that this would have a large detrimental effect on battery life.

The panel found the pump quite difficult to program and also reasonably noisy.

The panel felt there was a lot of background information that may be relevant for clinicians but not necessarily of interest to patients.

Possibly, the panel felt, that the giving set may be difficult for some patient to attach.

The panel were unable to look at the adult PN rucksack.

### Battery test result:

After the meeting Smiths Medical reported that the CADD Solis VIP will run for 11 hours running at 350mls an hour which would infuse 3850ml. This is assuming that the screen backlight is set to level 3.



## Acknowledgements

LITRE would like to thank the companies for attending and being receptive to the constructive feedback provided by the panel. While it was felt that many of the suggestions would certainly enhance to functionality of the pumps it was pointed out that some changes do take time to implement. LITRE noted that one company had been able to deliver all their promises and hope that, moving forward, changes could be implemented in a timely fashion. LITRE reiterated that they are always available, between meetings, to discuss or advise on changes that they suggest should modifications be necessary to restraints that were not evident at the time of discussions.

We wish to also thank the members of the panel for the time they invested in the LITRE assessment. No payment was made to any member of the panel; only out of pockets expenses were reimbursed.

## Considerations and Recommendations

### LITRE's position

We have given equal time to all companies during meetings to receive presentations and offer advice on product development and we have strongly advocated that we are not here to suggest nor recommend that any one pump will suit all users. We appreciate that particular units/hospitals may elect to use one model for continuity, however we hope that the individual patient needs will be a major factor when the decision making is undertaken.

It is our belief that if a patient or carer feels that the pump offered to them imposes restrictions to their lifestyle then suitable options, based on clinical safety and effectiveness, should be offered to the patient.

LITRE's position is to raise awareness as to the ambulatory pumps that are available within the market place; we do not endorse their suitability for individuals or units.

### Environmental Issues

Whilst LITRE are conscious that patients like the option of a dry cell back-up with their pump we would seriously ask people to consider smaller, lightweight, rechargeable power options with extended life to reduce the amount of batteries used, thus saving further detriment to the planet. LITRE do not advocate that dry cell batteries should be used on a daily basis, short term or emergency use only is recommend, however where dry cell batteries contribute to a better quality of life we endorse this philosophy.

### On-going relationships with pump manufacturers and distributors

Members of PINNT and LITRE will, from time to time, be asked to talk or present the patients view of ambulatory pumps. Where requests are made and given we wish to point out that this does not endorse the product but fulfils the role of presenting the users viewpoint in order to fulfil our mission statements as listed at the beginning of this report.

## Summary Ratings

| Final standings                          | No answer | Very poor | Less than acceptable | Acceptable | Good | Very good | Total      |
|------------------------------------------|-----------|-----------|----------------------|------------|------|-----------|------------|
| Rythmic Inspiration Healthcare           | 0         | 1         | 0                    | 99         | 420  | 375       | <b>895</b> |
| Ambix/FK                                 | 0         | 1         | 28                   | 150        | 328  | 335       | <b>842</b> |
| Bodyguard 323<br>CME Medical UK Limited  | 0         | 1         | 26                   | 132        | 332  | 340       | <b>831</b> |
| Bodyguard 2 Ch<br>CME Medical UK Limited | 0         | 3         | 38                   | 102        | 424  | 220       | <b>787</b> |
| CADD Solis VIP<br>Smiths Medical         | 0         | 6         | 24                   | 66         | 308  | 310       | <b>714</b> |
| Gemstar/Hospira                          | 0         | 2         | 18                   | 138        | 316  | 175       | <b>649</b> |

**We understand that manufacturers may wish to reproduce parts of this report for marketing, promotional or internal uses. Whilst permission will not be necessary be unreasonably withheld permission must be sought from LITRE via Richard Shawyer on [info@pinnt.com](mailto:info@pinnt.com)**

**This report in its entirety is subject to copyright and plagiarism laws.**

LITRE contact details:

LITRE, PO Box 3126, Christchurch, Dorset BH23 2XS

Email: [info@pinnt.com](mailto:info@pinnt.com)  
[rshawyer@pinnt.com](mailto:rshawyer@pinnt.com)  
[cwheatley@pinnt.com](mailto:cwheatley@pinnt.com)

© PINNT 2011 All rights, including copyright, in the content of this report are owned or controlled for these purposes by the PINNT.

Whilst PINNT have sought assurances from each manufacturer in relation to the data table, PINNT make no representation and issue no assurance that the technical data is correct, equipment is free from defects or errors, or fit for any particular purpose. PINNT provide no undertakings, warranties, terms of agreement as to the quality, standard and function of the Equipment. PINNT is not liable for any errors and this information is provided based solely on patient feedback only. PINNT advocate that all products should be thoroughly tested before any decision or purchase is made, PINNT cannot accept any loss or misrepresentation claims from this report.

## Appendix 1

Dear XXXXX,

Thank you for your interest in LITRE. As a background LITRE is a board of people with a professional or personal interest in nutrition. Before we progress this current formation we would like to know some more information about you and your clinical needs and your current regimes. We are looking for this information to ensure that the LITRE panel has a fair distribution of people to make sure all people are represented. We are currently in contact with pump manufacturers and are waiting to hear back from a number of them as to whether they wish to be included in this evaluation. We would be grateful if you complete the following questions.

