



LITRE Assessment - Ambulatory Pump for Parenteral Nutrition

Results of a LITRE Assessment Panel

November and December 2021

Product: Ambix nova ambulatory infusion pump

Company: Fresenius Kabi



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1 Background

1.1 What is LITRE?

LITRE is a standing committee of PINNT and convene a multi-professional panel led by patients on home artificial nutrition to review or assess products and services related to their treatment.

1.2 Our Mission

- To investigate and respond to the needs and concerns raised by patients, carers and healthcare professionals, “users”, regarding equipment and services.
- To forge links between users and product developers, manufacturers and service providers, “the industry”.
- To engage with the industry to support the user experience.
- To provide a forum for users to help the industry in product and service development and market research.

1.3 Our Core Philosophy

One pump will not fit all patients.

1.4 Our Position

- All patients are different and have different needs.
- The choice of pump should be made as a result of a discussion with the clinical team and the patient who will use it.
- The choice of pump should be based on a clear understanding of the patient’s lifestyle, ability to use the pump and expectations as well as their clinical needs, technical information, trust policy and user reports. The choice should not be made as a result of commercial considerations. Where a local policy is in place, we strongly advocate that this policy should be clearly explained and understood by the individual or family requiring the product.
- Patient safety is paramount; this is not necessarily achieved by a pump with an overly complex software package and accessories.
- Not all pumps are suitable for children. There needs to a choice of pumps for children.
- This report is the opinion of the panel but we recognise that it is not fully representative of all patients.
- Standard accessories are a vital part of the infusion package as an integral part of the infusion process.
- Clinical teams should ensure that patients and carers are aware of the full range of pumps that are available for their use.
- The allocated pump should be frequently reviewed in line with the changing needs of the patient.
- A review of the patient’s or carer’s satisfaction with their pump should be carried out regularly by the clinical team. Should it not meet either the clinical or personal expectations, a different pump should be considered.

1.5 Representation on the Committee

A LITRE panel consists of patients, carers and healthcare professionals. Expressions of interest are sought when the panel is convened. Depending on the topic, relevant experts may be invited onto the panel because of their specific knowledge and expertise to benefit the project undertaken by the panel.

1.6 Previous Projects

A list of the projects undertaken by LITRE can be found on <http://pinnt.com/About-Us/LITRE.aspx>

2 LITRE Panel for the User Assessment of the Ambix Nova

This is the first time LITRE have conducted a user assessment of the Ambix Nova which is used for delivering parenteral nutrition to patients within a home setting. This user assessment focuses on aspects that affect the need for parenteral nutrition in daily living situations.

This is not a technical assessment and LITRE do not pass clinical judgement on which pump a patient should use.

2.1 LITRE Panel Members

The selected panel below represents the range of patients who would use an ambulatory parenteral nutrition feeding pump.

Peter Austin	Consultant Pharmacist
Angela Cole	Lead Clinical Nurse Specialist for children with intestinal failure (at the time of the User Assessment)
Adam Duncombe	Adult on parenteral nutrition
David Lee	Adult on parenteral nutrition
Russell Mowbray	Adult on parenteral nutrition
Emma Norman	Procurement specialist
Mark Oldham	Carer for adult on parenteral nutrition
Anna Shepherd	Young adult on parenteral nutrition
Joanna Shepherd	Parent of a young adult on parenteral nutrition
Carolyn Wheatley	Administrator and meeting convenor

Please note Individual panel members must not be contacted regarding any aspect of this report.

The accumulated knowledge of the LITRE panel was evident by their approach to the detailed assessment as well as the numerous questions they asked. The panel were articulate and demonstrated a true understanding as to how the product could be perceived by those on home parenteral nutrition and the environment in which it would be used

2.2 Fresenius Kabi Representatives

Helen Hedges	Clinical Development Manager
Charlotte Mottram	Senior Product Manager

2.3 Methodology

- Each panel member conducted their assessment remotely.
- Each member received a standard kit (pump, rucksack, charger and user manuals) plus a couple of dedicated giving sets to conduct their individual user assessment.
- Each member of the panel graded all parameters on the feedback form.
- The members of the panel were unknown to each other until they attended the panel meeting in November 2021.
- The results presented are a collective summary of the individual user assessments.

2.4 Key Aspects of the Assessment

- Fresenius Kabi provided the dedicated giving set and standard kit.
- The manuals provided by the company were the only aid used to set up an infusion and programme the pump to run at 250 mL per hour.
- No clinical connection was made by any panel member during this assessment.
- The pump was assessed within the environment it would be used.
- The panel gave equal time to all parts of the standard kit provided.
- Feedback was given via an online platform and each member had to respond to all questions and sub-sections.
- The panel acknowledge the importance of the clinical impact, safety and practical aspects of the pump and kit.

