BAPEN

Advancing Clinical Nutrition

LITRE Assessment of Ambulatory Pumps for Parenteral Nutrition

Results of a LITRE Assessment Panel

8th November 2006

Registered Charity 1023927

BAPEN
Advancing Clinical Nutrition

www.bapen.org.uk

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 the British Association for Parenteral and Enteral Nutrition (BAPEN).

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

There will be at least 2 patients and/or carers on the committee, one receiving parenteral and the other enteral nutritional support. In addition, there will be nominated representatives from each of the Founder Organisations of BAPEN. The Founder Group will nominate their appropriate representative who will be allowed to serve for a term of five years.

In addition to the nominated representatives, further members may be nominated/invited to serve on the committee in a specific capacity especially when LITRE have projects with a specific focus.

Experts from various quarters will be invited onto the committee at given intervals as and when LITRE feels their expertise will enhance the work they do

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
The survey was presented at BAPEN in 1995, this is an ongoing problem and will be updated in the future.

LITRE Dressing Pack Survey
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 Home Care Company depending on their personal needs and duration 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 or 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. Ongoing patients were kept informed via online.

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 pinnt@dial.pipex.com for a copy.

Enteral Syringes
LITRE was approached for comment on the proto type for a new reusable syringe designed for longer life than the standard ones. This is now in production and in use.

TPN Line Occlusion
A common issue reported to LITRE, so an in depth survey was undertake in June 2003 to look at extensive parameters of incidence. The survey produced 103 returns which are currently under review and will shortly be published.

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

Rucksack Design
We have established a liaison group of users to comment on the Baxter 6060 pump rucksack and the first session 10 people were involved, this is ongoing.

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.

Current Project – Assessment of Ambulatory Pumps for Parenteral nutrition at home

Background

When Baxter announced in November 2005 its worldwide withdrawal of the 6060, LITRE and PINNT realised the gravity of the situation as the majority of UK patients were using the pump and it was felt there were no viable alternatives to the same standard. LITRE and PINNT immediately began investigating the pump options available and providing manufacturers with suggested changes to meet patient needs and UK clinical protocols.

LITRE has worked closely with PINNT to establish a forum in which consistent advice has been made available to everyone. We firmly believe that there should be a choice of pumps and we should not find ourselves in a similar position whereby there is only one pump dominating the market.

Previously we have made available two reports based on presentations received from manufacturers where we have provided advice and recommendations on the needs of patients and clinical requirements.

These reports can be found on www.bapen.org/litre

We recognise that time is against us and we are very conscious that patients need to know which pump they will be using in the future. There is a huge training implication for hospitals and homecare providers.

Objective of Litre Assessment of Ambulatory Pumps for Parenteral Nutrition Panel

Our objective was to make a final pump evaluation before centres and patients have to make a pump choice. We recognise that clinical centres and patients have to make a pump choice before the end of the year as there is a huge logistical and training requirement for hospitals and homecare providers.

LITRE Panel Members

Justine Bayes – HPN patient
Anthony Collins – Carer of HPN patient
Jennifer Collins – HPN patient
Simon Gabe – Gastroenterologist
Paul Glicker – HPN patient
Caroline Hartt – Paediatric Nutrition Nurse
Elena Skrybina – Representing CEP, NHS PASA
Carolyn Wheatley – HPN patient

LITRE wishes to stress that the views presented in this report are a collective response, therefore no member of the panel should be personally contacted in respect of this report. All communications should be addressed to the Chair of LITRE.

Pump Review

This pump review has been based on the final presentations received by LITRE on 8th November. LITRE acknowledges that manufacturers are still planning final changes to their pumps and we have made reference to these future changes accordingly; however our ratings are based on the specifications available on the 8th November.

We have based our advice and comments on the knowledge that we hold as a user focus group. Through PINNT we have contact with members who have been vocal about their preferences, and these have been extremely useful in providing an insight into patient requirements from a pump.

LITRE were also keen to consider the whole package; 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 and make it easier.