Name

DOB

Address

Telephone Number

Email address

Hospital you attend

How many nights per week do you feed

Do you currently work (please describe working hours)

Current Pump Used

Previous ambulatory PN pumps you have used

Do you use your pump

At home

socially

mostly during the night

During the day (please tick as many as necessary)

Volume infused

Time Infused

Any current problems relating to the pump or giving sets you are using?

Any other info you feel relevant to your application

Please confirm you are happy for us to give your name and address to the manufacturers so that they can supply the equipment

Many thanks

PINNT

Dear [●],

***Re: Forthcoming Trial of Parenteral Nutrition Portable feeding Equipment***

I write on behalf of Patients on Intravenous and Naso Gastric Nutrition Therapy ("PINNT") in relation to our exciting forthcoming in-home trial of cutting-edge Parenteral Nutrition Therapy Equipment.

The team at PINNT is most excited to be running its first in-home trial, to obtain your input, which we will then convey directly to manufacturers to seek to improve the design which will include convenience, usability and noise levels and general operation. This trial will hopefully transform the lives of various sufferers, requiring treatment by intravenous nutrition therapy in the future.

Most importantly, I write to sincerely thank you for taking part in this trial. As you know, we are a small, but growing, charity; we greatly appreciate the support of members such as yourselves, and it makes a huge difference to the work we do.

***Background Information***

I also write to provide you with a little more background information in relation to this trial. Equipment (comprising of pump, and all other equipment a typical PN patient requires (together, the "Equipment")) will be loaned to you [add details] between [●] 2011 and [●] 2011, being returned to us by you in substantially the same condition on the latter date.

If you have any problems then please call me on 0844 858 1133.

In advance of the trial, we attach, a sample questionnaire as well as the terms and condition between PINNT and yourself. Please review the instructions, sample questionnaire and standard terms and conditions of the trial carefully, and let me know have any questions.

I would be most grateful if you could please sign, date and print your name below and return a copy of this letter to me (which I am sending to you in duplicate) for our records.

Please do not hesitate to contact me, should you have any questions.

Many thanks again.

Yours sincerely,

Richard Shawyer

[Vice Chairman, PINNT]

*Encs.*

I hereby confirm safe receipt of this letter and agree to the terms and conditions set out in Annex 3

Signed: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

## Annex 2

### TERMS AND CONDITIONS

The below terms and conditions (the "**Ts&Cs**") constitute the basis of Patients on Intravenous and Naso Gastric Nutrition Therapy ("**PINNT**") entering into the trial of various medical equipment with [insert name of relevant party], in relation to the in-house trial of various intravenous/naso gastric nutrition therapy equipment:-

#### 1. Interpretation

##### 1.1 In the Ts&Cs, the definitions in this (Clause 1) will apply:

"**Charity**" means the manufacturer of Patients on Intravenous and Naso Gastric Nutrition Therapy (registered number and 327878);

"**Equipment**" means the of various intravenous and naso gastric nutrition therapy equipment lent by the medical equipment, including a pump [●];

"**Manufacturer**" means the manufacturer of the Equipment;

"**Purpose of the Trial**" means purely to test the cosmetic functions of the Equipment such as the various settings, ease of use and the level of noise generated; it does not include any attachment of the Equipment to a person's central line nor the attachment of the Equipment whatsoever to any person;

"**Trial Period**" means the period starting on [●] April 2011 and ending on [●] May 2011;

"**We**", "**we**", "**us**", "**Us**", "**Our**" or "**our**" shall refer to PINNT, lending the equipment to you on behalf of the Manufacturer; and

"**You**", "**you**", "**Your**" or "**your**" shall refer to you, the borrower of the Equipment.

##### 2. The Equipment and all associated material is supplied by us on behalf of the Manufacturer, to be used by you solely on the following basis, to which you have agreed:-

- 2.1 that neither you nor any other person shall, in any circumstances, attach the Equipment to your central line, nor internally at all, nor to any other person's central line, nor internally at all;
- 2.2 that your use of the Equipment shall be limited to testing the Cosmetic Function of the Equipment;
- 2.3 that you shall return the Equipment to us at the end of the Trial Period in substantially the same condition in which it is lent by us to you;
- 2.4 that you shall ensure, and take all appropriate steps to ensure, that no third party shall come into contact with the Equipment;
- 2.5 we shall not be liable for any consequences which arise as a result of the use of the Equipment and any associated material by you or any third party who is in contact with the Equipment

including, but not limited to, costs and damages whether direct or indirect and whether reasonably foreseeable or not;

- 2.6 that all the risk, liability and choice of testing the Equipment and any associated material is with you and you shall not seek to claim any sums from the us unless the death, or serious injury of a person is directly linked to and arises from their use of the Equipment and any associated material and was directly caused by the negligence of us;
- 2.7 we provide no undertakings, warranties, terms of agreement as to the quality, standard and function of the Equipment other than the Manufacturer's guarantee in relation to the Purpose of the Trial;
- 2.8 whilst we have sought assurances from each Manufacturer in any event for any foreseeable issues, beyond the Purpose of the Trial, we provide no representation and no assurance that the Equipment is free from defects, errors, is undamaged, fit for any particular purpose, or suitable to be used in conjunction with any other particular products or systems;
- 2.9 these Ts&Cs are governed by the laws of England and Wales; and
- 2.10 if a provision of these Ts&Cs is found to be illegal, invalid or unenforceable, then to the extent it is illegal, invalid or unenforceable, that provision will be given no effect and will be treated as though it were not included, but the legality, validity or enforceability of the remaining provisions of the remaining Ts&Cs will not be affected.