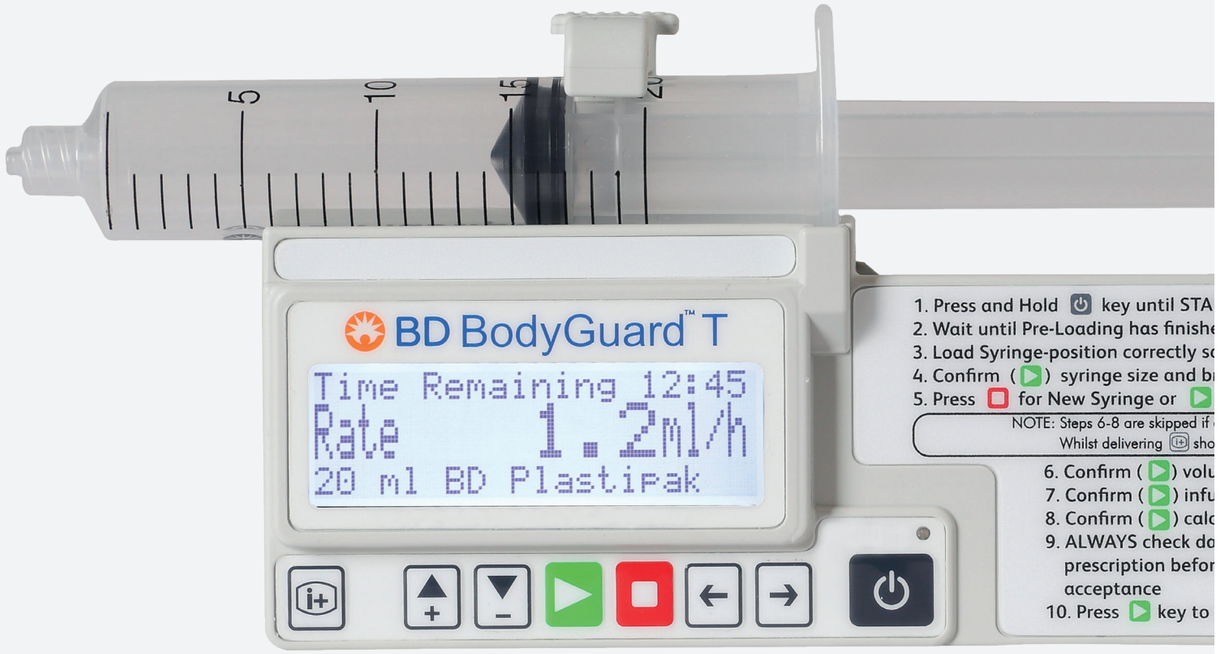
Ambulatory Syringe pump and Battery performance observational study

BD



Purpose

The purpose of the Battery Observational Study is to educate clinical users and biomedical departments on how the CME T34™ and the BD BodyGuard™ T syringe driver perform when using different 9V alkaline 6LR61 battery brands. The study highlights the potential for a 9V alkaline battery to experience random voltage drop events when used with an ambulatory syringe driver alongside the variability potential across brands, models and, sometimes, production batches.

It also shows the BD BodyGuard™ T syringe driver battery duration performance across battery brands at nominal conditions.

The aim is to provide biomedical, clinical, and procurement-department-relevant information in terms of product performance when selecting a 9V 6LR61 battery.

Note: BD recommends to always use 6LR61 batteries but does not recommend any battery brands as BD does not control the manufacturing process of these batteries.

