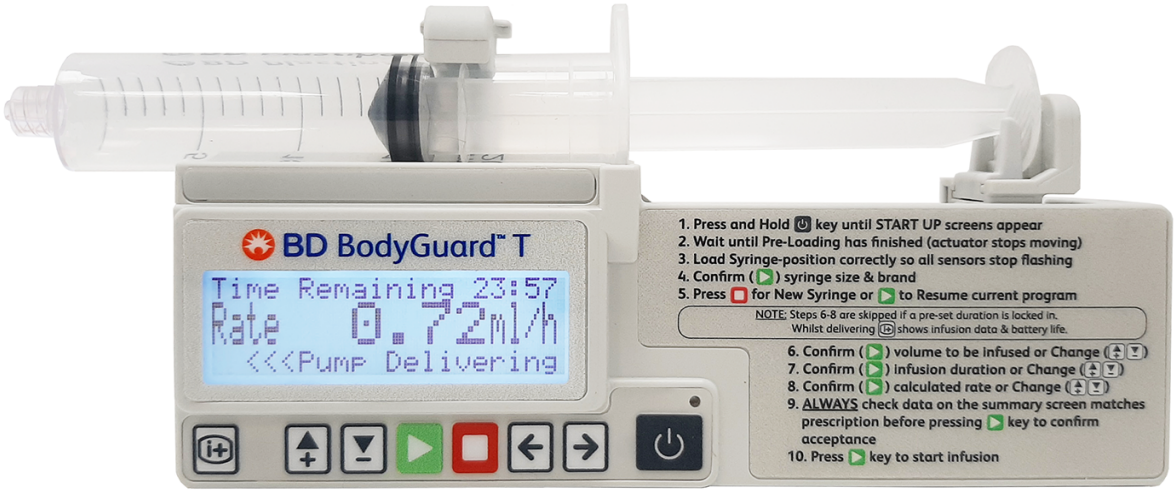
BD BodyGuard™ T

Syringe Pump*

Directions For Use



* Including T34™ Syringe Pump (REF: 999-103XX) 3rd edition with updated software version.

Ref.: DFU999-103BDEN Rev. 03

Caesarea Medical Electronics Ltd.
16 Shacham Street
Industrial Park Caesarea North
P.O.BOX 3009
Caesarea 3088900, Israel

CE 0344

EC REP **MedNet GmbH.**
Borkstrasse 10
48163 Muenster
Germany

BD.com

Table of Contents

1. General Information

1.1. About This Directions For Use

This *Directions For Use* provides information about the use of the BD BodyGuard™ T Syringe Pump (hereinafter referred to as 'pump'). The instructions are applicable both to the BD BodyGuard™ T Syringe Pump (REF: 999-103BDXX) and to the T34™ Syringe Pump (REF: 999-103XX) 3rd edition with updated software version (refer to section *1.5. Document History* on page 6).

Operators must be thoroughly familiar with the operation of infusion pumps. Safe use of the infusion pump can only be achieved if the infusion pump is operated in accordance with the *Directions For Use*.

All illustrations used in this *Directions For Use* show typical settings and values that may be used in setting up the functions of the syringe pump. These settings and values are for illustrative use only. The complete range of settings and values are listed in the specifications section of this *Directions For Use*.

This *Directions For Use* has been developed with consideration to the requirements in relevant Harmonised Standards. Data presented in the technical specifications reflect specific test conditions defined in this standard. Other external factors such as varying back pressure, temperature, head height, syringe extension set usage, fluid restrictions, solution viscosity or combinations of these factors, may result in deviations from the performance data enclosed.

NOTE: Keep this *Directions For Use* for future reference during the syringe pump's operational life.

1.2. Overview

The pump provides the following features:

- Compatible with a range of commonly used syringe brands and sizes.
- Three-point syringe detection system.
- Capable of small ml/h rate delivery.
- Configurable occlusion pressure.
- LCD display screen with backlight.
- Green LED indicator to indicate if infusion is in progress.
- Event log.

The pump's program can operate in two modes:

- Duration mode: The pump delivers the content of the syringe over a duration. The pump automatically calculates the infusion rate.
- Rate mode: The pump delivers the content of the syringe by rate. The pump automatically calculates the duration of the infusion.

The following safety features are available:

- Program lock.
- Keypad lock.
- Access codes to protect pump configuration.
- Post Occlusion Bolus Reduction System (POBRS).
- Comprehensive range of alerts and alarms.
- Lockable lockbox (optional).

1.3. Intended Use

The T34™ / BD BodyGuard™ T Syringe Pump is designed for infusion of medications or fluids requiring continuous or intermittent delivery at precisely controlled infusion rates through all clinically acceptable routes of administration including intravenous, subcutaneous, percutaneous, in close proximity to nerves, and into an intraoperative site (soft tissue/body cavity/surgical wound site). The system is intended for patients who require maintenance medications, analgesics, immunoglobulins, biosimilar, chemotherapeutic agents and general fluids therapy in hospital and homecare environments.

1.4. Contraindications

The following contraindications apply:

- Infusion of blood and blood products.
- Infusion of insulin.
- Infusion of critical medications whose stoppage or interruption could cause serious injury or death.
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy, or who are not under the care of a responsible individual.

1.5. Document History

Revision	Date	Software Version	Description
03	January 2021	T3.2A-XX	Updates to warnings (refer to section *2.4. General Precautions and Warnings* on page 8).
02	January 2021	T3.2A-XX	Date and time must be checked before first use of the pump and after storage (see sections *4.1. Pump Inspection and Unpacking* on page 14 and *8.3. Pump Storage* on page 41).
01	November 2020	T3.2A-XX	• Updates to section *4.2. Battery Power Supply* on page 14: added DURACELL® Plus to list of tested battery; added warning. • Added backup alarms to alarms list, see section *7.1. Alarms* on page 36. • Minor rewording.
00	November 2020	T3.2A-XX	Initial release, including T34™ Syringe Pump (REF: 999-103XX) 3rd edition with updated software version.

2. Safety Information

2.1. Safety and Advisory Terms

Warning: Indicates that the information is a warning. Warnings advise you of circumstances that could result in injury or death to the patient or operator.

Caution: Indicates that the information is a caution. Cautions advise you of circumstances that could result in damage to the device.

NOTE: Indicates that the information is additional important information or a tip that helps you operate the pump.

2.2. Operation Precautions and Warnings

Warning: Read the entire *Directions For Use* before using the pump, since the text includes important precautions.

Warning: Do not attempt to modify this equipment. Only BD certified technicians are approved to safely carry out maintenance, service or repair of this device. Contact your service representative for assistance.

Warning: A kinked or occluded syringe extension set may impair the operation of the pump and the accuracy of the infusion. Before operation, verify that the syringe extension set is not kinked or occluded.

Warning: Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system and supplied or recommended by the pump distributor.

Warning: Do not let the syringe pump operate when battery is fully depleted. Pump may turn off during operation on fully depleted battery.

Warning: Before beginning infusion, confirm the battery level is sufficient to complete delivery of the full infusion (see Expected Battery Life table, section *4.2. Battery Power Supply* on page 14).

Warning: 9V batteries may have a sudden drop in voltage, causing the infusion pump to stop abruptly. If the battery voltage drops below the operational threshold, the pump will shut down and the Backup Buzzer will sound for at least 3 minutes. In the event of a sudden pump shutdown, contact your Clinician, Biomed or BD Representative.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: Although the pump has been designed and manufactured to exact specifications, it is not intended to replace trained personnel in the supervision of infusions.

Warning: The specified accuracy of the syringe pump can only be maintained if the syringe pump is used in accordance with the *Directions For Use* and is maintained and serviced by a BD certified technician.

Warning: Adjustments, maintenance, or repair made by un-certified service personnel may impair the operation of the syringe pump and/or the accuracy of the infusion. Make sure any adjustments, maintenance, or repair of the syringe pump are carried out only by a BD certified technician.

Warning: Refer all service, repair and adjustments only to BD certified technicians. Unauthorised modifications or the use of any spare parts, other than those supplied by the manufacturer or their distributor, will void any warranty.

Warning: If the syringe pump is subjected to excessive moisture, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by a BD certified technician.

Warning: The pump has been designed to be as safe as possible to handle; however, care should be exercised to avoid trapping of fingers or other body parts in the mechanism.

Warning: The pump should be operated within the recommended environmental operating range. Operating the pump at temperatures and/or humidity outside that range may affect accuracy.

Caution: This pump is designed to withstand everyday handling. If the pump is dropped onto a hard surface, or is suspected of being dropped, the operation and calibration should be checked by a BD certified technician.

Caution: If the pump will be stored for longer than 60 days, remove the battery to prevent corrosion and decay.

2.3. Infusion Precautions and Warnings

Warning: Carefully read and follow accompanying syringe extension set instructions for priming the set and the recommended set change interval.

Warning: The syringe and syringe extension set should be disposed of in an appropriate manner, considering the nature of the residual fluid that may be contained within and in accordance with the hospital/homecare provider's disposal practices.

Warning: Drugs for infusion to be used with the pump may only be prescribed by a qualified medical practitioner. Caution must be exercised in the selection of drugs and the amount and rate intended to be delivered via the pump.

Warning: Disposables (as with any infusion) used with the syringe pump must be compatible with the drug/fluid being delivered and the expected environmental conditions where the infusion might take place (i.e., Sunlight, Heat, Cold, Humid, High Altitude, etc.). Check with the manufacturer of the disposables before use. Consult the fluid or drug manufacturer's information for precautions, guidelines, and instructions for preparation and use of disposables.

Warning: As with all automatic syringe pumps, whenever a toxic or dangerous level of drug is stored in the reservoir, constant/frequent monitoring of the infusion is required.

Warning: In all applications, time to alarm under occlusion or other fault conditions will depend on the infusion rate and levels of alarm settings. It is recommended to consider these parameters when using drugs requiring infusion stability or low flow rates and therefore a quick time to alarm.

Caution: Do not use slip-tip syringes. Luer-lock syringes must always be used to ensure secure connection of the syringe extension set and the syringe pump.

2.4. General Precautions and Warnings

Warning: The maximum volume that may be infused under single fault condition is 0.1 mL.

Warning: Potential strangulation may occur if the cables/tubing are of excessive length.

Warning: Potential choking may occur if small parts are inhaled or swallowed.

Warning: Potential allergic reactions may occur due to materials used in the pump.

Warning: The pump is not certified for use in oxygen-enriched environments.

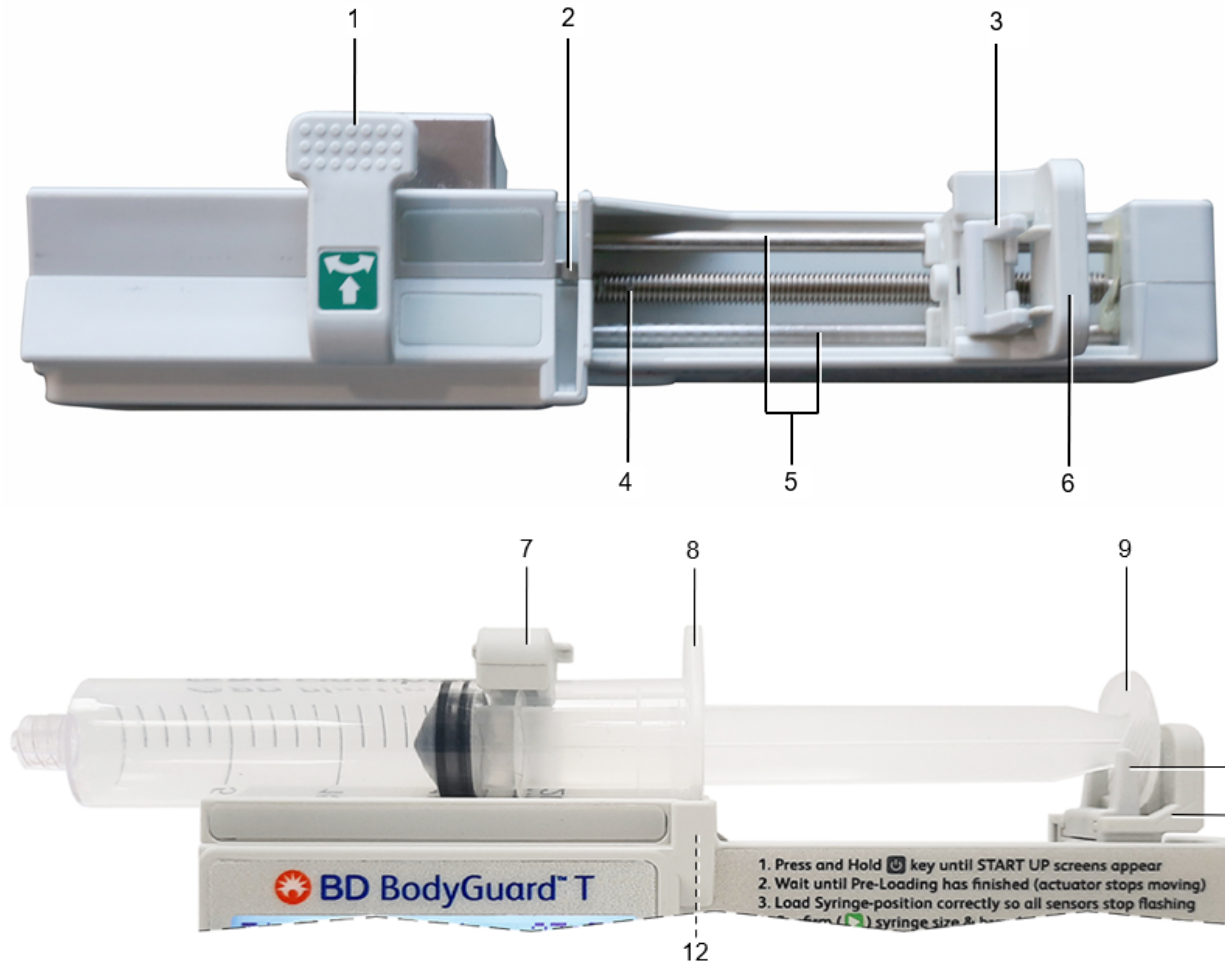
Warning: Do not operate the syringe pump near high-energy radio-frequency emitting equipment, (e.g. imaging equipment (i.e., X-Ray, MRI, CT Scan, etc.), high frequency (RF) surgical equipment, defibrillator, etc.) as this may cause degradation in performance of the syringe pump, which may affect proper infusate delivery.

