

LITRE Assessment of Ambulatory Pumps for Parenteral Nutrition

Results of a LITRE Assessment Panel

29th & 30th July 2016



What is LITRE?

A multi-professional panel led by patients that aims to improve the quality of life for patients on home artificial nutrition in terms of services and products. It is a standing committee of PINNT.

Our Mission

- Investigating and responding to the needs and concerns raised by patients, carers and healthcare professionals with regard to equipment and services.
- Forging links between patients, carers 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 meets to address individual projects and the most appropriate team of experts is assembled based on the nature of each project. LITRE will invite additional experts to join the panel with the clear intention of ensuring each additional person will bring knowledge and expertise to the project in hand.

Previous Projects

LITRE has historically undertaken a wide ranging number of projects over the years. A full list can be found on <http://pinnt.com/About-Us/LITRE.aspx>

LITRE Panel Members

PINNT advertised the proposed LITRE assessment in Online, on Facebook and on the website. Clear information was given in terms of how the assessment would work as the previous format has been revised. All applicants were asked to complete a simple questionnaire (Appendix 1). We were seeking applicants to represent the diverse feeding regimes as well as the various lifestyles in which home parenteral feeding is used and administered.

Once the deadline for applications was closed applicants were entered onto a database and assigned a number, all personal information was removed. Selection was made purely based on the appropriateness and variation in feeding, lifestyles and age. All candidates were notified of the outcome.

When the patient/carer members of the panel had been selected relevant non patient and carer members were invited; an independent buyer, a paediatric nutrition nurse, an adult nutrition nurse and a pharmacist. These were selected due to their patient focused approach as well as having either previously been a member of a LITRE panel or as someone with a particular interest in pumps.

Panel members: - Bethia Manson – HPN patient
June Kotey – HPN patient
Debbie Phillips – HPN patient
Charu Yagnik – HPN patient
James Ramsay – HPN patient
Kyle Lennox – HPN paediatric/teenage patient
Andrea Harvard – Carer of HPN paediatric patient
Mia Small – Adult Nurse Consultant Nutrition and Intestinal Failure
Gill Lazonby – Children's Nutrition Nurse Specialist
Manpreet Kaur - Nutrition and Surgery Pharmacist
Emma Norman – Independent Buyer

Carolyn Wheatley - Chair
Steve Brown - Secretary

This report is a collective summary based on the opinions 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 supplier/manufacturer

LITRE notified all previous suppliers and manufacturers that a LITRE user assessment was planned for 29th and 30th July 2016. Every effort was made to determine whether there were any new suppliers or manufacturers who should be contacted. It was pointed out that in line with the National Framework Agreement for the Supply of Home Parenteral Nutrition in England a LITRE user assessment is required prior to a new pump being considered for the framework.

Five companies responded and seven pumps were scheduled for the user assessment.

Pump Assessment

The previous pump assessment process was reviewed in light of logistics and cost. It was agreed to hold a two-day event during which the user assessment could take place.

- Each panel member had access to the assessment room which was run under exam conditions as well as being able to test/listen to a pump in the confines of their bedroom at the hotel.
- During the assessment time, panel members were prohibited from discussing the pumps with fellow panel members.
- Each company had provided a standard parenteral nutrition (PN) package to enable the pump to be fully tested by each panel member.
- Each pump was tested with the giving set provided by the company and normal saline was used to prime the set.
- No clinical connection was made by any patient panel member during this assessment.
- Each panel member completed an assessment form for each pump. The form used for previous LITRE assessments was modified to accommodate updates since the previous LITRE assessment.

Presentation given to LITRE

The panel received a presentation from each company the day after they had carried out their assessments.

LITRE has always allowed the panel to work with what has been sent both in terms of equipment and literature in order to carry out their initial assessment. They list questions which are then raised during the formal presentations the following day.

Each company received the same guidance in terms of the presentation required for their allocated slot.

Presentation: Overview of the pump
 What they class as the top five features of the pump package
 List any additional accessories related to the pump

Presentations were timed and a further timed slot for questions was held.

LITRE fully acknowledges that a patient or carer should receive comprehensive training on any pump they are expected to use at home.

In addition to this telephone support should be available at all times.

Pump Review

We have based our advice and comments on the knowledge that is held by an expert panel of people receiving home parenteral nutrition (HPN). The panel has been extremely eloquent in providing an insight into the patients' expectations of a pump and how this equates to enhancing or impeding their quality of life.

LITRE considered the whole package, not just the pump or the range of accessories. For us this included the corporate approach; their ability to understand how the product will be used by people for whom it will be part of their life-changing treatment. We value their ability to see how their product may enhance the patient's feeding experience and hopefully not make life more stressful.

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
- Maximum infusion rate 250mls per hour.
- The complete package needed to infuse; including rucksack and pole mounts where needed
- The manufacturers' response to questions raised at the assessment and how they responded to demonstrate their awareness and understanding of the patients' perspective regarding home parenteral nutrition.