2.5 Fresenius Kabi Presentation to the LITRE Panel

As part of the agreement with LITRE, Fresenius Kabi attended a meeting on Saturday 27th November 2021 to present to the panel.

The presentation took place after the user assessments as we believe that, given each panel members' expertise, they should be able to set up the pump and programme it to run at the correct flow rate without the need for training in advance. During the presentation questions, comments and concerns were raised. The main discussion took place at the end of the presentation. Panel members asked questions they had prepared during their individual user assessments. All were noted and will be used by LITRE and Fresenius Kabi for future reference and follow up. Key points are provided in the full pump assessment in 3.2.

LITRE felt the presentation covered all salient points within the brief and the representatives were receptive to hearing the views of the panel and responded well when answering questions. The representatives' response to questions raised at the assessment demonstrate their awareness and understanding of the patients' perspective as to how it would be used by someone on home parenteral nutrition. There were some questions they needed to seek further information to answer and they have consequently provided responses which have been shared with the panel.

3 Findings of the Panel

The findings of the user assessment 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.
- Battery life/infusion at 250 mL per hour.
- The standard package, including rucksack and pole clamp.

The panel acknowledge that a user would receive comprehensive training on the pump and accessories prior to use.

The findings are included in the following sections:

- 3.1 Summary data table of the key features of the pump and accessories perceived as important by LITRE.
- 3.2 User Assessment feedback.
- 3.3 Considerations and recommendations.

3.1 Summary data table of the key features of the pump and accessories

The information below has been taken from company literature and has been verified by Fresenius Kabi.

Pump	Weight Pump with internal battery	610 g
	Pump with charger	1070 g
	Charging unit/cradle/base	405 g
	Pump size	156.4 x 129.7 x 49 mm
	Pump with charger size	166.4 x 131.2 x 164 mm
	Smart Power Holder (pump holder/charger)	146 x 162 x 115 mm with pole clamp 132 x 118 x 46 mm without pole clamp
	Accuracy: +/-	5%
	Flow rates	Range from 1mL/hr to 600 mL/hr
	Delayed start	Delayed start enables to postpone start of a new infusion from 1 min. to 24 hrs
	Priming options	Automatic, semi-automatic and manual priming are available
	Night mode	Ability to set to minimum during the night to reduce brightness of the display
	Display panel	Colour LCD 64.8 x 48.7 mm (320 x 240 pixels)
Battery	Charging times from flat with pump off	6 hours
	Specification	Built-in 7.2 V Lithium Ion rechargeable battery / 16.2 W
	Battery life	Minimum of 24 hrs at 25 mL/hr Minimum of 14 hrs 600 mL/hr 250 mL/hr - 15 hr 6 mins per charge in standard mode
	Power consumption	In standard operating conditions: maximum 9 W
Alarms	Range of alarms	High priority, low priority, occlusion, air and end of infusion pre alarm
	Are they adjustable?	Yes
	Is there a warning when the infusion is due to end?	Customizable, can be set on volume or time left to minimum of 1 mL / 1 minute or from 1 mL to 999 mL
Is it a multi-therapy pump?		No
Giving set	Length	300 cm
	Filter position	Nearer to the pump than the patient
	Filter size	1.2 micron
	Air detector	Integral to pump. Ultrasonic® adjustable air in line detector, range: 0.125 mL to 0.75 mL
	Ability to manually prime	Yes
	Free flow protection	Ambix nova clamp prevents the risk of free-flow when the door is opened and when the set is disengaged
Pump holder	The pump holder is the charging unit	Yes

Instruction manual	Patient-friendly UK version	Copy sent for use did not specify patient version
	Quick reference cards/information	Yes
Travel information	Is it stated whether the pump can be x-rayed	Not stated. Fresenius Kabi have confirmed it can be x-rayed
	Are foreign adaptors available	Travel plugs can be used but no adaptor needed
Rucksack	Sizes (Fluid capacity and dimensions of an infusion bag may contribute to variations in the suitability of different sizes)	1. Up to 1.5 litres 2. Up to 5 litres
	Wheeled option	Currently not available. Expected June 2022
	Separate wheels	Currently not available. Expected June 2022

3.2 User Assessment Feedback (Questions and final opinion)

Parameters used: Poor, Less than acceptable, Acceptable, Good, Very good.

