

# BD BodyGuard™ T Syringe Pump\* Technical Service Manual



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





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# 1. General Information

## 1.1. Purpose of This Manual

This manual provides instructions for servicing the BD BodyGuard™ T Syringe Pump and its software. The instructions are applicable both to the BD BodyGuard™ T Syringe Pump (REF: 999-103BDXX) and to the T34™ Syringe Pump (REF: 999-103XX) 3<sup>rd</sup> edition with updated software version (refer to section 1.3. Document History on page 6).

The following requirements and conditions apply whilst servicing CME/BD products. Failure to follow these instructions invalidates the warranty and causes unacceptable risks:

- Servicing pumps and accessories must only be performed by BD certified technicians. Service must only be performed using the recommended equipment and BD-approved parts.
- This manual is intended to support BD certified technicians who are servicing the T34™ / BD BodyGuard™ T Syringe Pump.
- Clinical personnel, patients and other users are advised to return syringe pumps to an authorised service center for service.
- Refer to the pump *Directions For Use* for pump operation instructions, cautions and warnings.
- Refer to BD BodyComm™ Software Utility Tool *Directions For Use* (software version 3.x, latest available revision) for software operation instructions.
- Document the service performed in accordance with the service provider's prevailing procedures.

## 1.2. Overview

The BD BodyGuard™ T Syringe Pump (hereinafter referred to as 'pump') is a lightweight, battery-powered infusion pump, designed for ambulatory use in a hospital or homecare setting. It can deliver indicated medications via any common infusion route, including intravenous and subcutaneous.

The pump has three-point syringe detection, by which it can identify most commonly used syringe brands. This feature enables the pump to calculate the syringe volume and, depending on the mode of operation, to deliver the contents over a specified duration or at a specified rate, in milliliters per hour, therefore minimizing the risk of programming errors. Sensors activate an alarm if the syringe is removed or displaced during infusion.

Other safety features include three-level access-code protection, keypad lock, event log and full alarm protection.



Figure 1-1. BodyGuard™ T Syringe Pump in Lockbox

### 1.2.1. Modes of Operation

The pump can be configured and locked to one of four modes of operation. The default mode of operation is Duration Lock On. The mode-of-operation options are:

- **Duration Lock On:** Delivers the contents of the syringe over a fixed, preprogrammed duration (the pump default is 24 hours). The pump automatically calculates the ml/hr infusion rate for the confirmed deliverable volume.

- **Duration Lock Off:** This mode permits the user to set a custom duration for delivery of the infusion. The pump automatically calculates the ml/hr infusion rate based on the selected duration of delivery and the confirmed deliverable volume.
- **Rate Lock On:** Delivers the contents of the syringe over a fixed, preprogrammed rate. The pump detects the volume of the syringe and calculates the duration of the infusion accordingly.
- **Rate Lock Off:** Permits the user to set the required flow rate, in ml/hr. The pump detects the volume of the syringe and calculates the duration of the infusion accordingly.

## 1.2.2. 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.

## 1.3. Document History

Revision	Date	Software Version	Description
07	May 2022	T3.2A-xx	<ul style="list-style-type: none"> <li>• Updated Pressure Calibration method.</li> </ul>
06	February 2022	T3.2A-xx	<ul style="list-style-type: none"> <li>• Updated BodyGuard™ T Syringe Pump, including T34™ Syringe Pump following the CCR feedback.</li> </ul>
05	August 2021	T3.2A-xx	<ul style="list-style-type: none"> <li>• European Authorized Representative address change.</li> </ul>
04	February 2021	T3.2A-xx	<ul style="list-style-type: none"> <li>• Updated BodyGuard™ T Syringe Pump, including T34™ Syringe Pump (REF: 999-103XX) 3<sup>rd</sup> edition with updated software version.</li> <li>• Updated information about backup battery (refer to section 3.2.1. <i>Backup Battery</i> on page 16) and storage (refer to section 4.2.2. <i>Storage</i> on page 31).</li> <li>• Added reference to PumpMaster Software Utility Tool (refer to section 3.5. <i>Communication - Between PC and Syringe Pump</i> on page 30).</li> </ul>
03	July 2020	T34SW3.07D	<ul style="list-style-type: none"> <li>• Updated T34™ Syringe Pump following customer feedback.</li> </ul>
02	October 2019	T34SW3.07D	<ul style="list-style-type: none"> <li>• Updated T34™ Syringe Pump following the changes made in T34™ DFU (ECO12030) and general updates.</li> </ul>
01	July 2019	T34SW3.07D	<ul style="list-style-type: none"> <li>• Updated T34™ Syringe Pump Spare part list, PVP, Cleaning instructions, and general updates.</li> </ul>
00	December 2018	T34SW3.07D	<ul style="list-style-type: none"> <li>• Initial release.</li> </ul>

## 1.4. Pump Description



	<b>Icon</b>	<b>Description</b>
<b>T T34™</b>		
1	N/A N/A	<b>Barrel Clamp Arm Sensor:</b> Detects syringe size/width of barrel based on barrel diameter.
2	N/A N/A	<b>Syringe Collar Sensor:</b> Detects that the syringe collar is loaded correctly.
3	N/A N/A	<b>Plunger Sensor:</b> Detects that the syringe plunger is loaded correctly.
4	N/A N/A	<b>Actuator:</b> Drives the syringe plunger in order to deliver syringe contents.
5	N/A N/A	<b>Graphic LCD Display:</b> <ul style="list-style-type: none"> <li>• 128 pixels x 32 pixels.</li> <li>• The backlight duration is configurable.</li> <li>• When any key is pressed, the backlight turns on.</li> </ul>
6		<b>Info Menu key:</b> <ul style="list-style-type: none"> <li>• Shows the Event Log, Volume Infused, Volume to be Infused and battery status.</li> <li>• A long press locks/unlocks the keypad.</li> </ul>
7		<b>Up key:</b> <ul style="list-style-type: none"> <li>• Increases infusion parameters during programming/use.</li> <li>• Scrolls between options.</li> </ul>
8		<b>Down key:</b> <ul style="list-style-type: none"> <li>• Decreases infusion parameters during programming/use.</li> <li>• Scrolls between options.</li> </ul>
9		<b>START/OK key:</b> Confirms selections during programming.
10		<b>STOP/NO key:</b> Moves back one step during programming or stops the infusion.
11		<b>Move Actuator Forward key:</b> Moves the actuator forward when no syringe is loaded.
12		<b>Move Actuator Back key:</b> Moves the actuator backward when no syringe is present.
13		<b>ON/OFF key:</b> Turns the pump on or off whilst in the STOP state.
14	N/A N/A	<b>Operation LED:</b> <ul style="list-style-type: none"> <li>• Blinking green whilst infusing.</li> <li>• Yellow: low priority alarm.</li> <li>• Red: high priority alarm and pump stops.</li> </ul>
15	N/A N/A	Instructions for infusion setup.



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

## 1.5. Technical Overview

Syringe pumps are ideal for low-volume applications where accuracy is important.

A syringe pump is often called a piston pump or syringe driver, as the fluid is moved by the syringe piston. The accuracy of the pump is determined in conjunction with the syringe used, and should only be used with syringes approved by the pump manufacturer.

The driving mechanism is a lead screw, rotated either by a stepper motor or by a permanent-magnet motor with a gearbox. The pump uses a permanent-magnet motor, which can deliver the same torque as a stepper motor, but from a much smaller unit, as it draws much less current than a stepper motor of comparable rating. Both of these factors are significant in a pump for which size and battery life are important.

When testing a syringe pump at low rates, it is important to let the unit run long enough to take up the system backlash before attempting to measure volumetric accuracy. The pump includes a Technician menu, which speeds up this process. Because the displacement rate is determined by the lead screw pitch and the rate of the optical shaft encoder pulses as well as the syringe data in the pump database, the need to adjust the device is eliminated.

### 1.5.1. Occlusion Detection

The pump does not use a strain gauge to measure occlusion force. Instead, the motor current is monitored by a linear amplifier. The resulting voltage is roughly proportional to force.

Whilst this system is not as accurate as a strain gauge in a bridge configuration, it is adequate for the intended application of the pump.

Variations in friction of the syringe affect the occlusion pressure. Therefore, it is important to use a new syringe when verifying performance. A syringe friction rapidly increases after only a few occlusion measurements.

### 1.5.2. Motor Control

Motor rotation is monitored by an optical shaft encoder and a rotating magnet. The microprocessor uses data from both to confirm the motor speed.

The rotating magnet on the motor shaft operates a reed switch positioned just below the shaft end of the motor. A slotted disc on the end of the lead screw, together with an IR LED and photodiode, form a shaft encoder to monitor the lead screw position.

Two more reed switches, one at each end of the lead screw, slow the motor as the actuator approaches the end stop (also referred to as the End of Travel).

The motor can be stopped, started or reversed by means of an H-Bridge driving circuit.<sup>1</sup> With a large syringe size and a high occlusion setting, the motor current can easily exceed 100 mA, so it is important that an alkaline battery be used. A zinc carbon-type battery cannot provide the high current required as occlusion occurs.

As with most modern products, all functions are controlled by a microprocessor. The main crystal clock for the processor is checked against the RTC clock source to ensure correct timing. A watchdog timer is also employed to shut down the motor and keypad if the micro program stops executing.

The motor speed is locked via the encoder to the checked crystal source and confirmed by the motor reed switch pulses. There is no provision for speed adjustment as there is no need for it.

On power-up, the microprocessor carries out a self-test on most subsystems, including the motor and encoders.

### 1.5.3. Performance Verification

There are a number of items that the microprocessor cannot test without human intervention. These are the display and LEDs, acoustic alarm, keypad matrix, syringe size potentiometer, collar micro switch, plunger micro switch and accuracy of occlusion detection.

These items must be manually tested, by entering Technician mode and scrolling to the **Main Self-Test** menu, where several automated test routines allow rapid confirmation of all system alarms and functions.

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<sup>1</sup>An H-Bridge is an electronic circuit that enables a voltage to be applied across a load in either direction, in order to allow a DC motor to run forward and backward. H-Bridges are available as integrated circuits, or they can be built from discrete components.

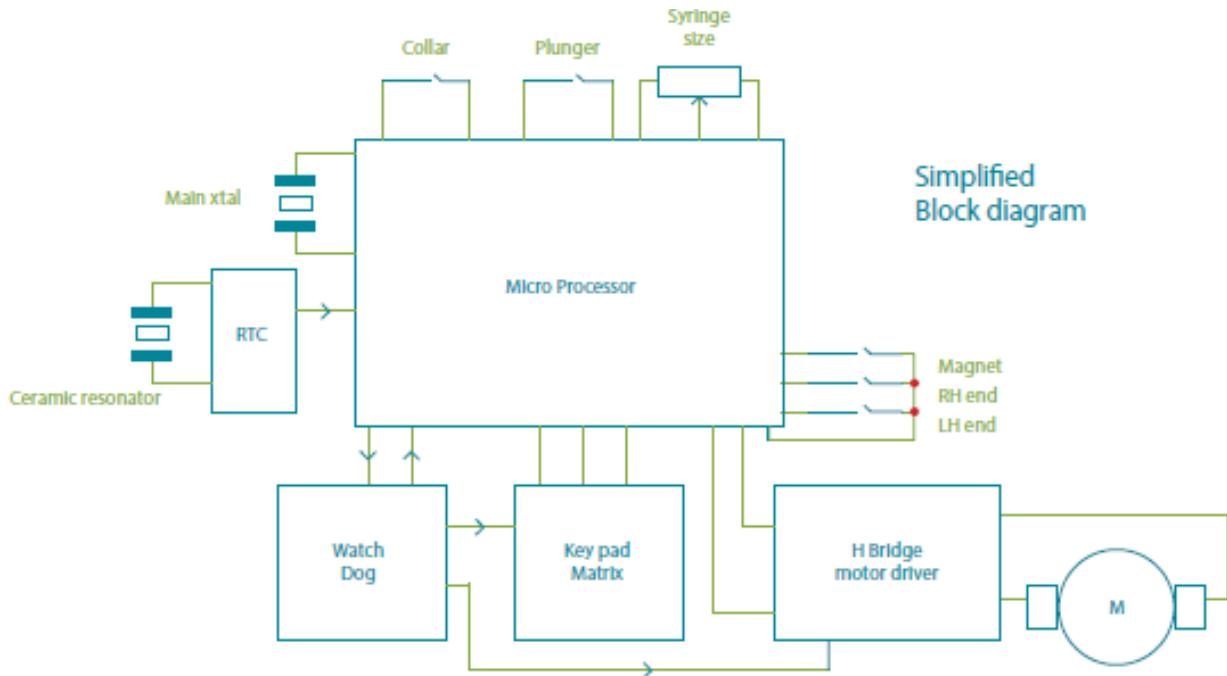


Figure 1-2. Pump Block Diagram

Only three actual physical measurements need to be made:

- Volume
- Occlusion pressure
- Syringe barrel clamp arm

All of these measurements can be made using built-in test routines that are accessed via the Technician menu.

## 2. Safety Information

### 2.1. Warnings and Cautions

#### 2.1.1. Document Notices



**Warning:** Warnings advise you of circumstances that could result in injury or death to the patient or operator.

Read and understand this manual and the pump *Directions For Use*, taking note of all warnings before operating or performing service on the pump.



**Caution:** Cautions advise you of circumstances that could result in damage to the device. Read and understand this manual and the pump *Directions For Use*, taking note of all cautions before operating or performing service on the pump.



**NOTE:** Indicates that the information that follows is additional important information or a tip to help you when operating or performing service on the pump.

#### 2.1.2. Warnings

To avoid possible personal injury or death, observe the following warnings:



**Warning:** An explosion hazard exists if the pump is used in the presence of flammable anesthetics. Exercise care to locate the pump away from any such hazardous sources.



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



**Warning:** Pump detection is based on the physical dimensions of the syringes programmed into the pump database by the manufacturer. However, the same-brand syringes may be manufactured at different sites bearing small differences that are beyond the control of the pump manufacturer. Therefore, do not use the pump if the correct syringe brand is not detected and promptly notify the pump manufacturer. Always ensure that the visual volume in the syringe matches the actual volume on the pump display.



**Warning:** Before starting an infusion, check that all parameters that are set, especially calculated parameters, are correct. Visually check that the volume in the syringe matches the actual volume on the pump display and the calculated rate. In case the default duration is set to zero, apply the required rate of infusion.



**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:** The pump should be operated within the recommended environmental operating range. Operation at temperatures and/or humidity outside this range may adversely affect accuracy.



**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:** Use an aseptic technique. 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 or syringes.



**Warning:** Ensure that the syringe brands used (at the medical provider) are enabled in the software. All other syringes should be disabled.



**Warning:** When starting a new program, allow the pump to perform a preloading procedure, as this procedure ensures correct detection of the volume in the syringe.



**Warning:** To know more about BD BodyComm™ v3.x compatibility with pump versions, refer to *BD BodyComm™ Software Utility Tool Compatibility Table* on page 30.

## 2.1.3. Cautions

To avoid possible damage to the equipment, observe the following cautions:



**Caution:** This pump contains static-sensitive components. Observe strict precautions for the protection of static-sensitive components when attempting to repair and service the pump.



**Caution:** If the pump is dropped, subjected to excessive moisture, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection.



**Caution:** Do not store the pump with the battery in it. Refer to storage instructions (4.2.2. Storage on page 31).



**Caution:** Avoid using chemicals that can damage the surfaces of the instrument (for example chlorinated solvents). Refer to cleaning instructions (4.2. Recommended Cleaning and Storage on page 31).



**Caution:** Immersing the pump into liquid may cause damage to components. Do not immerse the pump into any type of liquid.



**Caution:** Battery damage may occur if left in a temperature warmer than 50°C.

## 2.2. Safety

### 2.2.1. System Symbols

The following symbols are used on the pump and its components. Labels on the system or statements in this manual preceded by any of the following words and/or symbols are of special significance and are intended to help you operate the pump safely and efficiently.

#### Symbols on Both Pump and Syringe Extension Set Packaging

Symbol	Description
	The CE mark indicates conformance to the Medical Device Directive 93/42/EEC. The numeric code identifies the Notified Body.
	Manufacturer
	Authorized representative in the European Community.
	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 <i>Directions For Use</i> for important cautionary information that cannot be presented on the pump.
	Read the entire <i>Directions For Use</i> before using the pump.
	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.

Symbol	Description
	Type CF applied part (IEC 60601-1). Applied part is suitable for direct cardiac application.
<b>SN</b>	Serial Number
	Battery
	Direct current
<b>IP22</b>	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.
<b>P</b>	Indicates syringe infusion sets for single use with pressure infusion apparatus.
<b>STERILE EO</b>	Sterilized with ethylene oxide (applies to syringe extension sets).
<b>LOT</b>	Lot number
	Expiry date of disposable

## 2.2.2. Electrical Safety and Standard Compliance

The pump complies with the following standards:

- **IEC 60601-1, Ed. 3.1:2012:** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-8: 2006, +A1:2012:** Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- **IEC 60601-1-6, Ed. 3.1:2013:** General requirements for basic safety and essential performance - Collateral Standard: Usability
- **IEC 60601-1-11, Ed. 2.0: 2015:** Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- **IEC 60601-2-24, Ed. 2.0:2014:** Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
- **IEC 62304:2006+AMD1:2015:** Medical device software - Software life cycle processes

## 2.2.3. Electromagnetic Compatibility (EMC)

- **IEC 60601-1-2, Ed. 4.0:2014:** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

## 2.3. Alarms

### 2.3.1. Alarm Conditions

At any time, when the pump detects a problem, an alarm is activated and the following occurs:

- The infusion stops (high-priority alarms).
- An audible alarm sounds.
- An alarm message appears on the display, stating the cause of the alarm and indicates instructions for continued use. The operation LED lights red or yellow depending on alarm priority.