Battery Voltage Drops

Background (What we have observed in the field)

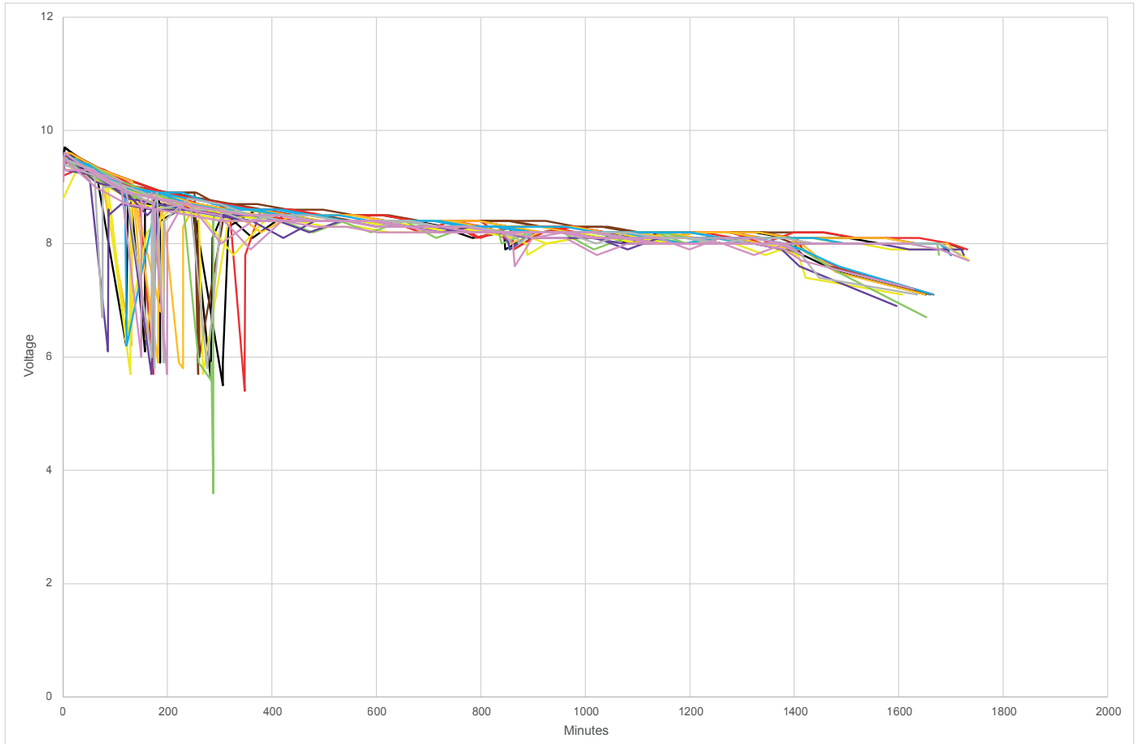
Our post market surveillance process has indicated to us that some unexpected early end battery alarms and pump shutdowns have been observed during use. No serious adverse events have been reported during those events. These events have led BD to investigate further and identify the root cause of such events.

BD Battery assessment on the CME T34™ and BD BodyGuard™ T Syringe driver

The CME T34™ syringe driver is susceptible to variations within the available consumer off-the-shelf 9V 6LR61 batteries. The pulsed power used to deliver the infusion combined with the internal resistance of the battery can cause situations where the battery voltage drops momentarily triggering low/end battery alarms or possible hardware shutdown. The issue is associated with T34™ pumps manufactured over 10+ years; The T34™ design was assessed but no pump hardware was linked with the unique aspects of this issue.

Higher impedance in some 9V batteries has been determined to have the best correlation to the occurrence of voltage drops associated with early low/end battery alarms and pump shut down issues because of the following characteristic behaviors:

- Impedance in batteries is higher early in the discharge life. This correlates with unexpected battery alarms within the first 1-12 hours of a 24-hour infusion. (See graph below).
- Higher battery impedance will cause larger voltage dips which are more likely to trigger alarms.
- Battery brands with higher impedance are more likely to have early battery alarm events reported than batteries with lower impedance.



Graph: Battery voltage from event logs. Resume as needed from early low/end battery alarms to finish ≥23-hour infusion.

Testing was conducted over several months first in the investigation of the issue and then to characterize more batteries available on the market.

Population[1]

Testing was conducted on 2nd edition and 3rd edition CME T34™syringe drivers.

Note: Testing is applicable to BD BodyGuard™ T syringe driver as it shares the same hardware, and the current draw is bounded by the test pumps.

