



LITRE Assessment – Ambulatory Pump for Parenteral Nutrition

Results of a LITRE Assessment Panel

October and November 2022

Product: Rythmic™ Serena ambulatory infusion pump

Company: Micrel Medical Devices



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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

In respect of ambulatory parenteral nutrition pumps ‘one pump will not fit all patients’.

1.4 Our Position

- Patients may have a common treatment but they will have different situations, needs and abilities.
- The choice of pump should be made as a result of a discussion with the clinical team and the patient and carer 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 be a choice of pumps for children.
- This report is the opinion of the panel and it is therefore recognised that it is not fully representative of all patients.
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- Light protection containers and giving sets must be available for children under two years of age where vitamins, amino acids and/or lipids are prescribed.
- 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 and accessories should be carried out regularly by the clinical team. Should it not meet either the clinical or personal expectations, an alternative 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 Rythmic™ Serena pump

This is the first time LITRE have conducted a user assessment of the Rythmic™ Serena, 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 panel below represents a range of patients and experts who would use or support someone using an ambulatory parenteral nutrition feeding pump.

Peter Austin	Consultant Pharmacist
Angela Cole	Lead Nutrition Nurse, former Lead Clinical Nurse Specialist for children with Intestinal Failure
Jo Gabbitas	Adult on parenteral nutrition (PN)
David Lee	Adult on parenteral nutrition (PN)
Russell Mowbray	Adult on parenteral nutrition (PN)
Emma Norman	Procurement specialist
Mark Oldham	Carer for adult on parenteral nutrition (PN)
Debbie Phillips	Adult on parenteral nutrition (PN)
Anna Shepherd	Young adult on parenteral nutrition (PN)
Joanna Shepherd	Parent of a young adult on parenteral nutrition (PN)
Mia Small	Nurse Consultant Nutrition and Intestinal Failure
Carolyn Wheatley	Administrator and meeting convenor

Note: Individual panel members must not be contacted regarding any aspect of this report – instead please contact PINNT with any queries using the details provided at the end of this report.

The accumulated knowledge of the LITRE panel was evident in their approach to the detailed user 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, in addition to the clinical and quality of life issues relating to home parenteral nutrition.

2.2 Inspiration Healthcare and Micrel Medical Devices Representatives

Katie McHale – Inspiration Healthcare, Business Unit Manager, Infusion Therapy
Achilleas Tsoukalis – Micrel Medical Devices, R&D and Quality Director

2.3 Methodology

- Each panel member conducted their assessment remotely.
- None of the panel conferred during the assessment process.
- 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.
- The panel graded all parameters on the feedback form.
- There were new panel members for this user assessment. Some members of the panel were known to each other following previous LITRE user assessments. The results presented are a collective summary of the individual user assessments.

2.4 Key Aspects of the Assessment

- Micrel Medical Devices provided the dedicated giving set and standard kit.
- The manuals and training eGuide provided by the company were the only aids provided for the panel to set up an infusion and programme the pump to run at 250mL per hour.
- No clinical connection was made by any panel member during this assessment.
- The pump was assessed within environments it would be used by the patients.
- 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 Inspiration Healthcare and Micrel Medical Devices Presentation to the LITRE Panel

As part of the agreement with LITRE, Inspiration Healthcare and Micrel Medical Devices attended a meeting with the panel members. This was held on Saturday 15th October 2022 via a virtual platform.

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. This also gave a greater opportunity to identify any practical issues or issues regarding the documentation provided with the pump.

The company representatives shared the presentation, addressing the key aspects requested of them. At the end of the presentation the panel asked questions that had been prepared during their personal assessment and had the opportunity for any clarification points they wished to raise.

All these questions and clarifications were noted and will be used by LITRE and Micrel Medical Devices for future reference and follow up. Key points are provided in the full pump assessment in section 3.2. below.

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' responses to questions raised at the assessment demonstrated their awareness and understanding of the patients' perspective as to how the pump and accessories would be used by someone on home parenteral nutrition.

The presence of someone with detailed knowledge about the research and development of the pump and accessories was deemed an asset to the dialogue and process without being overly technical. The panel noted the presentation to be 'fantastic, informative and insightful'.

3 Findings of the Panel

The findings of the user assessment have been based on:

- Initial impressions of the pump.
- Programming and, ease of use of the pump, and the giving set.
- How the pump is powered and the options available.
- Battery life/infusion at 250mL 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 for the pump assessed.
- 3.4 General 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 Micrel Medical Devices.