Caution: Do not use hard or sharp objects on the keypad.

Caution: Do not bathe or shower whilst using the pump. The pump is resistant to a limited amount of splashing, but its construction does not make it resistant to large amounts of spraying or immersion in liquids. Damage to the internal components may result.

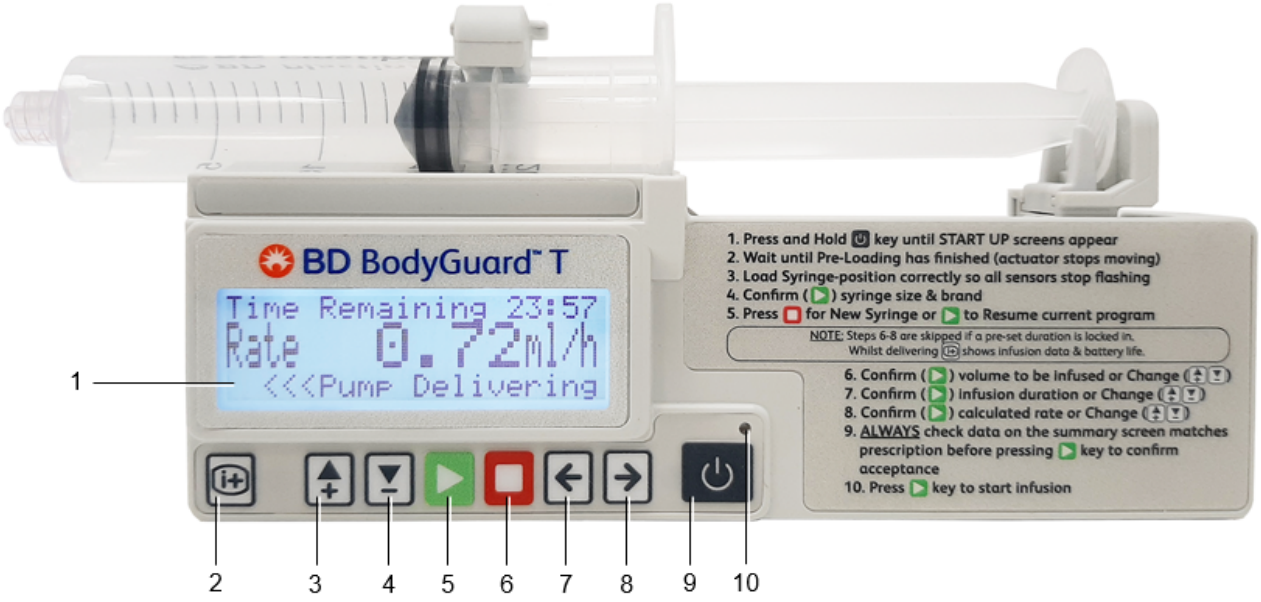
3. Pump Description

3.1. Syringe Fitting



	Item	Description
1	Barrel clamp arm sensor	Detects syringe barrel loading and secures the syringe in place.
2	Collar sensor	Detects correct loading of the syringe collar.
3	Plunger sensor	Detects correct loading of the syringe plunger.
4	Lead screw	Moves the actuator.
5	Guide rails	The two guide rails support the actuator position.
6	Actuator	Drives the syringe plunger to deliver syringe contents.
7	Barrel clamp arm sensor	Detects syringe barrel loading and secures the syringe in place.
8	Syringe collar	—
9	Syringe plunger	—
10	Plunger sensor	Detects correct loading of the syringe plunger.
11	Actuator	Drives the syringe plunger to deliver syringe contents.
12	Collar sensor	Detects correct loading of the syringe collar.

3.2. Pump Keypad



	Icon		Name	Description
	T	T34™		
1	N/A	N/A	LCD display screen	Displays pump and infusion status, programming choices and instructions.
2			Info Menu key	• Pressing once during infusion displays an infusion summary. • Pressing a second time during infusion displays the current battery level. • When the pump is in standby mode, accesses the main (Info) menu. • Activates/deactivates keypad lock.
3			Up key	• Scrolls between options. • Increases infusion parameters during programming/titration.
4			Down key	• Scrolls between options. • Decreases infusion parameters during programming/titration.
5			Start / OK key	• Confirms selection. • Starts infusion.
6			Stop / No key	• Takes the user one step back during programming. • Stops infusion.
7			Move Actuator Forward key	• Moves the actuator forward when no syringe is in place and the barrel clamp arm is down. • Accesses purge function (if enabled). • Accesses bolus function (if enabled).
8			Move Actuator Back key	Moves the actuator backward when no syringe is in place and barrel clamp arm is down.
9			ON / OFF key	Powers the pump on and off.
10	N/A	N/A	LED indicator	• The LED indicator light is a steady green during system self-tests. • The LED indicator flashes green to indicate infusion delivery. • The LED indicator is a steady yellow when the pump is in standby mode or to indicate a low-priority alarm. • The LED indicator flashes red to indicate a high-priority alarm.

NOTE: Icons of BD BodyGuard™ T Syringe Pump are used as reference throughout the instructions.

3.3. Rear of the Pump

	Item	Description
1	Pump information and symbols	Labelling (including universal symbols) identifies the pump's manufacturer and communicates information on safety, use and performance.
2	Battery compartment	Includes instructions for inserting the battery correctly.
3	Unique Device Identifier (UDI)	The UDI identifies the pump.

3.4. Symbols

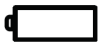
Symbols on Both Pump and Syringe Extension Set Packaging

Symbol	Description
CE 0344	The CE mark indicates conformance to the Medical Device Directive 93/42/EEC. The numeric code identifies the Notified Body.
	Manufacturer
EC REP	Authorized representative in the European Community.
REF	Manufacturer's catalogue number.

Symbols on Pump or on Pump Packaging Only

The pump is designed for infusion of medications or fluids. The pump is a reusable, serviceable medical device, intended to receive annual maintenance to preserve system accuracy.

Symbol	Description
	Read *Directions For Use* for important cautionary information that cannot be presented on the pump.
	Read the entire *Directions For Use* before using the pump.

Symbol	Description
	Date of manufacture
	Do not dispose of in municipal waste. Symbol indicates separate collection for electrical and electronic equipment. (WEEE Directive 2012/19/EU). NOTE: Does not apply to the battery.
	Type CF applied part (IEC 60601-1). Applied part is suitable for direct cardiac application.
	Serial Number
	Battery
	Direct current
	Degree of particle and water ingress protection. Protection from solid objects ≥ 12.5 mm and from dripping water when tilted at 15°.
	(On packaging) Indicates the temperature limits to which the medical device can be safely exposed.
	(On packaging) Indicates the acceptable upper and lower limits of atmospheric pressure (altitude).
	(On packaging) Indicates the acceptable upper and lower limits of relative humidity.

Symbols on Syringe Extension Set Packaging Only

Symbol	Description
	Read the instructions for use for important cautionary information that cannot be presented on the disposable.
	Read the instructions for use before using the disposable.
	Do not reuse single-use disposable components.
	Do not use the product if the package has been damaged or opened.
	The fluid path is non-pyrogenic.
	Indicates syringe extension sets for single use with pressure infusion apparatus.
	Sterilized with ethylene oxide.
	Lot number
	Expiry date of disposable

3.5. Post Occlusion Bolus Reduction System (POBRS)

During an occlusion, the pressure in the downstream section of the line and/or inside the syringe can increase above the occlusion pressure defined in pump settings. When the pump alarms the user must check the line and attempt to clear the occlusion. During an occlusion the pump's Post Occlusion Bolus Reduction System (POBRS) feature will reverse the operation of the motor and drive the actuator backwards otherwise the pressure build-up could cause a surge of fluid into the patient on release of the occlusion.

When the infusion is resumed, the user will notice that the volume to be infused (VTBI) increases and the volume infused (VI) decreases to indicate the pump back off feature and the infusion time remaining increases; this protects the ml/h infusion rate.

Following activation of the POBRS and if the user presses to resume the infusion VTBI increases and the VI decreases to indicate the pump back off feature.

Intermediate Rate	Occlusion Pressure	Unintended Bolus Volume
5 ml/h	200 mmHg (minimum) 1500 mmHg (maximum)	≤ 0.5 ml ≤ 0.5 ml

An occlusion may pressurize the infusion tubing and syringe, which can result in an unintended bolus of drug when the occlusion is cleared. In order to prevent this additional bolus, disconnect the tubing or relieve the excess pressure through a stopcock, if present. The clinician should weigh the relative risks of disconnection with the risks of an unintended bolus of drug.

Occlusion Pressure

The occlusion pressure of a pump is the pressure in the system, registered at the pump, when the pump is still operating but cannot sustain the flow rate. The resultant build-up of pressure sets off the occlusion alarm.

Occlusion and Response

An occlusion alarm can be activated by:

- A blockage in the delivery tubing – often inadvertently caused by kinking or leaving a clamp or a tap closed.
- A clotted-off cannula.
- A partially occluded cannula – if it causes the required driving pressure to rise above the occlusion alarm level.
- A very long or narrow bore cannula or/with extension line.

Occlusion response is characterised in terms of three measurable parameters:

1. Pressure to alarm.
2. Time to alarm.
3. Bolus release when occlusion is resolved.

1. Pressure to alarm

If an occlusion occurs the pump attempts to maintain sufficient pressure on the fluid to cause it to flow through all restrictions and overcome any additional resistance. Although fluid is incompressible, the syringe extension set and other components of the system have some give (compliance) and the tubing can expand under the increasing pressure. Other components of the system, such as the bung of the syringe, become compressed. This expansion and compression takes some time to occur.

2. Time to alarm

If the occlusion is present from the beginning of the infusion, the time to alarm will increase. The pressure in the pumping chamber increases from zero at the start of the infusion up to the alarm level. This is the most likely situation, as leaving clamps closed is the most usual cause of occlusions.

If the occlusion occurs after the pump has stabilised at its set flow rate, the alarm time will not be unusually long as the pressure in the pumping chamber increases from the already high running pressure up to the alarm level.

Generally, shorter time to occlusion alarm occur with high flow rates, small syringes and good quality syringes.

3. Unintended bolus release

In the case of a complete occlusion, there is no flow to the patient whilst pressure in the system is increasing. When the occlusion is released, the build-up of fluid in the tubing can result in a bolus being delivered to the patient.

4. Installation and Setup

4.1. Pump Inspection and Unpacking

To unpack the pump, do as follows:

1. Carefully remove the pump from the box.
2. Ensure that no items were damaged during shipment or storage.
3. Ensure that you have the following items:
   - BD BodyGuard™ T Syringe Pump
   - *Directions For Use* (this manual)
   - *Quick Reference Guide*
4. Verify that the date and time are accurate before starting the infusion by checking the last entry in the event log (refer to section *7.5. Event Log* on page 39). If the date and time are not correct, adjust the date and time (refer to section *6.3. Changing Pump Settings* on page 33).

If any items are missing or damaged, contact your supplies department.

Warning: Visually inspect packaging and contents before each use.

Warning: Do not use the pump and accessories if there are any obvious signs of damage. Return for inspection by authorised service personnel.

4.2. Battery Power Supply

Refer to section *5.7.3. Checking the Battery Level* on page 28 for checking battery levels.

Battery Types and Use

Always use a 9V alkaline disposable battery with the following attributes (refer to battery manufacturer's information):

- Designation: IEC: 6LR61

Warning: Do not use batteries marked 6LP3146 or 6LF22 with the pump. 6LP3146 and 6LF22 batteries can cause issues with the operation of the syringe pump, as the physical construction and internal resistance of this type of battery are different to the 6LR61 battery. Issues arising from use of 6LP3146 and 6LF22 batteries can include end of battery messages during pre-loading, volume test fails, pressure test/calibration issues and reduced amount of infusions from a battery.

Warning: 9V batteries may have a sudden drop in voltage, causing the infusion pump to stop abruptly. If the battery voltage drops below the operational threshold, the pump will shut down and the Backup Buzzer will sound for at least 3 minutes. In the event of a sudden pump shutdown, contact your Clinician, Biomed or BD Representative.

Expected Battery Life

Delivery Rate (ml/h)	Operating Time (h)
1	> 50
5	> 35

Battery life has been tested under the following conditions:

- BD Plastipak™ 20 ml and 50 ml syringes, syringe extension set M100-172SB, distilled water.
- Battery: VARTA Power One, manufacturer's P/N 4122210531.
- Battery: DURACELL® Ultra, manufacturer's P/N MX1604.
- Battery: DURACELL® Plus, manufacturer's P/N MN1604.