LITRE would like to stress that this is a non-technical test. It is based on user feedback. It is therefore an end user report. We do not look at line pressures or safety margins. LITRE is aware of on-going patient/carer concerns about under and over infusing with certain pumps. As this assessment was non-technical we are unable to comment on this. LITRE understands that pump manufacturers are aware of such reports and has been investigating this along with the support of relevant units, homecare companies and compounding units. LITRE is unable to pass any comment on this aspect and all figures stated come from the manufactures' information.

LITRE position

- The philosophy of LITRE remains the same – **one pump does not fit all patients.**
- The pump is part of the clinical decision making, it is **not** a commercial decision.
- Not all pumps are suitable for children; this is a clinical decision but we advocate there must be a choice for them to meet the diverse needs of the children.
- A common treatment does not deliver a standard patient therefore LITRE strongly believes that pumps should reflect their diverse needs.
- It was clear during this assessment that reviewers had differing perspectives on what they liked and didn't like, which features were more important to them and which pump best suited their lifestyle, personal ability and needs.
- Standard accessories are a vital part of the infusion package which are an integral part of the infusion process.
- Additional accessories enhance quality of life and choice in terms of potential acceptance, safety and compliance with home parenteral nutrition.
- The pump should be reviewed in line with the changing needs of the patient.

This report will not include a summary rating table.

Each product has been reviewed on its own merit.

All the pumps reviewed by LITRE are suitable for delivering parenteral nutrition to patients within the home setting.

Healthcare professionals should review pumps in line with their patients' needs and discuss perceived expectations in terms of lifestyle, ability to use the pump in conjunction with any local policies for pump selection that may exist.

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.

LITRE endorses the annual servicing of all pumps.

Included in this report:

- Summary table of key features perceived as important by LITRE.
- An individual summary of each pump reviewed along with suggestions from the panel.
- Considerations and recommendations from LITRE.

Specific to pumps supplied in England

When a pump is not currently on the National Framework Agreement for the Supply of Home Parenteral Nutrition in England.

We have a statement from the Chair of the Stakeholders group:

If a HPN prescribing hospital wishes to use a pump that is not currently on the framework the prescribing trust would need to contact the Commercial Medicines Unit or the Chair of the Stakeholders group.

Any request will undergo a governance procedure within the stakeholder group and NHS England.

Chair Stakeholders group: Jackie Eastwood - Jacqueline.Eastwood@lpp.nhs.uk
Commercial Medicines Unit: Elizabeth Payne - elizabeth.payne@dh.gsi.gov.uk

Features		Ambix activ	BodyGuard® 323	BodyGuard® 2 Channel	BodyGuard® ColourVision 323	CADD® - Solis VIP	Mini Rythmic™ PN+	Sapphire™
Weight:	Pump with battery	550g	390g	580g	390g	595g	300g	504g
	Pump with charger	1070g	765g	1018g	765g	487g	420g Includes 9V battery	725g Pump, battery and power cord
	Charging unit/cradle/base	500g	359g	467g	359g	354g	120g	221g
Size:	Pump	132 x 120 x 45mm	112 x 89 x 32mm	145 x 87 x 40mm	112 x 89 x 32mm	41 x 102 x 127mm	130 x 75 x 46mm	143 x 96 x 49mm
	Pump with charger	146 x 162 x 115mm	166 x 95 x 79mm	152 x 120 x 84mm	166 x 95 79mm	41 x 102 x 127mm	144 x 106 x 46mm	Not applicable
	Charger	146 x 162 x 115mm docking station is the charger	166 x 95 x 71mm docking station/pole mount is the charger	155 x 127 x 53mm pole mount charger	166 x 95 x 71mm docking station/pole mount charger	120 x 762 x 48mm Smaller mobile phone type charger will be available early 2017	25 x 80 x 50mm	70 x 48 x 67mm Power cord
Battery:	Charging times from flat	6 hours	Standard life battery - 6 hours Extended life battery - 10 hours	6 hours	Standard life battery - 6 hours Extended life battery - 10 hours	4 hours	2.5 hours to 90%	4 hours when pump not in use
	Dry cell capacity	Built-in rechargeable batteries NiMh 4.8V, 1.8AH	2 x 9V batteries	No	2 x 9V batteries	4 x AA batteries	1 x 9V battery	Built in rechargeable li-ion battery 7.4v 1960 mAh
	Battery life:	125ml/hr - 40 hours 350ml/hr – 20 hours	Standard battery: 125ml/hr – 15 hours 350ml/hr – 11 hours 33 minutes	With both chambers running simultaneously @ 125ml/hr – 9 hours	Standard battery: 125ml/hr – 17 hours 350ml/hr – 11 hours 33 minutes	AA batteries: 250ml/hr - 20/22 hours Rechargeable:	Minimum battery life of a 9V alkaline battery new and unused is:	125ml/hr – 24 hours Optional external battery pack