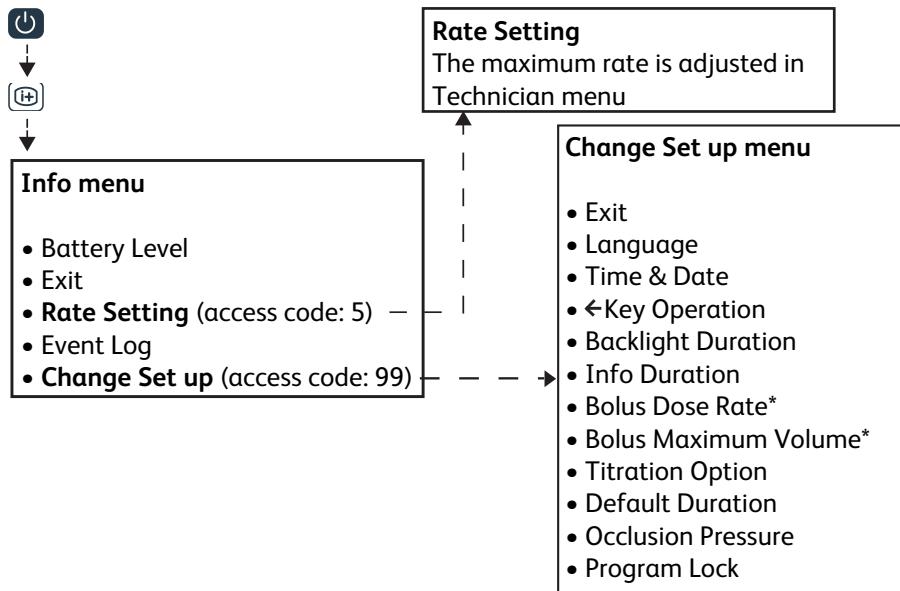
Table 2-1. Alarms

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	High Priority alarm <i>Requires immediate user response</i>	High Priority Volume=~ 58 dBA	RED Flashing visual Operation LED Flashes RED.
Syringe displaced during infusion			
Restart Pump Switch off & On ERROR XX			
Pump Paused too long	Low Priority Alarm <i>Requires user awareness</i>	Low Priority 3 tones Volume=~ 55 dBA	Yellow solid visual Operation LED is solid Yellow (Not flashing)
Low Battery			
Near End			
Bolus			
Started/Completed			
Keypad Lock/Unlock			
Syringe plunger hit the limit	Informational signal		
Syringe loaded	Provides information		
Purge started/End	that may, or may not require action from clinicians	1 or 2 pulses	No visual
Power On/Off			
Infusion started/ resumed/ Stopped by user			
Service interval alert			
9 V Battery Power Failure	Backup alarm	Buzzer	No visual
Alarm Output Volume Failure	Backup alarm	Buzzer	Red flashing visual Operation LED flashes red

# 3. Configuration and Calibration

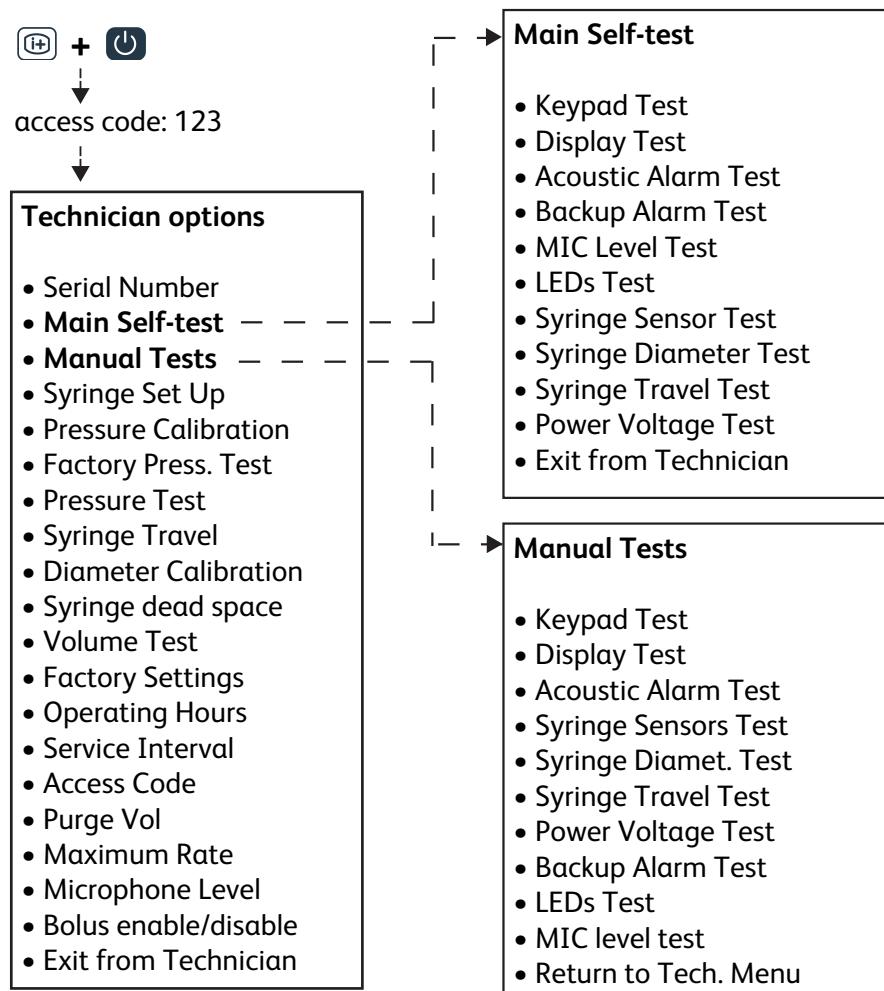
## 3.1. Menu Structure

### User mode (Info menu and Change Set up menu)



\* Available only if bolus delivery is enabled on Technician menu.

### Technician mode



## 3.2. Batteries

### 3.2.1. Backup Battery

The pump has a backup battery on the motor PCB. The backup battery is a lithium CR1220 3 V rechargeable battery. The backup battery powers the RTC (real-time clock), which is used to record time and date of events on the event log.

#### Testing the Alarm for the Backup Battery

To test the alarm for the backup battery, do as follows:

1. Switch on the pump and wait for the main menu to appear.
2. Remove the 9 V primary battery whilst the pump is on.  
The alarm beeps.
3. Verify that the alarm beeps for at least 3 minutes.

Since the battery is rechargeable, there is no requirement to replace it.

#### Checking the Backup Battery After Storage

When the pump is stored without a 9 V battery, the date and time can become inaccurate, due to a partial depletion of the backup battery. The partial depletion of the backup battery may cause the RTC to lag by several hours to days. There is no alarm or warning in case of time lag, as the pump will operate normally with no effect on infusion delivery.

To check the accuracy of the backup battery after storage, do as follows:

- Check time and date of the last entry in the event log on the **Info** menu (refer to sections *1.4. Pump Description* on page 7) or via the BD BodyComm™ Software Utility Tool.

If time and date are inaccurate, do as follows:

1. Insert a new 9 V battery (refer to *Directions For Use* for recommended battery brands and types).
2. Reset time and date (refer to section *3.4.2. Change Set Up Menu* on page 20 or use the BD BodyComm™ Software Utility Tool).
3. To keep the correct time and date, do as follows:
  - a. If the pump is used immediately, no action is needed. The backup battery will be charged by the 9 V battery during operation or infusion, and there is no risk of delay in infusion delivery.
  - b. If the pump is switched off after resetting time and date, keep the 9 V battery in the pump for 12 hours, to fully recharge the backup battery. If you cannot wait 12 hours before delivering new pumps to customers, ship the pump with the 9 V battery inside.

### 3.2.2. Battery Operation

The pump operates on battery power.

**i** NOTE: Only use 9 V alkaline, IEC 6LR61 type. 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 the 6LP3146 and 6LF22 batteries can include End Battery messages during Pre-Load, volume test fails, pressure test/calibration issues and reduced amount of infusions from a battery.

**i** NOTE: Verify that the battery is in good condition by pressing the  key during program setup or operation.  
Press the  key to display the battery status.

There are two battery alarm conditions:

- **Low Battery:** The pump warns that the battery is low before the End Battery alarm activates.

**Low Battery**

- **End Battery:** When the battery is depleted, the pump ceases operation and the End Battery alarm is activated:
  - If the battery runs out, End Battery appears on the display. The pump stops the infusion. The pump may shut down immediately.
  - From the End Battery state, the user cannot restart the pump until the battery is replaced with a new one.

**End Battery**

## 3.3. Locking

The pump provides three types of locking:

- Keypad Locking
- Program Locking
- Maximum Rate Locking

### 3.3.1. Keypad Locking

If the keypad is locked, all keys are disabled except the **□**, **□**, and **⊕** keys.

This feature enables the operator to lock the keypad. This option is important, as locking prevents users from tampering with the pump parameters.

To lock the keypad, do as follows:

- Press and hold the **⊕** key until the keypad lock bar graph is filled and a beep is heard. The beep indicates that locking is turned ON.



To unlock the keypad, do as follows:

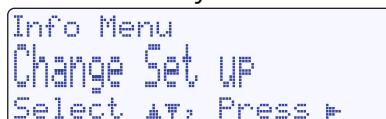
- Press and hold the **⊕** key until the keypad lock bar graph is depleted and a beep is heard. The beep indicates that locking is turned OFF. Some earlier software versions require code 99 to unlock the keypad.

### 3.3.2. Program Locking

This feature enables the operator to lock out the setting keys, so that entered parameters or set programs cannot be changed once they are set. This option is important, as locking the program prevents users from tampering with the pump parameters. This is especially important, for example, if there is the risk that a child may play with the pump and unknowingly change the program, or for home-care patients who need to repeat the same program daily.

To lock or unlock the program, do as follows:

1. Press the **⊕** key.
2. Use the arrow keys to scroll to **Change Setup**. Press **▷** to select this option.



3. The access code for **Change Setup** is **99**. Use the arrow keys to set this code. Press **▷** to enter.



4. Use the arrow keys to scroll to **Program Lock**. Press **►** to select this option.



- To lock the program: The default setting is OFF. Use the arrow keys to change the setting to ON.
- To unlock the program: If the program lock was ON, use the arrow keys to change it to OFF and unlock.



**i** NOTE: For program locking when the pump is set to **Volume over Rate**, press the **⊕** key whilst the program is in Setting mode or Stop mode, scroll to the **Rate** option and set the required rate to lock.

### 3.3.3. Maximum Rate Locking

This feature enables the operator to set a maximum infusion rate for the pump. The program rate can then be adjusted only up to the preset limit.

To set Maximum Rate Locking, do as follows:

1. Enter Technician menu, (refer to section 3.4.1. *Technician Menu* on page 18).
2. Use the arrow keys to scroll to **Maximum Rate**. Press the **►** key to select this option.



3. The pump displays the default maximum rate. Use the arrow keys to change the maximum rate setting. Press the **►** key to confirm and to exit. Press **□** to exit without saving changes in the rate setting.



## 3.4. Configuration and Calibration

The pump has adjustable operating parameters. These operating parameters and options may be viewed and adjusted to modify the operation of the pump. The operating parameters and options available are described in the following sections: 3.4.1. *Technician Menu* on page 18, 3.4.2. *Change Set Up Menu* on page 20, 3.3.2. *Program Locking* on page 17, and 3.3.1. *Keypad Locking* on page 17. If access to a specific mode of operation is required, refer to the pump *Directions For Use* for instructions.

### 3.4.1. Technician Menu

To access the Technician menu, do as follows:

1. Enter Technician mode by holding down the **⊕** key and then pressing the **⊖** key simultaneously until the software version is displayed. Then, release the **⊖** key. After several seconds, the access-code prompt displays. The display shows the software version for two seconds before the access-code prompt.
2. Using the arrow keys, set code **123** and confirm by pressing the **►** key. The pump displays all the parameters that can be set, calibrated or tested. The technician can scroll through all parameters using the arrow keys.

Table 3-1. Technician Menu Parameters

Menu Item	Parameter/Option	Description
1	Serial Number	Displays the serial number and production date.
2	Main Self-Test (follow display prompt)	Proceeds in sequence through the following tests: Keypad, Display, Acoustic Alarm, Back-up alarm, Mic level, LEDs test, Syringe Sensors, Diameter, Syringe Travel Test and Power Voltage.
3	Manual Tests	Same as Main Self-Test, but with a menu to focus the user on individual tests.

Menu Item	Parameter/Option	Description
4 Syringe Set Up		Enable/disable the default diameter for the list of approved syringes.
5 Pressure Calibration		Enables calibration and pressure settings.
6 Factory Press. Test		Fine-tunes pressure calibrations.
7 Pressure Test		Tests the actual pressure.
8 Syringe Travel		Calibrates syringe movement of approximately 68 mm.
9 Diameter Calibration		Tests the syringe barrel sensor.
10 Syringe dead space		Sets the actuator limitation for delivering the entire volume.
11 Volume Test		Performs a flow rate test.
12 Factory Settings		<b>Caution:</b> Pressing  restores factory defaults.
13 Operating Hours		Indicates the hours that have passed since the last service.
14 Service Interval		Sets the number of hours before a Send for Service message appears.
15 Access Codes		Sets access codes.
16 Purge Vol		Sets the maximum volume that a user can purge.
17 Maximum Rate		Sets the Rate Limit (0.1 ml/h - 650 ml/h).
18 Microphone Level		Sets microphone sensitivity.
19 Bolus enable/disable		Enables bolus.
20 Exit from Technician		Exits Technician mode.

## Enabling and Disabling a Predefined Syringe Type in the Pump Menu

To enable/disable a predefined syringe type, do as follows:

1. Enter Technician mode, as described above.
2. Use the arrow keys to scroll to **Syringe Setup**. Press to select this option.
3. The pump displays a syringe default size. Scroll up or down to the correct syringe size needed. Press to confirm.



4. Use the arrow keys to scroll through the list of brands to the required syringe brand. Press to confirm.



- **Enabling:** If the syringe has been disabled, **Syringe Disabled—Refer to Ops Manual** appears.



To re-enable this syringe, press the key and then the key to confirm at the **Enable this syringe?**



The display then shows a summary of the manufacturer's data for that syringe. Press the key to confirm and exit Syringe Setup.

- **Disabling:** To disable the selected syringe, from the screen in which the summary of the manufacturer's data for the syringe is displayed, press the key. When prompted to disable the syringe, press the key.



The Syringe Disabled screen displays.



- Press the key to exit Syringe Setup.

### 3.4.2. Change Set Up Menu

To change setup options, do as follows:

- Press the key to turn on the pump. Press the key twice.
- Use the arrow keys to scroll to **Change Set up**. Press to select this option.



- The access code for **Change Set up** is **99**. Use the arrow keys to set this code. Press to enter.



- Use the arrow keys to scroll through the setup options. Refer to *Table 3-2. Change Setup Options* on page 20 and change where necessary.



Table 3-2. Change Setup Options

Change Setup Option	Functional Description	Range
Exit	Select to exit the <b>Change Set up</b> menu.	
Language	Changes language.	
Set Time & Date	Enables you to adjust the date and time to ensure that all logged events are stamped with the correct date and time.	
Key Operation	Defines the actuator's forward movement distance when the  key is pressed during syringe loading.	0.1 mm–100 mm
Backlight Duration	Defines the duration that the backlight is illuminated to help preserve battery life.	0–60 seconds
Info Duration	Defines the duration that the Info screen displays.	1–20 seconds
Bolus Dose Rate	Enables to set the bolusing dose rate. NOTE: This setting is available only if bolus delivery is enabled on Technician menu.	1–650 ml/h
Bolus Maximum Volume	Enables you to set the bolus maximum volume value. Setting zero (0) disables bolus administration. NOTE: This setting is available only if bolus delivery is enabled on Technician menu.	0–20 ml
Titration Option	Enables/disables titration functionality.	Enabled/Disabled
Default Duration	Defines the program's default duration. If you set zero (0), the pump skips the duration step during programming. When the Program Lock is ON (see below), the default duration cannot be set to zero.	0:00–99:00
Occlusion Pressure	Enables you to set the pressure at which the occlusion alarm is activated.	200 mmHg–1,500 mmHg

Change Setup Option	Functional Description	Range
Program Lock	Enables you to set a lock on the program to prevent tampering with either the program duration or rate during setup (when Program Lock is ON, the Default Duration cannot be set to zero).	ON/OFF

### Info Mode During Operation

- Pressing the  key during operation displays the total Volume To Be Infused and the Infused Volume. The screen displays for seven seconds.



- Pressing the  key twice during operation displays the battery status. The screen displays for seven seconds.



 NOTE: To exit Info mode, press the  key or wait 10 seconds.

### 3.4.3. Occlusion Pressure Calibration

Occlusion Pressure Calibration includes the following steps:

- Setting the tool
- Pressure Test

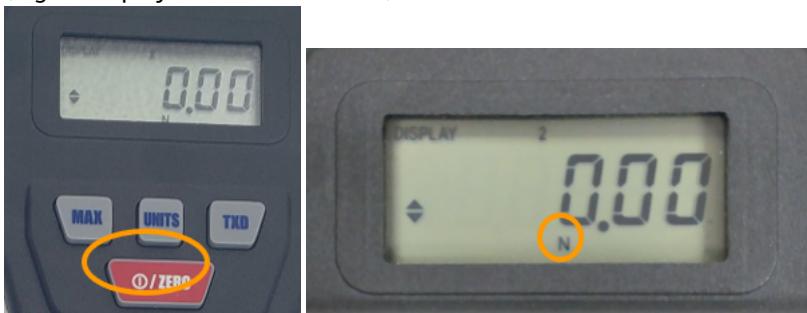
If calibration fails, you have to recalibrate the pump (See *Recalibration* on page 26)

#### Setting the Tool

- From the Change Set up menu, set the Occlusion Pressure setting to 540 mmHg.
- Remove force gauge from the case.



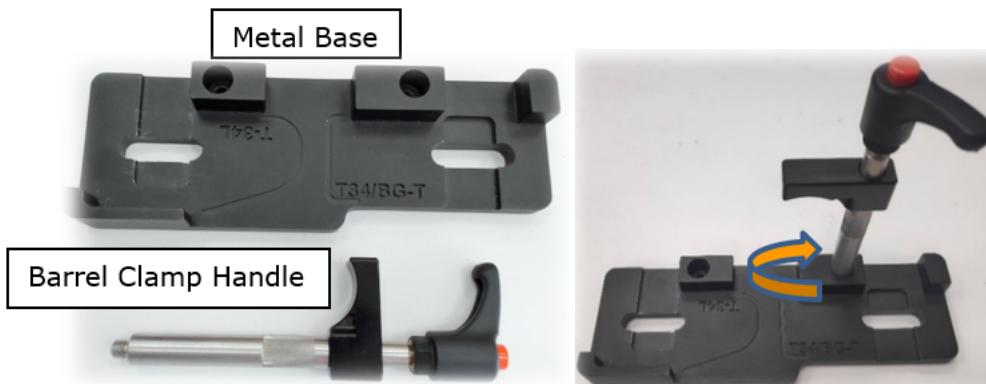
- Press the red power/zero button to turn on the force gauge. The default units should be 'N' Newtons (If not, change measurement value to Newtons by pressing UNITS button). Confirm the plunger is fully extended (digital display should read 0.00 N).



4. Make sure actuator is located properly allowing for gauge to be fully extended (digital display should remain 0.00 N) before fixing on the pump.