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

- Programmed flow rate
- Syringe size and brand
- Syringe diameter
- Syringe friction
- Battery type and brand
- Battery operating temperature
- Back pressure

- Frequency of use, backlight, and alarms
- Operating temperatures
- Battery type, brand and capacity
- Battery storage conditions
- Battery age

NOTE: These values were developed based on laboratory testing using distilled water and new batteries with a minimum of 4 years left for storage life remaining per the labelling. The pumps had minimal interactions and no alarm conditions beyond near end of infusion and end of infusion alarms that were attentively addressed.

The pump battery meter displays battery life remaining as a percentage (%):

- When the battery power is low a low battery alert will activate.
- When the battery power is almost depleted, an end of battery alarm will activate.

Changing the Battery

Guidance for battery changing may vary for different areas according to local policy, where the pump is to be used and who is managing the pump (healthcare professional or patient as end user). When the pump is being managed in an environment where designated personnel are available at all times to change a battery (if necessary), the low battery alarm provides warning at least 30 minutes before the battery ends. Low battery alarm can be used as an indication to change a battery.

When you change the battery, follow these recommendations:

- Use only new batteries.
- Use only valid (non-expired) 9V batteries in the device.
- Do not use batteries with signs of rust, bad odour, overheating, or other irregularities.
- Avoid any contact of the battery with liquids.

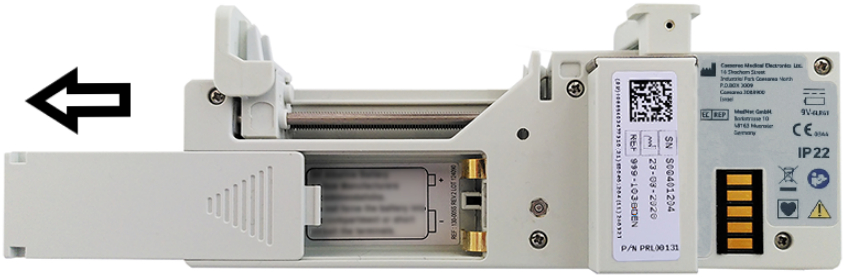
Warning: DO NOT use scissors or metal objects to remove a battery.

Warning: If a battery is too tight, do not try to force it into the battery compartment as this may damage the battery contacts.

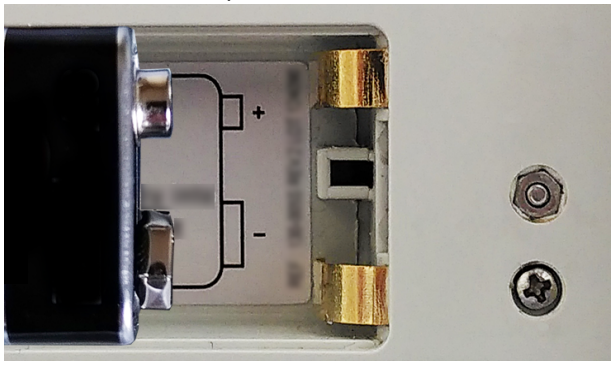
Warning If the pump is being managed in an environment where designated personnel are unavailable to change a battery with 30-minutes (low battery alarm) notification, the following rule applies: During set-up, confirm that the battery level is sufficient to complete delivery of the full infusion.

To insert the battery into the syringe pump:

1. Slide the compartment cover off at the back of the syringe pump.
   This reveals the empty battery compartment, with insertion instructions.



2. Push the battery into the compartment taking care to ensure that the battery + / – contacts are aligned on the label inside the compartment.



NOTE: The battery should fit securely to ensure good electrical contact.

3. Slide the cover back on.

To remove the battery from the syringe pump:

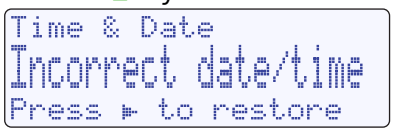
1. Slide the compartment cover off at the back of the syringe pump.
2. Remove the battery.
3. Slide the cover back on.

Backup Battery Depletion

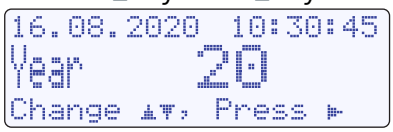
If the internal backup battery has been depleted, the pump displays an alarm and requires to enter the current date and time.

To enter date and time, do as follows:

1. Press the ▶ key.



2. Press the ▲ key or the ▼ key to change year, then press the ▶ key.

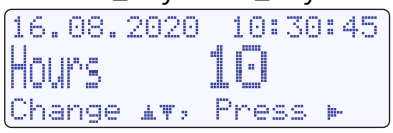


NOTE: Press the ■ key to go back to the previous step.

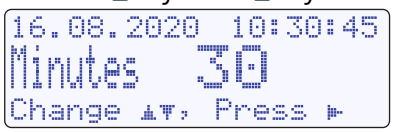
3. Press the ▲ key or the ▼ key to change month, then press the ▶ key.

4. Press the ▲ key or the ▼ key to change date, then press the ▶ key.

5. Press the ▲ key or the ▼ key to change hour, then press the ▶ key.



6. Press the ▲ key or the ▼ key to change minutes, then press the ▶ key.



4.3. Accessories (Optional)

The following accessories are available:

- Lockbox (supplied with two keys)
- Carry pouch (reusable or disposable)

Refer to your local sales representative or BD website for information on types, codes and costs.

Warning: Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system and supplied or recommended by the pump distributor.

NOTE: If any items are missing or damaged, contact your supplies department.

Lockbox

Lockboxes are designed to help protect the syringe from displacement and/or tampering. Lockboxes are made from polycarbonate due to its high impact, temperature resistance and optical properties.

Lockboxes are available in clear plastic.

- The lockbox can be used with any drug delivery route.
- The lockbox fits most commonly used syringe brands and sizes up to 30 ml.

NOTE: The design of the syringe extension set may prevent the lockbox from fully closing and locking.

To use the lockbox, do as follows:

1. Load the syringe on the pump and connect tubing.
2. Open the lockbox. Use the standard key that operates all lockbox types.
3. Place the pump into the lockbox so that the display screen and the keypad line up with the cut-out opening.
4. Guide the syringe extension set out of the slot at the side of the top section and close the lockbox.

Carry Pouch

The carry pouch protects the pump functionality and the medication in the syringe whilst the pump is infusing during transportation or patient ambulation. The pouch will also protect the pump from damage or syringe displacement.

Disposable and reusable (washable) carry pouches are available.

When using the reusable (washable) carry pouch, it is possible to access the display screen and the keypad of the pump during infusion by lifting the flap of the carry pouch whilst the pump remains in the carry pouch.

When using either a reusable (washable) or disposable (single patient use) carry pouch it is possible to remove the forward part of the pump during infusion from the carry pouch to inspect the syringe without removing the rear section of the pump. Carry pouches can be carried on the shoulder or around the waist for convenience.

5. Operation

5.1. Disposables

Warning: Component damage may occur if the syringe extension set is not correctly attached to the syringe. Assure all connections are secure: Do not over-tighten. This will help minimise leaks, disconnection and component damage.

Warning: Disposables (as with any infusion) used with the syringe pump must be compatible with the drug/fluid being delivered and the expected environmental conditions where the infusion might take place (i.e., Sunlight, Heat, Cold, Humid, High Altitude, etc.). Check with the manufacturer of the disposables before use. Consult the fluid or drug manufacturer's information for precautions, guidelines, and instructions for preparation and use of disposables.

Warning: Replace the syringe and/or syringe extension set in accordance with local guidelines.

Warning: Use aseptic technique when filling the syringe and priming the syringe extension set. Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components and do not re-use single-use syringe extension sets.

Warning: Syringes and syringe extension sets should be disposed of in an appropriate manner, considering the nature of the residual fluid that may be contained within, in accordance with the hospital/homecare provider's disposal practices.

5.1.1. Syringes

The pump is programmed to recognize the most commonly used syringes from 2 ml to 50 ml. Luer lock syringes should always be used to ensure secure connection of the syringe extension set and syringe.

To avoid accidental selection of an incorrect brand of syringe during setup, it is recommended to disable all syringe types not in regular use. Unused syringe types can be disabled by a BD certified technician.

Warning: Do not use slip tip syringes. Luer lock syringes must always be used to ensure secure connection of the syringe extension set and the pump.

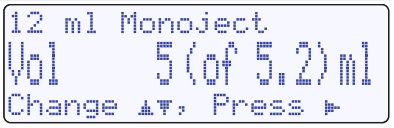
Should you need to operate the pump with a syringe manufacturer and/or brand other than those listed here, please consult either your local medical engineering department or BD Service Center.

Default Syringe Brands Configured for Use with the Pump

Manufacturer	Syringe Sizes (ml)					
B. Braun Omnifix®	2	5	10	20	30	50
BD Plastipak™	3	5	10	20	30	50
Monoject™	3	6	12	20	35	—
Codan/Once	—	—	10	20	30	50
Terumo	—	5	10	20	30	50
Nipro	—	5	10	20	30	50

Syringe Volumes

Due to the physical length of the lead screw that drives the syringe plunger forward, there are limits to the maximum amount of infusate that can be delivered from larger syringes and, on some smaller syringes, there is an undeliverable volume of infusate that will remain in the syringe, once the actuator has driven to the zero position.



Warning: B. Braun Omnifix® 2 ml, BD Plastipak™ 10 ml, Codan 10 ml, Monoject™ 3 ml, Monoject™ 12 ml, Monoject™ 35 ml, Nipro 10 ml and Nipro 20 ml syringes cannot empty completely, potentially a small volume of infusate will remain in the syringe due to limitations of the pump and the syringes design. The pump will display the volume as, for example, Vol 5 (of 5.2) ml. In this example the pump can only deliver 5 ml of the 5.2 ml in the syringe and when the pump has driven the syringe plunger as far forward as possible, 0.2 ml will remain in the syringe. The potential volumes that might remain in the syringes are listed in the table below:

Syringe size and brand	Undeliverable infusate volume
B. Braun Omnifix® 2 ml	0.000 ml to 0.114 ml
BD Plastipak™ 10 ml	0.000 ml to 0.177 ml
Codan/Once 10 ml	0.000 ml to 0.043 ml
Monoject™ 3 ml	0.000 ml to 0.007 ml
Monoject™ 12 ml	0.000 ml to 0.388 ml
Monoject™ 35 ml	0.000 ml to 0.348 ml
Nipro 10 ml	0.000 ml to 0.094 ml
Nipro 20 ml	0.000 ml to 0.006 ml

Warning: Some manufacturers have several brand names within their ranges (for example, B. Braun Omnifix® and B. Braun Original Perfusor®). Only use the brands named above with the pump, as failing to do so could result in an under- or over-infusion.

Maximum Fill Volume for Syringes 20 ml to 50 ml

Syringe brand	Syringe size			
	20 ml	30 ml	35 ml	50 ml
B. Braun Omnifix®	20 ml	24 ml	—	37.4 ml
BD Plastipak™	17.9 ml	23.1 ml	—	35.2 ml
Codan	20 ml	22.7 ml	—	36 ml
Monoject™	20 ml	—	28.6 ml	—
Nipro	20 ml	21 ml	—	35.7 ml
Terumo	19.3 ml	24.4 ml	—	38.3 ml

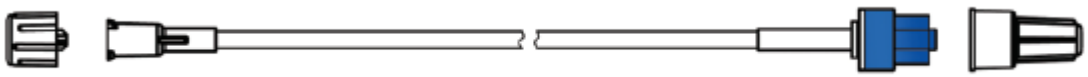
Time to Alarm from Occlusion

Flow Rate	Pressure Threshold	Time to Alarm (hh:mm:ss)
5 ml/h	200 mmHg	TTA < 00:06:00
1 ml/h	200 mmHg	TTA < 00:35:00
0.1 ml/h	200 mmHg	TTA < 06:00:00
5 ml/h	1500 mmHg	TTA < 00:25:00
1 ml/h	1500 mmHg	TTA < 03:45:00
0.1 ml/h	1500 mmHg	TTA < 24:00:00

NOTE: Time to alarm tested at flow rates and occlusion thresholds as described in the table above, using a BD Plastipak™ 20 ml syringe.

5.1.2. Syringe Extension Sets

The pump can be operated with any extension set with a Luer lock connection. However, it is recommended, to optimise system accuracy and performance, that proprietary syringe extension sets from BD are used. In the range of BD syringe extension sets there are configurations with siphon/free-flow protection.



Features and Characteristics

Feature	Description
Materials	The syringe extension sets are manufactured using PVC materials that do not contain latex or di-2-ethylhexyl phthalate (DEHP).
Tubing	Micro-bore: require small priming volumes. Anti-kink: to prevent kinking or occlusion particularly in configuration. Various lengths are available.
Slide clamp	Clamps: to prevent fluid flow to patient (optional on some sets).
Pressure-activated anti-siphon/anti-reflux valve 	Some BD syringe extension sets contain a combination check valve to prevent uncontrolled flow of fluid either into or from the patient. The syringe extension set with pressure-activated anti-siphon/anti-reflux valve reduces the potential for gravity flow and backflow (backtracking). The pressure-activated anti-siphon valve requires pressure to open. The pump occlusion pressure setting may require adjustment to prevent occlusion alarms. The combination check valve enhances pump functioning by: • Preventing siphoning (free-flow) in the event the set is detached from the pump or mechanical malfunction, and • Preventing reflux (back-flow) in the event several infusion pumps are connected simultaneously to the same patient.
Luer Lock end connector 	The syringe extension set is designed to be connected to Luer lock syringes. Luer lock syringes allow a connection between male and female Luer. This provides a secure connection and prevents accidental removal.