Features		Ambix activ	BodyGuard® 323	BodyGuard® 2 Channel	BodyGuard® ColourVision 323	CADD® - Solis VIP	Mini Rythmic™ PN+	Sapphire™
		No external battery	Extended life battery: 125ml/hr – 30 hours 9V battery 125ml/hr – 10 hours		Extended life battery: 125ml/hr – 34 hours 9V battery 125ml/hr – 12 hours	250mls/hr -16/18 hours	150ml/hr - 8.5 hours 200ml/hr - 8.5 hours 250ml/hr - 8 hours 300ml/hr - 7.5 hours. Minimum life of a battery pack fully charged when used with a Mini Rythmic PN+ is: 150ml/hr - 21 hours 200ml/hr - 20 hours 250ml/hr - 19 hours 300ml/hr - 18 hours.	extends pump operation time by an extra 15/20 hrs at 125mls/hr without interrupting therapy
Accuracy:	+/-	5%	5%	5%	5%	6%	5%	2.5%
Noise when running:	Low rate	Quiet	Acceptable	Quite noisy	Quiet	Acceptable	Quiet	Extremely quiet
	High rate	Quiet	Acceptable	Quite noisy	Quiet	Quite noisy	Quite noisy	Extremely quiet
Lights:	Ability to turn back light off:	Yes, it will come on when a button is pressed for approx 10 seconds	Yes, has time out after key press	Yes, has time out after key press	Yes, has time out after key press	Yes, on touching key – backlight intensity can be adjusted	Yes	Yes, 3 settings: full, partial and off
Display panel:	Easy to read?	Yes	Acceptable	Yes	Yes	Yes	Acceptable	Yes

Features		Ambix activ	BodyGuard® 323	BodyGuard® 2 Channel	BodyGuard® ColourVision 323	CADD® - Solis VIP	Mini Rythmic™ PN+	Sapphire™
Ease of programming:		Very easy	Very easy	Slightly more complicated but relatively easy with logical steps	Very easy	Easy	Very easy	Very easy
Size of keys: Numeric keypad/multi-function keys		Easy to press with a noticeable click	Quite small. Raised numeric keypad. Optional key press volume (adjustable)	Quite small. Raised numeric keypad. Optional key press volume (adjustable)	Quite small. Raised numeric keypad. Optional key press volume (adjustable)	Good size, raised function keys	Large, multi-function raised keys	Large function key + touch screen function
Alarms:	Are they adjustable?	Yes, can be set to low, medium or high	Yes and can be silenced for 2 minutes	Yes and can be silenced for 2 minutes	Yes and can be silenced for 2 minutes	Yes, programmable reservoir low trip point (0-999ml) Alarms volume can be adjusted. Also have low, medium and high, depending on the nature of the alarm	Yes	Yes
	Is there a warning when the infusion is due to end?	Pump can be set to alarm when 10% of volume is remaining	The pump will alarm when the volume to be infused equals 0mls	The pump will alarm when the volume to be infused equals 0mls	The pump will alarm when the volume to be infused equals 0mls	The pump will alarm when the programmed volume trip point has been reached	Yes, this is adjustable and can be set in time or volume	Yes, with four time options
Is it a multi-therapy pump?		No	Yes Can be preset to a single therapy device	Yes Can be preset to a single therapy device	Yes Can be preset to a single therapy device	Yes	No	Yes Can be preset to a single therapy device
Giving set:	Length	275cm	280cm	280cm	280cm	290cm	220cm	310cm
	Filter position	Filter is positioned nearer to the pump than the patient	30cm from patient access device	30cm from patient access device	30cm from patient access device	Between the pump and patient	Filter fits into the pump	210cm away from the patient end, below the pump

Features		Ambix activ	BodyGuard® 323	BodyGuard® 2 Channel	BodyGuard® ColourVision 323	CADD® - Solis VIP	Mini Rythmic™ PN+	Sapphire™
	Ease of spiking	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Filter size:		1.2 micron	0.2 and 1.2 micron	0.2 and 1.2 micron	0.2 and 1.2 micron	1.2 micron	1.2 micron	1.2 micron
Air detector:		0.15 ml	Integral to pump - Ultrasonic adjustable air in line detector	Integral to pump - Ultrasonic adjustable air in line detector	Integral to pump - Ultrasonic adjustable air in line detector	Integral to pump – low or high sensitivity	Yes, with three settings	Yes, integral to pump with adjustable air in line settings
Ability to manually prime:		Yes	Yes, on the 1.2 micron set	Yes, on the 1.2 micron set	Yes, on the 1.2 micron set	Yes	Yes	Yes
Integral anti-syphon valve:		Back flow valve	Yes	Yes	Yes	Yes	Yes	Anti-free flow valve
Cradle for dripstand:		Yes	The charger serves as the cradle	The charger serves as the cradle	The charger serves as the cradle	Yes	Yes	Yes
Instruction manual:	Patient-friendly UK version	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Quick reference cards/information	Yes	Yes, video guides in for early part 2017	Yes, video guides in for early part 2017	Yes, video guides in development for early 2017	Yes, online training course now available on request	Yes and videos	Yes and videos
Travel information	Is information available?	Not stated	Yes, upon request	Yes, upon request	Yes, upon request	Yes	Yes	Yes
	Is there access to guidances for X-raying at airports?	Safe to take through airport scanners	Yes, upon request	Yes, upon request	Yes, upon request	Yes, upon request	Yes	Yes
	Foreign adaptors available?	Travel plugs can be used but no adaptor needed, pump has a voltage range of 100-230v @ 50-60Hz	Yes, upon request	Yes, upon request	Yes, upon request	Yes for Europe, USA, Australia and Japan	Yes	Yes