5. Attach and screw the detachable barrel clamp handle onto the metal base, as shown in image below.



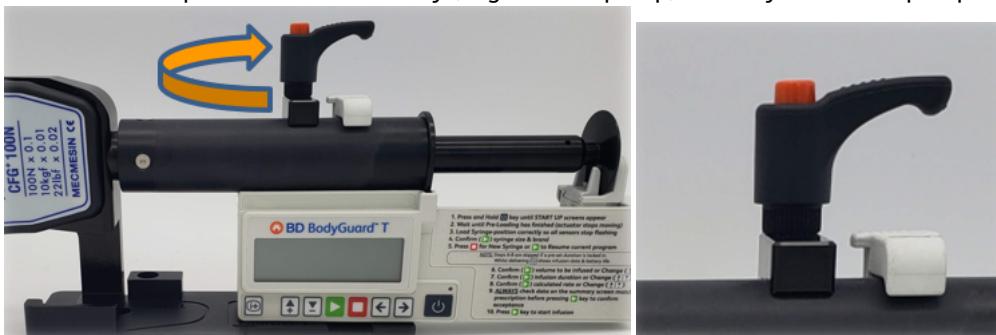
6. Fix the pump and tool onto the base and slowly tighten the clamp handle by rotating clockwise.



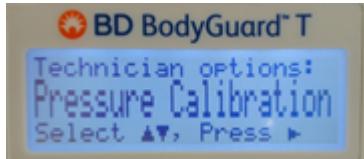
7. Make sure the pump is pushed to the right and there is no space on the left side of the collar slot. Fixing tool to the left will ensure it will stay in place when excessive force is applied during calibration.



8. Rotate the clamp handle clockwise fully (aligned with pump) to firmly secure the pump onto the base.



9. Access the Technician Menu on the pump and select Pressure Calibration.



10. Press the ► key to confirm and the following display appears:



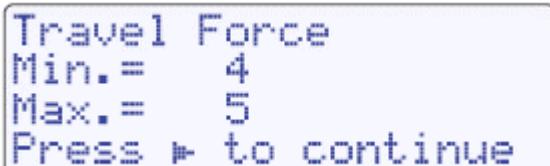
11. Use the ← and → keys to align to set the plunger to 1.4-1.6 N. Press the ► key to confirm.



12. After several seconds, the display summarizes the results.

Max. Travel Force value results:  $2 \leq \text{Max.} \leq 15$ .

Delta between Min. and Max.:  $\Delta = \text{Max.} - \text{Min.} \leq 5$



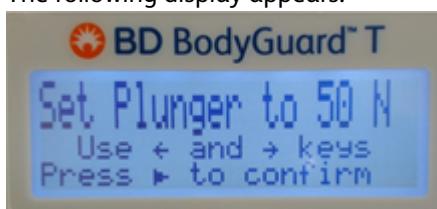
13. Press the ► key. The display shows the Travel Force. Record this initial result as  $A_0^*$ .

Initial Results	Pass Criteria
$A_0 =$	$2 \leq A \leq 15$



14. Do not change the setting and press the ► key.

The following display appears:



15. Use the  $\leftarrow$  and  $\rightarrow$  keys for setting plunger to show force gauge reading of 48-50 N. Press the  $\square$  key to confirm.



16. Pressure Sensitive value should be between 35-100. Record this initial result as  $B_0$ .

Initial Results	Pass Criteria
$B_0 =$	$35 \leq B \leq 100$

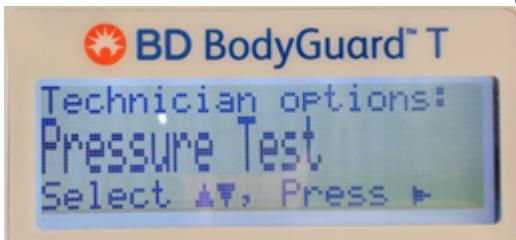


Do not change the setting and press the  $\square$  key.

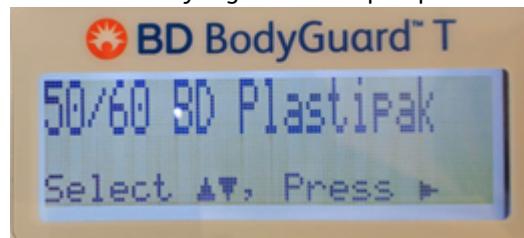
17. Proceed to Pressure Test.

### Pressure Test

1. In Technician Menu select **Pressure Test** and press the  $\square$  key to confirm.



2. Perform 50 ml Syringe Test. The pump identifies the gauge as 50/60 ml syringe.



3. Use the  $\leftarrow$  and  $\rightarrow$  keys for setting plunger to show gauge reading of 30-35 N. Press the  $\square$  key to confirm.



4. The display shows the mmHg values gradually increasing as the tool's plunger is slowly compressed. The test stops with a short beep and red LED lighting.

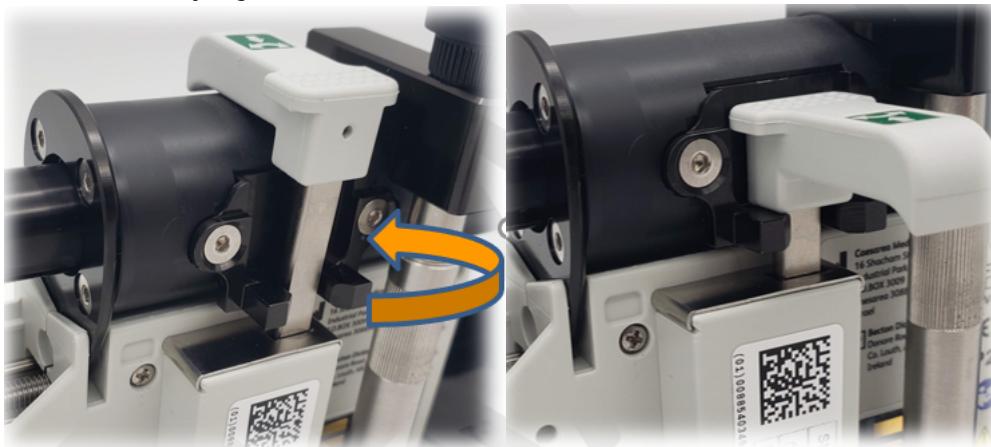


5. Force gauge reading pass criteria is 50-56 N. Record this result as  $C_0^*$ .

Initial Result	Pass Criteria	Pressure Test #1	Pressure Test #2	Pressure Test #3	Pressure Test #4
$C_0 =$	$50 \text{ N} \leq C \leq 56 \text{ N}$	$C_1 =$	$C_2 =$	$C_3 =$	$C_4 =$

\*Additional results after the initial result should be recorded accordingly as  $C_1, C_2, C_3$  and  $C_4$ .

6. Perform 5ml Syringe Test. Lift the pump barrel clamp, rotate 180 degrees, and release it on the rear fixture to simulate a 5 ml syringe.



7. The pump diameter mechanism identifies this new height as a 5 ml syringe.



8. Use the and keys for setting plunger to show force gauge reading of 4-5 N.



9. The display shows the mmHg values gradually increase as the tool's plunger is slowly compressed. The test stops with a short beep and red LED lighting.



10. Force gauge reading pass criteria is 10-12.5 N. Record this result as  $D_0^*$ .

Initial Results	Pass Criteria	Pressure Test #1	Pressure Test #2	Pressure Test #3	Pressure Test #4
$D_0 =$	$10\text{N} \leq D \leq 12.5\text{N}$	$D_1 =$	$D_2 =$	$D_3 =$	$D_4 =$

\*Additional results should be recorded accordingly as  $D_1, D_2, D_3$  and  $D_4$ .

If both C and D have passed the criteria (within tolerance), the pump is calibrated.

If either C or D (or both) are out of tolerance specification (on this attempt) proceed to *Recalibration* on page 26.

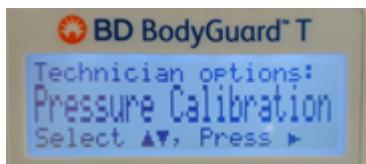
11. Press the key to return to Technician Menu.

12. Use table below to summarize values as required for each recalibration value:

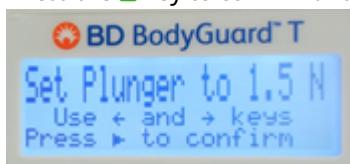
Initial Results	Pass Criteria	Recalibration + Pressure Test #1	Recalibration + Pressure Test #2	Recalibration + Pressure Test #3	Recalibration + Pressure Test #4
$A_0 =$	$2 \leq A \leq 15$	$A_1 =$	$A_2 =$	$A_3 =$	$A_4 =$
$B_0 =$	$35 \leq B \leq 100$	$B_1 =$	$B_2 =$	$B_3 =$	$B_4 =$
$C_0 =$	$50 \text{ N} \leq C \leq 56 \text{ N}$	$C_1 =$	$C_2 =$	$C_3 =$	$C_4 =$
$D_0 =$	$10 \text{ N} \leq D \leq 12.5 \text{ N}$	$D_1 =$	$D_2 =$	$D_3 =$	$D_4 =$

## Recalibration

1. In Technician Menu select **Pressure Calibration**.



Press the **▶** key to confirm and the following display appears:

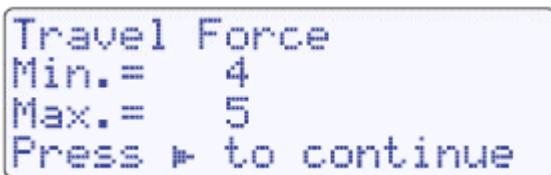


2. Use the **◀** and **▶** keys to align to set the plunger to 1.4-2 N.



Press the **▶** key to confirm.

3. After several seconds the display summarizes the results.



4. The new A value ( $A_1^*$ ) will be calculated based on C and D results (in Newtons)  
Record  $A_1^*$  in table below in one of the three columns (i, ii, or iii).

Recalibration	Pass Criteria	i. $C \leq 56$ and $D \leq 12.5$	ii. $C \leq 56$ and $D > 12.5$	iii. $C > 56$
Attempt #1	$2 \leq A \leq 15$	$A_1 = A_0 =$ _____	$A_1 = A_0 - 1 =$ _____	$A_1 = A_0 =$ _____
Attempt #2	$2 \leq A \leq 15$	$A_2 = A_1 =$ _____	$A_2 = A_1 - 1 =$ _____	$A_2 = A_1 =$ _____
Attempt #3	$2 \leq A \leq 15$	$A_3 = A_2 =$ _____	$A_3 = A_2 - 1 =$ _____	$A_3 = A_2 =$ _____
Attempt #4	$2 \leq A \leq 15$	$A_4 = A_3 =$ _____	$A_4 = A_3 - 1 =$ _____	$A_4 = A_3 =$ _____

\*Additional results should be recorded accordingly as  $A_1$ ,  $A_2$ ,  $A_3$  and  $A_4$ .

5. Use the and arrow keys to set new A (Travel Force) value to the pump.



Press the key to confirm.

6. Use the and keys for setting plunger to show force gauge reading of 48-50 N.



7. Press the key to confirm.

Pressure Sensitive value should appear after several seconds.



8. The new B value ( $B_1^*$ ) will be calculated based on C and D results (in Newtons).

Record  $B_1^*$  in table below in one of the three columns (i, ii or iii).

Recalibration	Pass Criteria	i. $C \leq 56$ and $D \leq 12.5$	ii. $C \leq 56$ and $D > 12.5$	iii. $C > 56$
Attempt #1	$35 \leq B \leq 100$	$B_1 = 54 - C_0 + B_0 = \underline{\hspace{2cm}}$	$B_1 = B_0 + 4 = \underline{\hspace{2cm}}$	$B_1 = B_0 - 2 = \underline{\hspace{2cm}}$
Attempt #2	$35 \leq B \leq 100$	$B_2 = B_1 + 4 = \underline{\hspace{2cm}}$	$B_2 = B_1 + 4 = \underline{\hspace{2cm}}$	$B_2 = B_1 - 2 = \underline{\hspace{2cm}}$
Attempt #3	$35 \leq B \leq 100$	$B_3 = B_2 + 4 = \underline{\hspace{2cm}}$	$B_3 = B_2 + 4 = \underline{\hspace{2cm}}$	$B_3 = B_2 - 2 = \underline{\hspace{2cm}}$
Attempt #4	$35 \leq B \leq 100$	$B_4 = B_3 + 4 = \underline{\hspace{2cm}}$	$B_4 = B_3 + 4 = \underline{\hspace{2cm}}$	$B_4 = B_3 - 2 = \underline{\hspace{2cm}}$

\*Additional results should be recorded accordingly as  $B_1$ ,  $B_2$ ,  $B_3$  and  $B_4$ .

9. Use the and arrow keys to input new B value to the pump.



Press the key to confirm.

10. After completing recalibration, perform Pressure Test on page 24.

### 3.4.4. Syringe Travel Calibration

To perform Syringe Travel calibration (use battery with metal casing), do as follows:

1. Switch on pump and move actuator so that it is located halfway between both ends. Switch off pump.
2. Enter Technician mode (refer to section 3.4.1. *Technician Menu* on page 18).
3. Use the arrow keys to scroll to **Syringe Travel**. Press **►** to select this option.
4. Follow the prompt and press the **◀** key. If a syringe is loaded, you are prompted to remove it first.

Press **◀** key

The actuator moves forward and the display screen displays **Locating min. travel**.

Locating min. travel

5. When the actuator reaches the end, the display screen changes to **Confirm min. travel**.

Confirm min. travel  
Press **►** to continue

Check that the actuator is touching the housing, then press the **►** key.

6. Follow the prompt and press the **►** key.

Press **►** key

The actuator moves backward and the display screen displays **Locating max. travel**.

Locating max. travel

7. Wait until the actuator reaches the other end completely and the display screen changes to **Confirm max. travel**.

Confirm max. travel  
Press **►** to continue

Press the **►** key.

8. At the prompt, press the **◀** key and after the actuator reaches the front once again, confirm the **min. travel** to continue.

Confirm min. travel  
Press **►** to continue

9. The travel information at the end, which is applicable to the specific pump, serves as a confirmation that the syringe travel calibration completed successfully. The travel result should be between 66 mm to 68 mm.

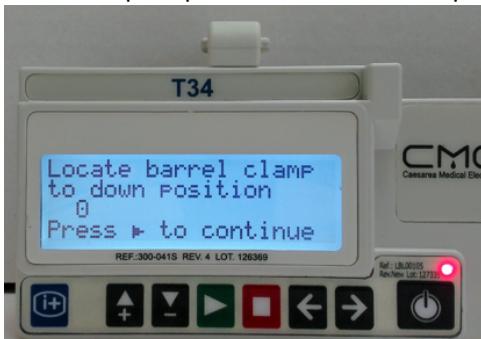
Travel 67.8mm  
Press **►** to continue

Press the **►** key to exit the procedure.

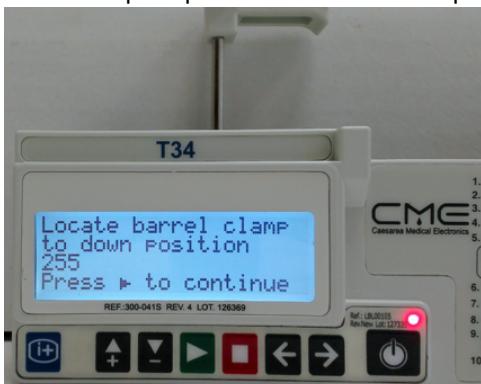
### 3.4.5. Syringe Diameter Calibration

To perform Syringe Diameter calibration, do as follows:

1. Enter Technician mode (refer to section 3.4.1. *Technician Menu* on page 18).
2. Use the arrow keys to scroll to **Diameter Calibration**. Press ▶ to select this option.
3. Follow the prompt to set the barrel clamp to the down position (between 0 and 1). Press □ to confirm.



4. Follow the prompt to set the barrel clamp to the upper position (between 254 and 255). Press □ to confirm.



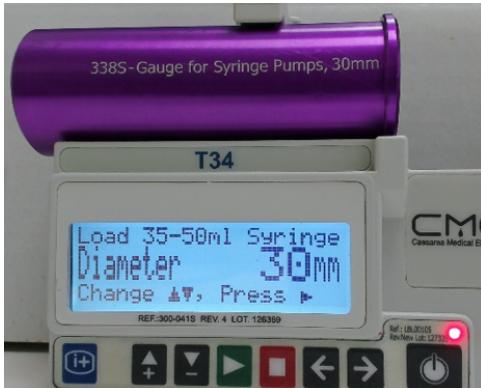
5. At the prompt, load a diameter gauge P/N 336S (8 mm). Verify that detection is correct. Press □ to confirm, or use the arrow keys to change to the correct syringe diameter and then confirm.



6. At the prompt, load a diameter gauge P/N 334S (19 mm). Verify that detection is correct ( $19\text{ mm}\pm0.2\text{ mm}$ ). Press □ to confirm, or use the arrow keys to change to the correct syringe diameter and then confirm.



7. At the prompt, load a diameter gauge P/N 338S (30 mm). Verify that detection is correct. Press  to confirm, or use the arrow keys to change to the correct syringe diameter and then confirm.



8. Test each of the diameter gauges, meaning that all the gauges' dimensions are detected correctly, with the following tolerances: 30 mm, 19 mm ( $\pm 0.2$  mm), 8 mm. If gauges are not detected correctly, press the  key to repeat the procedure.



9. Press the  key to exit the procedure.



NOTE: The pump applies dimensions automatically for all other brands and sizes.

## 3.5. Communication - Between PC and Syringe Pump

- To upgrade the software, refer to the PumpMaster Software Utility Tool (for more information, refer to *Technical Bulletin TB08832* ).
- To program the pump, refer to latest BD BodyComm™ Software Utility Tool *Directions For Use* (software version 3.x, latest available revision). Please note that older BD BodyComm™ Software Utility Tool versions are not fully compatible with 3rd edition pumps. Refer to *Table 3-3. BD BodyComm™ Software Utility Tool Compatibility Table*.

Table 3-3. BD BodyComm™ Software Utility Tool Compatibility Table

Pump Version	BD BodyComm™ Software Compatibility	
	Utility Tool Version	
2 <sup>nd</sup> edition	88-102 V3.x (latest release)	Compatible and supported. Not compatible. Information Message "The connected device is not supported in this version of BodyComm."
3 <sup>rd</sup> edition	88-102 V3.2 (latest release)	Not compatible/not intended for support. Compatible and supported.

## 3.6. Event Log

Refer to latest BD BodyComm™ Software Utility Tool *Directions For Use* (software version 3.x, latest available revision).

