T34™ Syringe Pump

3rd Edition updates

BD

This document describes the updates incorporated in the release of the BD/CME T34™ Syringe Pump that guarantee compliance with the latest standard.
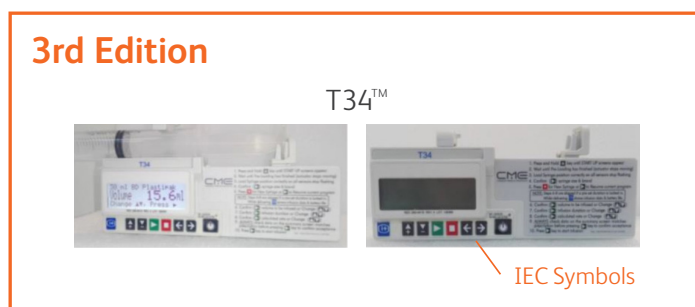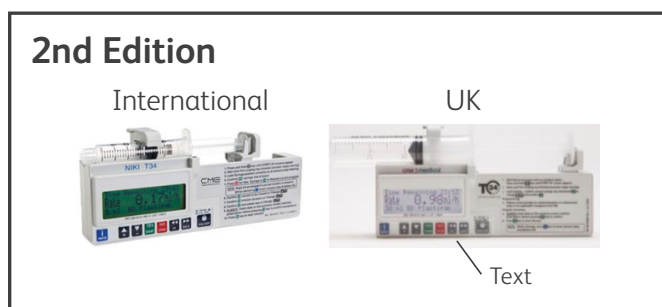
T34™ key changes include:

- Compliance with standard IEC 60601-1 Edition 3.1
- IP22
- Software updates
- PCBA update to alarms
- Update to DFU, QRG & Patient guide
- Bolus function default off from new - configurable enable/disable in change settings

Alarms

Product changes T34™ Syringe - alarm tones and priorities

Description	Alarm Type	Audio Signal as per 60601-1-8	Visual Signal as per 60601-1-8
Down occlusion End battery End of infusion Syringe displaced during infusion Restart pump Switch off and on ERROR XX	**High Priority Alarm** Requires immediate user response	**High Priority** Volume = ~ 58 dBA	**RED flashing visual** **Operation LED flashes RED**
End of infusion (keep vein open)	**Medium Priority Alarm** Requires prompt user response	**3 tones** Volume = ~ 58 dBA	**YELLOW flashing visual** **Operation LED flashes YELLOW**
Pump paused too long Low battery Near end	**Low Priority Alarm** Requires user awareness	**Low Priority** **2 or 3 pulses** Volume = ~ 54 dBA	**YELLOW solid visual** **Operation LED solid YELLOW**
Bolus started/completed Keypad lock/unlock Syringe plunger hit the limit Syringe loaded Purge started/end Power on/off Infusion started/resumed/stopped by user KVO stopped by user Service interval alert	**Information Signal** Provides information that may or may not require actions from clinicians	**1 or 2 pulses**	**No visual**

Visual changes

2nd Edition	**3rd Edition**
International UK	T34™
Text	IEC Symbols

3rd Edition Syringes

It is recommended that all but the brand of syringe in regular use are disabled via the BodyComm™* communication software to prevent accidental selection of the incorrect brand during set up. Should the need arise to program the T34™ syringe pump to operate with a manufacturer and/or brand other than one of those listed above, you should consult either your local medical engineering department or BD/CME Technical Services.

Default Syringe Brands Configured for Use

Manufacturer	Syringe Sizes (ml) 2nd Edition							Syringe Sizes (ml) 3rd Edition						
BD Plastipak	-	3	5	10	20	30	50	-	3	5	10	20	30	50
Braun Omnifix	2	-	5	10	20	30	50	2	-	5	10	20	30	50
Monoject	-	-	6	12	20	35	50	-	3	6	12	20	35	50
Codan/Once	2.5	-	5	10	20	30	50	-	-	-	10	20	30	50
Terumo	-	3	5	10	20	30	50	-	-	5	10	20	30	50
Nipro	-	-	-	-	-	-	-	-	-	5	10	20	30	50

It is possible to disable default syringes from memory or replace them with one not listed above. This procedure is not detailed in the DFU as it should only be undertaken by trained, certified service centres or biomedical engineers. Please consult a biomed engineer or your local T34™ syringe pump supplier should this need arise.

	Category	3rd Edition
Clinical updates	Battery life	Battery life update: 25h @ 1ml/h 20h @ 5ml/h Always check battery power prior to each infusion
	Time to alarm before end of infusion	Fixed to 3 min before end of infusion
	Epidural indication - intended use	Intended use removed
	Immunoglobulins, biosimilar - intended use	Intended use updated to include
	Minimum flow rate	Range updated to 0.1-650ml/h
	Flow rate increments	Range updated to 0.1–10 ml/h in 0.01 ml/h increments; 10–29.9 ml/h in 0.1 ml/h increments; 30–49.5 ml/h in 0.5 ml/h increments; 50–299 ml/h in 1 ml/h increments; 300–650 ml/h in 5 ml/h increments.
	Bolus function	Updated to include new function
	Minimum occlusion pressure	Updated from 100mmHg to 200mmHg
	Fluid ingress - classification	IP22
	Weight	Updated from 210g to 230g
	New connectors - battery	Update to rear assembly
	Cover labels and branding	Update to CME labels
	Rear label	Updated to comply with standard
	KVO Rate Operation	Update to range from 2.0 ml/h to 5.0 ml/h
	Rear drainage	New design feature to avoid fluid accumulation
	GTIN barcode labels	Updated to comply to GTIN standard

Category	3rd Edition
Software	Update to software
Add primary sound self-test into boot-up process	Update to software
Update BodyComm software for 3rd edition pump software	BodyComm v3.0 (and next) compatible (n.b. not compatible with 2nd edition pumps)
Service interval alert added (1-year period)	New default at 12 months - can be switched off in Tech. mode
Reduce safe stop current threshold and use this threshold during travel calibration ("Pinch Hazard")	New limits
Date input order changed	Updated to date: year, month, day
RTC battery changed	Updated from disposable battery to rechargeable 3V battery
Add microphone test and threshold	New alarm test during startup
Add backup alarm test into Tech. mode	New test function in 3rd edition
Add LEDs test into Tech. mode	New test function in 3rd edition
Add microphone level calibration into Tech. mode	New feature in 3rd edition
Keypad LED yellow colour	LED colour update from red and green to red, yellow and green
Part differences - hardware	Update included in TSM
Battery indication (vs voltage) was changed	Changes to battery measurement method in 3rd Edition
Pressing on/off or stop key disabled the alarm	Update 3rd edition pump alarms if 9v battery is removed

Technical updates

* BodyComm™ is intended to permit qualified and trained personnel only to configure BD BodyGuard™ infusion and syringe pumps