Warning: Ensure the syringe extension set is NOT connected to the patient during priming.

Warning: A kinked/occluded syringe extension set may impair the operation and accuracy of the pump. Before operation, verify that the syringe extension set is not kinked or occluded.

NOTE: The recommended syringe extension set change interval is 72 hours.

5.2. Setting Up the Mode of Operation

You can configure the pump for a continuous infusion by duration or rate, and lock the pump program:

- **Duration mode**: The pump uses syringe volume and duration to calculate the infusion rate. If the pump program is locked, the default duration cannot be changed.
- **Rate mode**: The pump uses syringe volume and rate to calculate the infusion duration. If the pump program is locked, the default rate cannot be changed.

By default, the pump is set to duration mode (24 hours) and the pump program is locked.

To change the mode of operation, do as follows (refer to section *6.3. Changing Pump Settings* on page 33):

- To use the pump in duration mode, set the **Default Duration** setting to a value greater than 00:00.
- To use the pump in rate mode, set the **Default Duration** setting to 00:00. To change the default rate, refer to section *6.4. Changing Rate Setting* on page 34.

To lock/unlock the pump program, do as follows (refer to section *6.3. Changing Pump Settings* on page 33):

- Set the **Program Lock** setting to **ON** (the pump program is locked) or **OFF** (the pump program is unlocked).

WARNING: For the correct pump configuration, mode of operation and start-up sequence, you must refer to your local policies.

5.3. Configurable Settings for Modes of Operation

Duration Mode

	Program Lock ON (Fixed duration)	Program Lock OFF (Adjustable duration)
Titration Option	Disabled	Enable if rate change during infusion is required.
Default Duration	For example 24:00 hours	For example 24:00 hours
Program Lock	ON	OFF
Rate Setting	0 ml	0 ml
Occlusion Pressure	Set the pressure for the drug delivery route e.g. subcutaneous, IV.	
Maximum Rate	Change if required. Pump default 5 ml/h.	
Purge	Set purge volume if required. Pump default 0 ml.	

Rate Mode

	Program Lock ON (Fixed ml/h rate)	Program Lock OFF (Adjustable ml/h rate)
Titration Option	Disabled	Enable if rate change during infusion is required.
Default Duration	0:00 hours	0:00 hours
Program Lock	ON	OFF
Rate Setting	e.g. 2 ml/h	e.g. 2 ml/h
Occlusion Pressure	Set the pressure for the drug delivery route e.g. subcutaneous, IV.	
Maximum Rate	Change if required. Pump default 5 ml/h.	
Purge	Set purge volume if required. Pump default 0 ml.	

NOTE: A Pump Configuration Authorisation form is available from BD to record authorisation and document pump settings. Contact your local Sales or Clinical representative.

NOTE: Pump maximum ml/h rate and purge volume are configured via the pump Technician menu. If these settings need to be changed, you must consult the technical staff.

NOTE: The pump uses an indirect method of pressure detection. The standard pump occlusion pressure setting for subcutaneous route is 720 mmHg and for Intravenous (IV) route is 540 mmHg.

5.4. Operation Workflow

The following operation workflow lists the general steps for starting the infusion procedure. The 'Prime and Load' method of syringe extension set priming is described. Refer to relevant sections for detailed instructions.

To start an infusion, proceed as follows:

1. Prime the syringe extension set (refer to section *5.4.1. Preparing the Syringe and Manually Priming the Syringe Extension Set* on page 22).
2. Check the pump (refer to section *5.4.2. Checking the Syringe Pump* on page 22).
3. Turn on the pump and preload (refer to section *5.4.3. Turning on the Pump and Performing Pre-Loading* on page 22).
4. Check the battery (refer to section *5.4.4. Checking the Battery Level* on page 23).
5. Load the syringe into the pump (refer to section *5.4.5. Loading the Syringe* on page 23).
6. Program the infusion (refer to section *5.4.6. Programming the Infusion* on page 25).

NOTE: An alternative sequence which may be used is the 'load and prime' method, which involves priming the syringe extension set after loading the pump. Which method to use should be decided based on which syringe extension sets are available, local circumstances and hospital policy. Consideration must be given to clinical risk, ease of use for the pump user and consistency in start-up procedure for all wards/departments and clinical areas.

NOTE: Please be aware that if you use the 'load and prime' method instead of the 'prime and load' method, the rate of delivery will be automatically adjusted to compensate for the lost priming volume whilst maintaining the preset duration. If you wish to maintain the rate, please work in rate mode.

5.4.1. Preparing the Syringe and Manually Priming the Syringe Extension Set

The syringe extension set can be primed manually, as described in this section. To prime the syringe extension set with the pump, please refer to section *5.5. Purging the System* on page 27.

To manually prime the syringe extension set, proceed as follows:

1. Prepare the syringe with the drug as per prescription and local policy and attach the drug label to the syringe, ensuring that the label lies flat.

Warning: Do not over-label the syringe or apply anything that changes the external diameter of the syringe at the point where the barrel clamp is applied, as incorrect syringe detection may result.

2. Select the correct syringe extension set, and remove the syringe extension set from the packaging.
3. Attach the syringe extension set to the prepared Luer lock of the syringe, maintaining sterility.
4. Remove the cap from the end of the syringe extension set.
5. Gently push the syringe plunger forward until the air is expressed from the syringe extension set.
6. Cap the end of the syringe extension set.

5.4.2. Checking the Syringe Pump

Ensure that the syringe pump is clean, visually intact, appropriate for intended use, and within service date. It is good practice to inspect medical equipment and accessories between patients and certainly immediately before use (for example, whilst setting it up on the patient).

Inspection of the syringe pump and/or accessories should include checking the following:

- The pump is undamaged.
- The lockbox is locked and intact (if in use).

5.4.3. Turning on the Pump and Performing Pre-Loading

When you turn on the pump with no syringe in place and the barrel clamp arm down, the pump performs a pre-loading sequence and automatically moves the actuator.

Pre-loading is a simultaneous sequence of information that appears on the display screen and automatic actuator movements. During pre-loading:

- The syringe pump performs an internal self-test.
- The display screen displays important information.
- The actuator moves forwards/backwards automatically.

Pre-loading deletes any program in the pump memory and, at the end of the pre-loading sequence, the actuator returns to the start position of the last infusion. If the user regularly uses the same syringe brand, size and fills to the same volume, turning off and on the pump allows automatic actuator movement which returns the actuator to the correct position each time.

Warning: Do not insert foreign objects around or near the actuator during the movement of the actuator or when manually adjusting the actuator. To release a foreign object from the actuator, refer to section *7.4. Releasing a Trapped Foreign Object From the Actuator* on page 38.

Caution: Do not use force to try to move the actuator manually as this could cause damage to the syringe pump and/or affect calibration.

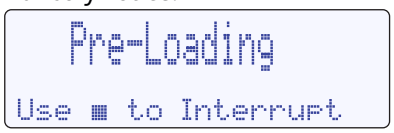
NOTE: If the syringe pump is turned on with no syringe in place but with the barrel clamp arm raised, pre-loading does not take place.

To turn on the pump and perform pre-loading, do as follows:

1. With no syringe in place and the barrel clamp arm down, press and hold the ⏻ key.
2. The display screen displays the following screens:
   a. Pump identification.

   The default identification name (ID) can be changed by a BD certified technician, for example to an asset number or site name. Up to 17 characters are permitted.

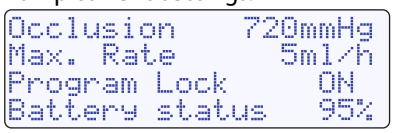
b. Advisory notice.



If you press the ■ key, the actuator stops moving and the final **Load Syringe** screen appears.

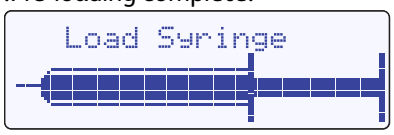
NOTE: It is advisable not to interrupt the automatic actuator movement to ensure that a previous program is deleted.

c. Pump current settings.



- **Occlusion**: Occlusion pressure setting.
- **Max. Rate**: Maximum rate limit.
- **Program Lock**: Program lock status (**ON**: the pump is locked; **OFF**: the pump is unlocked).
- **Battery status**: Battery status. During actuator movement this value may fluctuate. Do not rely on this figure as the true battery percentage.

d. .Pre-loading complete.

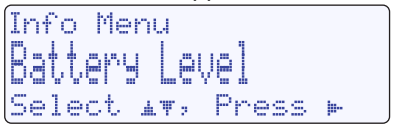


The screen flashes until a syringe is detected in all three syringe sensors.

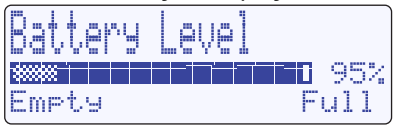
5.4.4. Checking the Battery Level

To check the battery level, do as follows:

1. Press the ⊕ key.
   The **Info Menu** appears and **Battery Level** is selected.



2. Press the ▶ key to display the battery level.

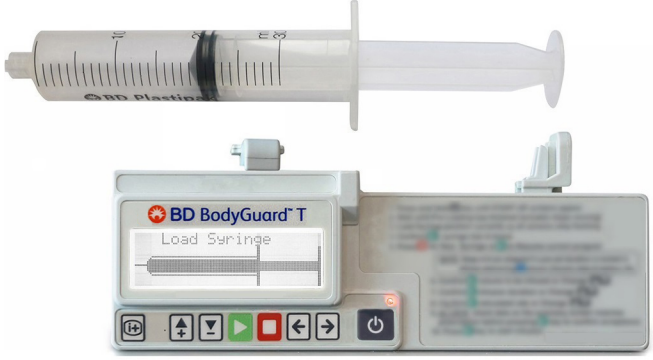


3. Press the ▶ key twice to exit the info menu or wait a few seconds.

5.4.5. Loading the Syringe

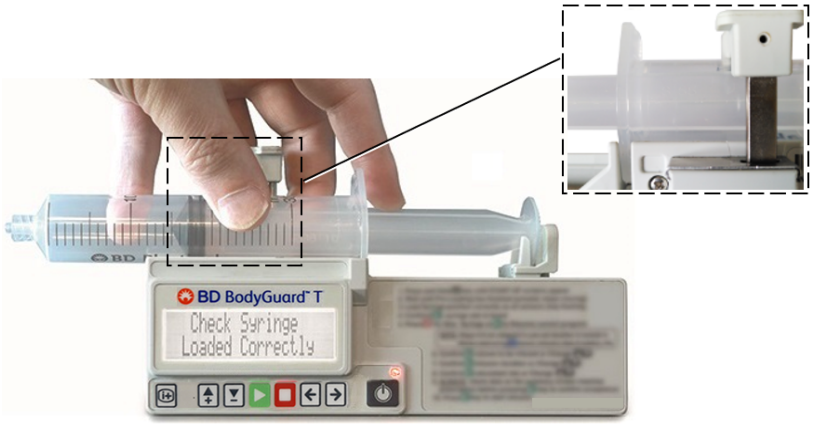
To load the syring into the pump, do as follows:

1. Ensure that the barrel clamp arm is down.
2. Place the prepared syringe above the pump to visually align the syringe collar to the collar sensor. Use the ← key and the → key (if required) to move the actuator to the correct position for placing the syringe collar and the syringe plunger into the matching sensor areas of the pump.

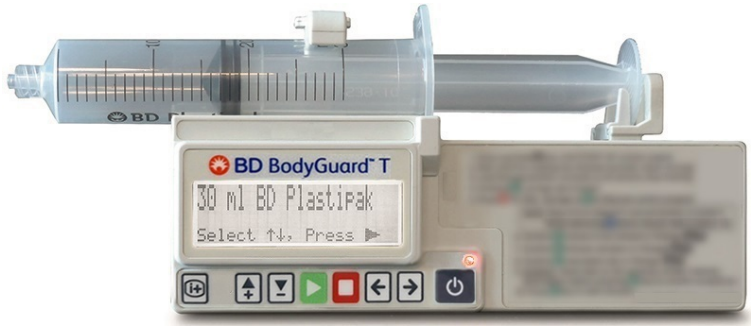


3. Lift the barrel clamp arm fully and turn the arm 90° (either way).

4. Load the syringe: Place the syringe collar vertically (long side) into the pump collar slot and the syringe plunger into the pump plunger slot. The syringe should click into position.
5. Turn and lower the barrel clamp arm onto the syringe.



The pump identifies the syringe brand, size and volume by measuring the syringe dimensions from the three sensors. As each point of the syringe is correctly seated, the display screen displays syringe size and brand.



.

If the syringe is not detected, the display screen displays **Check Plunger Sensor** or **Check Collar Sensor**.

6. Check that brand and size of the syringe inserted into the pump matches brand and size displayed. If they match, confirm by pressing the ▶ key.

Incorrect Syringe Size/Brand Detected

The pump may sometimes misidentify a syringe as a different type or brand from the one being inserted. Common causes are the following ones:

- The syringe is not correctly fitted into the three sensor areas and the pump has wrongly detected another syringe with very similar dimensions (within ±1 mm of another syringe brand in the syringe library).
- Over-labelling of the syringe or applying anything that changes its external diameter at the point where the barrel clamp is applied.

