Attn: Biomedical departments

RE: New T34™ CME battery

Affected Infusion pumps models:

- T34™ syringe pump CME Brand 3rd Edition

Dear valued customer,

We appreciate your inquiry regarding the battery life of newly introduced T34 pumps.

As you've correctly noticed, the battery life on this new syringe driver is different from the version previously distributed and currently in use. The main reason for this difference is the need to comply with IEC60601, 3rd edition standards, which require certain circuitry and software upgrades related to alarm management, as well as additional components and redundancy to improve patient safety. Some examples of these changes include:

- 2 tone alarms
- additional components on PCB board
- yellow LED alarm mode
- back up battery changed to rechargeable

In addition, we have improved other performances, such as keypad sensitivity, and introduced updates to pumps software.

The above changes consume additional battery power to optimally operate during infusion administration, thus restricting the battery life to ~25 hours at 1 ml/hour rate. This performance claim is outlined in our DFU (see page 10. ref. DFU999-103EN Rev. 02).

BD does acknowledge that ~25 hours claim represents a significant departure from the previous, 2nd edition device claims of 3 to 5 days of operation on a single battery. BD also understands both the economic and the workflow implications of frequent battery changes now required. However, at this point, we do not consider the observed battery life reduction poses any patient safety risk, also considering that local policies stipulate that all infusions should be monitored at least at~25 hours interval.

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Nevertheless, in order to improve our Customers’ experience, BD has recently initiated an R&D project to however extend battery performance. Potential pathways being explored include software and hardware changes to maximize battery life without compromising on patient safety and pumps performances. We anticipate the initial phase of this project to be completed in early December, at which point we should be able to communicate the expected improvement and the related timeline.

In the meantime, we advise our customers to ensure the battery is replaced at the end of each infusion/set-up of the new syringe. (i.e. max within 24 hours from the start of each infusion, assuming ~ 1 ml/hour or lower rate).

BD appreciates your understanding and will be happy to provide additional clarifications if required.

Best regards,

Sylvain Iff
Product Manager
Global Ambulatory infusion

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