Features		Ambix activ	BodyGuard® 323	BodyGuard® 2 Channel	BodyGuard® ColourVision 323	CADD® - Solis VIP	Mini Rythmic™ PN+	Sapphire™
Rucksack	Sizes (Fluid capacity and dimensions of the infusion bags may contribute to variations)	1.5 litres 5 litres	Extra small/up to 100mls Small/up to 500mls Medium/up to 3 litres Large/up to 4 litres	Medium/up to 3 litres Large/up to 4 litres	Extra small/up to 100mls Small/up to 500mls Medium/up to 3 litres Large/up to 4 litres	1 litre 3 litres	1 litre 2-3 litres 4-5 litres 5-6 litres	3-5 litres 2 litre option in development for 2017
	Wheeled option	No	Yes For medium bag, will be available for large bag mid 2017	Yes For medium bag, will be available for large bag mid 2017	Yes For medium bag, will be available for large bag mid 2017	No	Yes 2-3 litre rucksack 4-5 litre rucksack 5-6 litre rucksack	Yes
	Separate wheels	Not applicable	Yes	Yes	Yes	Not applicable	Yes, except the 1 litre rucksack	Yes

All information in the table above has been provided and approved by each pump manufacturer or supplier.

LITRE/PINNT are not responsible for any inaccuracies within the information.

Where a clinical team is considering a pump they should look at both the technical and user reports.

LITRE recommend that a pump should not be given to a patient without a clear understanding of individual needs, lifestyle and expectations.

Review of individual pumps presented to LITRE

Ambix activ

Two representatives from Calea UK Ltd & Fresenius Kabi Ltd represented the Ambix activ.

The panel agreed the pump was an acceptable size, possibly a little heavy. There is an integral battery but still no external battery pack.

Recharging the internal battery took five hours.

It was generally felt that the noise level while the pump was running was very quiet.

LITRE liked the choice of rucksacks. Both offered different carrying options and robustness. The panel wondered why the pump was stored sideways in the rucksack.

Giving set – generally it was felt that the giving set was acceptable, easy to use but the ability to spike the bag with ease was not as easy for all panel members. The colour code matching was liked but some panel members found it fiddly to load the set into the pump.

Programming the pump was deemed acceptable. The use of symbols instead of words was questionable in terms of remembering what they were for but felt over time this would be okay.



The panel offer the following thoughts:

- An external battery would still benefit the functionality of the pump in terms of the user experience.
- The addition of wheels as an optional extra would enhance the rucksacks available.
- Giving set – revisit the plastic part that is easily removable from the filter on the giving set.
- Giving set – put an arrow on the filter on the giving set.
- Consider adding words instead of symbols to the screen on the pump.
- The pump would benefit from a colour screen.
- A small pump holder/charging unit.
- Ability to remove clamp from charging/pole clamp.
- Alarm activation – could be faster when occlusion occurs
- Include written information and pictures as to how the battery works when placed in the unit to charge.

LITRE felt that the presentation received covered all salient points within the brief and the representatives were receptive to hearing the views of the panel. It was felt however that they were unable to answer some questions as well as the panel would have liked but were keen to find out and report back. It was also noted that aspects of the presentation were given as additional selling points of the pump which are basic requirements of the framework for the National Framework Agreement for the Supply of Home Parenteral Nutrition in England.

No additional accessories were noted.

BodyGuard® 323

Two representatives from CME Medical represented the Bodyguard 323.

The panel agreed that the pump was small and an acceptable weight prior to the battery being added. It was easy to programme and the majority of the panel felt the running noise was very acceptable although it does have an irregular infusion noise.

There were questions about the alarms and key stroke noises. The representatives commented that new directives were due out via the International Electrotechnical Commission (IEC) in relation to audible alarms for medical equipment. This would be part of technical assessment which is outside LITRE's remit.

There were two external battery options and the ability to charge via the docking station. There was a concern that the lever on the battery was fragile and could snap off. Combined weight of pump and battery could be heavy for some people.

Different sized rucksacks are available. The panel favoured the style and design of the small rucksack but had reservations about the fixed middle dividing panel in the new rucksack. They did however accept that some patients may like it. A wider range of colours would be welcomed bearing in mind that they should appeal to a people of all ages. The panel suggested they offered muted and brighter colours.

Giving set – generally this was found to be acceptable. There were mixed reviews on the ease of spiking as well as loading the set into the pump. Overall the panel liked the set. There was mention of the filter being safer if it sat inside the rucksack during use.

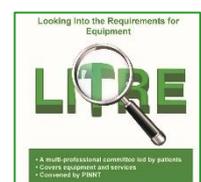
There were observations about the set exterior being wide and prone to kinking as well as the use of slide clamps being used which can be fiddly.