To rectify, do as follows:

1. Scroll between syringe brands of similar dimensions using the ▲ key and the ▼ key.
2. When the correct syringe displays, press the ▶ key to confirm and continue programming.

Failure to Detect a Syringe

Failure to detect any brand/size of syringe can be caused by the following reasons:

- The syringe is positioned incorrectly or not fully engaged with any or all of the sensors.
- The syringe brand or size being fitted is not configured into the pump.

To rectify, do as follows:

- Reposition or refit the syringe and ensure that the syringe is firmly placed into the three sensor areas. The display screen will indicate which sensor or sensors are affected. For the collar sensor, ensure that the collar of the syringe is facing downwards into the slot because the sensor is positioned at the bottom of the slot.
- Either use a compatible syringe brand or arrange for the new size or brand of syringe to be configured into the pump (this change can only be performed by authorised personnel).

Warning: Never take a syringe that is not empty off the pump if it is still connected to the patient. The syringe extension set must be disconnected or clamped before removing the syringe to prevent free flow and the risk of serious injury or death to the patient.

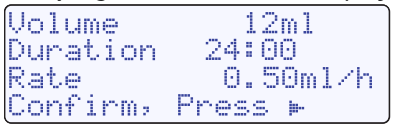
Warning: If the Volume to be Infused displayed on the pump LCD after confirming the syringe varies by more than 5% of the actual syringe volume visually confirmed on the syringe scale, remove the syringe, turn off the pump and, with the barrel clamp arm down, turn the pump on to allow pre-loading to occur. Repeat the syringe placement and detection steps and ensure the correct syringe size and brand are confirmed. If the calculated volume reading is still significantly different from the visually confirmed contents, remove the pump from use and return to an authorized service center for inspection, testing and calibration.

Warning: Using a syringe which is not approved by the pump manufacturer or a syringe type which is not compatible with syringe pumps, could affect pump performance, resulting in over-delivery or under-delivery of medication to the patient.

5.4.6. Programming the Infusion

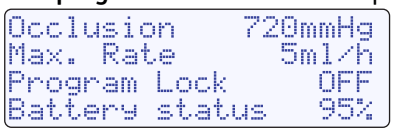
After confirming syringe brand and size (refer to section *5.4.5. Loading the Syringe* on page 23), the display screen displays a different screen depending on the lock status of the program (refer to section *5.2. Setting Up the Mode of Operation* on page 20):

- **The program is locked**: The display screen displays the infusion summary.



NOTE: If the program is set to rate mode and the **Rate Setting** setting is still set to the default value 0 (no value has yet been entered), the program requires to set the rate before displaying the infusion summary.

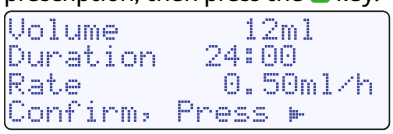
- **The program is unlocked**: The display screen displays pump settings, including **Program Lock** (**OFF**).



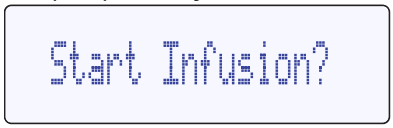
Programming the Infusion When the Program Is Locked

If the program is locked, to program the infusion do as follows:

1. If the program is set to rate mode and the **Rate Setting** setting is still set to the default value 0 (no value has been entered yet), the initial rate is automatically set to 0.1 ml/h. The program requires you to confirm or change the rate (refer to section *6.4. Changing Rate Setting* on page 34). The rate you set becomes the default value.
2. Review the infusion summary to check that the parameters displayed (volume, duration, rate) match the prescription, then press the ▶ key.



The pump is ready to start the infusion.

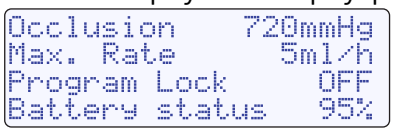


3. Site/connect the cannula/syringe extension set to the patient. Follow local policy for the recommended cannula and syringe extension set to use.
4. To start the infusion, press the ▶ key.
5. Visually check that the infusion running screen is visible and the green LED light flashes intermittently. When the pump is operating, note that the bottom line alternates between the syringe brand and size confirmed and **<<<< Pump Delivering** (with moving chevrons):

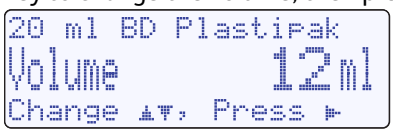
Programming the Infusion When the Program Is Unlocked

If the program is unlocked, to program the infusion do as follows:

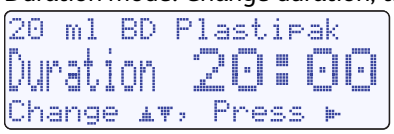
1. When the display screen displays pump settings, press the ▶ key or wait 7 seconds.



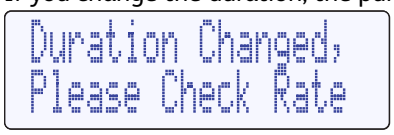
2. Visually check if the volume in the syringe matches the volume displayed. If needed, press the ▲ key or the ▼ key to change the volume, then press the ▶ key.



3. Press the ▲ key or the ▼ key to change duration or rate (depending on the current operation mode):
   - Duration mode: Change duration, then press the ▶ key.

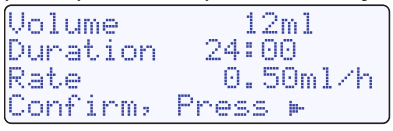


   If you change the duration, the pump adjusts the rate accordingly. Press the ▶ key to confirm the new rate.

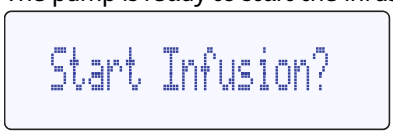


   - Rate mode: Change rate, then press the ▶ key.

4. Review the infusion summary to check that the parameters displayed (volume, duration, rate) match the prescription, then press the ▶ key.



   The pump is ready to start the infusion.



5. Site/connect the cannula/syringe extension set to the patient. Follow local policy for the recommended cannula and syringe extension set to use.
6. To start the infusion, press the ▶ key.
7. Visually check that the infusion running screen is visible and the green LED light flashes intermittently. When

the pump is operating, note that the bottom line alternates between the syringe brand and size confirmed and **<<<< Pump Delivering** (with moving chevrons):

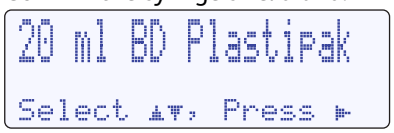
5.5. Purging the System

In order to eliminate/reduce mechanical slack (visible spaces at the syringe collar and plunger loading points) and ensure a faster start-up time (time to start delivering the fluid to the patient/reach the programmed infusion rate) the user can purge the system.

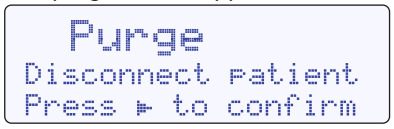
- This facility is available (if enabled) once only, after pre-loading prior to commencing an infusion.
- The purge facility is disabled by default (0 ml) and the maximum deliverable is 2.0 ml.
- The purge rate is 200 ml/h.
- The purge function can be configured via the pump Technician menu.
- The purge function can be used with any mode of operation.

To purge the system (all modes of operation), do as follows:

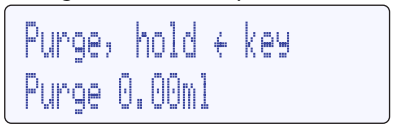
1. Turn the syringe pump on without syringe and wait until the preloading process is complete.
2. Load the syringe.
3. Confirm the syringe size/brand.



4. Press the ← key.
   The purge screen appears.



5. Ensure that the syringe extension set is disconnected from the patient.
6. Press the ► key to confirm.
7. Press and hold the ← key until the slack is removed or purge volume is delivered (a purge volume will be configured, for example, 0.2 ml).



8. Wait for the next screen to display.

9. If the syringe size/brand displayed matches the one used, confirm by pressing the ► key. (Use the ▲/▼ keys to select the matching syringe, if necessary).

5.6. Titrating the Rate

If enabled, you can titrate (change) continuous infusion flow rates during infusion. It is recommended that the keypad lock is used as an additional protection against accidental rate change during infusion.

The maximum ml/h rate limit will be the pump maximum rate that is configured via the pump Technician menu. The minimum rate is 0.1 ml/h. If this setting needs to be changed, you must consult the technical staff.

Rate change can be enabled in the following modes of operation:

- Lock Off Mode (duration)
- Rate Mode (ml/h)
- Rate Setting Mode (ml/h, Lock Off)

Rate change cannot be enabled in Lock On mode.

To titrate rate during infusion, do as follows:

1. Deactivate keypad lock.
2. With infusion running, press the ▲▼ key and the ▼ key to change the rate, then press the ▶ key.

3. Check that the rate change completed and is correct. (Note change to time remaining).
4. Activate keypad lock.

5.7. Monitoring and Managing Infusions

Ensure that the pump is clean, visually intact, appropriate for the intended use, and within service date. It is good practice to inspect medical equipment and accessories between patients and certainly immediately before use (e.g. whilst setting it up on the patient).

It is recommended that procedures are established for regular checks on the pump, accessories and the progress of the infusion.

Inspect the lead screw prior to use. If there is white plastic debris on the lead screw, this is an indication of wear on the syringe mechanism. Therefore, discontinue use and send the syringe pump for service.

Inspect for signs of physical damage to the syringe pump, and to lockbox and carry pouch (optional).

5.7.1. Positioning the Pump

It is good practice to minimise disturbance to the pumps and to maintain the pump at the same height level throughout an infusion as far as possible. Optimal operation occurs with positive pressure infusion devices are positioned at the same height level as the infusion site.

Warning: If a pump has been accidentally damaged, dropped or subject to fluid ingress/spillage it should be withdrawn from service immediately and a suitable replacement pump located. Contact your local service centre.

5.7.2. Monitoring the Infusion

During an infusion, note the following pump information:

- The indicator LED will flash green.
- The LCD screen will display the following information:
  - Line 1 – infusion time remaining
  - Line 2 – ml/h infusion rate
  - Line 3 – alternates between the syringe size and brand confirmed by the user during set up and **Pump Delivering**

Regular monitoring should include checking:

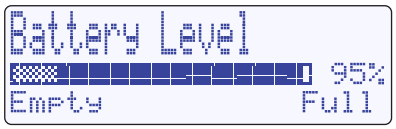
- All connections on the syringe/syringe extension set are secure.
- There are no kinks in the tubing.
- There are no signs of physical damage to the pump or lockbox.
- The keypad lock is on.
- Infusion is in progress.
- Volume history and battery status are as expected.

NOTE: Follow local guidance for a full list of infusion monitoring checks.

5.7.3. Checking the Battery Level

Checking the Battery Level During Infusion (LED Light Is Green)

1. Press the ⓘ key twice.
   The battery level displays as a percentage (%).



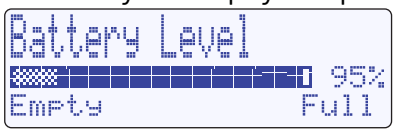
2. Wait a few seconds for the screen to default back to infusion running screen again or press the key again to display infusion volume history screen.

NOTE: With the infusion running, repeated key presses on the key cycles through volume history, battery level and infusion running screen. Excessive key presses or usage of the feature will reduce battery life. Use only as required to optimize battery performance.

Checking the Battery Level With Infusion Paused (LED Light Is Red)

1. Stop infusion by pressing the key.
2. Press the key once.
3. Press the key.

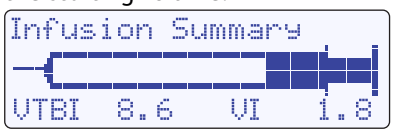
The battery level displays as a percentage (%).



4. Wait a few seconds for the default display to reappear or press the key to exit the battery screen immediately.

5.7.4. Checking the Volume History During Infusion

- Press the key once.
  The syringe volume to be infused (VTBI) and volume infused (VI) are displayed. The total of VTBI + VI equals the starting volume.



NOTE: After pressing the key, either a third press or waiting a few seconds returns the display to the base display screen.

NOTE: Excessive key presses or usage of the feature will reduce battery life. Use only as required to optimize battery performance.

5.8. Locking the Keypad

The keypad has a locking feature that prevents unintentional powering off of the unit, as well as the ability to lock or limit certain infusion parameters or pump settings. The pump allows users to lock the operation of the keypad if they are concerned about patients, relatives or untrained personnel tampering with the syringe pump.

The key and the key are active as there may be a need to stop/pause the infusion short-term (for example, in an emergency situation or for other clinical interventions).

If the syringe pump is stopped/paused for longer than 2 minutes, the **Pump Paused Too Long** alarm will activate to alert the user to the syringe pump status. In this instance, the Event Log records these events.

When the syringe pump is used with the keypad lock activated:

- The user can stop and start an infusion, and with the infusion running use the key to review the infusion status. If the infusion is stopped/paused, the only option available is to restart the infusion.
- The syringe pump cannot be powered off using the Power key.
- The user cannot scroll through the menu to access the available options.
- The user cannot change rate during continuous infusion (if enabled in lock off or rate modes).

Note the following principles with keypad lock:

- If the power supply is interrupted during an infusion and the user powers the syringe pump on again (with syringe in place): if the **Press to Resume, for New Syringe** screen displays, the infusion can be resumed.