LITRE 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

Pump Review Table

Features	Bodyguard	CADD	Gemstar	Rythmic
Weight: pump with battery alone pump with charger	390g Docking station -765g combined	490g including 9v battery	482g with rechargeable battery – 700g	300g 300g + 120g
Size: pump alone pump with charger	112 x 89 x 32 mm Docking station 165 x 94 x 79 mm	4.4 x 10.4 x 14.1 cm	5.5 x 3.8 x 2.0 inches Not applicable	80 x 130 x 46 mm 106 x 144 x 46 mm
Battery: Charging times Dry cell capacity	6 – 8 hours Pump will have 2 x 9v option	7 hours 9v x 1 Rates over 250ml/h are recommended to use the battery pack. 350 ml/h will last 39 hrs. Battery pack must be discharged for 8 hours every 30 days.	6 hours 2 x AA Using two fresh AA batteries or a charged battery pack the pump is capable of delivering the following: 96 hrs @ rates below 5ml/hr. 48 hrs @ rates above 5ml/hr but below 25ml/hr.24 hrs @ rates above 25ml/hr but below 125ml/hr. 3000ml @ a rate of 125ml/hr or higher.	2½ hours external battery pack from flat to fully charged. Battery pack - 9v 30 hours @125 ml/h, 9 hours @400 ml/h 12 hours at 300ml/h dry cell battery. Internal battery is standard alkaline dry cell PP3 Battery 9V
Charger: size weight	Docking station 165 x 94 x 41 mm 375g There is a rapid charger available, which is mobile phone size and will charge in under an hour.	16cm x 9.7cm x 3.7cm 630g	Not applicable – battery pack is directly charged from the mains	Mobile phone size charger with integral 2-pin plug for continental use 120g

Accuracy:	+/-5%	+/-6% (nominal)	+/-5%	+/-5%
Noise when running: low rate high rate	Quite noisy at both rates	Noticeable	Extremely quiet at both rates	Quiet in operation
Lights: Ability to turn backlight off:	Yes	Backlight goes off after 2 minutes.	Not lit at night.	Yes. Has a time-out, after key press or alarm.
Display panel: easy to read?	Yes. Key pad volume can be turned off.	Yes.	Yes. Keypad - the audible alarm is user-adjustable from the maximum volume down to silent	Yes. Keypad volume can be turned off.
Ease of programming: Size of keys Numeric keypad/multi-function keys	Very easy with logical steps. Buttons quite small but raised Numeric keypad.	Simple with promoting steps. Large buttons. Multi-function keys	Simple. Different infusion protocols can be stored for ease of programming. Numeric keypad with sizeable buttons.	Very easy with logical steps. Large, multi-function keys.
Alarms: Are they adjustable? Is there a warning when the infusion is due to end?	Yes. No.	The alarm volume is loud and cannot be adjusted. Alarms indicate when the Reservoir Volume is Low or Stopped.	Alarms can be silenced. 'Help' screen will inform the user of the steps needed to address and correct an alarm.	Adjustable volume level. Warning when infusion due to end - visual and audible.
Is it a multi-therapy pump?	Yes.	Yes.	Yes. The Gemstar is a 7 Therapy pump	No – dedicated PN pump.
Giving set: Length Filter position Ease of spiking	3000 mm Filter is positioned nearer to the pump than the patient which makes it more comfortable. Very easy to spike. The filter has air exhaust ports	305, 234 (separate anti-syphon valve), and 300cm sets available. Filter is within tubing, near patient end. The giving set has a cassette which is loaded into the pump with a coin-operated catch	In process of change.	2½m. Bag to pump 85cm, pump to patient 1.5m (rest of the set is in the pump) Filter in the pump. Easy to spike. The spike has an air-inlet valve which will remain integral to the set. Set made of microbore tubing which means it is