Questions		User Assessment panel opinion
What were your initial thoughts on the pump and PN kit when you unpacked it?		Good
Operating manual/instructions: How did you find the Instructions for Use and Quick Reference Guide in order to set up the pump and to seek information required?		Less than acceptable
Pump	Weight	Acceptable
	Size	Less than acceptable
	Noise level at 250 mL/hr	Acceptable
Battery	Time to fully charge as per user manual	Good
	Ease of charging the battery	Acceptable
	Instructions on how to charge the battery	Acceptable
Pump holder/charger unit	Ease of attaching pump to holder/charger unit	Good
	Ease of removing pump from the holder/charger unit	Acceptable/good
	Ease of use of the clamp handle	Good
	Ease of inserting the power cable	Acceptable/good
Giving set	Overall length of the giving set	Good
	Length of set - fluid bag to pump	Good
	Length of set - pump to patient	Good
	Position of filter	Good
	Ease of gripping the spiking	Good
	Ease of spiking the fluid bag	Good
	Diameter of the giving set tubing	Acceptable
Rucksack The panel reviewed the black rucksack	General appearance	Less than acceptable/acceptable
	Size	Poor
	Carrying options offered	Good

intended to hold up to a 5 litre bag of fluid	Durability	Acceptable
	Weight without pump or fluid	Poor
	Weight with pump and fluid	Poor
	Hanging/securing system for fluid	Less than acceptable
	Securing the pump in allocated	Less than acceptable
	Comfort when placed on your back	Poor
	Material	Acceptable/good
	Ability to access the pump when the rucksack is in use and zipped up	Less than acceptable
Loading the giving set into the pump	Ease of opening the pump	Acceptable
	Ease of loading the giving set into the pump	Good
	Ability to align colour coded sections into the right positions	Acceptable/good
Programming the pump for an infusion	How did you find using the controls/keys on the pump?	Acceptable
	How would you rate the symbols/images on the controls/key?	Acceptable
	How did you find programming the infusion?	Good
	Please rate the clarity of the information on screen	Good
	How did you find priming the giving set via the pump?	Acceptable/good
General questions about the pump's functionality	If you tested the alarms, were the error messages easy to understand?	Yes
	For any error messages shown, were you able to troubleshoot easily with the information provided?	Yes
	If an alarm occurred did the infusion restart automatically once corrected?	No
Are there any features that you expected to see on the pump that were not present?	Covered in the panels summary below	
Was there any information you felt was missing from what you received?	Covered in the panels summary below	

Overall, the Ambix nova is a user-friendly infusion pump.

Front panel controls: Clearly set out, and the keys are self-explanatory and a good size. Different colours for all the keys would be preferable to avoid blue ones blending into other aspects of the design. Main key functions on the pump:

- On / Off
- Up and Down and '+' and '-' chevrons for value setting
- Alarm beep mute
- Prime
- Keypad lock / unlock
- Menu / Information
- Start / Validate
- Stop / Cancel



Keypad Security: Keypad is lockable by pressing the Keypad lock key but is easily unlocked.

The door: Situated on the left of the pump, which is opened via the lever. Inside there are colour coded sections which match the colour coding on the giving set to aid loading, and the direction in which the set must be inserted. Dexterity issues could prevent ease of opening.

Loading the giving set: Good, matching the colour coded sections is a useful guide and the pinch clamp only fits in one way.

The weight of the pump: While the panel found it acceptable they advocate that an ambulatory pump should always be as light as possible. The pump is not used in isolation, there is the combined weight of the feed plus any accessories required. There were concerns about transporting two pumps and the accessories when on holiday due to size and weight.

Pump size: There is an integral battery but still no external battery pack as previously recommended during previous LITRE User Assessments on an Ambix pump.

Priming the pump: There are two methods to priming the set:

- Automatic priming: Pump automatically fills the infusion set once the Start key is pressed.
- Semi-automatic priming: Pump fills the infusion set as the Prime key is pressed and held.

The pump has four modes of operation: Flow Rate only mode, Continuous mode, Ramp mode and intermittent mode.

Giving set: Overall the giving set was good.

Alarms: When evaluated it was clear which alarm was being raised which alerted the user by audible and visual alarms.

Following the alarm, it had to be cancelled by pressing the Stop key and then started again using the Start key. Even a minor self-correcting occlusion required these steps. This requirement is not detailed in the instructions for use and would be a massive inconvenience at night. This would also disturb a carer if they were required to correct an alarm.