The panel offered the following thoughts:

- Ensure information about the battery life and set-up is included.
- Position of filter could be reviewed.
- The overall weight of the pump could benefit from a smaller and lighter external battery.
- Rucksacks – more colours that will appeal to a wider range of patients with consideration to improve straps overall.
- Consider a rucksack that can hold two pumps.
- New rucksack – modify some of the internal sections and flaps.
- Seek wider opinion if they were to consider changing the spike on the set.

LITRE felt that the presentation received covered all salient points within the brief and the representatives were receptive to hearing the views of the panel. They were keen to respond to the constructive feedback.

- Training videos were noted as accessories available to support the use of the pump.
- There are planned enhancements to the Bodyguard 323 with the Bodyguard ColourVision 323. Phase 1 release of the Bodyguard ColourVision 323 will not have Wi-Fi capability. Phase 2 release will be Wi-Fi enabled and will also coincide with a communication system. The planned date for the Phase 2 introduction is September 2017.



BodyGuard® 2 Channel

Two representatives from CME Medical represented the Bodyguard 2 Channel.

The panel was split on the weight of this pump but noted its unique functionality. The running noise was felt to be acceptable.

There is now an external battery supply and when the pump is on the charger it was deemed heavy.

This pump is best suited to a drip stand especially given the charging base unit but does fit into a rucksack.

The panel questioned the ability to get two bags of PN into the rucksack along with the pump with ease.

A wheeled rucksack would certainly work well with this pump given the potential for it to be heavier than a single bag and one pump.

Giving set – generally this was found to be acceptable. The tubing and length of the giving set scored well. There were mixed reviews on the ease of spiking as well as loading the set into the pump. The position of the filter was debated, the slide clamps deemed fiddly and the roller clamp too loose on the set.

Programming the pump received mixed reviews. Generally acceptable. The panel liked the clear display, easy to read and a good size screen. It would be good to change infusion type without the need for a code.

The panel offered the following thoughts:

- Ensure information about the battery life and set-up is included.
- Extended battery life for those feeding 24 hours.
- The introduction of an external battery.
- Ability to change infusion type without a code.
- Position of filter could be reviewed.
- Giving set instructions could be improved re priming button.
- Rucksacks - more colours that will appeal to a wider range of patients with consideration to improve straps all over.
- Consider a rucksack that can hold two pumps.
- New rucksack – modify some of the internal sections and flap.
- Seek wider opinion if they were to consider changing the spike on the set.

LITRE felt that the presentation received covered all salient points within the brief and the representatives were receptive to hearing the views of the panel. There were questions about the feedback on the wheeled rucksack which resulted in everyone agreeing to review this. They were keen to respond to the constructive feedback.



BodyGuard® ColourVision 323

Two representatives from CME Medical represented the Bodyguard ColourVision 323.

The panel agreed that the pump was small and an acceptable weight. The bigger screen was well received.

The majority of the panel felt the running noise was very acceptable although it does have an irregular infusion noise. There were two external battery options and the ability to charge via the docking station. There was a concern that the lever on the battery was fragile and could snap off. Combined weight of pump and battery could be heavy for some people.

Different sized rucksacks are available. The panel favoured the style and design of the small rucksack but had reservations about the panel in the new rucksack. A wider range of colours would be welcomed bearing in mind that they should appeal to a wide range of people. Suggested they offered muted and brighter colours.

Giving set – generally this was found to be acceptable. The tubing and length of the giving set scored well, however the use of a slide clamp was mentioned as they can be fiddly. There were mixed reviews on the ease of spiking as well as loading the set into the pump. Overall the panel liked the set. There was mention of the filter being safer if it sat inside the rucksack during use.

There were observations about the set exterior being wide and prone to kinking as well as the use of slide clamps being used which can be fiddly.

The panel offered the following thoughts:

- Ensure information about the battery life and set-up is included.
- Position of filter could be reviewed.
- The overall weight of the pump could benefit from a smaller and lighter external battery.
- Ability to change infusion type without a code.
- Giving set instructions could be improved re priming button.
- Rucksacks – more colours that will appeal to a wider range of patients with consideration to improve straps overall.
- Consider a rucksack that can hold two pumps.
- New rucksack – modify some of the internal sections and flap.
- Seek wider opinion if they were to consider changing the spike on the set.

LITRE felt that the presentation received covered all salient points within the brief and the representatives were receptive to hearing the views of the panel. They were keen to respond to the constructive feedback.

- Training videos were noted as accessories available to support the use of the pump.
- There are planned enhancements to the Bodyguard 323 with the Bodyguard ColourVision 323. Phase 1 release of the Bodyguard ColourVision 323 will not have Wi-Fi capability. Phase 2 release will be Wi-Fi enabled and will also coincide with a communication system. The planned date for the Phase 2 introduction is September 2017.



CADD® - Solis VIP

Two representatives from Smiths Medical represented the CADD Solis VIP.

The panel agreed the pump was an acceptable size, possibly a little heavy. It was reassuring that it was quoted as being 'a bit chunky but in a way quite friendly'.

It was noted that the AC adaptor and power leads are large and heavy.