		and a key-operated lock to prevent accidental removal. Anti-kink tubing.		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.
Filter size	1.2 micron. 0.22 micron must be primed through the pump.	1.2 micron 0.22 micron	0.22 micron & 1.2 micron	1.2 micron 0.22 micron Air filter is placed before the air sensor to eliminate nuisance alarms.
Air detector:	0.1 – 2.0 ml (0.1-0.5 suggested)	0.1 ml	On: pump alarms at approximately 0.5ml of air. Alarms for any bubble greater than 500 micro-litres with a tolerance of 200 microlitres…more information is available upon request.	0.1, 0.5 or 2ml
Ability to manually prime:	Yes. Anti-syphon valve manual over-ride push button system.	There is now and admin set available with separate anti-syphon valve. With this set there is the ability to manually prime.	The giving set cassette has a rocker switch that can be turned on to allow free-flow.	Yes. Anti-syphon valve manual over-ride push button system is ergonomically designed.
Integral anti-syphon valve:	Yes.	Both integral ASV and separate ASV options are available. Possibly in early 2007 there will be an anti-free flow valve on the cassette.	No. See note 1 at end of table, with regard to MHRA advice.	The anti-free-flow valve is incorporated in the giving set as standard.
Cradle for dripstand:	The charger serves as the cradle. A pole clamp will be considered.	Yes.	Yes.	Yes, the fabric bag which holds the pump can be attached. A pole clamp is available but the fabric bag will be

				supplied as standard.
Design of rucksack: Can you view/access the pump easily Is there sufficient capacity to hang a wide range of PN containers How safe is the hanging facility? Is the giving set safe and secure in situ Are there sufficient pockets to store medical/personal items Are there a wide range of carrying options? How would large volumes be managed by the patient? Is there a guide included to show how to position the items in the rucksack?	A rucksack is available but it needs modifications. Has shoulder straps plus waist straps, pockets for storage both internally and externally on the rucksack. Additional pockets on the front, rear and inside for additional spares. Further Paediatric pack planned for up to 2 litres. Guide will be available soon. See note 2 at end of table.	The outer section must be unzipped to view the pump. Has shoulder straps plus waist straps, pockets for storage both internally and externally on the rucksack. One litre size now available. Instruction leaflet on how to position things in the rucksack.	Will have a clear flap on the front which shows both the pump and the battery, so that the battery life indicator can be seen. Currently working on modifying a rucksack to ensure it fits the pump and accessories. Currently rucksack has shoulder straps, pockets for storage both internally and externally on the rucksack. A waiststrap can be added. See note 2 at end of table.	Yes, clear panel at the front. Can accommodate up to 4 litres. Has a sturdy hook which has undergone significant modification to suit all type of containers and user applications. Retaining clasps to hold the giving set. A secure system has been developed to accommodate various sizes and styles of PN containers with buckle fastenings supports which secure the bag both horizontally and vertically. Inside pocket for ancillaries. Waist-strap as well as shoulder straps. For large volumes of feed where weight is an issue the bag can be supplied (optional) with wheels and a strap to pull the rucksack. Photo instruction guide supplied. See note 2 at end of table.

Instruction manual: Patient-friendly UK version Quick reference cards/information	Full manual and quick guides.	User guide can be tailored on request.	Full manual and quick guides. This can be adapted to suit the patient.	In development – draft already exists, due out end of November 2006. 3 types . Setup, alarms and troubleshooting
Travel information: Is there access to guidance for X-raying at airports Foreign adaptors available	Currently no information	Yes - 'Memo to inform aircraft carriers of testing regarding airborne equipment'.	Guidance under development. Uses a standard travel adaptor. Us power lead can be provided.	Yes, information supplied as standard. Charger has integral 2-pin plug for continental use.
Have trials been carried out with HPN patients?	Yes, trials are currently being undertaken.	Used in US for PN patients.	Yes, trials are currently being undertaken.	Trials starting w/c 20 November 2006

NOTE 1: MHRA ADVICE REGARDING ANTI-SYPHON VALVES IS BELOW (TAKEN FROM THEIR DEVICE BULLETIN ON INFUSION SYSTEMS)

Volumetric pumps:

Use of volumetric pumps

5.1.1 Recommendations for using administration sets

- always use the administration set recommended by the manufacturer;
- check that the administration set is compatible with the infusion pump. The correct pump should be listed specified on the administration set's packaging;
- always inspect the administration set for damage before priming the line;
- inspect the drop chamber, after loading the set and during infusion, to ensure the drip rate is as anticipated;
- **consider using an administration set fitted with an anti free-flow device**;
- always use the roller clamp to occlude the line when removing the administration set, regardless of whether the set has an anti-free flow device;
- replace the administration set within the lifetime specified by the manufacturer, in order to maintain accurate delivery.

