

LITRE

Interim Assessment of an Ambulatory Pump for Parenteral Nutrition

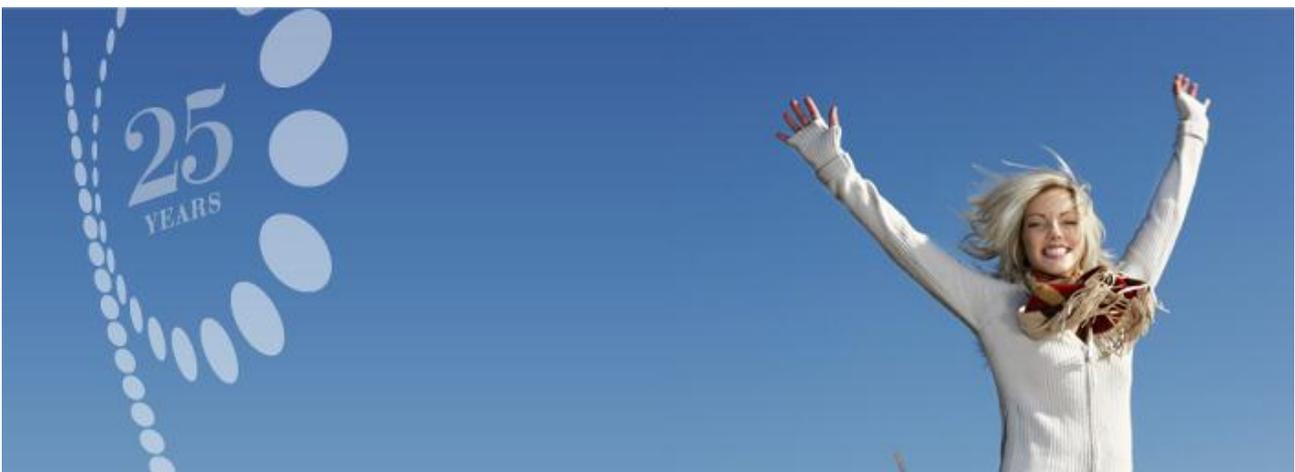
Results of the LITRE User Assessment Panel

12th January 2013

Embargoed until 25th June 2013

LITRE

Looking Into The Requirements for Equipment



Await new image from Dreamscape

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 has the required knowledge and expertise for 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 Home Care 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. 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 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 PN pumps was carried in October 2009

Full Patient led review of Ambulatory Pumps in 2011.

LITRE Panel Members

PINNT advertised the proposed assessment in Online and requested volunteers to complete a simple questionnaire in 2011; the vast majority of these members have stayed on the panel and we will not re-advertise for appointment until our next major review or price of work. 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 committee 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 committee members were invited; an independent buyer and an adult nutrition nurse. Unfortunately our paediatric nutrition nurse was unable to join in the assessment process.

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:-

Jasmine Cheesman – Carer of HPN paediatric patient
Mia Small – Nurse Consultant Nutrition and Intestinal Failure
Adam Duncombe – HPN patient
Richard Shawyer – HPN patient
Carolyn Wheatley – HPN patient
Tracy Hill – HPN patient
Mark Rooney – HPN patient
Lauren Sainty – Interested party
Emma Norman – Independent Buyer

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 has become historic for this type of LITRE assessment. The 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 set.

The testing took place over a 4 week period and each personal assessment had to be completed prior to the committee meeting on 12th January 2013.

The form used was identical to the one used for previous LITRE ambulatory parenteral nutrition user assessments.

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

In addition to the user assessment LITRE requested a test from 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 requested to know the battery life and consistency of life over this period. The panel feel that this was a much more realistic running rate than 150ml per hour for a home patient. The result of this test for the IVantage is shown at the end of the LITRE findings.

Pump Review

This pump review has been based on testing of equipment at home and the final presentations received by LITRE on 12th January 2013.

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 requirements from a pump. As patient advocates we endorse the quality of life issues related to home feeding and therefore do not spend any large amount of time looking at the commercials of the pump. LITRE strongly advocate that one pump does not fit all patients.

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 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 **the use of** parenteral nutrition at home.