Giving set – the panel were split on their views of the giving set. The spike, mixed reviews about the ease of spiking the bag. The panel also found loading the set a little awkward. Overall the length of the set was acceptable however there were comments that the top section (PN bag to pump) was a little short and the lower section (pump to patient connection point) was too long.

Programming the pump posed a few problems for some panel members and some were unable to get it to start. It was felt that possibly there were too many screens to work through. This may offer reassurance for some and not others, however the screen was very clear and easy to read, well-lit and legible.

Overall the panel felt that the rucksacks were acceptable, basic but fit for purpose. They could be a little more robust in terms of stability.



The panel offer the following thoughts:

- Following initial questions, it became apparent that unfortunately the wrong giving set was sent for the assessment.
- Welcome the news that a smaller charger is due soon; early 2017.
- Would like to see more secure hanging inside the rucksack along with a window on the front to view the pump while in use.
- The ability to add or remove wheels would enhance the user experience. Pleased to hear this was under review.
- Check messages shown in trouble shooting guide in terms of wording about end cap, strongly suggest this is removed.
- Loading the giving set could be fiddly for some users.
- Instructions need to be reviewed especially in relation to set-up. Need to mention the removal of specific protective parts.
- Decisions about which parameters are actually needed for the patients in terms of data storage should be reviewed and hidden if possible. Excellent for nursing and clinical reference.
- LITRE strongly suggest a dedicated PN pump, or clear exclusions of screen and parameters to achieve this.

LITRE felt that the presentation received covered all salient points within the brief and the representatives were receptive to hearing the views of the panel. However, the panel felt it was a little too technical. The panel felt that the representatives left them a little confused with some unanswered questions but looked forward to working with them to meet the needs of the users.

Mini Rythmic™ PN+

One representative from Inspiration Healthcare and one from Micrel represented the Rythmic PN+.

The panel agreed that the Rythmic PN+ was small and lightweight. The external battery is extremely small and appears to be able to deliver at a reasonable rate for an acceptable time.

Recharging the external battery was noted as being very good at only three hours.

The improved connectors on the external battery were more robust but sadly still prone to damage as demonstrated by one member of the panel.

The opinion of the panel was split in terms of the noise level while the pump was running. It was deemed noisier than previous models and there was a comment about the 'irregular' infusion noise.

LITRE liked the choice of sizes for the rucksack as well as multiple pump bags and felt the addition of wheels was an asset for the varying needs of people on home parenteral nutrition. The rucksacks offered a good choice in terms of carrying options and robustness.

Giving set - while some had no issue with the spike the size and length was discussed by some. We were told a shorter spike in overall length was on its way. The tubing and length of the giving set scored well, however the position of the slide clamp was deemed to be in the wrong position and difficult to access. The use of slide clamps was debated. Opening the main door on the back of the pump might also be awkward for some along with actually loading the set into the pump. It was noted that once done the set was secure and the filter is safely stored.

Overall the panel felt the pump was easy to programme; the quick set up guide easy to follow.

The panel offer the following thoughts:

- The pump would benefit from a colour screen.
- An easier way to open the pump and insert the giving set.
- Rucksacks could be in more muted tones, less vivid and no trim.
- Move the slide clamp to allow safer and easier access for the purpose it is designed for.
- During programming it would be nice to be able to go back a step.
- Within the information, written or other media, show and describe how to charge the battery and also how to attach it to the pump.

LITRE felt that the presentation received covered all salient points within the brief and the representatives were receptive to hearing the views of the panel. Very keen to respond to the constructive feedback given.

- Additional accessories were noted: external amplifier, multiple spike connecting set, Micrelcare (A wireless system enables clinicians, nurses and homecare providers to remotely control/problem solve the infusion therapy through the web) and an E-learning platform.



Sapphire™

Two representatives from Hospira presented the Sapphire.

On the whole the panel felt that the pump was an acceptable size but was split on acceptable weight. Half felt it was a little heavy and chunky.

The optional external battery pack received mixed reviews in terms of weight and bulkiness when attached to the pump but opinion was favourable in terms of charging time and ease of charging.

LITRE panel members were surprised at the depth of the rucksack and did not accept that previous feedback had achieved the desired product. The rucksack was fit for purpose and most suitable for large volumes of PN but received negative comments in terms of appearance and functionality.

Giving set – favourable comments from the panel. A couple of comments on it being difficult to spike and also load into the pump but overall good to handle, easy to use and no problem loading it into the pump. The length of the giving set was deemed good although there were observations about the position of the filter once in use, possibly dangling outside the rucksack. Overall, panel members were happy with the giving set.

Programming the pump – overall the panel felt the pump was very easy to programme – intuitive! Clear and concise screen, good prompts and easy to understand. The alarms were felt to be a little severe but overall the panel was very pleased with the process of programming this pump.

The panel offer the following thoughts:

- Videos to support patient training in terms of standard set up and accessories.
- Clearer information sheets in terms of all processes and equipment use.
- Ensure information about the battery life and set-up is included.
- The panel suggest that despite the belief that this was in line with previous patient feedback, somehow it has not resulted in an ideal product and communications must be clear and effective for all to deliver the best possible rucksack. This rucksack must be modified in numerous ways to make the user experience better. Additional straps, viewing window for pump, shoulder strap, reduced depth in places, modifications to the external presentation and the pump pouch would enhance the product.
- A smaller capacity rucksack would be welcomed along with different colours, nothing too vivid.
- Alarms; review tones and timings of the alarms.