5.1.2 Preventing free-flow (siphonage)

Free-flow will not occur if the set is loaded correctly and the door is closed. However, users should check that the roller clamp is closed before removing the administration set from the pump, as a primary means of occluding the line. If the administration set is fitted with a flow-stop mechanism, this should not be relied upon and the roller clamp should still be used.

In Appendix 1 of the Device Bulletin, we list important features:

Table 4b: Important safety features in descending order of importance
Anti-free flow device in administration set
Free-flow clamp in pump when door opened
Provision against accidental modification of settings
Two distinct actions to change rate
Two distinct and/or simultaneous actions to initiate bolus
Syringe barrel clamp alarm, door open alarm or equivalent
Syringe plunger disengagement alarm or equivalent
Patient history log
Volume infused display
Technical history back-up
Battery back-up

Therefore, although MHRA recognises that an anti-free flow valve is an important safety feature, they do not stipulate that one should be incorporated in the design of the pump [volumetric or syringe] set, nor whether this should be removable or not.

NOTE 2: RUCKSACK DESIGN

PINNT and LITRE provided all companies that requested it advice on rucksack design, so that the most desirable features could be incorporated. Baxter did a European survey amongst patients asking for their views on rucksack design for the 6060, and the feedback from this was used to make a prototype, which PINNT/LITRE have made freely available to all who asked, along with suggestions for further useful modification.

Review of Individual Pumps

Bodyguard 323

The panel agreed that the pump is compact and lightweight. There is a rechargeable battery and the pump can be powered via the mains while infusing. The pole mounted charger is lightweight but LITRE would prefer to see a smaller independent pole clamp with a separate small lightweight charger unit.

McKinley have responded very well to the advice given regarding changes to the giving set although it was felt that the length of the set could be shortened slightly.

The introduction of the integral anti-syphon allowed gravity priming of the set which was welcomed.

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 rucksack had been modified in line with recommendations from LITRE and PINNT based on a previous LITRE project. McKinley expressed an interested in continuing to focus on improving it in line with user feedback. LITRE have encouraged McKinley to ensure they personalise the rucksack while retaining the recommended features suggested.

Trials have taken place with prototype equipment and LITRE were aware that further changes were being made therefore were unable to make final conclusions given that the full kit range was still undergoing changes.

CADD VIP

The panel felt that the pump and accessories were rather heavy. The rechargeable battery had ample lifespan but came at the price of being heavy. Long life products were applauded but it was generally agreed that a compromise between size and weight versus delivery time should be re-accessed. In addition to the battery pack the pump could be run on a dry cell battery.

The giving set remains unchanged and the point at which it attached to the pump was again felt to be difficult and with the need for a 'key' to lock the set in place possibly a lengthy process to carry out, possibly proving difficult for those with dexterity problems.

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

The rucksack also remained the same; it gives ample and appropriate hanging spaces with additional carrying options and pockets.

The CADD VIP is currently being used for HPN use. LITRE felt the product would benefit from modification on the pump and battery. LITRE suggested further discussions with Smiths Medical if they felt this appropriate.

Gemstar

The panel felt that the pump was slightly large but this did not detract from its functionality. The charger base unit has been withdrawn after feedback suggested that it is not necessary and would pose problems when pole mounted. A smaller lightweight charging system has been identified, LITRE were delighted to hear this. There is a small lightweight pole mount and the pump comes with two external battery packs. In addition to this the pump can be run on dry cell batteries.

The 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 had 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 backpack had been modified in line with PINNT and LITRE recommendations based on a previous LITRE project. We were pleased to hear that further work was being undertaken to improve the rucksack to give greater convenience to the patients. LITRE have encouraged Hospira to ensure they personalise the rucksack while retaining the recommended features suggested.

Rythmic

Eden Medical had not presented to LITRE prior to this meeting therefore this section contains more detail than the three above.

The panel agreed that the pump was small and lightweight. First impressions were that the function panel looked straight forward; keys are of a good size.