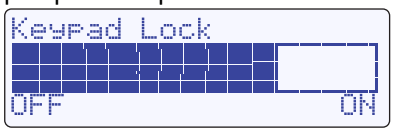
- The use of the ←/→ keys for manual actuator adjustment is not accessible (when no syringe is in place and barrel clamp arm is down).
- The syringe brand and size displayed cannot be changed using the ↑ and ↓ arrow keys as this would delete the current program.
- The purpose of pre-loading (automatic actuator movement) is to delete the current program in the syringe pump. Pre-loading will not take place even when there is no syringe in place and the barrel clamp arm is down.
- If the power supply is interrupted during an infusion and the user powers the syringe pump on again (with no syringe in place and the barrel clamp arm down), pre-loading does not take place. Because pre-loading (automatic actuator movement) has not occurred, the program is still available to be resumed. Use of the keypad lock prevents automatic actuator movement.
- If the user then loads and confirms a syringe, the **Press ▶ to Resume, ■ for New Syringe** screen displays, and the infusion can be resumed.

NOTE: It is recommended that the keypad lock is used if rate change (titration) is enabled. This gives additional protection.

The keypad lock can be activated and deactivated at any time by pressing and holding the ⇥ key.

To lock the keypad, do as follows:

- With the syringe pump infusing, press and hold the ⇥ key down for approximately 5 seconds.
  The lock indicator graphic will fill up from left to right. When the progress bar is completely black, the syringe pump will beep to confirm that the lock has been activated.



To unlock the keypad, do as follows:

- Press and hold the ⇥ key down for approximately 5 seconds. The lock indicator graphic will empty from right to left. When the progress bar is completely white, the syringe pump will beep to confirm that the lock has been deactivated.

5.9. Program Protection and Resume

The current program (infusion) is the only one available in the pump memory for use. In certain situations, it is possible to continue use of the current program using Resume after therapy interruption. Program protection and the ability to Resume applies specifically to the programmed ml/h rate. Pre-loading (automatic actuator movement) will clear a program from the pump memory.

5.9.1. Resume and New Syringe Options

An infusion can be interrupted, for example, by alarm activation (like in case of occlusion), syringe change, or power interruption. Depending on the cause of interruption, ‘Resume’ and ‘New Syringe’ are the two options that may be presented.

Resume

The Resume option saves the current infusion rate and eliminates the need to reprogram/confirm settings (volume, duration, and rate) after therapy interruption. The Resume option is available to continue an infusion in the following situations:

- Syringe displacement or occlusion alarm
- Power supply interruption or failure

Resume is not available in the following situations:

- A different syringe brand and/or size is placed in the pump.
- The volume in the syringe is changed during therapy interruption.

To resume therapy, press the ▶ key to confirm syringe brand and size, then press the ▶ key to resume. Follow the prompts to confirm the settings summary, then press the ▶ key to start the infusion.

NOTE: Pressing **for New Syringe** immediately deletes the current program. A new program is then calculated or entered (depending on the mode of operation).

New Syringe

A program (infusion) may be interrupted to change the syringe (brand, type, or increase/decrease of the syringe volume), which requires programming infusion settings (volume, duration, and rate). This type of interruption deletes the previous program, rate is not saved, and the options **to Resume, for New Syringe** will not be provided.

Following an interruption, verify that the syringe brand and size displayed matches the syringe placed into the pump. If they match, press the key to confirm. Follow the prompts to change and/or confirm each setting for the current infusion, review the setting summary, and if correct press the key to start the infusion. If incorrect, press the key to go back.

NOTE: Follow local policy/procedure for the appropriate option to press when the **to Resume, for New Syringe** screen displays following purge.

Syringe fitting and confirmation:

1. The pump will automatically attempt to detect the syringe brand and size, but if it identifies a syringe incorrectly, lift the barrel clamp arm and re-seat the syringe.
2. If the incorrect syringe brand and size continue to be displayed, use the key and the key to scroll and select the correct syringe. When the correct syringe is displayed, press the key to confirm. The options **to Resume, for New Syringe** will be provided.
3. If the options for **to Resume, for New Syringe** are not provided, then there is no current program available and a new program must be entered.

5.10. Stopping/Pausing the Infusion and Powering Off

Stopping the Infusion (Pump Stopped)

1. If the user presses the key during an infusion, the pump is paused (stopped) for 2 minutes, the LED light changes from green to red and a screen message displays.

2. Either press the key to restart the infusion or the key to pause for another 2 minutes.
3. If the paused state continues with no key presses, after two minutes the pump will alarm and a 'Pump Paused Too Long' screen message displays.

4. Either press the key twice to restart the infusion or press the key (or the key once) to pause for another 2 minutes.

Powering Off

1. Remove keypad lock if necessary and stop/pause the infusion if running.
2. Press and hold down the key until the progress graphic (moving from left to right) fills completely black, a beep is heard and the display screen power is removed.
3. Disconnect the syringe and the syringe extension set from the patient access device.
4. Remove the syringe from the pump and place the barrel clamp arm down.
5. Remove the battery if the pump is no longer required.

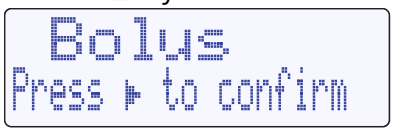
5.11. Delivering a Bolus

Bolus can only be delivered during an infusion. To change bolus rate (**Bolus Dose Rate** setting) and bolus maximum volume (**Bolus Maximum Volume** setting), refer to section *6.3. Changing Pump Settings* on page 33.

Note: Bolus delivery is disabled by default. Bolus delivery can be enabled from the Technician menu (refer to section *6.2. Access Codes* on page 33).

To deliver a bolus, do as follows:

1. During the infusion, press the ← key.
2. Press the ▶ key to confirm.



3. To deliver the bolus, press and hold the ← key.

NOTE: After confirming the bolus, the ← key must be held continuously. If the ← key is released, bolus delivery stops and the pump changes back to normal infusion.

5.12. Operation Checklists

This section provides options for managing an infusion in the form of checklists. They are intended as guidance only, not as user instructions.

The way the infusion is managed in your own clinical area will vary, depending on, for example, local policy, types of syringe extension sets and drugs being infused. You must refer to your local policy for specific infusion management requirements and instructions for managing infusions.

5.12.1. Checklist for Changing a Syringe (New Program, Same Set)

Remember to de-activate and activate the keypad lock as necessary.

1. Stop the infusion:
   a. If the infusion complete alarm has activated, press the ▶ key to confirm the end of the infusion.
   b. If the **Program nearly Complete** alert has activated, press the ⊞ key to access the volume history and record the VI (Volume Infused), then press the ■ key to stop the infusion.
2. Turn off the pump.
3. Clamp and disconnect the syringe extension set from the empty syringe.
4. Raise the barrel clamp arm, remove the empty syringe and lower the barrel clamp arm.
5. Prepare a new syringe and attach the syringe extension set.
6. Turn on the pump, observe pre-loading and wait for the screen to display **Load Syringe**.
7. Check battery level.
8. Load the new syringe into the pump, check if syringe brand/size is correct and to confirm press the ▶ key.
9. Enter/check new program, if correct, press the ▶ key.
10. The screen will display **Start infusion?** Connect the syringe extension set to the syringe and when ready to do so, press the ▶ key.
11. Check that the infusion is running.

5.12.2. Checklist for Discontinuing the Infusion and Pump

Remember to de-activate the keypad lock.

1. Stop the infusion:
   a. If the infusion complete alarm has activated, press the ▶ key to confirm the end of the infusion.
   b. If the **Program nearly Complete** alert has activated, press the ⊞ key to access the volume history and record the VI (Volume Infused), then press the ■ key to stop the infusion.
2. Turn off the pump.
3. Disconnect the syringe extension set/cannula from the patient.
4. Raise the barrel clamp arm, remove the syringe and lower the barrel clamp arm.
5. Remove the battery from the pump.
6. Dispose of the syringe and line according to local policy.
7. Clean and store the pump as per local policy.

6. Pump Settings

6.1. Configuration Authorization

Pump configuration must only be carried out by designated and authorised personnel. You must check with your technical department and/or line manager if you are designated and have the authority to change the syringe pump configuration.

When configuring a pump, ensure that the following requirements are met:

- The pumps are configured for the required application, for example, occlusion pressure settings are correct for drug delivery route.
- The mode of operation is correct for the drug prescription.
- Optional features and functions that may be required are configured (for example, Purge, titration, pump maximum ml/h rate).

Any program/pump changes that are made must be fully documented, checked with a second person and against a pump setting authorisation form, which is available from local or BD technical service staff.

6.2. Access Codes

The pump has three areas of access code protection to prevent unauthorised changes to set up, configuration or programming:

- **Change Set up** menu.
- **Rate Setting** setting.
- Technician menu. The technician code is only provided to fully trained and authorised service personnel.

Certain settings and features may be configured and locked based on patient or clinical need or to configure the pump for a specific clinical application. No access code is required to turn on the pump and run an infusion. In normal clinical use the pump user will not see these fields or be prompted for access codes.

WARNING: Do not attempt to access code protected areas if you are not trained or authorised to do so. Authorised personnel should not share codes with unauthorised personnel and should only give code access to designated personnel.

NOTE: Access codes are only provided to designated and authorised clinical or technical staff when they are trained and certified in their use. No access codes are contained in *Directions For Use* (this manual).

6.3. Changing Pump Settings

To change pump settings, do as follows:

1. With no infusion running, press the ⓘ key.
   The **Info** menu appears.
2. Press the ▲▼ key to select **Change Set up**, then press the ▶ key.

3. Press the ▲▼ key to enter the code, then press the ▶ key.

4. Press the ▲ key or the ▼ key to select an option, then press the ▶ key.
5. Press the ▲ key or the ▼ key to change the setting.

NOTE: When the ▲ key or the ▼ key are pressed and held down, the pump will count up in single digits to ten, then in tens to one hundred and then in thousands thereafter.

6. Press the ▶ key to confirm.
   The **Exit** option appears.

7. Press the ▶ key to exit the **Info** menu.

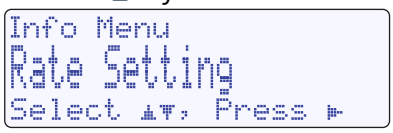
The table shows the configurable settings in the **Change Set up** menu.

Setting	Default	Range	Description
Exit	—	—	Exit the **Change Set up** menu.
Language	English	English, local language	The pump can be set to English or one local language which varies according to where the pump is sold.
Time & Date	Current date/time	Month/year Hour/minute	Sets a date and time stamp for the event log. This does not automatically change for daylight saving.
◀ Key Operation	5 mm	0.1-100 mm	Limits the forward movement of the actuator when the ◀ key is pressed with no syring in place and barrel clamp arm down.
Backlight Duration	5 seconds	0 (OFF)-60 seconds	Limits the screen backlight duration following key presses.
Info Duration	5 seconds	1-20 seconds	Limits the screen information duration which displays when the key is pressed during an infusion.
Bolus Dose Rate	300 ml/h	1-650 ml/h	1-299 ml/h in 1 ml/h increments; 300-650 ml/h in 5 ml/h increments. NOTE: This setting is available only if bolus delivery is enabled on Technician menu.
Bolus Maximum Volume	0 ml (Disabled)	0 (OFF)-20 ml	0-20 ml in 0.1 ml increments. NOTE: This setting is available only if bolus delivery is enabled on Technician menu.
Titration Option	Disabled	Enabled/Disabled	Enables rate change during infusion. Maximum rate is the pump max. ml/h rate. Minimum is 0.1 ml/h. Can only be enabled if program lock is OFF.
Default Duration	24:00 hours	• 0:00 hours (ml/h) • 00:0-99:00 hours (volume over time)	With default duration set to 0:00 hours, the pump runs as an ml/h infusion. With a nonzero default duration set, the pump runs as a volume over time infusion.
Occlusion Pressure	720 mmHg	200-1500 mmHg	Sets the pressure level at which the occlusion alarm will activate.
Program Lock	ON	OFF/ON	With lock on, prevents alteration of default duration or ml/h rate.

6.4. Changing Rate Setting

To change the rate setting, do as follows:

1. With no infusion running, press the ⊕ key.
   The **Info** menu appears.
2. Press the ▲▼ key to select **Rate Setting** , then press the ▶ key.



3. Press the ▲▼ key to enter the code, then press the ▶ key.

4. Press the ▲ key or the ▼ key to change the rate, then press the ▶ key.

Parameter	Default	Range	Description
Rate Setting	0 ml/h	0.1 ml/h – (adjustable maximum rate)	Sets the default rate on rate mode. **Note**: Maximum rate can be changed from the Technician menu (**Maximum Rate** parameter). Default maximum rate: 5 ml/h. Range: 0.1 ml/h to 650 ml/h.

7. Troubleshooting

7.1. Alarms

Alarm Condition

When the syringe pump detects a problem, four things may occur:

- If a high-priority alarm occurs, infusion will stop. For low-priority alarms, infusion continues.
- An audible alarm is activated. The alarm sounds until either the pump is paused or the problem is rectified.
- A message appears on the display screen indicating the cause of the alarm, and
- The LED indicator will change to red/yellow.

Warning: If the occlusion pressure alarm is set too high **(Occlusion Pressure** setting, refer to section *6.3. Changing Pump Settings* on page 33), the occlusion alarm may take long time to occur. Ensure that the occlusion pressure alarm is set in relation to the clinical conditions. Refer to table *Time to Alarm from Occlusion* on page 19 for more information.

Warning: Alarm settings and other setup parameters should only be changed by clinical or technical staff with user code access rights and the authority to change pump settings.

NOTE: See the *Technical Service Manual* for test procedures to check alarms functionality.