LITRE felt that the presentation received covered all salient points within the brief and the representatives were receptive to hearing the views of the panel. Very keen to respond to the constructive feedback given.

- There are two pumps in the Sapphire portfolio, both of which are able to deliver PN and continuous therapy modes. The Sapphire Multi-therapy pump and the Sapphire H100. Both pumps have the same software but the Sapphire H100 does not have the pain therapy option.



Previous LITRE reports

No comparison between previous LITRE reports can be made.

All references to previous LITRE reports and historic scoring should be removed from corporate websites and literature.

Each LITRE user assessment review will constitute a new panel. Any comments that differ from previous feedback will reflect the changing needs of the PN patient population.

Considerations

- The 2016 assessment demonstrated that we need a choice of pumps.
- The pump is fundamental in terms of the safe delivery of the PN.
- While patient safety is paramount this is not necessarily achieved by having higher or lower levels of technical functionality.
- The pump should not be viewed in isolation. The accessories are vital parts to the overall functionality of the pump.
- Given the UK's decision to leave the European Union we wish to flag up that we hope this will not affect the supply or have unrealistic price increases for any products associated with any of the pumps we have accessed.

Recommendations

- All manufacturers should supply wheels as an option for their rucksacks.
- All manufacturers should ensure that all their rucksacks and wheels are interchangeable to ensure cost effective replacements when required. It will not always be necessary to replace both at the same time.
- Where wheels are offered they should be suitable for all sizes of rucksack. If this means two different sizes, then so be it.
- There should be a common language in terms of rucksack sizes and/or estimated volume capacity.
- Updates and modifications to a pump and their accessories should be made only when absolutely necessary.
- To allow greater freedom while connected all manufacturers should consider an integral section of the giving set that is coiled. Suggested location would be from the outlet of the rucksack and before the patient connection point. This could prevent dragging of the set while using it and could eliminate an additional connection where coiled extension sets are being used.
- All accessories should be light-weight, fit for purpose, sufficiently robust and make the need for home parenteral nutrition a user-friendly safe experience.
- All patient/user information booklets or quick reference sheets should be easy to read, concise with as many relevant images as possible. Small font sizes should be avoided.
- Patient/user information should not be restricted to written materials. All methods should be considered in order for the best patient/user experience to be achieved.
- Holiday adaptors/information: it should be clear who the request should be directed to. LITRE recommends that each homecare company should hold this information which can be made directly available to patients.
- A national reporting process should be established to register incidents of pump failure.

LITRE's position is to raise awareness of the ambulatory pumps that are available within the market place; we **do not** endorse their suitability for individual patients. We support the ethos that there should be a selection of pumps both in terms of patient needs and to prevent a major crisis in the event of a pump withdrawal or failure.

Environmental Issues

Whilst LITRE appreciates that some pumps require an internal dry cell battery for the pump to function we would like to see these phased out, or their life extended as pumps are modified and developed.

LITRE does not advocate that dry cell batteries should be used on a daily basis to deliver PN. It is recognised that there are incidents where short term or emergency use may be necessary. Dry cell batteries are expensive and should only be used where absolutely necessary.

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.

Feedback from the pump manufacturers and distributors

Each company/distributor was asked the following questions after the meeting had taken place:

- 1) Did the pre-meeting information provide all you needed to prepare and attend feeling fully informed with clear expectation of what was required of you?
- 2) Did you feel welcome at the meeting?
- 3) Did you feel the panel was receptive and engaging with you?
- 4) Any suggestions for future meetings?

Questions 1 – 3 all received high praise. Indeed, there were comments that the information was extremely concise and explicit. Everyone felt welcome and felt that the engagement with the panel had been a truly enlightening experience and would welcome access to a panel in the future. Question 4 raised a couple of comments. Being able to present to the panel prior to the user assessment was raised as well as having on-going access to such a productive and helpful panel.

Acknowledgements

LITRE would like to thank the companies for attending and being receptive to the constructive feedback provided by the panel. Whilst it was felt that many of the suggestions would certainly enhance the 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 have been suggested. Modifications may be necessary with regards to restraints that were not evident at the time of discussions.

LITRE also thanked the companies for arranging delivery and collection of the equipment supplied for the user assessment.

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 pocket expenses were reimbursed and accommodation and relevant refreshments provided.

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Whilst PINNT has sought assurances from each manufacturer in relation to the data table, PINNT makes no representation and issues no assurance that the technical data is correct, equipment is free from defects or errors, or fit for any particular purpose. PINNT provides 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 advocates 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.