The battery was extremely small and appears to be able to deliver at a reasonable rate for an acceptable time; trials are yet to be undertaken.

The panel were delighted to see an extremely compact charger. This came ready for use both in the UK and within the EU; a small cover made this safe and secure.

The pump could be attached onto a pole via a small padded pouch which was felt to be a good way to protect the pump while also accommodating a battery pack. The pump can be viewed via a clear panel on the front of the pouch.

The giving set was felt to be excellent. Serious consideration had been given to the safety of the set and all key components could be safely housed within the pump itself.

The door on the pump could be easier to open and it was suggested that this could be looked at.

The noise of the pump both in the lower and upper ranges were deemed acceptable by the panel.

The backpack was still in the design process but the panel were informed that it was only minor changes that were necessary. The rucksack had been developed in line with recommendations from LITRE and PINNT based on a previous LITRE project. LITRE have encouraged Eden Medical to ensure they personalise the rucksack while retaining the recommended features suggested.

The hanging system was deemed very acceptable. There were plenty of internal and external pockets along. For those patients with larger volumes of feed the rucksack could be supplied upon request with wheels and a strap to pull the bag when the overall weight was at its peak.

In addition to the backpack small padded pouches were available to provide options to the patients during feeding.

The panel found little they could suggest in relation to modification of the pump.

LITRE would like to thank the companies for attending and being receptive to the constructive feedback provided by the panel.

Considerations and Recommendations

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's 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.

Many patients are unhappy that their Baxter 6060 pump is being withdrawn – if they have not been experiencing problems then even a newer product may not be welcomed into their feeding lives. Acceptance of a new product should be gradual and we would hope that the existing product will not be withdrawn until patients and carers are confident with the new pump that they are to use.

We would like to commend those units/hospitals that have sent out questionnaires to their patients to determine their 'wish list' for a new pump.

LITRE are also pleased to hear that some units/hospitals are holding patient sessions to inform them of the pumps they deem suitable and allowing them the opportunity to find out which one will work for them.

We are aware that if a product is imposed upon them without their having been part of the decision-making process then this could cause a loss of confidence in their ability to carry out their treatment.

Environmental Issues

While LITRE are conscious that patients like the option of 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 that are used, thus saving further detriment to the planet. Dry cell batteries should be for short term or emergency use only.

Summary ratings

The following scores are 0 poor - 10 excellent

Features	Bodyguard	CADD	Gemstar	Rythmic
Noise level	6	6	9	8
Ease of use	8	5	8	8
Size and weight (pump and internal battery)	8	3	6	9
Giving set	8	6	8	8
Battery life options (longevity not weight)	7	9	8	8
Rucksack	8	8	8	9
Manufacturer's response to requested changes	7	2	7	9

Summary

Following this meeting we had hoped that we would be in a position whereby we could base our findings on completed products, accessories and supporting literature. Unfortunately, this is not the case. Since our initial meetings certain manufacturers have been slow to change and we have not seen final packages from anyone.

Trials have taken place with certain products in their prototype stage, which is actually not very helpful as the rating will be significantly lower than if the trial had been completed on the final package. We appreciate the desire for the manufacturers to launch their product into the marketplace as quickly as possible; however, it seems that in some cases this has been to the detriment of the product. It is a daunting prospect for the patient to have to trial a new pump and we would have preferred that all products were presented for trial in their finished state.

Two pumps new to the ambulatory parenteral nutrition market have made considerable advances. One company had internal changes which unfortunately prevented progress as they would have preferred. We believe their commitment to correcting this will allow them to develop their product making it a viable option.

One late entrant into the arena appears to have been quietly working in the wings and presented LITRE with the closest complete package. Minor amendments did not detract from allowing LITRE to envisage the final package.

One product has been available for some years now but sadly we have not seen significant changes that take into account the needs of today's patients.

LITRE would like to thank members of the panel, several of whom are patients involved in trials, for their time and commitment to this project.

LITRE Committee
November 2006

Contacts: Chair, LITRE – Justine Bayes – justine@bayes3721.fsnet.co.uk
Chair, PINNT – Carolyn Wheatley – pinnt@dial.pipex.com