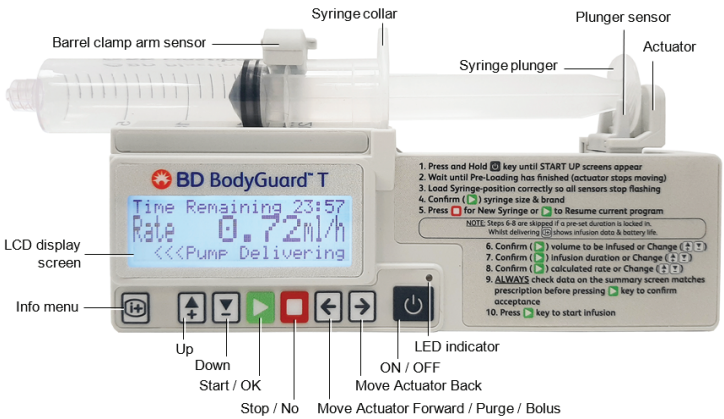
BD BodyGuard™ T Syringe Pump*
LOCK ON DURATION
Quick Reference Guide

* Including T34™ Syringe Pump (REF: 999-103XX) 3rd edition with updated software version. See page 19 for reference.

BD BodyGuard™ T



Note: Instructions on the pump label are for reference only and do not reflect all possible settings. Please, refer to the *Directions For Use* for full instructions.

- This guide is not intended to be comprehensive instructions for the set-up and operation of the infusion pump. For complete pump information, refer to the *Directions For Use.*
- Some screens in this guide may vary depending on the way the pump is set up. They are for reference purposes only and may be different than the information displayed on your system.
- Before operating the pump, users should consult the full *Directions For Use*.
- If you need assistance with setting up or maintaining the equipment or to report unexpected operation or events, contact the manufacturer or manufacturer's representative.

Warnings and Cautions

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 *Disposal and 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.

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.

Warnings and Cautions

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.

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.

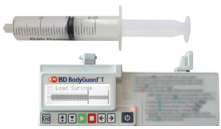
Caution: Do not use slip-tip syringes. Luer-lock syringes must always be used to ensure secure connection of the syringe extension set and the syringe pump.

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.

Loading Syringe

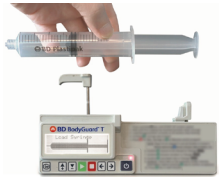
STEP 1

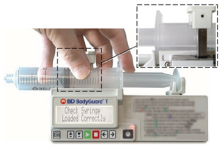


Manual adjustment of the actuator

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

STEP 2





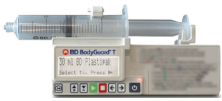
Syringe loading

- Lift the barrel clamp arm fully and turn the arm 90° (either way).
- 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.
- Turn and lower the barrel clamp arm onto the syringe. If barrel clamp arm is not down, the display shows 'Check Syringe Loaded Correctly'.

If the syringe is not loaded correctly, the display will show 'Check Plunger Sensor' or 'Check Collar Sensor.'

WARNING: Ensure the syringe loaded is appropriate, and that the correct syringe extension set has been selected.

STEP 3



Syringe detection and confirmation

The pump identifies the syringe brand, size and volume by measuring the syringe dimensions from the three sensors.

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

WARNING: Ensure the appropriate syringe size and brand have been selected.

Starting a New Infusion

Scenario

- Lock on, default duration 24 hours.
- Infusion required: deliver syringe contents over 24 hours.
- 20ml BD Plastipak syringe.
- Syringe volume after priming is 17.5ml.

A. Prepare syringe

Manually prime the syringe extension set. How to prime the syringe extension set with the pump is described in section G.

Note: Please be aware if using 'load and prime' instead of 'prime and load' sequence, the rate of delivery will be automatically adjusted to compensate for the lost priming volume while maintaining the preset duration. If you wish to maintain the rate, please work in Rate mode.

B. Check the pump

Ensure that the pump is clean, visually intact and appropriate for the intended use.

C. Insert battery

Fit the battery correctly.

D. Power on and observe Pre-Loading

With no syringe in place and barrel clamp arm down, press the ⏻ key until the screen illuminates.

Observe Pre-Loading: automatic actuator movement and screen information.

WARNING: keep fingers away from actuator moving parts.

Wait until the **Load Syringe** prompt displays.

Starting a New Infusion
Continued

E. Check battery level

Press the ⓘ key.

Press the ▶ key.

F. Load and confirm syringe

Align the syringe to pump syringe fitting sensors.

- Use the ← / → keys to move the actuator as necessary.
- Fit the syringe into the sensors.

If the syringe size/brand displayed matches the one used, press the ▶ key. (If they do not match, use the ↑ / ↓ keys.)

G. Program the pump

- If prime / purge required, press the ← key and follow screen prompts.
- Review the program summary, if correct, press the ▶ key.

H. Start infusion

- To start the infusion, press the ▶ key.

- When the infusion is in progress, this screen displays:

Monitoring During Infusion

Regular monitoring includes the following checks:

- All connections between the syringe and the syringe extension set are secure.
- There are no kinks in the syringe extension set.
- 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.

To activate or deactivate the keypad lock:

Press and hold the ⊕ key for approximately 5 seconds.