# 4. Preventative Maintenance

## 4.1. Introduction

This chapter describes preventive maintenance, which should be performed on the pump. The maintenance procedures outlined in this chapter may be performed in the hospital or homecare company, by qualified and certified biomedical engineers. If an abnormal condition occurs that is not corrected by performing the following procedures, remove the device from service and troubleshoot in accordance with the troubleshooting table (refer to *Table 5-1. Troubleshooting* on page 39), or return to the manufacturer or service center for service.

Review this section whenever a condition exists that does not appear to be normal. Perform the specified checks and corrections.

## 4.2. Recommended Cleaning and Storage

### 4.2.1. Cleaning

Start any schedule and unscheduled maintenance by applying the Manufacturer Recommended Cleaning (MRC) protocol. To clean the pump, wipe the external pump surface by exclusively using disposable wipes impregnated with isopropyl alcohol (IPA) 70%, to minimize pump exposure to excessive quantities of liquids. Isopropyl alcohol is volatile and leaves no residue upon evaporation, therefore surfaces are left dry quickly after wiping.

The intent of the MRC protocol is to remove particles and chemical residue that could accumulate over time on pump surface resulting from normal use and from the “disinfection protocol/regime” developed by users at point of use. It is highly recommended to apply on pump the MRC protocol on a regular basis and after each disinfection sequence as a preventive measure to maintain pump performance. It is also recommended to clean the pump using the MRC protocol between patient use and when the pump is visibly soiled.



Note: For complete cleaning instructions relating to clinical environments, refer to *Directions For Use*.



**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 in water.



**Warning:** Do not steam, autoclave, EtO sterilize, immerse the instrument or charger in any type of fluids, or allow fluids to enter the instrument case.



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



**Caution:** If other chemical cleaning agents are used for “disinfection protocol / regime”. Ensure to follow the Manufacturer recommended cleaning to preserve pump performance, post completion of 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.

### 4.2.2. 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 for protection. Perform functional tests using a fully charged battery once every 60 days (refer to section *4.5. Performance Verification and Calibration Tests* on page 32).

When the pump is stored without a 9 V battery, the date and time can become inaccurate (refer to section *3.2.1. Backup Battery* on page 16).

## 4.3. Routine Preventive Maintenance

Schedule: At least every 12 months, or as required:

- Clean pump housing with a suitable cleaning agent,(refer to section 4.2.1. *Cleaning* on page 31).
- Check housing for damage and replace any labels that are damaged.
- Perform all tests, including the Functional Test Procedures (refer to 4.5. *Performance Verification and Calibration Tests* on page 32).

## 4.4. Tools and Test Equipment

The following tools and test equipment are required to perform the procedures described in this chapter. Since all fasteners on the device are metric, ensure that all tools used are for metric fasteners:

- Multimeter
- 3 mm Phillips screwdriver
- Pressure meter with tubing and a three-way tap
- Anti-static mat/anti-static work surface
- Small utility knife
- Flat 3 mm screwdriver
- Allen angled wrench/spanner, 1.5 mm 4 mm open wrench/spanner
- Anti-static tweezers
- Metric feeler gauge (for 0.05–1.00 mm)\*
- Thread-locking glue (for example, omniFIT M50)
- Silicone (engineering adhesive sealant)
- Soldering iron\*
- Solder wire, rosin core, 0.6 mm
- Small-diameter test gauge (8 mm) – P/N: 336S
- Medium-diameter test gauge (19 mm) – P/N: 334S
- Large-diameter test gauge (30 mm) – P/N: 338S
- Cutting pliers\*
- Needle-nose pliers\*
- 1.5 mm ball-point Allen wrench/spanner\*

\* optional - not mandatory

## 4.5. Performance Verification and Calibration Tests

### 4.5.1. Introduction

The Performance Verification Procedure (PVP) described in this section determines whether the device is operating correctly. The PVP should be carried out before any service work is performed. If the device fails any test in the checklist, the fault must be recorded and corrected prior to placing the device back into clinical use. Any test failures should be analysed using the troubleshooting procedure that follows to determine service action. After all service is completed, the PVP should be repeated and the device should be re-calibrated, if required. For more details about the PVP refer to section *Appendix B. Performance Verification Procedure (PVP)* on page 71.

If a complaint is associated with the returned device, the device should be tested with any associated products (for example, sets and so on). Devices subject to complaint evaluation should be tested to try to replicate the customer's complaint. After the complaint evaluation with the associated product has been completed, the device should be retested without the associated product in the normal service process.

If the problem cannot be resolved, withdraw the pump from user service and troubleshoot it according to the troubleshooting table (refer to *Table 5-1. Troubleshooting* on page 39), or return the device to the manufacturer for service.

Once a problem has been identified and isolated to a single assembly, the assembly should be replaced in accordance with the disassembly procedures provided in this manual.

The following test equipment is required to perform the tests in the PVP:

- Force gauge (Kit P/N: 900-000 – includes all three syringe force gauges)
- Calibrated stop watch

- Connecting flat cable between the front and rear housing (optional)

## 4.5.2. Preservice Checklist

Before performing any service procedure:

### Authorised Service Personnel

You must have training and certification from either the manufacturer or manufacturer- authorised service center and have the recommended equipment and authorised spare parts on hand to perform the required maintenance procedures or repairs.

### Disinfection/Decontamination

Disinfect the pump according to cleaning instructions, also described in the user manual. Elimination of fluid ingress effects is done either by cleaning with IPA wipes or component replacement where required (corrosion). Connection seals/gaskets (Kit P/N: 100-190SM) between front and rear cases must be replaced each time the pump is opened for maintenance intervention. When replacing seals/gaskets, always use new component and carefully assemble to avoid pinching/damaging seals as this could facilitate further fluid ingress effects.

### Confirm Customer Information

Confirm that a proper document record has been completed (log receipt, pump serial number and physical appearance). Note any damage or signs of tampering.

### Event Log

Check the history events to define the frequency and nature of the complaint, and record the program and calibration settings at the time of the event.

### Manual Review of Pump Calibration Settings by Running Basic Tests

1. Enter the Technician menu (refer to section 3.4.1. *Technician Menu* on page 18).
2. Press the  key to confirm.
3. Scroll to **Main Self-Test** and perform the test.
4. Record any failures or issues identified during the test.

## 4.5.3. Setting Up the Pump for Testing

Ensure that you have and are familiar with the pump *Directions For Use* before performing these tests. The procedures in this section are designed to check that the pump is infusing correctly before testing the effectiveness of the alarms. If the pump fails to perform as described or displays an error code, troubleshoot and repair before repeating the test. If an alarm occurs, the pump displays an error code. Press and hold the  key to reveal a description of the specific error.

To set up the pump for testing, do as follows:

1. Switch the pump on. Allow the preloading procedure to be completed. **Make sure that the syringe holder is set to the down position.**
2. Verify that all sensors (as depicted by the graphic on the display of the syringe holder, barrel ear and plunger ear) are blinking.



Figure 4-1. Checking the Sensors

3. Load a syringe and verify that the pump detects the syringe size and brand. The pump may detect a different brand, but never a different size (refer to the pump *Directions For Use*).
4. Select the correct brand and press the  key to confirm.
5. The pump displays the calculated volume. Verify visually that the volume detected is correct. The syringe tolerance should be  $\pm 5\%$  (refer to section *Volume Delivery Test* on page 35). If it is not, return to step 1.
6. Confirm or change the data for the time default that will affect the calculated rate on the next screen. The display shows the following prompt: **Start infusion.** Press  to start infusing.
7. Verify that the operation LED colour changes from red to flashing green.

## 4.5.4. Infusion Test

The following test checks that the pump does not exhibit alarms or errors during normal operation.

To perform an Infusion Test, do as follows:

1. Switch the pump on using the  key. Allow the preloading procedure to be completed. Completing the preloading procedure ensures correct detection of the volume in the syringe.
2. Load a syringe with 5.3 ml of water solution (refer to the pump *Directions For Use* for the list of default syringe brands configured for use with the pumps).
3. Verify that the pump detects the syringe correctly. To confirm the syringe type, press the  key or use the arrow keys to select another brand of the same size.
4. Verify that the volume displayed is identical,  $\pm 5\%$ , to the actual volume visually present in the syringe (out of the total volume of the syringe). If they correspond, press the  key to confirm.  
If the pump is configured to a time default greater than 24:00 hours, the pump displays the calculated rate (the volume in the syringe divided by the default time). If the calculated rate is above the maximum rate (the default is 5 ml/h), increase the maximum rate setting (refer to section 3.3.3. *Maximum Rate Locking* on page 18) or proceed to the next step.
5. Change the calculated rate to 25 ml/h and press the  key. Verify that the warning screen appears.
6. Press the  key to confirm the calculated/set rate.
7. Check the accumulated data on the summary screen and confirm.
8. Press the  key to start infusion.  
If the pump stops infusing and reports an alarm, refer to section 5. *Troubleshooting* on page 39. For the list of alarms and events during operation, refer to section 5.1. *List of Events and Alarms* on page 43.
9. To restart infusion, press the  key.  
When the pump has delivered the programmed volume, an audible alarm is activated, and the display shows **Program End**. To stop the alarm, press the .

## 4.5.5. Performance Verification Workflow

### Remove Program Lock

Remove the program lock to change the default duration so that the infusion rate available for these tests is any value up to the 5 ml/hr maximum rate set in the Technician menu.

To perform the following tests, disable the program lock:

1. Switch the pump on and allow Preloading to complete.
2. Press the  key, and then scroll down (using / arrow keys) to **Change Set up**. Enter code **99** by using the arrow keys. Press  to confirm the code.
3. Scroll up the menu to **Program Lock**. Press  to confirm selection.
4. Use either of the arrow keys to change the Program Lock status from ON (default) to OFF. Press  to confirm the change.
5. Scroll down to **Exit**. Press  to exit the **Change Set up** menu.

### Syringe Recognition and Volume Detection Test

Required equipment:

- T34™/ BD BodyGuard™ T Syringe Pump
- Selection of syringes used in the hospital, trust or homecare company

### Method

Switch the pump on and allow Preloading to complete. The position of the actuator is not important, except possibly for some smaller syringes where the actuator may have moved beyond the fully extended size of the syringe. Use the  key to move the actuator to the preferred position.  key movement is limited for safety reasons, so repeated presses may be necessary for correct positioning. See the **Change Set up** menu to adjust this feature, if necessary.

### For each of the syringes:

1. Lift the barrel clamp arm and place the syringe as described in the pump *Directions For Use*, making sure that the collar/flange and plunger are positioned correctly. Place and lower the barrel clamp arm down on top of the syringe barrel.

2. The LCD screen should display the Load Syringe message, and after a few seconds the correlating volume and brand of the syringe displays. If the Load Syringe message remains with parts of the syringe graphic flashing (or a specific message, such as Check Syringe Loaded Correctly), check that the corresponding syringe part is loaded correctly. Alternatively, follow the specific message (for example, Check Plunger Sensor) to ensure correct placement of the syringe.
3. The pump should display the correct size but may not always immediately give the correct brand. Use the arrow keys to scroll through the list of syringe brands (the pump shows those within  $\pm 3\%$  diameter of the one loaded). Select the correct syringe brand and press the  key to confirm selection. The pump may not display the correct size if a certain syringe of one brand is within  $\pm 0.5$  mm diameter of the diameter of a syringe by another brand.
4. Read the actual volume on the syringe and compare it with what the pump reads as the volume. These results should be within  $\pm 5\%$ . If the result does not fall within the expected range, proceed as follows:
  - Check that there is no slack in the system (visible space in the seating of the plunger or the collar/flange). In such cases, purging may be required before repeating the test (refer to the pump *Directions For Use*).
  - Re-check that the syringe loaded is the same as the brand confirmed in step 3.
 If the error remains outside of specification after performing step 4, the pump has failed this test and corrective action is required.
5. Remove the syringe, turn the pump off, place the arm down and repeat steps 1 to 4.

## Volume Delivery Test

Required equipment:

- 20 ml syringe filled with water for injection
- Stop watch

To perform a Volume Delivery Test, do as follows:

1. Prepare a 20 ml syringe filled with water all the way and attach an extension set.
2. Switch the pump on with the barrel clamp arm down and allow Preloading to complete.
3. Purge the system to ensure that all the slack is taken up, and ensure the syringe is filled to approximately 15.3 ml.
4. Position the actuator to fit the syringe at a little over 15 ml using the  or  keys. Visually check the plunger/seal location.
5. Lift the barrel clamp arm and load the syringe. Use the arrow scroll keys to select the correct brand from the list of brands (refer to the pump *Directions For Use* for more information). Press  to confirm selection.
6. Change the volume to be infused to 15 ml by using the arrow keys. Press  to confirm (make sure that Program Lock is switched OFF).
7. The pump displays the rate, but without the option to change it (in most software versions). All changes to the rate must be done by pressing  to reach the Duration screen and then changing the Duration (HH:mm). Confirm that the Rate is 100 ml/hr. Press  three times to start infusion:
  - The Near End Alarm sounds 15 minutes before the program ends.
  - The pump indicates End Program or an End Travel alarm when it finishes delivering the 15 ml.
8. Press  to confirm End Program, and make sure that 15 ml  $\pm 5\%$  fluid has been delivered.
9. Check that the time predicted to End Program (9 minutes) corresponds to the actual operation time measured with the stopwatch.



NOTE: Please make sure to return settings back to original (or default).

## Alarms Test

Table 4-1. Alarm Tests

Alarm	When Activated and Where Tested
Syringe Displaced	Test whilst the pump is infusing. Remove the syringe from the pump. The alarm is activated and a screen message describes the cause.
Occlusion/Syringe Empty	The pump sensed a pressure greater than the Occlusion Pressure level set in the pump. Possible causes: Occlusion or the actuator reached the end of travel/syringe empty.

<b>Alarm</b>	<b>When Activated and Where Tested</b>
Near End (program nearly complete)	This alarm is activated 15 minutes from the end of infusion.
End Program	The pre-set Volume to be Infused has been infused. Program completed.
Pump Paused Too Long	Test whilst the pump is displaying any setting screen. No key was pressed for two minutes.
Low Battery	This alarm is activated when the battery voltage drops to 7 V. Refer to section 3.2.2. <i>Battery Operation</i> on page 16 for the expected alarm display. <b>Note:</b> When using a power supply, the alarm takes several minutes to activate.
End Battery	This alarm is activated when the battery voltage drops to 6.8 V. Refer to section 3.2.2. <i>Battery Operation</i> on page 16 for the expected alarm display. <b>Note:</b> When using a power supply, the alarm takes several minutes to activate.

## Restore Program Lock

Restore the program lock after all the tests have been performed (if this is the preferred configuration of the device user).

To restore the program lock, do as follows:

1. Switch the pump on and allow Preloading to complete.
2. Press the key. Scroll down to **Change Setup** and enter code **99** by using the arrow keys. Press to confirm the code.
3. Scroll to **Program Lock**. Use the arrow key to change the setting from OFF to ON and press the key to confirm.
4. Scroll down to **Exit**. Press . The LCD displays the flashing syringe graphic.
5. Turn the pump off.

## 4.6. Visual Inspection

Visually inspect the exterior of the pump, checking the following:

- Labels should be replaced if not flat, legible or fully adhered.
- Check all labels for any sign of wear and replace as required.
- Housing and other components must be checked for damage and replaced if necessary.
- Check that the syringe barrel arm mechanism is working correctly by lifting and twisting it and then by lowering it to its default position.
- The housing should be clean and free from IV solution residue, especially near moving parts, connectors and inlets.
- Check for dried solution deposits on accessible areas of the screw drive mechanism. Evidence of fluid ingress effects include moisture, salt residue and trace of corrosion. This would require further examination by disassembling and opening the pump.
- Look for any white plastic debris along the lead screw. This may indicate continuous wear and tear to the actuator's plastic nut threading. In the most extreme cases constant grinding of the plastic nut may eventually prevent actuator from moving during infusion. Please replace preventively leadscrew and/or motor block assembly.

## 4.7. Service Decision Route

When a pump is returned for service, always request a full description of the reported error or the reason for removing the device from use, and if possible and appropriate, ask for the return of the syringe extension set in use at the time. Be mindful of the following factors as part of the service/repair procedure:

- Use the event log to determine the last events that affected service. For example, did the user operate the pump correctly? Cross reference the operator's report with the pump *Directions For Use* to ensure that the steps taken by the operator prior to the alarm did not cause or result in the alarm state or cause an error.
- Was the fault in one of the pump sensors? If so, identify which one and replace it.
- Was the fault in one of the circuit boards? If so, identify which PCB failed and replace the board).
- Using Technician mode, select either **Main Self-Test** to test all testable options or **Manual Test** to test a specific function.

Table 4-2. Possible Service Issues

Possible Issues	Corrective Action
1 User error	Refer issues back to the department lead and suggest training/alerting all users, in order to prevent the same error from repeating.
2 Fault with syringe or syringe extension set	Check that the correct syringe was used. Is the syringe on the list of approved syringes?
3 Pump failure	Perform the <b>Main Self-Test</b> from Technician menu.
4 Mechanical failure	Change the defective part.
5 Electronic failure	Change the relevant PCB.
6 Failure of sensors: Syringe detection, sensors 1–3	Replace the module.

## 4.8. Service Process Flow Chart

Figure 4-2 describes the process for servicing the pump.