Pump	Weight with internal battery	398g with rechargeable battery
	With charger	549g (UK plug – type G)
	Charging unit/cradle/base	Mains charger 99mm x 53mm x 26mm
	Size	131mm x 90mm x 48mm
	Accuracy +/-	5%
	Flow rates	0.1 to 600mL/hr
	Delayed start	Yes
	Priming options	- Priming with the pump, with automatic and manual stop - Manual set priming
	Night mode	Backlight keys
	Display panel	Graphic LCD display with backlight 66mm x 32mm (264 x 128 pixels)
Battery	Charging time from fully depelpted with pump off	3.5 hours
	Specification	- Rechargeable battery, 7.2 V, Lithium Ion, 1400mAh or - 2 x AA alkaline batteries User can remove the batteries and options are interchangeable External battery pack is also available.
	Battery life	At 25mL/hr: 104 hours operating time – 2.6 litres delivered volume At 125mL/hr: 52 hours operating time – 6.5 litres delivered volume

		At 250mL/hr: 40 hours operating time – 10 litres delivered volume At 600mL/hr: 17.5 hours operating time – 10.5 litres delivered volume (Typical values using a new, fully charged internal rechargeable battery)
	Power consumption	Maximum 1 W (without charging batteries via the mains)
Alarms	Range of alarms	High priority alarms (including air in line, battery depleted, downstream occlusion, infusion complete, set misplacement, upstream occlusion) and low priority alarms (including battery low and infusion near end)
	Are they adjustable?	Yes
	Is there a warning when the infusion is due to end?	Yes, configurable. It can be set in time (5–180 min), or volume, or off
Is it a multi-therapy pump?		Yes, optimised for parenteral nutrition
Giving set	Overall length	330cm
	Filter position	After the pumping segment, and fits inside the pump
	Filter size	1.2µm and 0.2µm micron filter
	Air detector	Yes. Two air detectors. The air detection can be configured before or after the filter to eliminate nuisance alarms.
	Ability to manually prime	Yes
	Free flow protection	Yes
Pump holder	Pump holder for a dripstand?	Yes
Instruction for use manual	Patient-friendly UK version	Yes
	Quick reference cards/information	Yes
	Are there alternative training resources?	Yes, online training guide
Travel information	Is it stated if the pump can be X-rayed?	Yes
	Are foreign adaptors available?	No, commercial travel plugs can be used
Rucksack	Sizes available*	1. Hydration rucksack – up to 1 litre – 1 pump 2. Rucksack+ – up to 3 litres – 2 pumps 3. Rucksack – up to 6 litres – 1 pump 4. Rucksack – up to 6 litres – 2 pumps 5. Rucksack – up to 6 litres – 3 pumps 6. Rucksack for multiple bags – 2 pumps *Available in 3 colours
		*LITRE advocate that the right size rucksack should be considered when the original order is placed – volume of fluid/rucksack size ratio.
	Wheeled option	Yes
	Separate wheels	Yes
	Are the wheels interchangeable between all rucksacks?	Yes on rucksacks 3 litres and above

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?		Very 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?		Very good
Pump	Weight	Very good
	Size	Good/very good
	Noise level at 250mL/hr	Acceptable
Battery	Time to fully charge as per user manual	Good/very good
	Ease of charging the battery	Good
	Instructions on how to charge the battery	Good
	Battery life @ 250mL/hr	Very good
Pump holder/charger unit	Ease of attaching pump to holder/charger unit	Very good
	Ease of removing pump from the holder/charger unit	Very good
	Ease of inserting the power	Good/very good
Giving set	Overall length of the giving set	Good
	Length of set – fluid bag to pump	Good
	Length of set – pump to patient	Acceptable/good
	Position of filter	Acceptable/good
	Ease of gripping the spiking	Good
	Ease of spiking the fluid bag	Good
	Diameter of the giving set tubing	Good
Rucksack	General appearance	Good/very good
	Size	Good
	Carrying options offered	Good/very good
	Durability	Good/very good
	Weight without pump or fluid	Good
	Weight with pump and fluid	Acceptable/good
	Hanging/securing system for	Good
	Securing the pump in allocated space	Good
	Comfort when placed on your	Good
	Material	Good
	Ability to access the pump when the rucksack is in use and	Good
Loading the giving set into the pump	Ease of opening the pump	Good/very good
	Ease of opening the tube covering door	Good

	Ease of loading the giving set into the pump	Good
Programming the pump for an infusion	How did you find using the controls/keys on the pump?	Good
	How would you rate the symbols/images on the	Good
	How did you find programming the infusion?	Good
	Please rate the clarity of the information on screen	Good/very good
	How did you find priming the giving set via the pump?	Good/very good
General questions about the pump's functionality	Were error messages easy to understand?	Yes
	Error message information – were you able to troubleshoot easily with the information provided?	Yes
	If an alarm occurred, did the infusion restart automatically?	Yes
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	

Rythmic™ Serena



Overall, the Rythmic™ Serena pump is a user-friendly infusion pump.

