

LITRE ASSESSMENT OF AMBULATORY PUMPS FOR PARENTERAL NUTRITION

REPORTS TO THE COMMITTEE OF LATEST DEVELOPMENTS

19TH FEBRUARY 2007

The four companies that had previously presented their product to LITRE were invited back to give the committee the latest updates.

Eden Medical (Rythmic), Hospira (Gemstar) and McKinley (Bodyguard) reported that they had new developments which they wished to make LITRE aware of; Smiths Medical felt that as their pump (CADD VIP) had not undergone any changes then they would not attend, but wished to remain in contact with LITRE.

Eden Medical:

At the last LITRE meeting in November 2006, the Rythmic was waiting to undergo CE marked trials – these were carried out in December 2006.

Three things have been slightly changed –

- The anti-syphon valve on the giving set now has a thicker membrane, and perhaps at a later date will be made of a different type of plastic, with a leaflet to warn of the possible danger of rupture. This had come about as a result of someone with long nails puncturing the membrane.
- The giving set is now longer at 2.2 metres (was previously 1.5m) and the pumping segment (the part of the set that sits in the pump) has been extended slightly to enable ease of loading.
- Pump software – the sequence for programming is now as similar as possible to the Baxter 6060.

The rucksack was demonstrated. It has cross-straps over the 'nappy-style' fluid-bag holding section, with clips to attach to the top of the bag to support the weight. There is a padded pocket for the pump. A laminated instruction guide is provided. There is a gusseted pocket on the front, and a pocket on the back. There is a cross-strap for the waist or chest.

The soft bag which can be used to house the pump now has easier access for the giving set.

The charger originally had an option where it could be converted to a 2-pin plug, but this does not meet with MHRA guidelines, so the two segments of the charger are now locked together.

The standard kit supplied will consist of the pump, rucksack, charger, one internal battery and one external battery.

Optional extras will be the soft bag, a pole clamp, and an extra external battery.

The auto ramp feature is in the final stage of validation (implementation March 2007). However in the meantime it is possible for the patient to change / reduce the flat rate as an alternative to the ramp down. This will all be resolved with the latest revision of software whose release is imminent.

It is hoped to develop a smaller rucksack that can hold two pumps, but can also be used for smaller volumes of fluid with just one pump.

Eden demonstrated a prototype of an idea for greater stability of the fluid bag on the LITRE stand. The committee were very interested in working together with Eden on this idea. It was agreed to follow this up with them once the pump issues has been sorted out.

Hospira:

LITRE asked for assurance from Hospira that they were keen to enter into serious discussions about the Gemstar as they had given time in the past to be them but no progress had been made. They confirmed they were committed to furthering development of the pump and to take on board the thoughts of LITRE.

Hospira are in the process of developing a new giving set and showed LITRE the prototype drawings. The current set (which is the PN set used in the US) has the air-in-line filter way below the cassette, and the pump alarms at 0.3ml of air. This configuration cannot be changed due to the way that the pump operates.

The new set will have the following features:

- The cassette will be nearer to the filter
- The anti-syphon valve will be discarded as there is protection from free-flow with the on/off switch.
- There will be longer proximal tubing from the bag to the pump.

It was estimated that it would take six weeks to manufacture prototype sets. There was discussion as to whether the whole set needs to be sterile or just the fluid pathway; LITRE are under the impression that it is just the fluid pathway – this is due to the information given on the packaging of the giving set for the Baxter 6060.

Future giving sets will have more compact packaging than at present.

The rucksack was demonstrated and has the 'nappy-style' securing system.

The standard kit will comprise of the pump, rucksack, pole clamp, external battery and charger.

LITRE urged Hospira to complete the giving set project as soon as possible because it had been delayed for too long.

McKinley:

A smaller size rucksack is in development. McKinley would like to offer 'bespoke' rucksacks but LITRE felt that this would be unworkable due to cost.

McKinley plan to undertake a review of the kit issued to the individual patient when their six-month maintenance check takes place.

McKinley gave the committee copies of their new user guide, which they said they could feature the PINNT logo and some information on the back, and laminated 'Using Your Backpack' instruction guide and accessories list. One of the committee had just received the backpack and it did not have the laminated guide and accessories list in it; the homecare companies are not sending them out.

LITRE stated that they felt McKinley were concentrating too much on the accessories. Ideally when travelling patients do not want to have to carry the pole-mounted charger and the big mains lead; they want just the pump and a small mains lead rapid charger, with dry-cell battery back-up. McKinley said they will investigate the options.

Conclusion:

LITRE are very encouraged to see that all the companies are enthusiastic and willing to listen and action, where possible, LITRE's suggestions for improvement.

The problem of making patients aware of what is available was discussed with all companies. Patients have asked about purchasing their own 'extras' but the committee realised that there would be a lot of problems with liability and insurance. The homecare companies obviously want to provide a basic kit which does the job effectively and efficiently; but many patients will feel that an accessory will enhance their feeding lifestyle and therefore their quality of life.

LITRE asked each company to make sure they offer the best standard kit to the homecare providers as patients have already provided feedback that they were not happy with the new kit they have received.