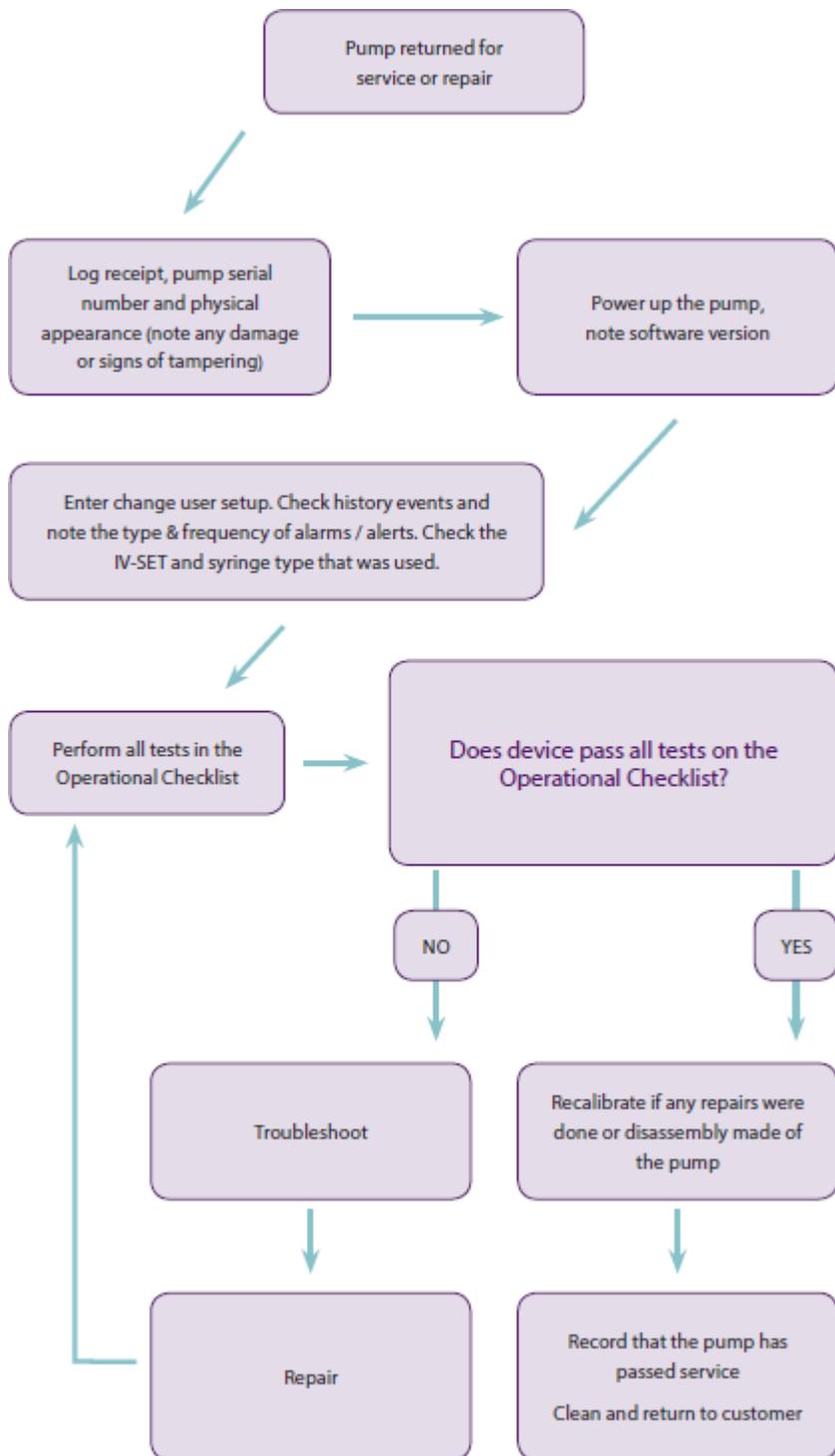


Figure 4-2. Service Process

# 5. Troubleshooting

In the event that a corrective action does not solve the problem, a Return Material Authorization (RMA) should be requested from the manufacturer.

Table 5-1. Troubleshooting

Problem	Possible Cause	Corrective Action
Different Volume Infused (VI) than expected.	Incorrect detection of syringe or incorrect setting of syringe data.	Check that the correct syringe was selected. Perform Syringe Travel Calibration (Technician menu). Check the <b>Hard Height</b> measurement in the Technician menu. Ensure preloading before rechecking.
Actual pressure differs from pressure detected.	Calibration is due.	Recalibrate pressure accuracy (refer to section 3.4.3. <i>Occlusion Pressure Calibration</i> on page 21).
Pump does not switch on.	Battery is missing. Battery depleted. Battery contacts on the rear PCB unsoldered.	Insert a battery in the battery compartment. Change battery. Re-solder battery contacts.
Power-up alarm.	Encoder plate not mounted properly. Encoder LEDs or phototransistors are damaged. Motor does not rotate. ON/OFF key malfunction.	Remount the encoder plate. Replace the encoder PCB. Replace the motor. Replace the main PCB.
Pump does not perform preloading.	Syringe holder is in the upper position. Syringe present in the pump.	Set the syringe holder to the down position. Remove the syringe.
The  and  keys do not function.	A syringe is loaded. Syringe holder is in the upper position. Syringe sensor malfunction.	Remove the syringe. Set the syringe holder to the down position. Replace the syringe sensor. Check the connection on the front pumping block. If it has no fault, replace the slide potentiometer.
Purge disabled.	The pump was switched on whilst a syringe was loaded.	Remove the syringe, and then switch the pump off and then on again.
Volume cannot be increased.	The pump does not allow increasing the volume above the volume in the syringe.	This is the intended functionality. No need to resolve.
Syringe holder sensor not sliding.	Syringe detection sensor malfunction.	Replace the syringe holder.
Operation LED does not flash.	Operation LED is not working during operation.	Check the setup to see whether the LED is enabled. If this is not the cause, change the main PCB.
Maximum basal rate limited.	The maximum rate setting was set to a lower value.	Change the maximum rate to a higher limit in the <b>Change Set up</b> options.
User cannot titrate rate during operation.	In the <b>Change Set up</b> options, the rate titration setting was disabled.  Program is in Lock state.	Enable titration in the <b>Change Set up</b> options.  Unlock the program.
Down occlusion.	Occlusion detection malfunction.	Recalibrate pressure accuracy (refer to section 3.4.3. <i>Occlusion Pressure Calibration</i> on page 21). If this does not resolve the issue, replace the main PCB. If this does not resolve the issue, change the entire pumping mechanism.

Problem	Possible Cause	Corrective Action
Hardware reset or reset by external pin.	External noise.	Turn the pump off and on again. If the problem persists, replace the main PCB.
	9 V battery low or depleted.	Replace the battery.
	Battery contacts are dirty.	Clean the battery contacts.
	Mechanical malfunction.	Check the motor and replace, if needed.
	Motor PCB malfunction.	Replace the motor PCB.
	Main PCB malfunction.	Replace the main PCB.
Setting-Test failed.	RAM corruption.	Turn the pump off and then on again using the same syringe. If the problem persists, send for service.
	Syringe data out of range.	Enter Technician mode and check the data for the current syringe.
	Data setting corrupted.	Restore data by performing a factory reset ( <b>Factory Settings</b> ).
	Device not calibrated after main PCB replacement.	Perform calibration of the Syringe Travel, Syringe Diameter and Pressure Calibration.
	Corruption of serial number, production date and dead space.	Enter these parameters and confirm.
Long Stop mode interval or reset by COP counter	Timer communication failure.	Turn the pump off and then on again. If the problem persists, replace the lithium battery.
		Check and replace the motor PCB.
		Replace the main PCB.
Startup motor failure.	Failure during switch-on test.	Restart the pump. If the problem persists, perform the two procedures below.
	Motor PCB malfunction.	Replace the motor PCB.
	Malfunction of main PCB.	Replace the main PCB.
Actual rate test fails or long revolution time error.	Mechanical malfunction or high friction of syringe.	Check the syringe. The pump is calibrated to operate with new syringes or replace the pumping assembly.
	End of travel, forcing against housing.	
	Check the revolution encoder to ensure the correct motor speed and infusion rate.	
Revolution encoder failure.	External noise	Turn the pump off and then on again. If the problem persists, perform the following:
	Magnet on motor adaptor is weak or disconnected.	Replace the contact screw (black) on the bottom of the front pumping block to m3 x 5 mm.
	Reed switch 1, 2 broken.	Replace the motor PCB.
Watchdog current.	Encoder plate is loose.	Tighten the encoder plate.
	Motor PCB malfunction.	Replace the motor PCB.
	Main PCB malfunction.	Replace the main PCB.
Watchdog time error.	Main PCB malfunction.	Replace the main PCB.
Shadow compare error.	RAM corruption.	Turn the pump off and then on again. If the problem persists, replace the main PCB.

Problem	Possible Cause	Corrective Action
Oscillator failure.	Lithium battery is discharged.	Turn the pump off and then on again. If the problem persists, check and replace the lithium battery.
	Water ingress.	Dry the device.
	Clogged/dirty PCB – pins connector.	Clean the pins of the connector between the main and motor PCBs.
	Motor PCB malfunction.	Replace the motor PCB.
	Main PCB malfunction.	Replace the main PCB.
Stack overflow.	Microprocessor malfunction.	Replace the main PCB.
UPD counter overflow or motor current overflow.	Mechanical malfunction.	Perform Syringe Travel calibration. Perform a Motor Test in the <b>Manual Test</b> menu.
		Replace the pumping block.
	Motor PCB or connection to main PCB.	Replace the motor PCB and clean the connectors.
	Encoder PCB malfunction.	Replace the encoder PCB.
	Encoder plate is loose.	Fasten the encoder plate.
ADC converter failure.	External interrupt or electronic malfunction (electrostatic discharge).	Turn the pump off and then on again. If the problem persists, replace the main PCB.
External light failure.	Encoder detects external light.	Make sure that the pump case is not broken and is closed with six screws.
	External noise.	Turn the pump off and then on again. If the problem persists, send for service.
	Malfunction of encoder PCB.	Replace the encoder PCB.
	Connecting cable between encoder and main PCB is damaged.	Check or replace the connecting cable.
	Main PCB malfunction.	Replace the main PCB.
Internal EEPROM failure.	Microprocessor malfunction.	Replace the main PCB.
	Memory malfunction.	Turn the pump off and on again. If the problem persists, do the following:  Perform a factory reset ( <b>Factory Settings</b> ) using Technician mode. If the problem persists, do the following:
		Perform reset calibration and calibrate the pump again. If the problem persists, do the following:  Burn software again (refer to section <i>6.3. Software Burning Instructions (without Using PumpMaster Software Utility Tool)</i> on page 44). Do not save previous calibrations. Calibrate the pump again. If the problem persists, do the following:  Replace the main PCB.
No motor steps for 20 minutes.	Main PCB malfunction.	Replace the main PCB.
No rotation detected.	Encoder malfunction.	Turn the pump off and on again.
	Motor malfunction.	Replace the block assembly.
		Replace the main PCB.
		If the problem persists, send for service.

Problem	Possible Cause	Corrective Action
Startup motor move failure	Lock at end travel.	From Technician mode, run Syringe Travel Test. Alternatively, move manually out of locking.
	Mechanical or motor malfunction.	Turn the pump off and then on again. If problem persists, replace pump mechanics.
	Motor PCB malfunction.	Replace the motor PCB and check the pins of the connector to the main PCB.
	Malfunction of main PCB.	Replace the main PCB.
	Encoder plates is loose.	Tighten the encoder plates.
Ends sensor failure.	Encoder or connecting flat cable malfunction.	Check and replace the encoder PCB and flat cable to the main PCB.
	Limit sensors malfunction.	Check or replace Reed switches, K1.
	Magnet on actuator is weak.	Replace the actuator magnet.
Current sensor failure.	Flat cable malfunction.	Check or replace the flat cable that connects the main PCB and encoder PCB.
	Motor PCB malfunction.	Replace the motor PCB.
	Main PCB malfunction.	Replace the main PCB.
Incorrect syringe detection.	Syringe diameter not calibrated.	Enter Technician mode and perform a Syringe Diameter Test. Recalibrate if necessary.
Incorrect Volume lengths.	Incorrect data entered in mm/ml.	Recalibrate the syringe, check the syringe data and update if necessary.
CPU test error.	Microprocessor malfunction.	Replace the main PCB.
Send for Service message appears	<b>Operating Hours</b> counter reached preset <b>Service Interval</b> value (hours and months)	Reset <b>Operating Hours</b> counter and set <b>Service Interval</b> for required time.
Timer communication failure.	External noise during communication.	Turn the pump off and then on again and set the pump to operate at a 0.1 ml/hr rate. If the problem persists, do the following:
	Timer battery – low.	Check the voltage on the lithium battery. If less than 3 V, replace the battery.
	Motor PCB malfunction.	Replace the motor PCB.
	Main PCB malfunction.	Replace the main PCB.
Timer's battery failure (or pump is experiencing time lag/delay of real-time clock).	When it is the first pump operation after service or pump was left without 9 V battery installed, causing the internal 3 V battery to deplete.	Turn the pump off and then on again and allow internal 3 V battery to charge. Make sure that date and time are correct.
	Lithium 3 V battery is damaged.	Replace the 3 V lithium battery.
"Incorrect Date/Time" message appears	The internal backup battery has been depleted and the date/time values have been reset.	Enter current date and time.
"Primary Sound Fail" message appears	The detected primary sound volume is below a required threshold during the pre-loading sequence (e.g. due to excessive background noise).	Turn the pump off and on again. Ensure that there is no external noise or disturbance in the room, while switching on again.
External E-EPROM failure.	External noise during communication.	Turn the pump off and then on again and set the pump to operate at a 0.1 ml/hr rate. If the problem persists, do the following:
	Motor PCB malfunction.	Replace the motor PCB.
	Main PCB malfunction.	Replace the main PCB.

**i** NOTE: In order to prevent the possibility of the pump not discerning between syringes, we recommend using only approved brands. Avoid using brands with similar external diameters, meaning those that have a difference of less than 0.5mm. The medical staff of the specific site must decide on one of the syringe types. Use only Luer Lock syringes. Luer tips are not approved for use with the pump.

## 5.1. List of Events and Alarms

The event log messages are of two types: operation events and alarms.

Table 5-2. Event Log Messages

Alarms	
Timer communication failure	Revolution encoder failure
External EEPROM failure	No motor steps – 20 minutes
Timer battery failure	Motor voltage overflow
Internal EEPROM failure	Long revolution time
Hardware reset	Short revolution time
Setting test failure	Over revolution, in minutes
Startup motor stop failure	Less revolution, in minutes
Watchdog current	No rotation detected
Watchdog time error	Actual Rate test error
CPU test error	Startup motor move failure
Shadow compare error	Ends sensors failure
ADC converter failure	Current sensor failure
Oscillators failure	Syringe type diameter
STACK overflow	Incorrect volume length
UPD counter overflow	Long stop mode interval (int.)
External light failure	Reset by COP counter
Operation Events	
Event number	Actual pressure
Date and time	Battery voltage
Switch on	Rate titration
Info: Volume infused	Stop
Volume to be infused	Low battery
Rate	Pump unattended
Type of syringe	Down occlusion
Length, in ml/mm	End travel
Pressure settings	Syringe displaced

## 5.2. Failure Identification

Specific errors, which may occur in the operation of the pump and the remedy of each problem, are presented in the troubleshooting section (refer to section 5. Troubleshooting on page 39).

Using INFO mode, technicians can display the pump's history to help identify the cause of failure and its nature. Use the arrow keys to scroll through the last 512 events in the event log. The events are displayed from the most recent to the oldest. Press the  key to display the full details of all data relevant to the displayed event.

**i** NOTE: It is recommended to view pump history on the PC via BD BodyComm™ Software Utility Tool V3.x.

# 6. Corrective Maintenance

## 6.1. Introduction

This section of the service manual contains procedures required to properly disassemble, repair and replace parts and then to reassemble the pumps. After all spare part replacement and repair action, testing must be performed in accordance with the Performance Verification Procedure (PVP) after completing any of the procedures in this chapter. Disassembly of the pumps is limited to complete subassemblies and mechanical components. It is recommended that electrical problems be corrected by replacing the entire PCB. Use only the replacement parts supplied by the manufacturer or an authorised distributor. Read **all** steps in a procedure before undertaking the work. The procedures are given in the order of disassembly and then reassembly. Disassemble the device only as far as required to complete service. All fastening components (such as screws, washers and nuts) used in the device are metric. Be sure to use metric tools and replace only with metric components.

 The components inside the device are sensitive to electrostatic discharge (ESD). Always wear a grounded wrist strap and use a protective ESD mat when performing service on the device to prevent damage to components.

## 6.2. Access Code List

The pump has three access codes and a Key Lock feature to prevent tampering with settings and to restrict user access to authorised personnel only. Service technicians must be familiar with these codes in order to access all areas of the pump for servicing and repairs.

- |                 |   |
|-----------------|---|
| Code <b>99</b>  | Accesses the pump's <b>Change Setup</b> options; enables program parameters to be locked.   |
| Code <b>123</b> | Enables authorised technicians to access the Technician testing and service menu.   |
| Code <b>5</b>   | Enables authorised personnel to change the Rate Setting via the <b>Info</b> menu.   |
| Key Lock        | Enables users to lock all keys except the  key, the  key, and the  key, in order to prevent tampering with the pump. |

 NOTE: The above-mentioned codes are default numbers, and can be changed via Technician mode, under **Access Codes**, whenever required.

 NOTE: Any changes to the default access codes must be properly recorded and stored to avoid delays in therapy. To revert back to the default access codes, select the **Factory Settings** option in the Technician menu.

## 6.3. Software Burning Instructions (without Using PumpMaster Software Utility Tool)

The following technician instructions are provided for burning/flashing the pump's software whenever necessary, or when you need to burn software on a newly installed main PCB. This procedure applies to all syringe pumps that include MC68HC908AZ60A microprocessors. This procedure is not relating to the PumpMaster Software Utility Tool, which does not require to open the pump to update the software.

 **Caution:** Never burn a different software version on a pump before you receive a software upgrade license from the manufacturer for the appropriate device serial number. Upon upgrading the software, the manufacturer should be promptly notified of the new software version and the device serial number.

 NOTE: Burning new software requires recalibrating the pump unless otherwise stated in writing by the manufacturer or its authorised service center.

### 6.3.1. Equipment

- Burning Station Kit P/N 100-405PX (includes cables):
  - Burning Station Cable
- Pump DC power supply (included in the 100-405PX kit), or 9 V battery
- DB9 Male-Female RS-232 cable
- Computer with original or extended serial port

**i** NOTE: The program does not run with a USB-to-serial adapter.

- PC with PROG08SZ – Flash Programmer installed. The PROG08SZ – Flash Programmer is a product of P&E Microcomputer systems and can be purchased from their website: [www.pemicro.com](http://www.pemicro.com). For more information, contact CME/BD at [GMB-INTL-TechnicalSupportInfusion@bd.com](mailto:GMB-INTL-TechnicalSupportInfusion@bd.com).

### 6.3.2. Burning Station Connections

**Connector RS 232:** Connects the burning station to the computer.



Figure 6-1. RS-232 Burning Station Connector



Figure 6-2. RS-232 Connector Connected to Burning Station

**DC:** For connecting the DC power supply cable to the burning station.

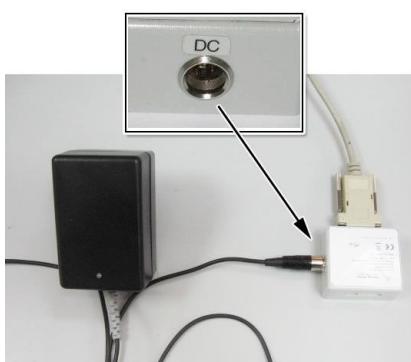


Figure 6-3. DC Cable with Wall Charger Connected to Burning Station

**Connection 1 (Burning Station Cable):** Connects the syringe pump to the burning station:

1. Connect the connector 5P to the burning station.

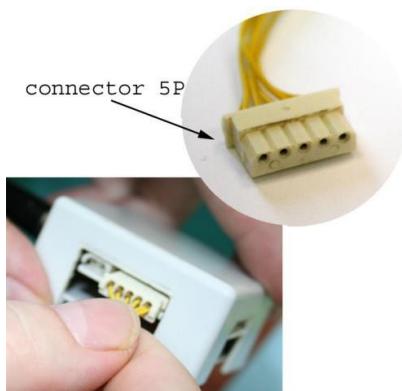


Figure 6-4. Burning Station Cable 5P Connector Connected to Burning Station

2. Connect the other two connectors as follows: The connector with two wires connects to J3 on the PCB and the connector with four wires connects to J4 on the PCB.