Front Panel Controls: Clearly set out, eight main function keys, a main screen with the battery charging status visible, which shows current battery charge as percent remaining.

The eight function keys are:

- On / Off
- Prime Key
- Enter Key – to navigate the pump screens, confirm values and select options
- Start / Stop
- Four soft keys – enter codes, edit values, confirm and reset alarms and navigate the pump menus

The front panel controls can be set to 'locked' or 'unlocked' via the configuration menu.

Opening the pump: There is a key on the bottom left-hand side of the pump (front view of pump) to open the door on the back of the pump. While opening it was deemed good, it was felt that the key was on the small side.

Loading the giving set: This is very user friendly. There is a key on the front case which turns to open (with pump front facing). The line can also only be loaded one way. There are dedicated places for relevant parts of the set to be placed. The 'blue to blue' colour matching is good.

The weight of the pump: The panel found it very good, even more impressive given the rechargeable battery pack was included.

Battery/power supply: The pump has a changeable rechargeable battery pack. There are three power options:

1. Battery pack
2. Direct via the mains, battery pack must be in the pump
3. 2 x AA alkaline batteries

- The changeable rechargeable battery pack can be removed and replaced by the user.
- The changeable rechargeable battery pack can also be exchanged for two AA alkaline batteries, which would not have a negative impact of the overall weight.

The panel recognise the advantage of the single use AA alkaline batteries as a back-up option. Rechargeable AA alkaline batteries are not recommended by the manufacturer.

- The battery door is retractable which must be twisted to open it. It may be small for some people and difficult to operate if someone has dexterity issues.

Mains power adaptor: Small and lightweight.

Pump size: The panel agreed that the pump was a good size; compact and neat. Given that the changeable rechargeable battery pack is an integral part of the design, this was impressive.

Battery life: Based on an infusion of 250mL/hr (rate used by LITRE for assessment) 40 hours operating time can be achieved according to the manufacturer's testing as requested by LITRE.

During the presentation the panel noted that the battery life was very good. It was agreed that battery life, considering variation in terms of infusion time and volume, is key to people being able to choose how and where they wish to infuse. 'Home' artificial nutrition infusions should not be limited to the home, people must have a choice as to how and where they infuse. This is vital with potential for long infusion times (not all done while the person is in bed) and the need for additional fluid infusions, especially in hot weather.

Charging time for the battery from fully depleted: The panel felt that 3.5 hours was a good time to fully recharge the battery.

Priming the set: There are two methods:

- With the pump, with automatic and manual stop
- Manual set priming

During the user assessment, when priming the giving set via the pump, some panel members had an issue with the 'air in line' alarm, which was frequently activated. This was raised during the main meeting. Both representatives were keen to address this and have since reported that the issue will be resolved by a software modification which will be made available in the next release.

The pump has five modes of operation: Flow rate only mode, continuous mode, ramp mode, intermittent mode and step mode.

Giving set:

- Overall, the giving set was good on all aspects assessed by the panel.
- The panel noted the development of the light protection giving set. LITRE has been notified that the giving set is ready.

Alarms:

- When evaluated it was clear which alarm was being raised, which alerted the user by audible and visual prompts.
- When assessing the alarms, attempts to kink the giving set tubing was difficult, which is a positive! This should reduce unnecessary alarms. If the line were to kink then, once corrected, often when sleeping, the alarm self-corrects and the infusion resets when the error is naturally removed.
- Once programmed, if an alarm is activated and the infusion is not restarted an alert will be given.

Charging the rechargeable battery can be done while the pump is off, on or when running an infusion. When charging the rechargeable battery, the dedicated power adaptor should be connected to the mains and to the power inlet port on the pump.

Pump dripstand clamp: Mixed views on ease of fitting pump into the dripstand clamp. Information on use should be included in the Patient Guides.

Instructions for use: There are three options; Instructions for Use (full manual), Patient Guide and an eGuide.

Rucksack: The range of sizes is good. The parenteral nutrition or fluid bag can be securely fastened into the securing system. Some people may struggle with the clips but generally the system is good.

Noise during infusion: Assessed at 250mL per hour and deemed acceptable. It was acknowledged that this would be relative to the individual in their own surroundings and their perception as to what is acceptable.

MicrelCare: Is a web-based care management platform. The pump has integrated cellular communication capability, which enables patients, carers and clinical teams to have visibility of the therapy information; infused volumes, alarms, line pressure and clinical observations. Noted this is an optional service. Access to the patient portal in MicrelCare is a clinical decision.