NOTE: During the power on sequence the audible speaker is activated and LEDs will illuminate to verify alarm functionality. No action is required during this self-test.

NOTE: Alarm tone settings are normally preserved in the case of power loss, however some system faults will result in loss of alarm settings.

NOTE: Logs are maintained for when the pump is powered down, but in cases of unexpected power loss the logs will not be maintained.

NOTE: In the event of complete loss of power supply, the backup audio alarm will sound, but there will be no visual indicators.

Alarms

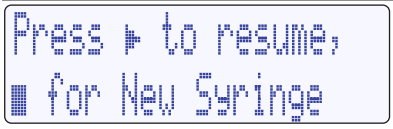
The pump will activate an alarm when:

Description	Alarm Type	Audio Signal as per 60601-1-8	Visual Signal as per 60601-1-8 Operational LED
Down Occlusion **End Battery** **End Of Infusion** **Syringe displaced during infusion** **Restart Pump Switch off & On ERROR XX**	High-priority alarm Requires immediate user response	High priority 5 tones Volume min. 45 dBA approx.	Red flashing visual Operation LED flashes red
Pump Paused Too Long **Low Battery** **Near End**	Low-priority alarm Requires user awareness	Low-priority 3 tones Volume min. 45 dBA	Yellow solid visual Operation LED is solid yellow (Not flashing)
Bolus Started / Completed **Keypad Lock / Unlock** **Syringe plunger at the limit of travel**	Informational signal Provides information that may, or may not require action from user	1 or 2 pulses	No visual

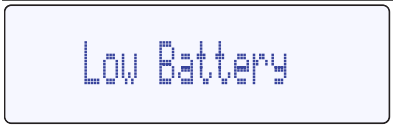
Description	Alarm Type	Audio Signal as per 60601-1-8	Visual Signal as per 60601-1-8 Operational LED
Syringe loaded	Informational signal Provides information that may, or may not require action from user	1 or 2 pulses	No visual
Purge Start / End			
Power On / Off			
Infusion started / resumed / stopped by user			
Service interval alert			
9V Battery Power Failure	Backup alarm	Buzzer	No Visual
Alarm Output Volume Failure	Backup alarm	Buzzer	Red flashing visual Operation LED flashes red

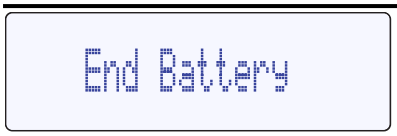
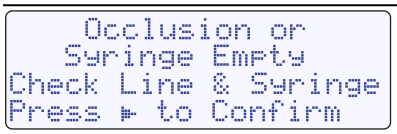
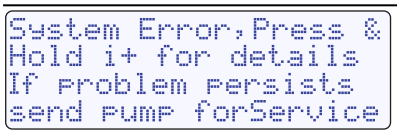
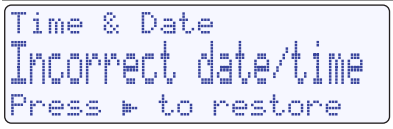
7.2. Screen Prompts

In certain situations screen prompts display to prompt the user and provide information:

Screen prompt	Result/cause	Possible actions
	Only the ■, ▶ and ⊕ keys are accessible.	Disengage keypad lock if further access is required.
	The current program has been interrupted and two options are available for programming.	Press the ▶ key resumes the current program. Press the ■ key to delete the current program (to allow a new program to be set up).
	The infusion has been stopped.	Press the ▶ key to resume the infusion or press the ■ key to continue stopped state.

7.3. Troubleshooting Instructions

Screen information	Result/cause	Possible actions
	Alert: Program is about to end in 15 minutes/syringe is almost empty.	Prepare to change syringe or discontinue pump use.
	Alert: Battery is almost depleted (at least 30 minutes are left). NOTE: The activation of the alarm depends on battery model, capacity, and brand.	Prepare to change battery.
	Alarm: The program is completed and the VTBI volume is fully infused.	Press the ▶ key to confirm, then change syringe or discontinue pump use.
	Alarm: The pump has been stopped/paused for more than 2 minutes without any key presses.	Either press the ▶ key to resume the infusion, press the ■ key to continue pause for another two minutes, or turn the power off.

Screen information	Result/cause	Possible actions
	Alarm: Battery will fail imminently.	Change battery.
	Alarm: One or more of the syringe detection sensors is not detecting.	Check the syringe and re-seat as necessary. Check screen messages for assistance.
	Alarm: Clamped line, occluded or kinked.	Release the clamp, flush/replace the access device or clear the occlusion.
	Alarm: Clamped line, occluded or kinked, and the actuator has reached the minimum travel position.	
	Alarm: An internal system error has occurred. (Two examples of system failure screen messages are shown here).	If error recurs: Take pump out of use. Press the i+ key to obtain error message. Record error code and summary of fault and return pump to designated service centre.
		
	The internal backup battery has been depleted and the date/time values have been reset.	Press the ▶ key, then enter current date and time (refer to section *4.2. Battery Power Supply* on page 14).

Technical Problem/Error and Failure Identification

- The pump alarms if an internal system fault has been detected and the unit will be inoperative.
- The user may be prompted to power off and restart, which may rectify the error.
- If the problem cannot be rectified, power off and remove from patient use.
- Refer to the *Technical Service Manual* for full details of all technical alarms.
- Follow local policy and/or contact your authorised Medical Engineering Department for advice.

The Event Log will record the error/alarm event.

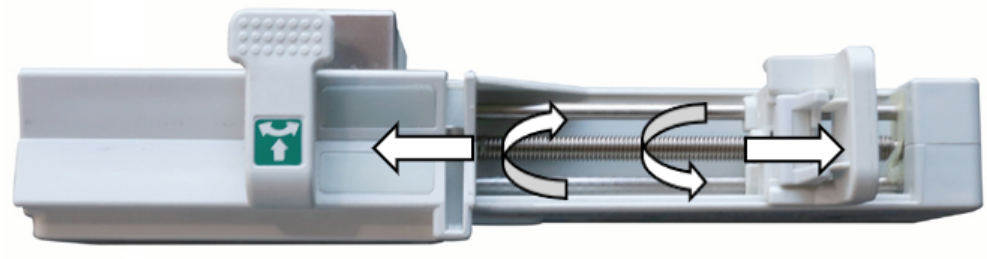
7.4. Releasing a Trapped Foreign Object From the Actuator

If an object or a finger is trapped either during pre-loading or when manually adjusting the actuator, the alarm and screen messages will depend on the battery level and on the force or resistance that moves against the actuator. Alerts or alarms that may display include low battery alert, end battery alarm, system failure alarm or a high motor current alarm.

If a foreign object or finger is trapped in front of, or behind the actuator during pre-loading (automatic actuator movement) or when manually adjusting the actuator, do as follows:

Option 1 (manual adjustment of actuator)

1. Turn off the pump.
2. Place finger on the lead screw and do as follows:
   a. To move the actuator towards the barrel clamp arm, roll finger towards the battery compartment.
   b. To move the actuator towards the side opposite to the barrel clamp arm, roll finger towards the display screen.



Option 2 (adjustment of actuator using the ◄ key and the ► key)

1. Turn off the pump.
2. Turn on the pump.
3. Press the ◄ key or the ► key to release the object.

NOTE: Interpretation of the pump event log can assist in identifying the effects on the pump with an object being trapped in front of, or behind the actuator. Recorded events will reflect the alarm that was activated at the time. If a low or end battery alarm was activated, you may see that the battery voltage has dropped substantially and the activation of a low or end battery alarm is dependent on the battery level at the time of the alarm.

7.5. Event Log

The event log shows a complete time and date stamped record of the last 512 pump events along with a record of pump status (volume infused, rate, etc.) at the time of the event. Event log data cannot be deleted or altered and it is not patient-specific, i.e. the 512 events are likely to span multiple patients treated with that particular pump.

Each event is assigned a new number and the pump stores the most recent 512 events in memory. When more than 512 events have occurred, the oldest event will be deleted each time a new event occurs.

For example, after some time, the first event to appear when you enter the events history might be number 754. This means there have been 754 events in this pump's life and events 242–754 are currently stored. When event 755 occurs, the oldest event, number 252, will be deleted and the pump will store events 243–755, then 244–756, and so on.

Events recorded include hourly self-testing when an infusion is running and certain key presses.

When the pump is infusing, the pump will record pump status every hour regardless of any key presses.

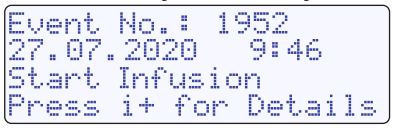
The event log cannot be accessed whilst an infusion is running. If necessary, stop the infusion and remove keypad lock.

To access the event log, do as follows:

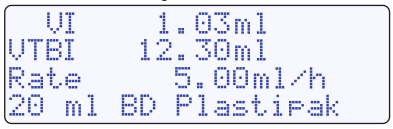
1. Press the ⊕ key.
2. Press the ▲▼ key to select **Event Log**, then press the ▶ key.

   The last event is shown, including event number, date and time.
3. Press the ▲ key or the ▲ key to scroll through events.

4. Press the ⊕ key for more information. Press the ▲ key or the ▼ key to scroll through information, if needed.

5. To exit the **Event Log** menu, press the ▶ key.

NOTE: The pump does not automatically change for daylight saving. The date and time can be updated manually via the pump **Change Set up** menu.

8. Service and Maintenance

8.1. Periodic Maintenance

Periodic maintenance is recommended every 12 months. The pump displays a maintenance reminder alert for the user to send the pump for service yearly. Periodic maintenance is designed to help ensure pump accuracy and to detect and repair any potential pump inconsistencies prior to their occurrence in the field. During periodic maintenance, a BD certified technician should perform the following procedures:

- Clean the pump thoroughly.
- Visually inspect the pump to verify its structural integrity.
- Perform all the manual tests in the **Change Set up** menu.
- Perform calibration procedures as per the *Technical Service Manual*.
- Run the pump for several hours to make sure no abnormalities occur during infusion such as alarms, inaccurate infusion, and battery inconsistencies.

NOTE: Service and maintenance should be performed by a BD certified technician. The only maintenance a patient can perform is the changing of the battery and cleaning of the device.

NOTE: It is the technician's responsibility to repair any faults found during periodic maintenance.

NOTE: Do not service the pump whilst it is in use and/or attached to a patient.

8.2. Cleaning

8.2.1. Pump Cleaning - MRC Protocol

IMPORTANT!

- The Manufacturer Recommended Cleaning (MRC) protocol is **NOT intended to replace** local Infection Prevention and Control Policy. The decision about the level of decontamination required depends not only on how the device is used, but also on the risk of the device transmitting infection or acting as a source of infection.
- Best prevention practices against HAI (Hospital Acquired Infections) recommend a 2 steps process: Step 1. Removing unwanted soils from all surfaces with a cleaning agent (pathogens can use soils for harborage limiting accessibility to disinfectant agents). Step 2. Disinfecting the freshly cleaned surfaces.

MRC Protocol

INTENT:

- To preserve pump performance.
- To remove soil, particles and chemical residue that could accumulate over time on pump surface. Soil, particles and chemical residue result from normal use and from the 'disinfection protocol' developed by users at point of use.

INSTRUCTIONS:

- To clean the pump, wipe the external pump surface using a disposable alcohol wipe impregnated with isopropyl alcohol (IPA) 70%, to minimize pump exposure to excessive quantities of liquids.
- Isopropyl alcohol (IPA) is volatile and leaves no residue upon evaporation, therefore surfaces are left dry quickly after wiping.

FREQUENCY:

- It is recommended to apply the MRC protocol to the pump after each disinfection sequence as a preventive measure to maintain pump performance and longevity (removal of chemical residue).
- Note: Preventive maintenance also helps to maintain pump performance over time. This should be performed as recommended in the Periodic Maintenance section.

Warning: Turn off the pump before cleaning.

Warning: When fluid ingress is suspected, stop using the pump and request pump verification through maintenance to identify potential need of corrections.

Warning: Immersing the pump into liquid could cause damage to components. Do not soak or immerse any part of the pump into any type of liquid.

Warning: Do not steam, autoclave, EO (ethylene oxide) sterilize, immerse the pump in any type of fluids, or allow fluids to enter the pump case.

Caution: If other chemical cleaning agents are used for the "disinfection protocol / regime", ensure to follow the manufacturer recommended cleaning to preserve pump performance, after completing the "disinfection protocol / regime".

Caution: Do not spray or rinse cleaning solutions directly on pump surfaces or in potential liquid retention areas or open ports such as electrical connections.

Caution: Avoid using chemicals that can damage the surfaces of the instrument (for example, chlorinated solvents).

Caution: When using cleaning solutions containing chemicals (such as corrosive agents), do not use concentrated solutions and do not expose surfaces above the recommended dwell time. After application, rinse surfaces with IPA disposable wipes to eliminate chemical residue.

8.2.2. Accessories Cleaning

Lockbox Cleaning

BD recommends the use of alcohol sprays and wipes to decontaminate the lockbox. Other products may be used but users should be aware that extended usage could result in the lockbox becoming brittle and susceptible to damage. The substances listed below may adversely impact products constructed from polycarbonate:

- Alkali bleaches such as sodium hypochlorite
- Butyl acetate
- Methanol
- Acetone
- Sodium hydroxide
- Methyl ethyl ketone
- Acrylonitrile
- Chloroform
- Styrene
- Ammonia
- Dimethylformamide
- Tetrachloroethylene
- Amyl acetate
- Concentrated hydrochloric acid
- Toluene
- Benzene
- Concentrated hydrofluoric acid
- Concentrated sulphuric acid
- Bromine
- Iodine
- Xylene

Re-Usable Pouch Cleaning

Clean fabric-made products according to need with wet wipes containing water or alcohol. When thorough cleaning is required, use machine laundry at 60°C.