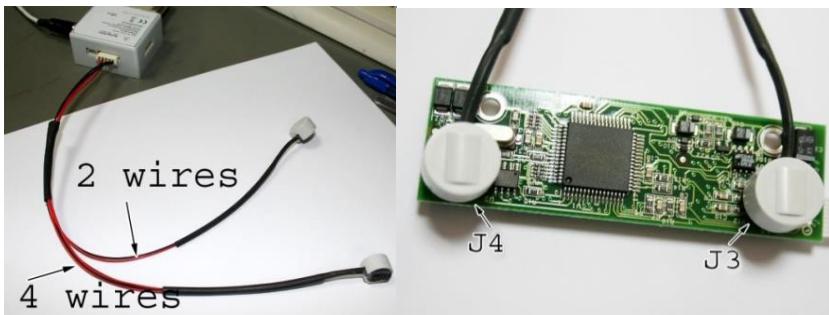


Figure 6-5. Burning Station Cable Connected to PCB

See Figure 6-6 for the full connections of the burning station to the main PCB of the pump.

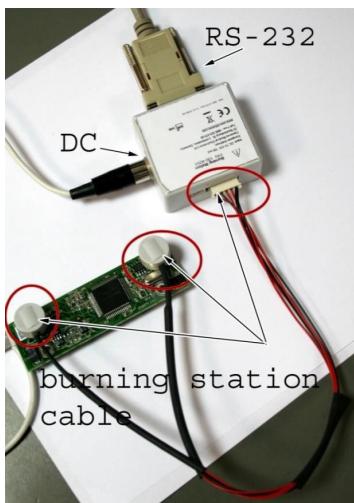


Figure 6-6. Main PCB Connected to Burning Station

### 6.3.3. Procedure

This procedure describes the software burning instructions for the pump without saving the settings, calibration data, serial number, and production date.

- i** NOTE: Burning new software requires recalibrating the pump unless otherwise stated in writing by the manufacturer or its authorised service center.

To burn software for a CME infusion pump, do as follows:

1. Connect the burning station to the computer's serial port.
2. Open the pump, as described in section 6.4. *Disassembly* on page 51, remove the motor PCB, as described in section C – *Replacement of PCBs – Motor and Main* on page 57, and connect the main PCB to the burning station, as shown in the section 6.3.2. *Burning Station Connections* on page 45.
3. Connect the DC power supply to the burning station.

- i** NOTE: Make sure that all the connections are secure.

4. Start the PROG08SZ flash programmer. For example, if installed in the Windows programs folder, click **Start > Programs > PROG08SZ**.

5. The Attempting to contact target and pass security window appears.

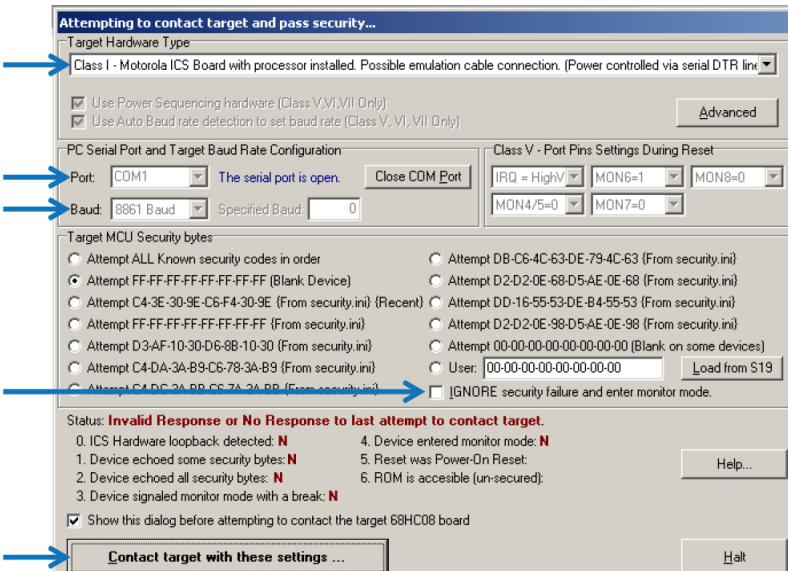


Figure 6-7. Attempting to Contact Target and Pass Security Window

Do the following in this window:

- In the **Target Hardware Type** field, select **Class I – Motorola ICS Board with processor installed**.
  - In the **Baud** field, keep the default of: 8861 baud.
  - In the Target MCU Security bytes area, there are two options:
    - If you are upgrading the existing software version, select () **IGNORE security failure and enter monitor mode**.
    - If you are burning a software version on a new main PCB, select **Attempt FF-FF-FF- FF- FF-FF-FF-FF (Blank Device)**.
  - Click the **Contact target with these settings ...** button.
6. When the connection succeeds, the *Specify Programming Algorithm to Use!* window appears. Select **908\_az60a\_highspeed.08p** and click **Open**. Wait until you see that it writes **Done** in the Status window. This indicates that initialization is complete.



Figure 6-8. Specifying Programming Algorithm to Use Window

7. In the *Choose Programming Function* window, use the keyboard arrows to select **EM Erase module**. Press the **ENTER** key on your keyboard to apply this selection.

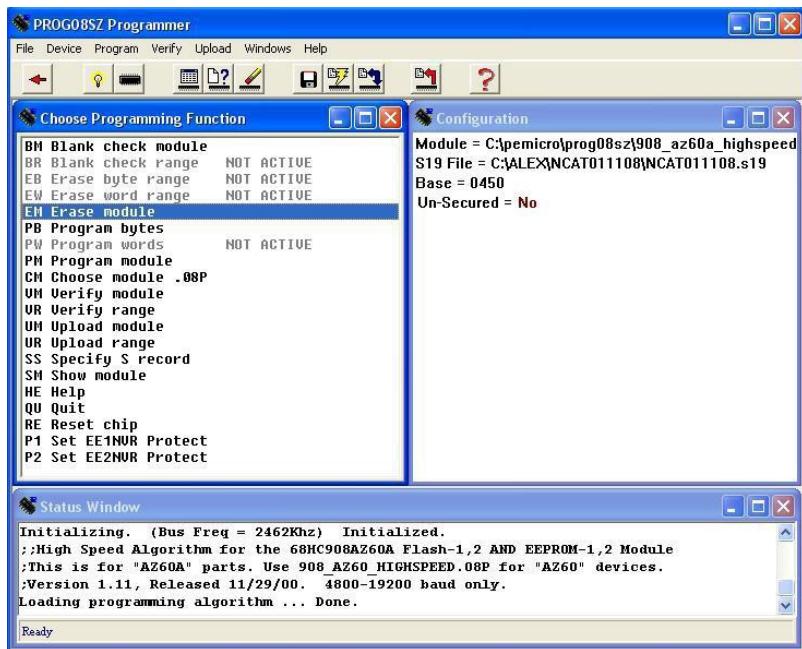


Figure 6-9. Choose Programming Function Window – 1

- If you are upgrading the software, a prompt appears for you to confirm. Click **Yes** to confirm erasing the installed software version from the PCB. Wait until you see that it writes **Done** in the *Status* window. This indicates that it has finished erasing the software.

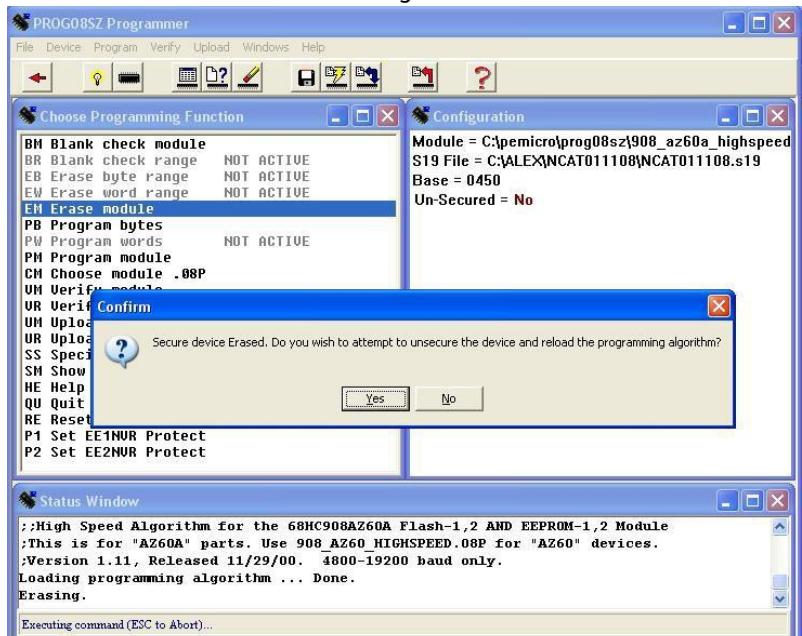


Figure 6-10. Choose Programming Function Window – 2



**NOTE:** If you are burning software on a new main PCB, this prompt is not displayed.

- In the *Choose Programming Function* window, select **SS Specify S record**. Press the **ENTER** key on your keyboard to confirm this selection.

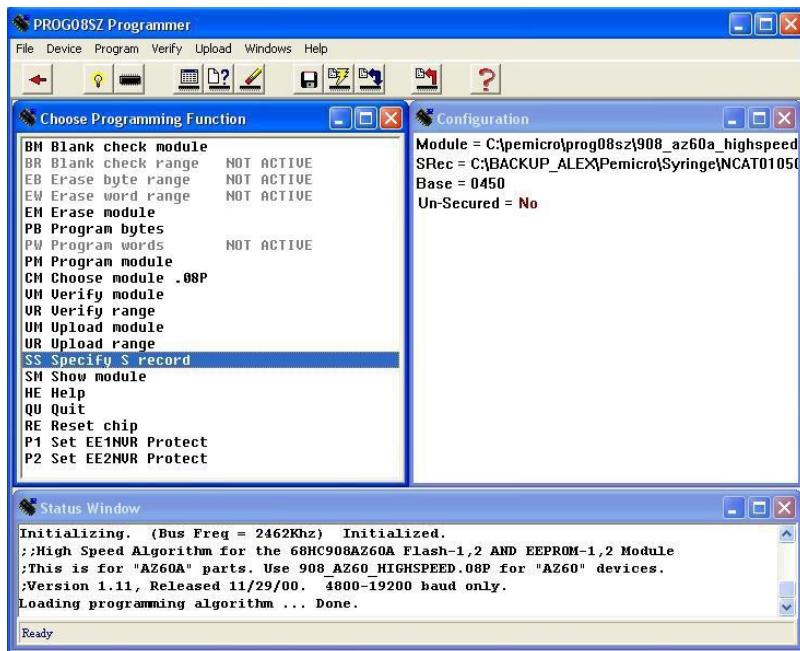


Figure 6-11. Choose Programming Function Window – 3

10. The *Specify S19 File to Load* window appears. Browse to the program file you need to burn on the PCB and click **Open**.

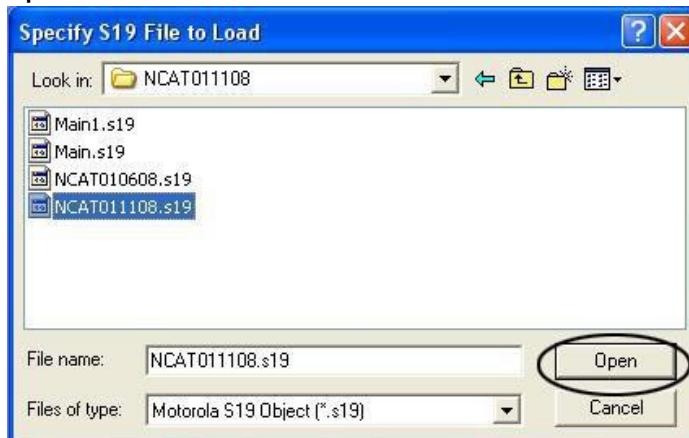


Figure 6-12. Specify S19 File to Load Window

11. In the *Choose Programming Function* window, select **PM Program module** and press the **ENTER** key on your keyboard to run the programming process. Wait until you see that it writes **Programmed** in the *Status* window. This indicates that it has finished loading the software to the PCB.

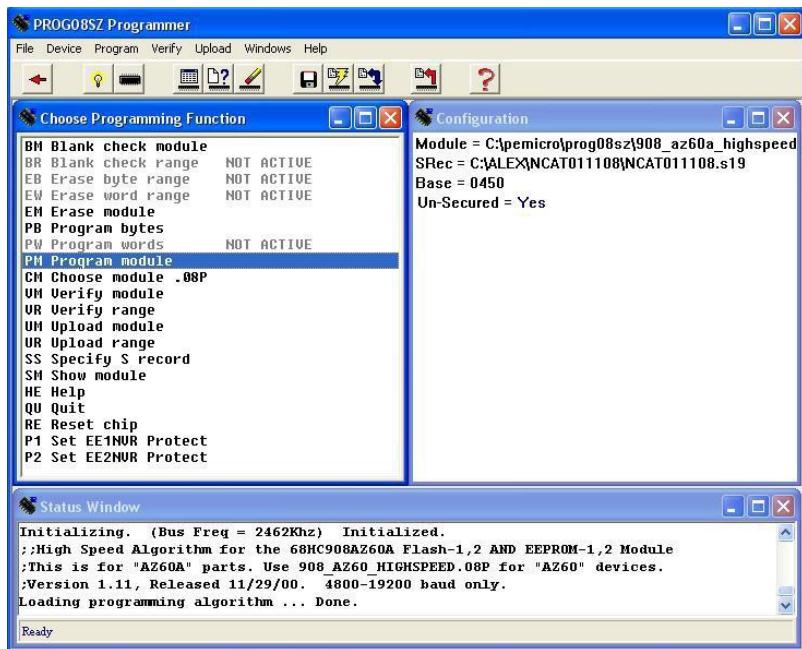


Figure 6-13. Choose Programming Function Window – 4

- In the *Choose Programming Function* window, select **QU Quit** and then press the **ENTER** key on your keyboard to exit the program.

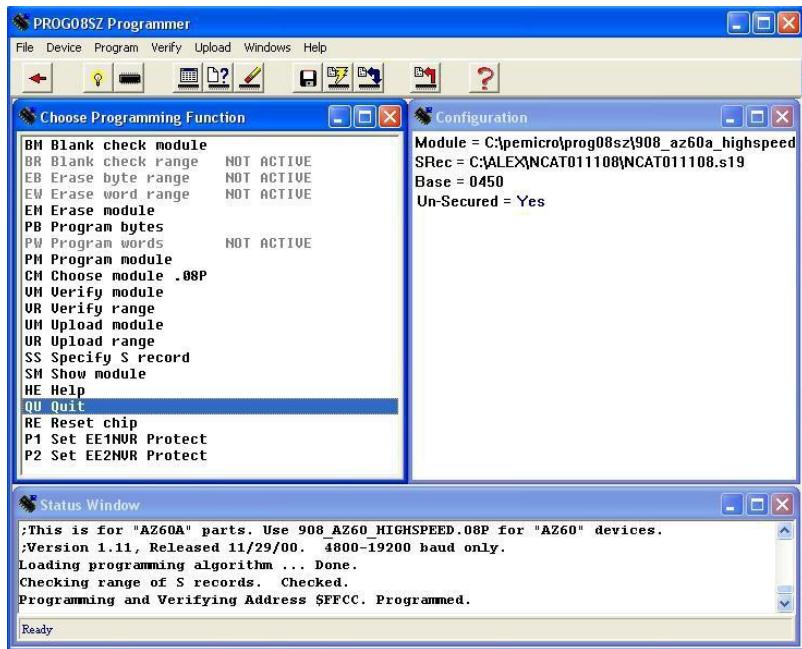


Figure 6-14. Choose Programming Function Window – 5

- Disconnect the burning cables from the PCB.
- Reassemble the pump and calibrate, as described in section 6.4. *Disassembly* on page 51.

## 6.4. Disassembly

This section describes the procedures, method and test equipment required for maintenance and replacement of different pump assemblies.



**Caution:** Do not perform any procedure beyond what is described in this manual unless otherwise advised by the manufacturer.

To ensure that the device is operational, make sure that you complete the procedures in this section and the PVP, as described in sections *4.5. Performance Verification and Calibration Tests* on page 32 and *Appendix B. Performance Verification Procedure (PVP)* on page 71.

### 6.4.1. Tools and Test Equipment

The following tools and test equipment are required to perform the procedures in this chapter. Since all fasteners on the device are metric, ensure that all tools used are suited for metric fasteners:

- Multimeter
- Torque 3 mm Phillips screwdriver
- BD BODYGUARD T DIGITAL SYRINGE OCCLUSION TEST GEAR
- Anti-static mat/Anti-static work surface
- Pump front and rear extension cables
- Small utility knife
- Flat 3 mm screwdriver
- Allen angled wrench/spanner, 1.5 mm
- #4 open wrench/spanner
- Anti-static tweezer forceps
- Metric feeler gauge
- Thread-locking glue (for example, omniFIT M50)
- Silicone (engineering adhesive sealant)
- Soldering iron
- Solder wire, rosin core 0.6 mm
- Diameter Test gauge (8 mm) (refer to *Table A-4Service/Test Tools* on page 1)
- Diameter Test gauge (19 mm) (refer to *Table A-4Service/Test Tools* on page 1)
- Diameter Test gauge (30 mm) (refer to *Table A-4Service/Test Tools* on page 1)
- Optional: Cutting pliers, Needle-nose pliers, 1.5 mm ballpoint Allen wrench/spanner

### 6.4.2. Pump Disassembly/Assembly

Disassembly of the pump is limited to mechanical components. It is recommended that electrical problems be corrected by replacing an entire printed circuit board (PCB) with a new one (main PCB, motor PCB or rear PCB), unless circumstances warrant component repair. Use only replacements from the replacement parts list on page 68.