Pump holder/charger unit: Can be used independently from the pole clamp. The instructions could be clearer that the pump can only be charged when connected via the smart holder power unit (pole clamp.)

Pole clamp: When attached to the pump base/charger the unit can be rotated for better viewing.

User manual: It provided the information required during the User Assessment. The images and figures were clear and helpful. However the panel noted numerous typographical errors and omissions. We are aware that the UK patient version is currently being developed. LITRE would encourage further engagement during the development.

The instructions for use for the rucksack are extremely poor both in detail and print quality. It is very difficult to ascertain how to use the rucksack from the instructions provided.

Quick Reference Guide: Easy to understand but requires checking for typographical errors. The use of pale font colours should be reconsidered.

Rucksack: Aspects of the rucksack were good, however there were aspects that need improving to make the user experience more comfortable. Colour, weight and accessibility during feeding were not well received. Interchangeable wheels, expected in June 2022 were deemed necessary to enhance mobility and provide options during feeding.

Noise during infusion: Assessed at 250 mL per hour and deemed acceptable.

Brightness: The ability to dim the display was welcomed.

Battery/power supply: There was some concern regarding no back up supply in the event of the battery depleting and no main power being accessible. Potential to limit mobility outside the home or the need to carry the charger unit at all times.

3.3 Considerations and Recommendations

- An **external battery pack** would enhance the user experience. Mobility and freedom can be impacted if there is a need to connect to the mains power supply to complete an infusion. This would apply to within the home environment and outside. The panel expected to see this as a standard item for an ambulatory system.
- The panel were disappointed not to see **wheels** available. The planned addition, expected in June 2022 was welcomed by the panel.
- **Rucksack** – the panel expected to see a much better user-friendly design. A stronger focus must be placed on the user-experience.
- **Giving set**
 - The end cap should be replaced with a gas-permeable one.
 - The position of the filter - when in use the filter sits just outside the rucksack. There is potential for adverse events. It would be preferable for it to be positioned closer to the pump so it was housed in the rucksack. Also, for children it would be advantageous to remove the accessibility for chewing and fiddling aspects.
 - Light protection required as recommend by the Medicines and Healthcare Regulatory Agency (MHRA) for under two-year-olds. The panel felt this would benefit everyone.
 - Encourage the development and introduction of double or triple spike connecting lines to support the way patients now infuse.

- The **Instructions For Use** has numerous typographical errors. It's been translated which has produced the errors. The booklet does not state on the front cover who it is aimed at; healthcare professionals, patients/carers or other. A comprehensive booklet, clear images and a user-friendly size version is encouraged. We understand a UK version is being written and will be thoroughly checked.
- **Quick Reference Guide** Comprehensive, clear and concise. The use of a light grey font colour throughout the guide should be reconsidered as in areas it is difficult to read.

Both the Instructions For Use and Quick Reference Guide should be checked with a strong focus on typographical errors, font colours and abbreviations. *LITRE strongly suggest this is seen and reviewed by the panel.*

- **Colour coded sections, giving set and inside pump** – consideration should be given for those who may have blue-green colour blindness.
- **Alarms** – there may be a place for words instead of symbols
- It was agreed that being able to **charge the pump** directly from the mains supply would be beneficial, especially if there was a need to charge while infusing during the night. Fitting the smart pump holder into the rucksack is far from ideal.



General LITRE recommendations for all ambulatory parenteral nutrition pumps:

- In the event of the user needing to seek advice or support from the manufacturer when using the product, full contact details must be supplied as part of the kit.
- Out of office hours support must be provided by the homecare company.
- All manufacturers should supply wheels as an interchangeable option for all the rucksacks.
 - 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 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 as well as light colours.
 - Patient/user information should not be restricted to written materials. All methods should be considered for the best patient/user experience to be achieved.
 - Holiday adaptors/information: if required, it should be clear to whom the request should be directed. 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 and accessory failure within the homecare environment.
 - Everyone using a medical device should know how to report a faulty product via the Yellow Card Scheme.

LITRE's position is to raise awareness of the ambulatory pumps that are available within the marketplace; LITRE **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 lifestyles, usability and choice to prevent a major crisis in the event of a pump withdrawal or failure.

LITRE supports the regular servicing of all pumps in line with the recommended guidance.

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 daily 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 necessary.

All pumps should have the facility to have an internal battery replaced rather than there be a need for a new pump.

On-going relationships with pump manufacturers and distributors

Members of PINNT and LITRE will engage with pump distributors or manufacturers. At no point does this engagement imply or give endorsement of a product. This is essential to fulfil our mission statements as listed at the beginning of this report.

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