3.3 Considerations and Recommendations for the Rythmic™ Serena pump User Assessment

- An **on-screen pressure display** was deemed a feature that people would like to see. It has been noted that the ability to check line pressure is available through MicrelCare.
- Power options: The panel recognise the advantage of single use **AA alkaline batteries** as a back-up option. LITRE would not wish to see this used on a regular basis for general infusions.
- The **rucksack:**
 - Although good, the panel would like to see a colour other than black as the default option. The panel felt that the rucksack would benefit from a style update.
 - The clips on the rucksack and straps are not easy for everyone to use. These should be reviewed at the time of the rucksack update.
 - The hydration rucksack (1 litre) would benefit from a clip or means for securing on a buggy or wheelchair.

- Removing the rucksack from the wheels was deemed difficult by some due to the Velcro. Ensuring the security of the rucksack onto the base plate on the wheels and the user friendliness of being able to remove it needs a little consideration.
- **Instructions for Use:**
 - The **Patient Guide** would benefit from the addition of a contents page and page numbers, overall, it is very thorough.
 - The **electronic patient guide (eGuide)** was deemed a great support for people. It would benefit from a searchable Q&A database for problem solving or quick reference.
 - Consider the use of the word 'shall' in the instructions. If an instruction is intended to be complied with it is preferable to use 'must'.
 - Information on how to use the rucksack should be in both the **Patient Guide** and **eGuide**. It would be good to have all information that may be required in one place.
- The **external buzzer** is good for people with hearing impairments, also for carers and parents to hear alarms that may arise. A carer may not be in the same room during an infusion. Currently the buzzer is part of the standard kit for paediatrics. The panel felt that it could be an important accessory for anyone who may infuse outside the home. External noises can mask the ability to hear an alarm if in a busy or noisy environment. Volume control would be preferable too. Consideration must be given to alerting people of an alarm who may be completely deaf.



3.4 General Considerations and Recommendations

- **Size and shape of PN containers:** The panel noted that, due to the increased use of multi-chamber bags (MCB) and the range of PN containers for compounded PN and intravenous fluids, some may not fit into a rucksack as easily as others. General information should be made available to people to ensure that a PN bag can be safely folded or rolled and secured within the existing system to ensure product safety. Safety is paramount for the needs of the patients. Also avoiding any interruption to an infusion with unnecessary alarms which may be triggered if ports or the giving set is not secured properly and safely.
- LITRE would expect a common-sense approach to providing the patient with the appropriate size rucksack for the volume of their intended infusion.
- LITRE encourage and support the development and introduction of multiple spike options and extensions to facilitate a smoother feeding regime for people using more than one bag of PN or fluid.

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.
- All devices must have free-flow protection.
- The user must be able to hear or have a visual alert to an alarm.
- 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 lightweight, fit for purpose, sufficiently robust and make the need for home parenteral nutrition a user-friendly, safe experience.
- Rucksacks: The exit point from the rucksack for the giving set to the patient should no longer have fixed tabs at the bottom of the bag. The way in which they are used now means they may be on wheels or carried on the back. The set will need to exit the rucksack at different points to adapt to the user's preference.
- All patient/user information booklets and quick reference information must be easy to read with as many relevant images as possible. The font size and colour should be carefully considered.
- Patient/user information should not be restricted to written materials. All methods should be considered for the best patient/user experience to be achieved.
- Where videos or other virtual platform resources are used, they must be clear, concise and have caption text.
- 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.
- If a patient is travelling overseas, a spare pump must be supplied to support a product failure where a replacement would not be possible under the usual replacement process.
- 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 contribute the landfill.

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

LITRE recognise the need for single use packaging on some items. We advocate that manufacturers must meet their waste packaging recycling responsibilities.

Ongoing 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.

Regulating medical devices in the UK

Change to required CE mark: A CE mark is a symbol applied to products to indicate that they conform with relevant EU directives regarding health and safety or environmental protection. A CE mark means a product satisfies the legislative requirements for it to be sold in the European Economic Area (EEA).

In the UK, from January 2021 the CE markings have begun to be gradually phased out and replaced by UKCA marking. The UKCA (UK Conformity Assessed) marking is a new UK product marking that will be used for goods being placed on the market in Great Britain (England, Wales and Scotland). It covers most goods which previously required the CE marking. The deadline for using the UKCA mark has been extended until 31 December 2024. Full information can be found via this link: <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#UKCA>

Full information regarding the regulation of medical devices in the UK can be found via this link: <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk>

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