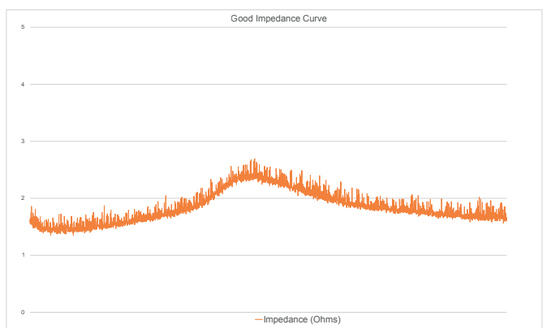
Test Method

Testing performed:

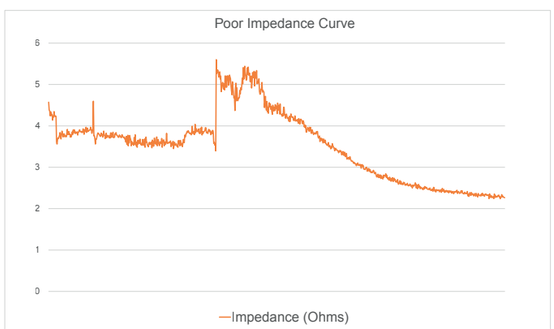
- Simulated use testing: Constant rate test with a 20ml BD Plastipak™ syringe running at 0.76ml/h generating a ≥23-hour infusion through an administration set (M100-172SB) with an anti-siphon valve and water (22°C ± 3°C). This test was run on many 2nd and 3rd edition CME T34™ pumps and could be conducted with no additional test equipment. Multiple tests run on batteries and battery lots
    - Acceptance criteria – no battery alarms during the infusion and no unintended pump shutdowns
- Impedance measurement – An oscilloscope was connected to measure the battery voltage and battery current as close to the battery as possible. The scope logged data when a significant current pulse occurred which was normal operation with the pulsed motor of the syringe driver. The measured voltage and current were used to calculate the impedance. This test was run with the same setup as the simulated use test. Due to the monitoring equipment, the single test unit setups allowed only limited test through put. Usually, a single test run on battery per battery lot
    - No acceptance criteria, but data was reported and categorized. This impedance is specific to the pump load and current pulse which is unique to the pump/battery system. For comparison, a battery with 2x the impedance would have 2x the voltage drop. A 4ohm battery would have a 2x bigger voltage drop than a 2ohm battery used in the same pump. General categories by observation:

Impedance range	<3 ohms	3 – 4 ohms	> 4 ohms
Performance	**Good**	**Marginal**	**Less good**

- Also, batteries with lower steady impedance curves performed better



Example of good Impedance Curve – smooth and less than 3 ohms during the infusion



Example of poor impedance curve – more erratic & > 4 ohms during the infusion

Results

Consistency of performace observed with T34™ syringe drivers	Battery Brand /Model (6LR61)	Sample size	Failure rate	Complaint indicator	*Impedance/ **Impedance Variability (ohms)
Good	**Duracell Plus**	90	0.00%	Low	1.83 to 2.7
Good	**Duracell Procell Intense Gen 2**	120	0.00%	-	1.10 to 1.37
Good	**Panasonic Power line**	120	0.00%	Low	2.52 to 2.66
Good	**NX Power Plus**	30	0.00%	-	3.08 to 3.62
Marginal	**Duracell Procell Intense**	60	2.00%	Low	3.0
Marginal	**Energizer Max**	120	7.50%	Low	2.83 to 5.48
Less good	**Varta Industrial Pro**	30	10.00%	-	5.83
Less good	**Duracell Ultra Power**	30	0.00%	High	6.58
Less good	**NX Power tech**	27	11.00%	High	5.92
Less good	**Duracel Procell**	83	49.00%	High	4.26 to 5.26

Sample size, failure rate and impedance all internal testing.

Customer complaint indicator is an external source of data.

**Note: Impedance was measured with the syringe pump and will be different from the impedance found on battery data sheets.*

***Minimum 1 sample per lot.*

Conclusions

Impedance can vary between the battery brands and lots.

Based on the testing performed on the CME T34™ 2nd edition and 3rd edition pumps with over 750 battery samples, Duracell Plus, Duracell Procell Intense Gen. 2, and Panasonic Powerline had the most consistent performance in the syringe driver/ battery system.