- Do not spin wash.
- Do not bleach.
- Do not heat dry.
- Do not iron.

8.3. Pump Storage

If the pump is to be stored it should be cleaned and the battery removed. Store in a clean, dry atmosphere at room temperature and, if available, use the original packaging or a suitable alternative, for protection.

NOTE: When the pump is stored without a 9V battery the date and time can become inaccurate. For more information refer to section *4.1. Pump Inspection and Unpacking* on page 14.

8.4. Disposal and Decommissioning

When the time comes to dispose of the pump, accessories or packaging do so in the best way to minimise any negative impact on the environment. You may be able to use special recycling or disposal schemes. To find out about these, contact your technical service department or local waste disposal service. Existing national or local regulations concerning waste disposal must take precedence over the above advice.

Used syringe extension sets should be considered bio-hazardous and treated (handled, disposed or processed) as potentially posing significant risks of infection transmission to humans or harming the environment. Please follow any applicable national and institutional guidelines for bio-hazardous materials treatment.

9. Specifications

Type	Linear syringe driver mechanism, pulsed motion (540 pulses per mm).
Flow rate	Flow rate is adjustable between 0.1 ml/h and 650 ml/h. • 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 parameters	Bolus flow rate 1-650 ml/h: • 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 volume: 0-20 ml in 0.1 ml increments. Maximum bolus volume is 20 ml.
Actuator travel	67 mm available.
Syringe sizes	2 ml to 50 ml. See section *5.1.1. Syringes* on page 18 for more information.
Accuracy	±5% system accuracy (pump and set combined) by volume under nominal conditions, defined as follows: • Flow rates: 1 ml/h and 5 ml/h; • Tested with extension set model M100-172SB; • Needle: 18 gauge; • Solution Type: Distilled water; • Temperature: 22°C ± 3°C; • Back Pressure: 0 ± 10 mmHg; • Syringe size and brand: BD Plastipak™ 20 ml. Accuracy measured using the trumpet curve test method defined in EN/IEC60601-2-24.
Occlusion pressure	200-1500 mmHg configurable (10 mmHg increments).
Battery	9 V alkaline, IEC 6LR61 type.
Operating time	**Rate** / **Approximate battery life** 1 ml/h / > 50 hours 5 ml/h / > 35 hours Refer to section *4.2. Battery Power Supply* on page 14 for more information.
Indicators	4 line LCD display (122 x 32 pixels), dual color operation LED.
Alarms	When a problem is detected, the pump displays the following alarm messages, sounds an audible alarm and the LED lights red: • Occlusion or Syringe Empty • End Program • End Battery • Syringe Displaced during infusion • System Error
Dimensions	167 x 68 x 39 mm
Classification	Type CF Equipment (degree of protection against electrical shock). IP22 protection against ingress of water and solid objects. Definition of code: I = Ingress P = Protection 2 = Protection from solid objects ≥12.5 mm 2 = Protection from dripping water (15° tilted)
Housing	PC-ABS (fire retardant). Complies with standard UL94 V-0.
Weight	230 g without battery.

Medical electrical equipment standards	Complies with: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-2-24.
Standards and regulations	Designed and manufactured in accordance with ISO 13485, IEC 62304, IEC 62366-1, ISO 14971, IEC 60529, ISO 8536-8 and UL 94. CE marked in accordance with the Medical Devices Directive 93/42/EEC.
EMC Specifications:	The BD BodyGuard™ T Syringe Pump is designed to be in compliance with IEC 60601-1 (safety), IEC 60601-1-2 (EMC), and IEC 60601-2-24 (infusion pump). The BD BodyGuard™ T Syringe Pump has been tested and found to comply with the limits for a Class B digital device. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: • Reorient or relocate the receiving antenna. • Increase the separation between the equipment and receiver. • Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. • Consult the dealer or an experienced radio/TV technician for help. The BD BodyGuard™ T Syringe Pump has been tested to comply with the requirements of IEC 60601-1-2:2014.

EMC – Emissions Compliance	**EMC Standard**	**Range**	**Compliance**
Radiated emissions	CISPR 11:2015	30 MHz – 1 GHz	Class B, Group 1

EMC – Immunity Compliance	**EMC Standard**	**Test level**		**Compliance**
Electrostatic Discharge (ESD) Immunity	IEC 61000-4-2	Contact discharge	± 2 kV ± 4 kV ± 6 kV	No degradation of performance
		Air discharge	± 2 kV ± 4 kV ± 8 kV	
	IEC 60601-2-24	Contact discharge	± 8 kV	Operator intervention may be required as pump may intermittently reset, requiring user to restart the infusion.
		Air discharge	± 15 kV	
Radiated RF Immunity	IEC 61000-4-3:2006 +A1:2007 +A2:2010	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz		Yes
Proximity fields from RF wireless communications equipment	IEC 61000-4-3:2006 +A1:2007 +A2:2010	380 - 390 MHz 27 V/m 430 - 470 MHz 28 V/m 704 - 787 MHz 9 V/m 800 - 960 MHz 28 V/m 1.7 - 1.99 GHz 28 V/m 2.4 - 2.57 GHz 28 V/m 5.1 - 5.80 GHz 9 V/m		Yes
Conducted RF Immunity	IEC 61000-4-6:2013	• 3 V/m 0.15 MHz - 80 MHz • 6 V/m in ISM and amateur radio bands between 0.15 MHz and 80 MHz • 80% AM at 1 kHz		Yes
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009	30 A/m 50 Hz		Yes

Environmental specifications

Operating Environment Range:

- Ambient temperature: 5°C to 40°C.
- Relative humidity: 15% to 90%, non-condensing.
- Ambient pressure: 70 kPa to 106 kPa.

Transport and Storage Conditions:

- Ambient temperature: –25°C to 70°C.
- Relative humidity: 0% to 90%, non-condensing.
- Ambient pressure: 48 kPa to 110 kPa.

Pump Accuracy

With the BD BodyGuard™ T Syringe Pump, as with all infusion systems, variations cause short term fluctuations in rate accuracy. The following curves show typical performance of the system:

1. Start-up curves show the delay in onset of fluid flow when infusion commences.
2. Trumpet curves show the accuracy of fluid delivery over various time periods.

The following graphs and curves were derived from testing described in IEC60601-2-24. Testing was performed under normal conditions at room temperature (72°F or 22°C). Any deviations from normal conditions and room temperature may cause changes in the accuracy of the pump.

Start-up Curves

Start-up curves represent continuous flow versus operating time for two hours from the start of the infusion, measured for infusion rates of 5 ml/h and 1 ml/h. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

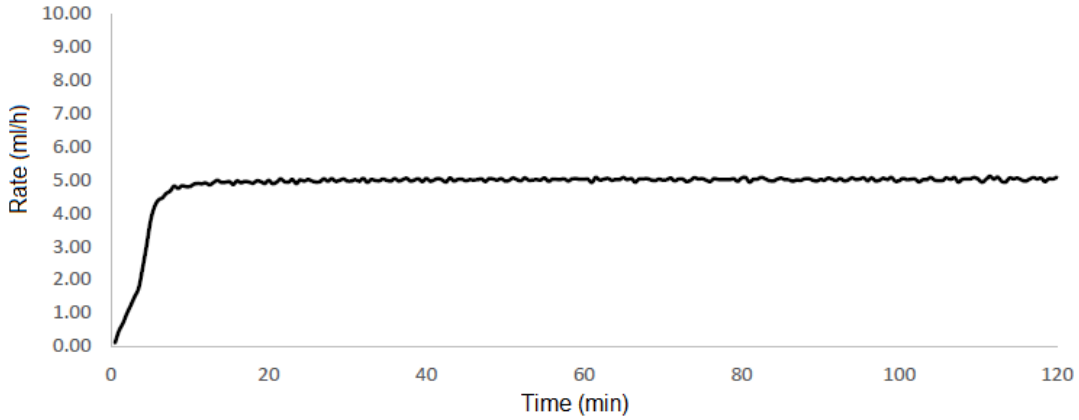


Figure 9-1. Long Term Rate Accuracy at 5 ml/h

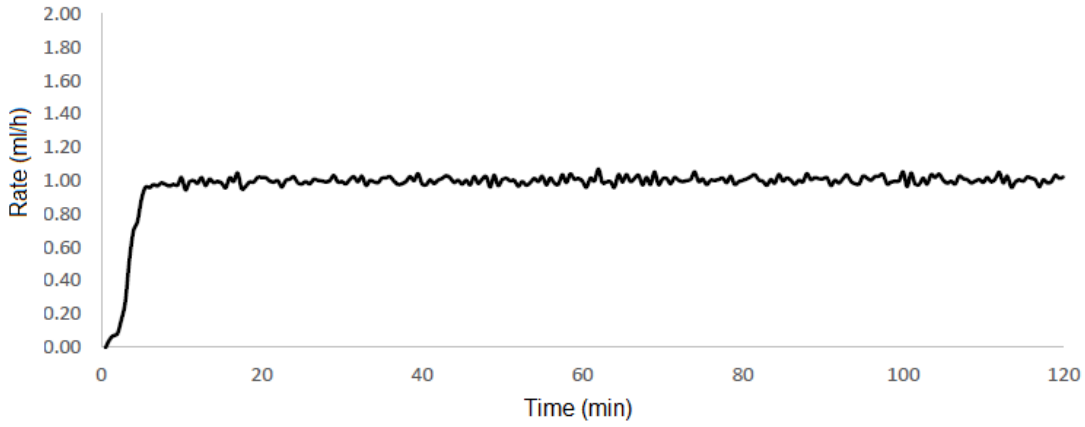


Figure 9-2. Long Term Rate Accuracy at 1 ml/h

Trumpet Curves

Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods, named ‘observation windows’, as opposed to continuous data versus operating time. Over long observation windows, short-term fluctuation has little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effects as represented by the ‘mouth’ of the trumpet. Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short-term fluctuations in rate accuracy may have clinical impact depending on the shelf life of the drug being infused and the degree of inter-vascular integration. The clinical effect cannot be determined from the trumpet curves alone.

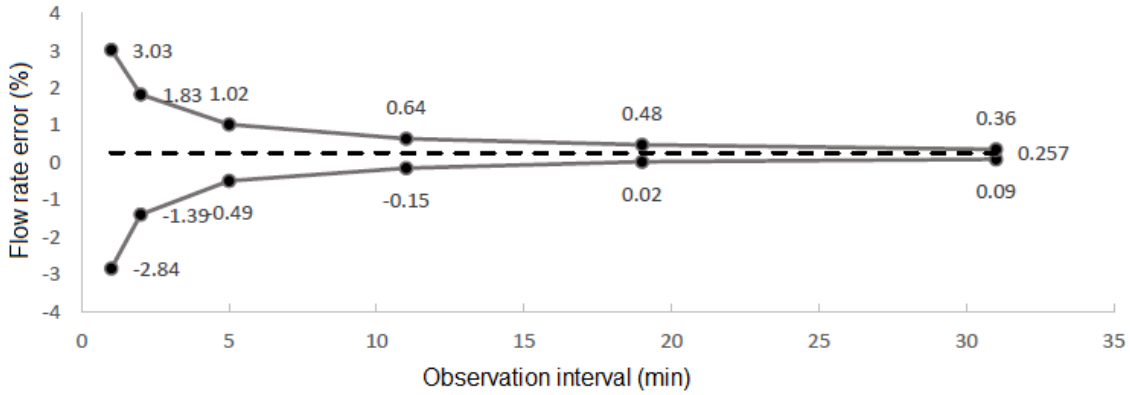


Figure 9-3. Trumpet Curve at 5 ml/h

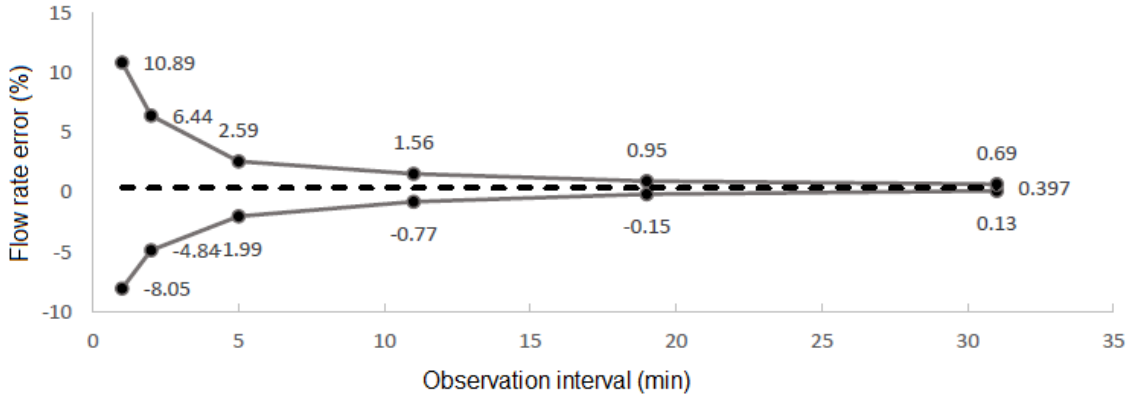


Figure 9-4. Trumpet Curve at 1 ml/h