**Looking Into the Requirements for
Equipment**



LITRE

- A multi-professional committee led by patients
- Covers equipment and services
- Convened by PINNT

Assessment day – 29th July 2016



Presentation day – 30th July 2016

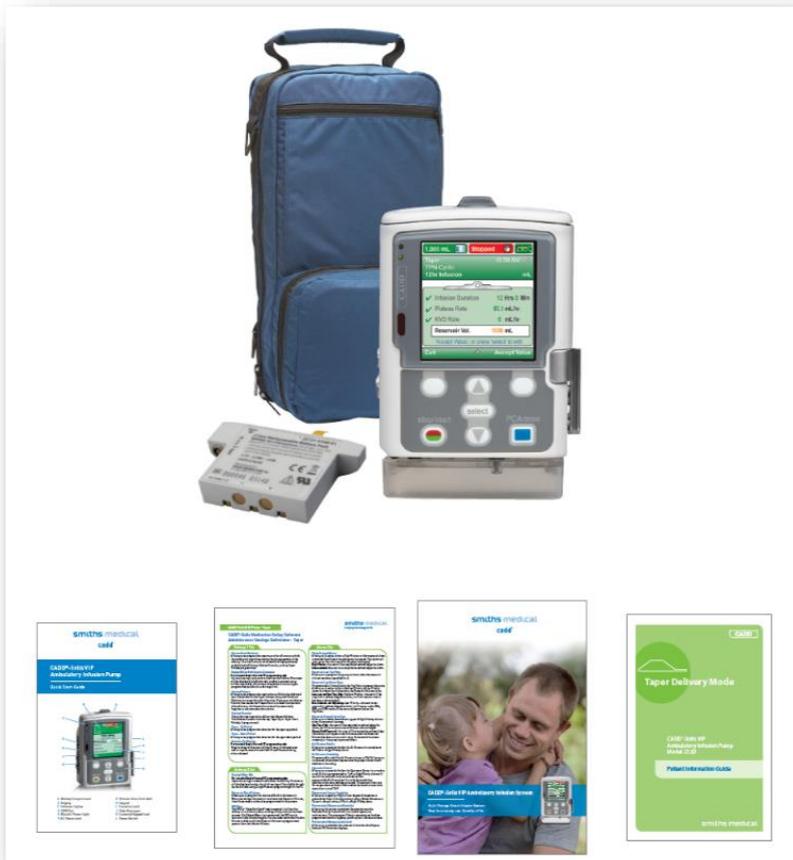


Standard kit for each pump





**BodyGuard®
ColourVision
323**



**CADD® -
Solis VIP**



Each company was asked to provide a photo showing the following: pump, charger, external battery where applicable, rucksack (if you have more than one size please show up to two), wheels if you have them and patient info brochures/quick reference cards.

Only one rucksack is provided as part of the standard kit

Appendix 1



LITRE – Looking Into The Requirements for Equipment

Thank you for expressing an interest in being a member of the LITRE panel for the 2016 ambulatory parenteral nutrition (PN) pump user assessment meeting.

Our panel will represent the varying views of those who receive and deliver PN. This is a 'user assessment' and **not** a technical assessment.

It's one form per applicant.

If you have a carer who may wish to apply, then please ensure they complete a separate form.

We are looking to ensure we incorporate the views of all those concerned with using these pumps which is reflected in the questions being asked.

Please complete the following and return it to: info@pinnt.com or PINNT, PO Box 3126, Christchurch, Dorset BH23 2XS by **Friday 1st July 2016**.

By completing this expression of interest you are declaring you are available on 29th & 30th July 2016 to attend the meeting in St. Pancras, London.

Once completed - thank you.

Please email or post back as outlined above.

Your application will be processed and you will be contacted by 7th July 2016 if your application has been successful, or before if further information is required.

PINNT will reimburse travel expenses in line with the Charity's expenses policy. Overnight accommodation, meals and refreshments will be provided.

If you have any questions before submitting this, please ask – info@pinnt.com or ring Carolyn on 01202 481625 / 07971 571709 (not available between 12 – 18 June 2016).

Your name	
Are you the person who receives PN?	
Are you a parent/guardian/carer/family member who is responsible for connecting/disconnecting the PN?	
Name of person you connect/disconnect	
Your phone number	
Your address	
Your email address	
How long have you/they been on PN	
Current pump used	
Please list any previous portable PN pumps you have used	
Number of days/nights you/they feed	
Volume infused	
Do you/they require extra fluid infusions	
Please confirm you able to attend the LITRE user assessment meeting on 29 th (afternoon & evening) and 30 th July (all day) in St. Pancras, London	

LITRE is a standing committee of PINNT



PINNT contact details:

PINNT

PO Box 3126, Christchurch, Dorset BH23 2XS

Website

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info@pinnt.com



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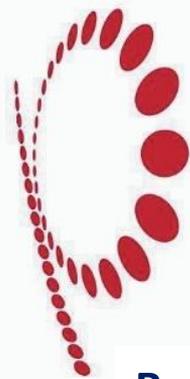
PINNT: "Supporting people on home artificial nutrition"



Looking Into the Requirements for
Equipment



- A multi-professional committee led by patients
- Covers equipment and services
- Convened by PINNT



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RECEIVING ARTIFICIAL NUTRITION

Registered Charity: 1157655



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