To confirm the infusion is in progress:

a) The pump LED light will intermittently flash green

b) The LCD screen will display information:

Line 1 - infusion time remaining
Line 2 - ml/h infusion rate
Line 3 - alternates between syringe size and brand confirmed and <<< **Pump Delivering.**

To check volume history and battery level:

Press the ⊕ key once:

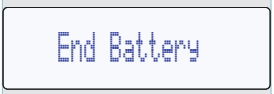
Press the ⊕ key twice:

I. Powering off

- Remove keypad lock if necessary and stop the infusion if running by pressing the ☐ key.
- Press and hold down the ⏻ key until a beep is heard and the pump switches off.

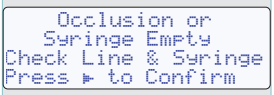
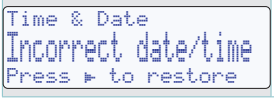
Note: When an alarm activates, infusion stops (high-priority alarms) or continues (low-priority alarms), and the LED indicator turns red (high-priority alarms) or yellow (low-priority alarms). The alarm sounds continuously until the problem is rectified. Always note the alarm condition before stopping the pump.

Alerts, Alarms and Troubleshooting

Screen prompts	Result/cause
	Only the ■, ▶ and ⏻ keys are accessible.
	The infusion has been stopped.
	Alert: Program is about to end / syringe is almost empty.
	Alert: Battery is almost depleted.
	Alarm: The pump has been stopped / paused for more than two minutes without any key presses.
	Alarm: The program is completed and the VTBI volume is fully infused
	Alarm: Battery will fail imminently.
	Alarm: One or more of the syringe detection sensors is not detecting.

Possible actions
Disengage keypad lock if further access required.
Press the ▶ key to Resume the infusion or press the ■ key to continue stopped state.
Prepare to change syringe or discontinue pump use.
Prepare to change battery.
Press the ▶ key to resume the infusion, press the ■ key to continue pause for another two minutes or power off.
Press the ▶ key to confirm, then change syringe or discontinue pump use.
Change battery.
Check the syringe and re-seat as necessary. Check screen messages for assistance.

Alerts, Alarms and Troubleshooting

Screen prompts	Result/cause
	Alarm: Clamped line, occluded or kinked.
	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, refer to the pump service manual for a full list of error codes.
	
	The internal backup battery has been depleted and the date/time values have been reset.

Program protection and **Resume**:

- Pre-Loading and syringe empty alarm clears a program from the pump memory.
- If the option is available to resume a program, a screen prompt displays.

Possible actions
Release the clamp, flush/replace the access device or clear the occlusion.
The user may be prompted to power off and restart, which may rectify the error. If the error recurs, take pump out of use. Press the key to obtain error message, record error code and summary of fault and return pump to designated service centre.
Press the key, then enter current date and time.

If the syringe size/brand displayed matches the one used, press the key.

Press the key to retain the current program (ml/h rate is protected). Press the key to delete the current program which allows a new infusion to be programmed.

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.

Cleaning and Maintenance

- Turn off the pump before cleaning.
- When fluid ingress is suspected, stop using the pump and request pump verification through maintenance to identify potential need of corrections.
- 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.
- Do not steam, autoclave, EO (ethylene oxide) sterilize, immerse the pump in any type of fluids, or allow fluids to enter the pump case.

- 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".
- Do not spray or rinse cleaning solutions directly on pump surfaces or in potential liquid retention areas or open ports such as electrical connections.
- Avoid using chemicals that can damage the surfaces of the instrument (for example, chlorinated solvents).
- 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.

Periodic maintenance is recommended every 12 months. Periodic maintenance is designed to help ensure the pump's accuracy and detect and repair any potential inconsistencies prior to their occurence in the field. Refer to *Directions For Use* manual about periodic maintenance.

IP Rating

The rating of the pump is IP22. This is the moisture protection rating and indicates the degree of particle and water ingress protection.

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.

Contraindications

- 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

Note: Failure to use this equipment in the specified type of shielded location could result in degradation of performance, interference with other equipment or interference with radio services.

Note: No modification to this equipment is permitted.

Hazards

- Potential strangulation may occur if tubing is of excessive length.
- Potential choking may occur if small parts are inhaled or swallowed.
- Potential allergic reactions may occur due to materials used in the pump.
- Children, pets, fireplaces, dust, lint and direct sunlight may all affect pump operation.
- The use of single-use disposable components on more than one patient is a biological hazard. Do not re-use single-use disposable components.
- 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.
- Do not use this equipment with other infusion systems or accessories that are not approved to be used with this pump system.

Operating and Transport Conditions

There is no additional time required for the unit to equilibrate once removed from minimum to maximum storage temperatures.

Ensure to operate the pump within the specified operating range.

Operating Conditions

- 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

- Temperature: −25°C to +70°C
- Relative Humidity: 0% to 90%
- Air Pressure: 48 kPa to 110 kPa

System Accuracy

System accuracy of ±5% achieved under nominal conditions, defined as follows:

- Flow rates: 1ml/h and 5ml/h.
- Tested with syringe 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 20ml;

Disposal and Battery

Proper Disposal

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.

Battery

Always use a 9 volt alkaline disposable battery, type 6LR61.

Expected Battery Life

Rate	Approximate battery life
1 ml/h	> 50 hours
5 ml/h	> 35 hours

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.

T34™ Syringe Pump (REF: 999-103XX)

Place Contact Information Here

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