The low impedance of these batteries may indicate a favorable outcome with regards to early alarms and pump shutdown:

- Higher battery impedance will cause larger voltage dips which are more likely to trigger alarms
- Battery brands with higher impedance are more likely to have early battery alarm events reported than batteries with lower impedance

The complaint indicator is related to the number of issues reported to BD with regards to early battery alarms and shut down.

If 9V batteries have a sudden significant drop in voltage below the operational threshold, it can cause the infusion pump to stop infusing and shutdown. On the 3rd edition, pump shutdown causes the backup buzzer to sound for at least 3 minutes.

1. 2nd and 3rd Editions refer to the version of the applicable standard and not to the pump generation

Battery duration summary on the BD BodyGuard™ T syringe driver

Background - What we have observed on the field

Historically, the CME T34™ 2nd edition syringe driver could typically dispense fluid at 1ml/h for several days on a single 6LR61 9V battery. When the CME T34™ 3rd edition syringe driver was released, several software and hardware additions were made to add functionality to support backup alarms and other requirements in place with the latest standards. The combination of changes caused a decrease in the performance at 1ml/h to 25h with a single 6LR61 9V battery.

One of the goals for the launch of the BD BodyGuard™ T project was to improve the battery duration from the initial release of the 3rd edition syringe driver. Improvements were made to the software while keeping all the required updates in hardware to improve the battery duration while meeting the standards requirements.

Population

BD BodyGuard™ T Syringe pumps and software.

Note: testing is also applicable to CME T34 3rd edition pumps that receive BD BodyGuard™ T Software updates.

Test Method

Testing was conducted across two syringe types and at two rates to characterize the battery duration performance.

Testing performed:

- Simulated use testing: Constant rate test with a 20ml BD Plastipak™ syringe running at 1ml/h through an administration set with anti-siphon valve. At the end of each infusion, another infusion was started until the battery was exhausted

Only results at 1ml/h with a 20ml BD Plastipak™ syringe are communicated here as it represents the worst case that was tested (results at at 5ml/h not shown).

Test conditions:

- Flow rates: 1 ml/h
- Tested with extension set model M100-172SB
- Solution Type: Distilled water
- Temperature: 22°C ± 3°C
- Back Pressure
- Syringe size and brand: BD Plastipak™ 20 ml

Results

Battery Model	Rate	Syringe	Pump Samples	Avg* (hrs:min)	Min*	Max*
Duracel Ultra	1 ml/h	20 ml	30	79:36	69:52	82:37
Duracel Plus	1 ml/h	20 ml	30	77:55	73:05	81:05
Duracel Procell Intense Gen 2	1 ml/h	20 ml	30	86:37	76:05	89:51
NX Power Plus	1 ml/h	20 ml	30	79:27	69:24	83.00
Panasonic Powerline	1 ml/h	20 ml	30	70:59	66:44	75:41

**Time until End battery alarm.*
The End battery alarm will continue until the battery is exhausted, but the pump will not infuse in the End battery alarm state.

Claim in DFU is based on clinically relevant requirement of 50hrs to support 2x 24hr infusions.

Note: The battery duration could be impacted by a number of factors, such as:

- Programmed flow rate
- Syringe size and brand
- Syringe diameter
- Syringe friction
- Back pressure
- Frequency of use, backlight, and alarms
- Operating temperatures
- Battery type, brand and capacity

Overall Conclusion

The studies indicate the range of performance of different battery brands and lots with regards to the syringe pump. These two studies are important to consider when selecting a suitable battery for your facility.

The performance of the CME T34™ and the BD BodyGuard™ T syringe pump can be impacted as a result of variability between different battery brands and lots.

The two observatinoal studies performed by BD provides data to biomedical, clinical, and procurement departments for consideration when selecting a 9V 6LR61 battery for their syringe pump.

BD recommends to always use 6LR61 batteries with the syringe pump.

BD Switzerland Sarl Route de Crassier 17 1262 Eysins Switzerland

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