As this is an interim report, the LITRE panel do not publish scores but provide user feedback to comply with the recommendation in the HPN framework specification. The next full LITRE review of all ambulatory pumps will include a full results table.

The areas that the panel looked out when making the following comments are:-

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

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 an 'Assessment User Report'. We do not look at line pressures or safety margins.

Kimal IVantage

Noise level – All panel members commented on how quiet the pump was.

Pump:

Ease of use – The panel felt the pump would be suitable for most patients however those with dexterity issues may find the device to lock the giving set difficult to use (top sliding security feature) The panel liked the fact that the pump was self correcting.

Pole mounting – The panel raised concerns over the placement of an external battery if the pole mount was used and we suggested this was revisiting the current concept. The majority of patients do not infuse whilst connected to the mains at the night.

Size and weight - The panel agreed that the pump is extremely compact, lightweight, robust and reliable. We were pleased to learn that the pump was manufactured in the UK.

Battery life/options - There is a rechargeable external battery and the pump can be powered via the mains while infusing. The panel felt that the external battery was too big and too heavy and questioned whether it was modern technology. It was recommended that equivalent battery life should be achieved with a much more compact products which has new technology and is considerably lighter. LITRE have been in discussion with Kimal and have received written information that provides us with their intention to act upon this recommendation. They aim to produce a new external battery which will weigh approximately 240g (current battery 600g)

Backpack –The panel are aware that Kimal have spent time redesigning the original backpack design. We felt that the current backpack remained unsuitable. However, it was felt that with improvements they would make the product fully fit for purpose and accommodate relevant items in a much more logistical and safer manner. LITRE worked

with Kimal to progress this. To date we have received drawings which demonstrate appropriate changes however we have yet to see a final product for comment.

Giving set - The panel would like to see the giving set made easier to load into the pump, as some panel members felt that the 'safety catch' was difficult to manage; the giving set also needs to be lengthened and made from a non-kink material. The panel liked the fact that the moving parts within the pump are replaced in every giving set and this should mean less in field break downs; this will hopefully reduce night time issues. We are pleased to learn that Kimal have moved the clamp and filter to a more patient friendly position.

Literature – We were disappointed with aspects of the literature and strongly suggested some important changes. The literature should be more user friendly and we suggested the marketing material focused solely on the pump itself.. The panel suggested a review of all manuals and quick user guides before going to market.

Manufacturer's response to recommended changes – LITRE offered a number of key changes to enhance the IVantage. Important aspects from the users' perspective are the external battery and the rucksack. While we have written assurances of these changes we will be contacting Kimal six months on from the assessment to ascertain that updates have been finalised.

Battery test result

Kimal were asked to provide the findings of a test on the battery to detail the number of hours a battery would last while being infused at 350mls per hours for a 3955mls bag of feed. This information was not made available to LITRE.

Pump Information

Requirements for LITRE report	Specific Technical Aspects	IVantage Specifications
Weight	Pump Alone Pump and Charger	390g with integrated rechargeable battery 440g
Size	Pump Alone	14cm X 6cm X 4.4cm
Battery	Charge Time	Initial Charge 26 hours and subsequently 4 hours
Charger	Size Weight	Mobile phone size 50g
Accuracy		+/- 5%
Noise when Running		Very quiet at high running rates
Lights	Ability to turn backlight off	Switches off after 20 seconds automatically
Display Panel	Easy to Read	LCD display with words
Ease of programming		Intuitive to setup
Alarms	Adjustable Warning at end of infusion	Yes – they can be adjusted by the homecare company The pump alarms and switches to KVO

Multi Therapy		PN, Continuous, Dose mode and PCA
Giving Set	Length Filter Position	2m from spike to Leur Connector Near the pump
Filter Size		1.2 microns
Air Detector		>100: Alarm occurs when a single air bubble of 100 µL or larger—or a cumulative value exceeding 500 mL in 7 minutes—is detected. >300: Alarm occurs when a single air bubble of 300 µL or larger—or a cumulative value exceeding 500 µL in 7 minutes—is detected
Manual Prime		Manual prime possible and pump prime possible
Integral anti-syphon Valve		Yes
Cradle for Drip Stand		Yes
Instruction Manual	Patient Friendly Quick Guides	Patient manual available on CD and in print format Quick Guide Available

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.

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

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