The disassembly/assembly procedures described in this chapter are:

- [A – Separation of Front and Rear](#)
- [B – Replacement of Motor and Pumping](#)
- [C – Replacement of PCBs – Motor and Main](#)
- [D – Replacement of Pump Motor](#)
- [E – Replacement of Rear PCB](#)

Make sure that you read all steps in the procedure before you begin to disassemble the device. The procedures are presented in the order of disassembly. Disassemble the device only as far as needed to complete the repair.

- i** NOTE: Ensure that all gasket material is put back in place during reassembly. It is advised to entirely replace all four gaskets (Kit P/N: 100-190SM) before reassembling pump.

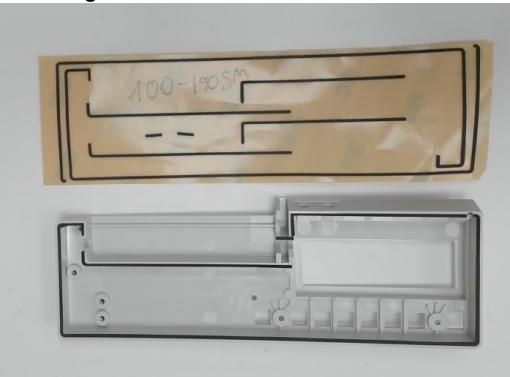


Figure 6-15. Gasket Kit P/N 100-190SM

## A – Separation of Front and Rear Housing

To separate the front and rear housing, do as follows:

1. Turn the device on. After preloading is completed, ensure that the actuator is positioned away from the rear end of the drive assembly. This will simplify separation of the front and rear housing later.
2. Turn the device off and place it face down on an anti-static mat or a soft work surface. In order to avoid scratches to the pump housing, make sure that there are no metal parts (such as screws and nuts) on the work surface.
3. Remove the battery from the battery compartment at the rear of the device.



Figure 6-16. Battery Removal

4. Remove the six mounting screws. Five are in the rear housing of the pump and one mounting screw (#6) is located beneath the battery cover. These six screws connect the front and rear housing. All six screws are M2 screws of different lengths.

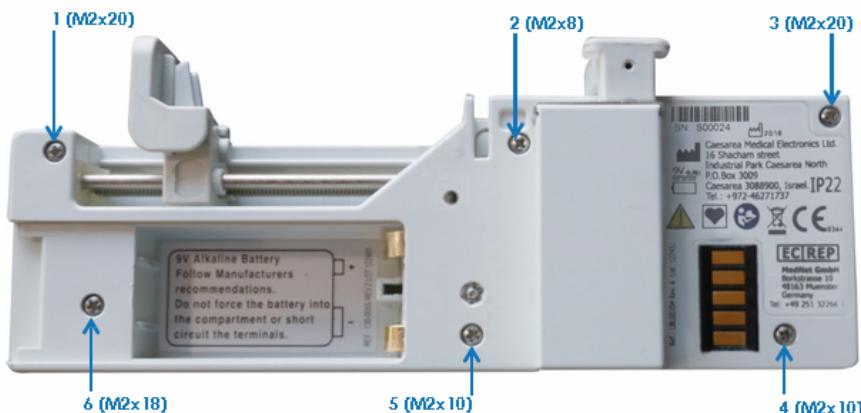


Figure 6-17. Pump – Rear View – Housing Screw Locations

5. Stand the device upright and separate the front and rear housing (see Figure 6-17). RTV silicone 3140 will prevent you from smoothly separating the housing. You may require some force in doing so.



NOTE: Apply RTV 3140 silicone on areas below before reassembling.



NOTE: Ensure that all gasket material (Kit P/N 100-190SM) are replaced before reassembly.



NOTE: Ensure that adhesive silicone seal (100-195S) is placed on a clean surface (that has been properly wiped from any excess silicone that may have squeezed out of the inner casing).

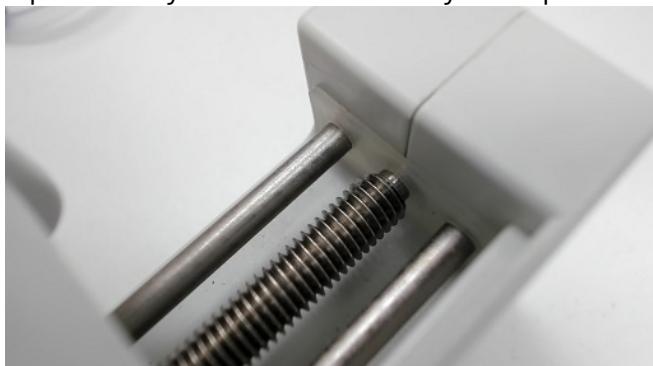


Figure 6-18. Silicone Seal P/N 100-195S

6. Reassemble the housing in the reverse order. Make sure that the front and rear housing surfaces are lined up parallel and that the connectors mate properly, apply the silicone RTV 3140 (as shown below) and then press them together and affix the respective screws, as shown in Figure 6-17.



Figure 6-19. Applying RTV 3140 Silicone



Figure 6-20. After placing Block

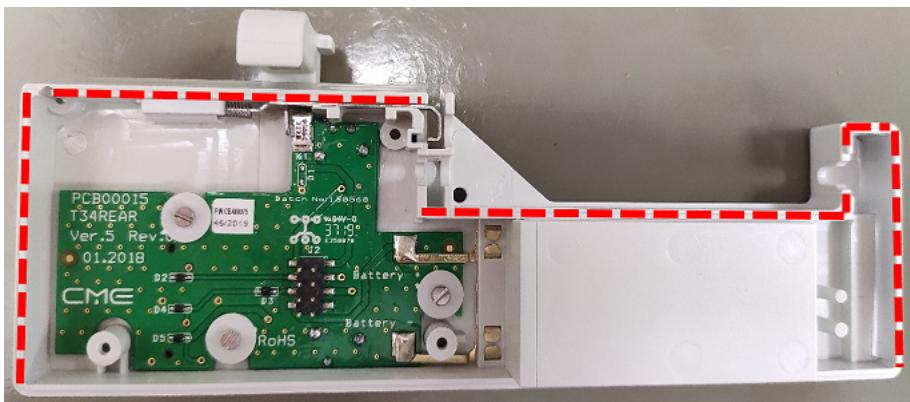


Figure 6-21. Rear view

- If when pressing the front and rear housing parts together there is an obstruction in the middle, rotate the actuator screw manually (b) to move the actuator from the edge, where it is tight against the housing (a) to a location where there is no overlap between the actuator and the housing (c).

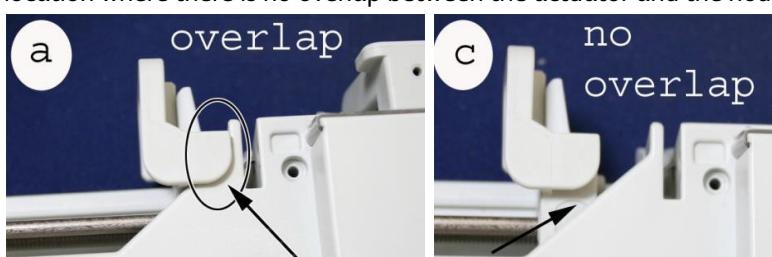


Figure 6-22. Actuator Repositioning

- Insert the six mounting screws and tighten them to 0.20 N with a calibrated torque screwdriver. Note that the respective screw sizes are as depicted in Figure 6-17.
- After reassembling, ensure that the silicone seal label (100-195S) is applied properly. Place a 9 V battery inside and turn the pump on. Check that the Self-Test and preloading procedures are performed correctly.

## B – Replacement of Motor and Pumping Block

To replace the motor and pumping block, do as follows:

- Separate the front from the rear housing of the pump, as described in section *A – Separation of Front and Rear Housing* on page 52.
- Remove the upper screw label from the front housing (where the syringe sits), and then remove the fixing screw beneath.

## Screw Labels (300-043S)

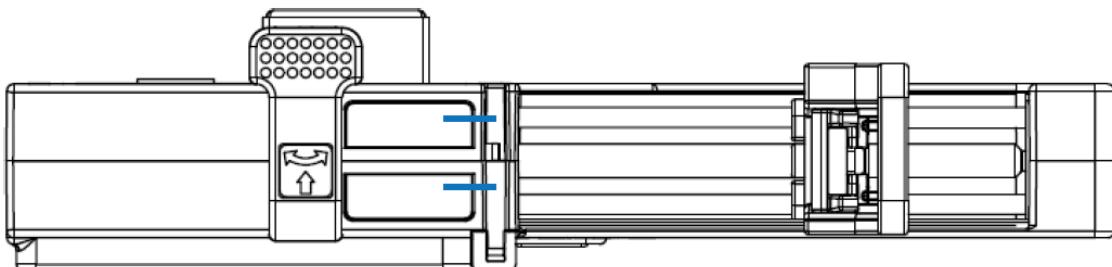


Figure 6-23. Pump – Top View

3. Be sure to remove the M2x8 fixing screw from the rear housing (screw #2 in Figure 6-17).
4. Disconnect the motor encoder connector on the main PCB.

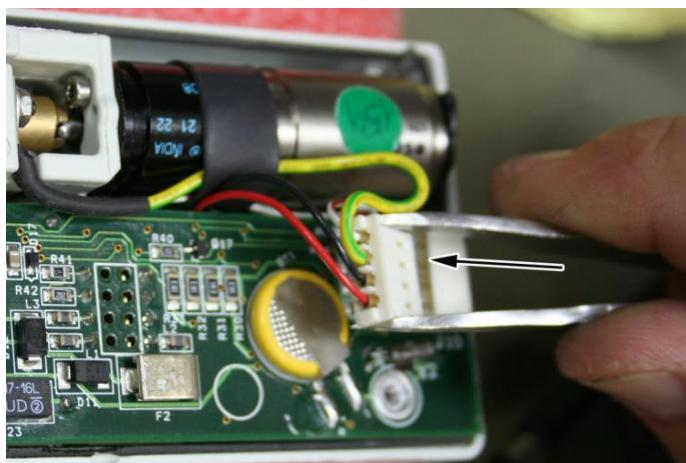


Figure 6-24. Disconnecting the Motor Encoder Connector

5. Pull out the block assembly.

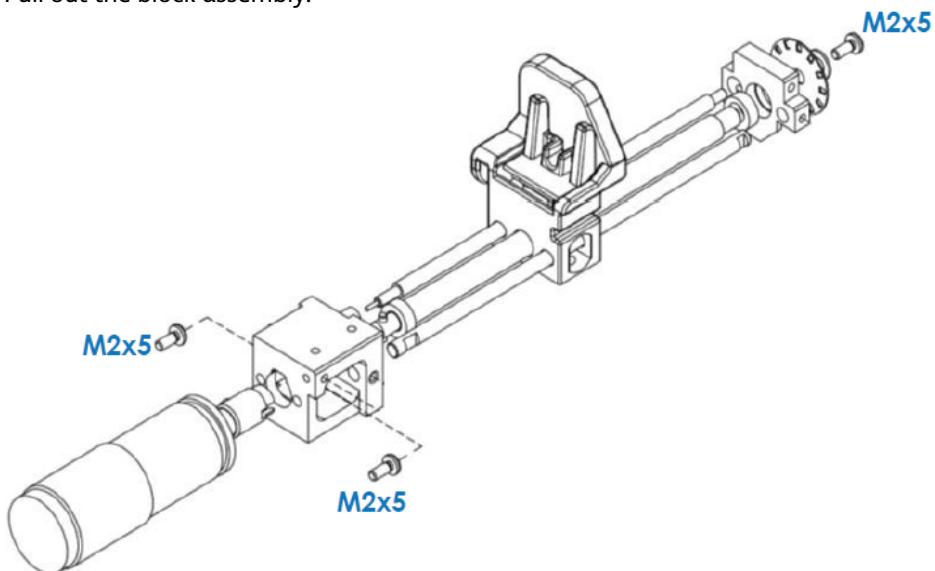


Figure 6-25. Block Assembly

6. Before reassembling new block, apply one drop of hydraulic Zinc Free 32 grade (ZF 32) oil in to the groove of the red gasket.

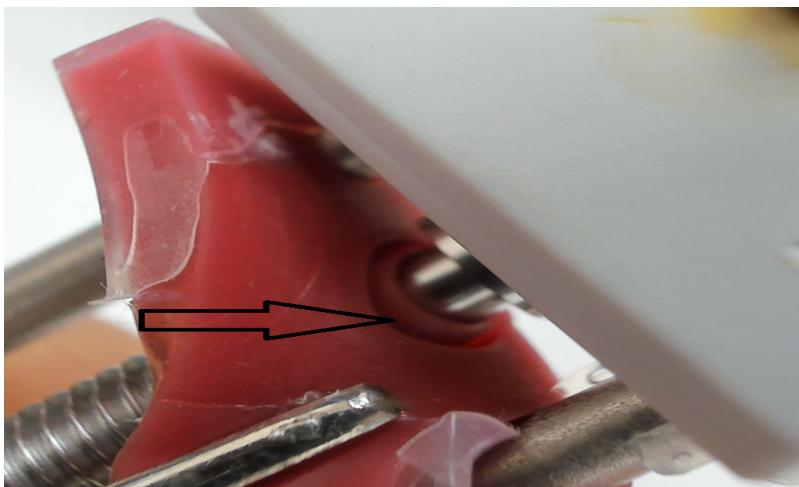


Figure 6-26. Gasket

## 7. Reassemble in the following order:

- Start by taking the front housing and checking that the LCD display is seated properly within the surrounding plastic confinement and not on top of it. Make sure that the LCD display's plastic corner is level with the surrounding ridge.

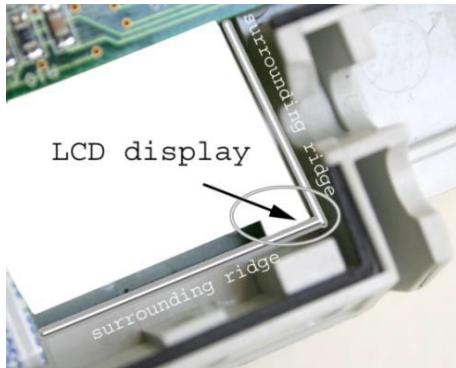


Figure 6-27. LCD Display Level with Surrounding Ridge

- To ensure that the pump block's actuator inserts and turns easily, verify that QF1 and DIL2 on the motor encoder PCB are upright and not tilted.

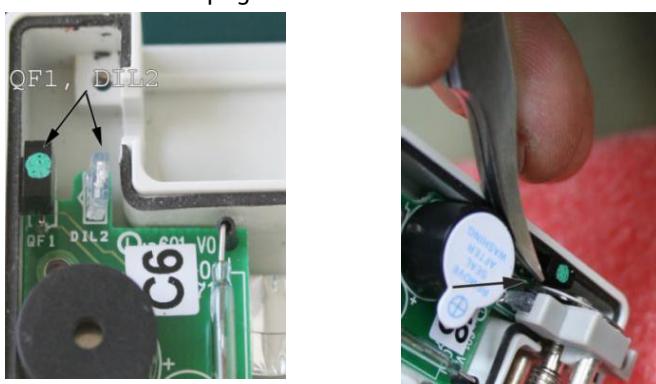


Figure 6-28. QF1 and DIL2 (Left) – Verifying That the Encoder Moves Easily (Right) Note: If a new PCB was assembled, remove the seal from the buzzer.

- Insert the block assembly, making sure that the motor encoder wires are inserted in between the two PCBs, and not tucked beneath the motor.

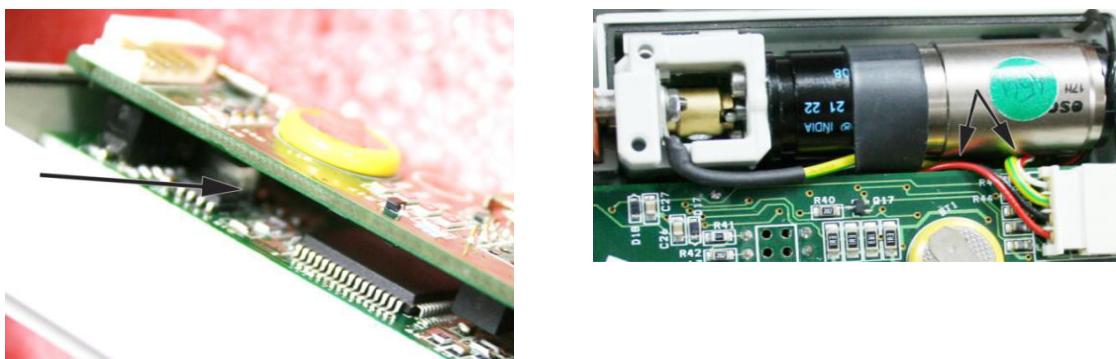


Figure 6-29. Correct Encoder Wire Location

- d. Connect the motor encoder connector. See Figure 6-24.
- e. Screw in the upper fixing screw and then reattach the upper screw label to cover the screw, as described on page 54.
- f. Reassemble the front and rear housing, as described in section A – *Separation of Front and Rear Housing* on page 52.

After replacing the motor and pump block, the following calibrations are required:

- **Syringe Travel** (refer to section 3.4.4. *Syringe Travel Calibration* on page 28)
- **Diameter Calibration** (refer to section 3.4.5. *Syringe Diameter Calibration* on page 29)
- **Pressure Calibration** (refer to section 3.4.3. *Occlusion Pressure Calibration* on page 21)

Perform the PVP (refer to section *Appendix B. Performance Verification Procedure (PVP)* on page 71).

## C – Replacement of PCBs – Motor and Main

To replace the PCBs, do as follows:

1. Separate the front and rear housing of the pump, as described in section A – *Separation of Front and Rear Housing* on page 52.
2. Remove the block assembly, as described in *B – Replacement of Motor and Pumping Block* on page 54.
3. Remove the keypad label from the front housing and release the two M2x5 spacer screws.

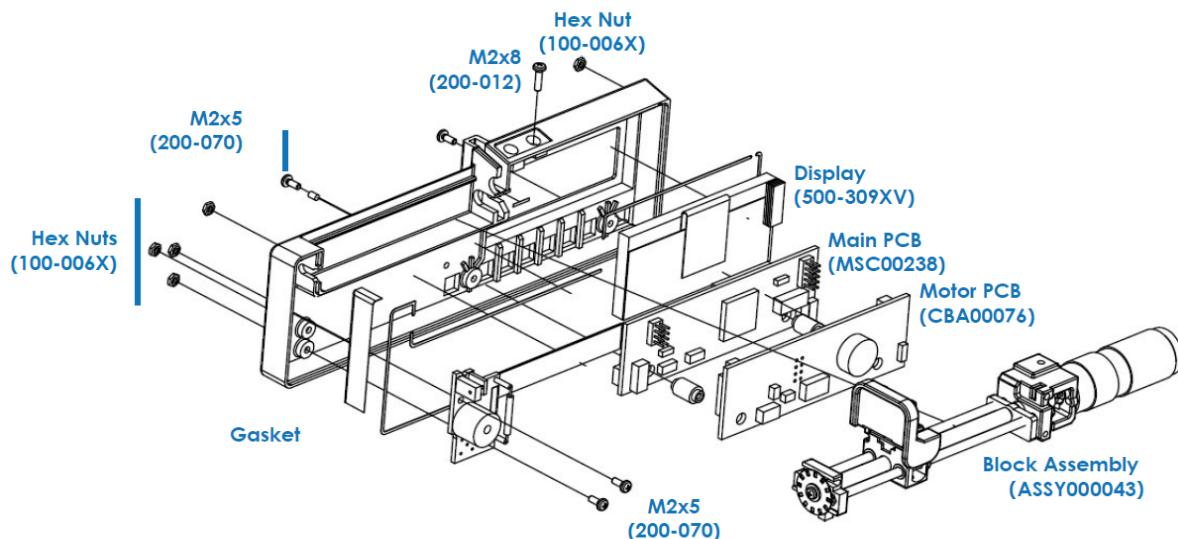


Figure 6-30. Front Assembly (300-031S)

4. Detach the motor PCB (top PCB) carefully, noting the spacers.
5. Remove the two M2 x 5 encoder PCB fixing screws, taking care not to harm the reed switch.
6. Lift out the encoder PCB and the main PCB connected with the flat cable. Remove the silicone sealant covering the flat cable connection and gently disconnect the display's connector from the main PCB.



Figure 6-31. Step-1 Disconnecting the Display from the Main PCB

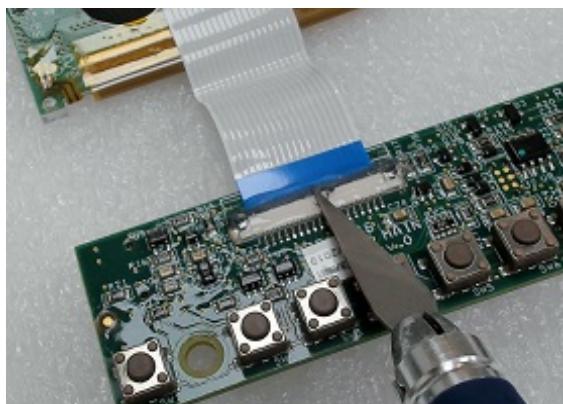


Figure 6-32. Step-2

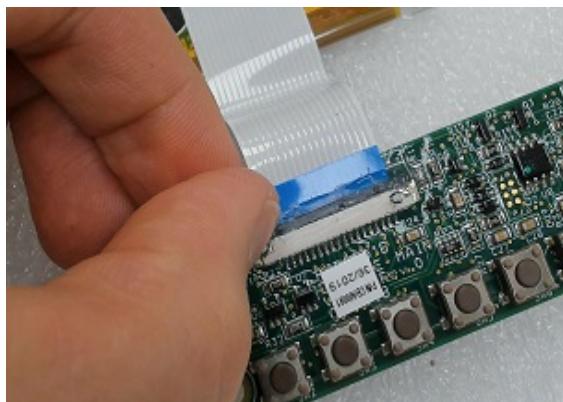


Figure 6-33. Step-3

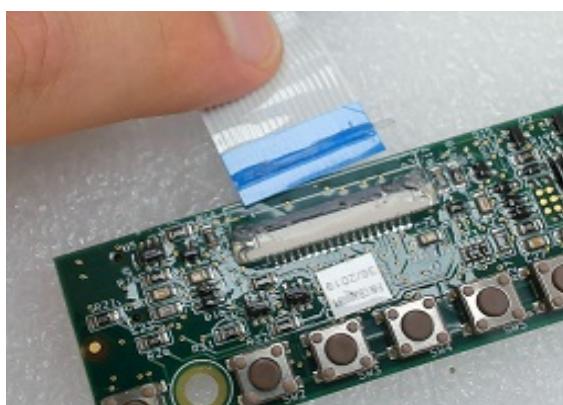


Figure 6-34. Step-4

7. Install a new motor PCB or a new main PCB and reassemble in reverse order, as follows:



**NOTE:** Make sure that the new PCB contains the correct software version.

- a. Start by connecting the display connector to the main PCB. See Figure 6-31.
  - b. Check that the LCD display is seated properly within the surrounding plastic confinement and not on top of it. Make sure that the LCD display's plastic corner is level with the surrounding ridge (see Figure 6-27).
  - c. Insert and secure the main PCB and encoder PCB units: two screws in the encoder PCB and two screws that secure the main PCB via spacers (see Figure 6-30 and Figure 6-31), for a total of four M2x5 screws.
  - d. Click the motor PCB to the main PCB.
- Important: When replacing the main PCB unit, remove the protective seal from the buzzer.**
- e. Insert the block assembly, as described on page 56.
  - f. Connect the motor encoder connector, as described on page 57.
  - g. Screw in the upper fixing screw and then reattach the upper screw label to cover the screw, as described on page 54.
  - h. Reassemble the front and rear housing, as described in section A – *Separation of Front and Rear Housing* on page 52.

When replacing the main PCB, because some of the calibrations are specific to every pump, the following calibrations are required (as part of the PVP, refer to section *Appendix B. Performance Verification Procedure (PVP)* on page 71):

- **Syringe Travel** (refer to section *3.4.4. Syringe Travel Calibration* on page 28)
- **Diameter Calibration** (refer to section *3.4.5. Syringe Diameter Calibration* on page 29)
- **Pressure Calibration** (refer to section *3.4.3. Occlusion Pressure Calibration* on page 21)

## D – Replacement of Pump Motor

To replace the pump motor, do as follows:

1. Separate the front and rear housing of the pump.
2. Remove the block assembly, as described in section *B – Replacement of Motor and Pumping Block* on page 54.
3. Release the motor's wire connector loop, fastening nuts, and washers using a #4 open wrench/spanner.

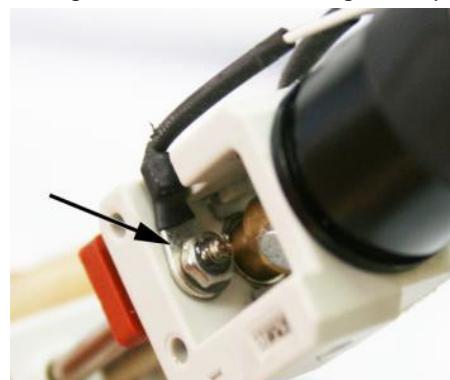


Figure 6-35. Required Tools (Left) – Releasing the Wire Connectors (Right)

4. Remove the two cylindrical head cap screws M2x5 (Allen screws) from the front block housing using an angled Allen wrench/spanner.

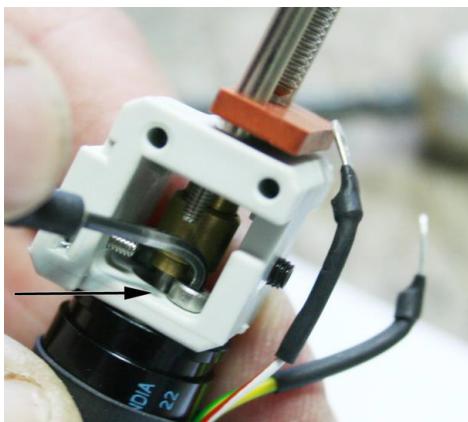


Figure 6-36. Releasing the Motor from the Block

## 5. Separate the motor from the front block.



Figure 6-37. Separated Motor and Front Block

## 6. Install a new motor in reverse order, as follows:

- Secure the two M2x5 cylindrical head cap screws (Allen screws) to connect the motor to the block (see Figure 6-36).
- Secure the motor's wire loops to the block — place the yellow-green wire loop above the horseshoe washer in the inner side of the block and secure it with a washer and closing nut (see Figure 6-35).
- Insert a washer on the leading bar on the other side of the block, and then place the red and white wire loop on the washer that was upon it and secure by bolting the nut. Secure the screws using a thread-locking glue, such as omniFIT M50.

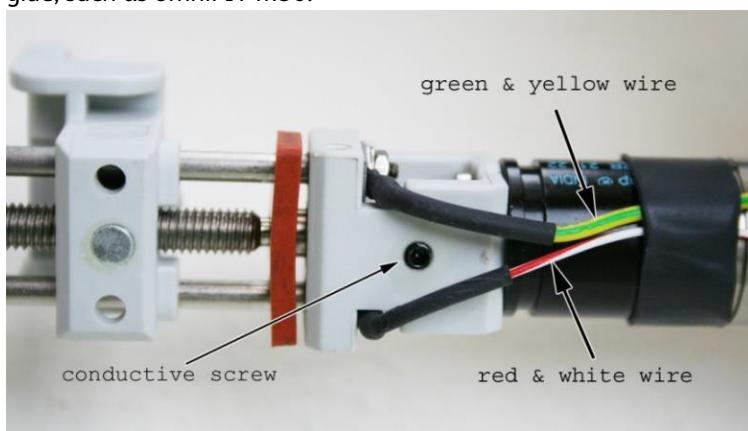


Figure 6-38. Wiring Placements

**(i)** NOTE: Be careful not to release the conductive screw, which creates a magnetic field from the magnet on the motor shaft to the reed switch K2.

- Insert the reassembled actuator and motor block in the front housing, as described in section *B – Replacement of Motor and Pumping Block* on page 54.
- Connect the motor encoder connector, making sure that the wires are not tucked beneath the motor, as described on page 57.

- f. Screw in the upper fixing screw and then reattach the upper screw label to cover the screw, as described on page 54.
- g. Reassemble the front and rear housing, as described in section A – *Separation of Front and Rear Housing* on page 52.

After replacing the motor, the following calibrations are required (as required in PVP, refer to section *Appendix B. Performance Verification Procedure (PVP)* on page 71):

- **Syringe Travel** (refer to section *3.4.4. Syringe Travel Calibration* on page 28)
- **Diameter Calibration** (refer to section *3.4.5. Syringe Diameter Calibration* on page 29)
- **Pressure Calibration** (refer to section *3.4.3. Occlusion Pressure Calibration* on page 21)

## E – Replacement of Rear PCB

To replace the rear PCB, do as follows:

1. Separate the front and rear housing of the pump.
2. Unsolder copper contacts from the rear PCB. **Be careful not to harm the copper pads beneath the soldered contacts on the PCB.**

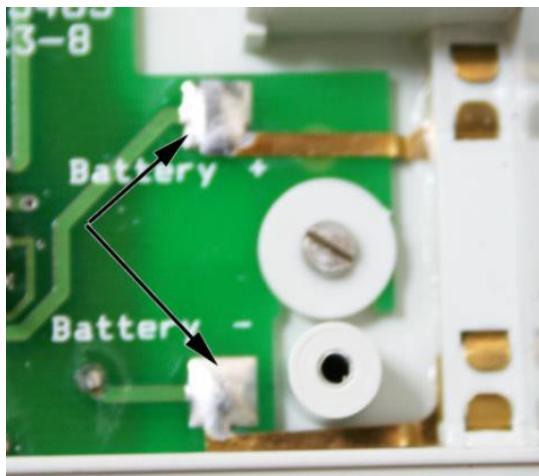


Figure 6-39. Soldered Contacts

3. Remove the collar sensor by lifting it out of its slot and carefully holding the spring locker unit.

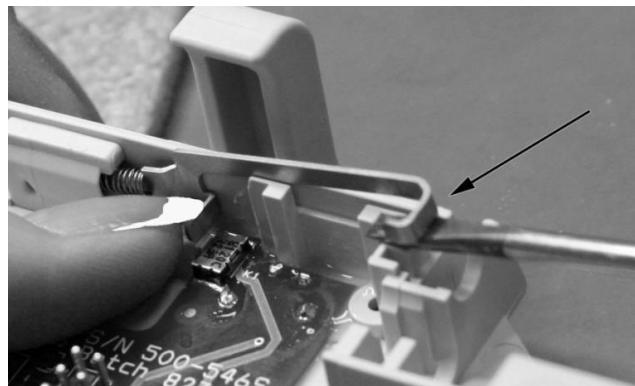


Figure 6-40. Collar Sensor (400-005S) with Spring Locker (250-012X) (Left) – Removal of Collar Sensor (Right)

4. Unscrew the three M2x4 screws and remove the washers.

**Holder Assembly (230-020S)**

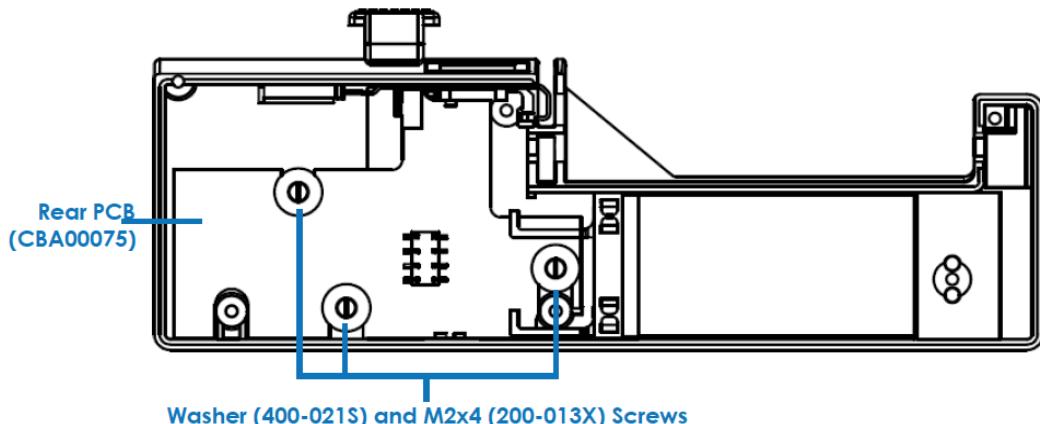


Figure 6-41. Rear Assembly

5. Slightly lift the PCB from the left side and slide out the PCB, taking care not to damage the copper contacts in any way.
6. Install a new rear PCB and reassemble in reverse order, as follows:
  - a. Place the rear PCB in its correct position in the housing, making sure that the protruding boss of the potentiometer matches its socket in the lower part of the case and that the syringe holder works smoothly.

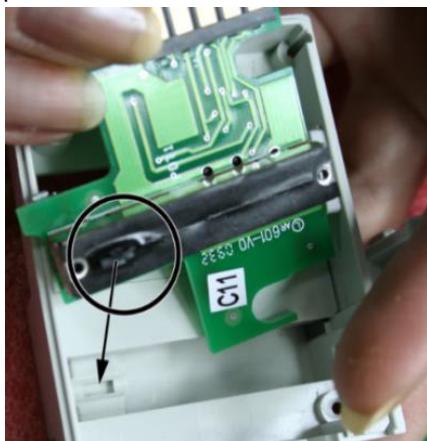


Figure 6-42. Rear PCB Positioning

- b. Remove the PCB and apply silicone to the potentiometer's two panels. Then, reinsert. Press the PCB in place and keep pressing for several seconds. Then, leave it for a few minutes to let the silicone dry.



Figure 6-43. Treating the Rear PCB's Potentiometer Part

- c. Insert the three M2 plastic washers in place (see Figure 6-41) and screw the slotted cheese head screw M2x4 through each washer into each of the inserts.

- d. Apply silicone to fill the gap between the housing and PCB in the area marked with the arrow.



Figure 6-44. Sealing the Gap Between the Rear PCB and the Housing

- e. Solder the contacts of the contact wall assembly to the PCB, using a solder iron heated to 350°C, flux solution and 0.6 mm rosin core wire.
- f. Insert the collar sensor and spring locker unit in place. First insert the collar sensor into the spring (see Figure 6-40). Then insert the spring part into its cavity in the housing wall (a). Finally, insert the collar sensor into its place adjacent to the housing wall (b). Whilst doing so, **take care not to harm the button of the sensor on the PCB** (c).

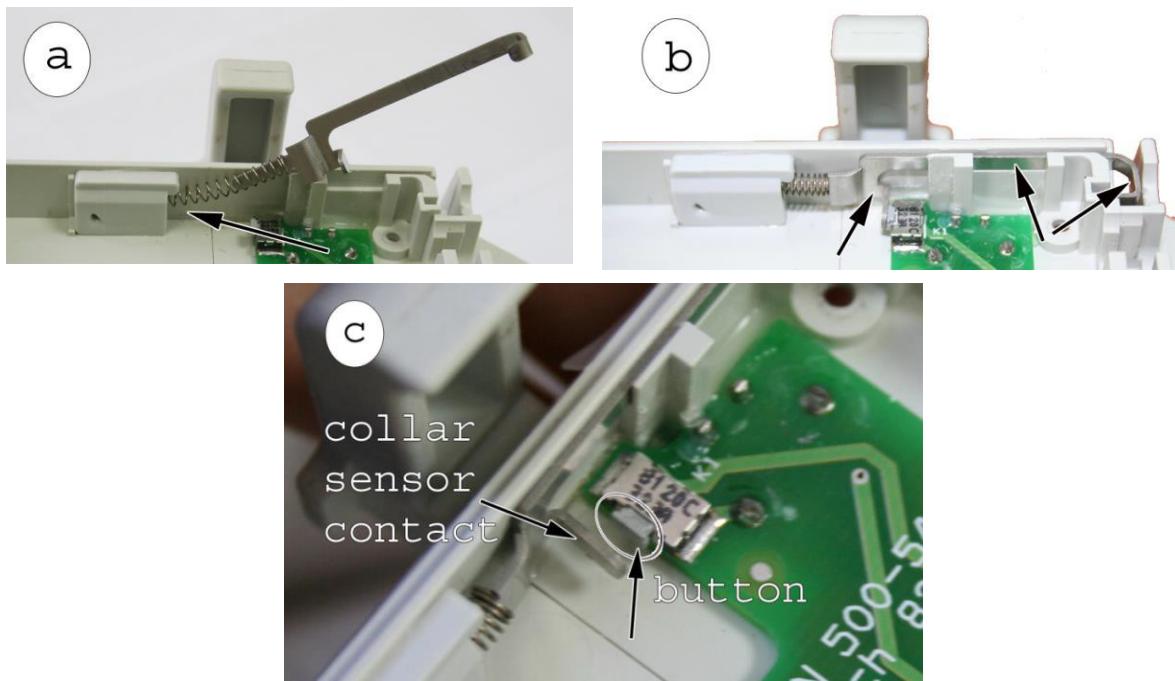


Figure 6-45. Collar Sensor Insertion

- g. Check with a metric feeler gauge that the distance between the bended contact and the housing is 0.8 mm.

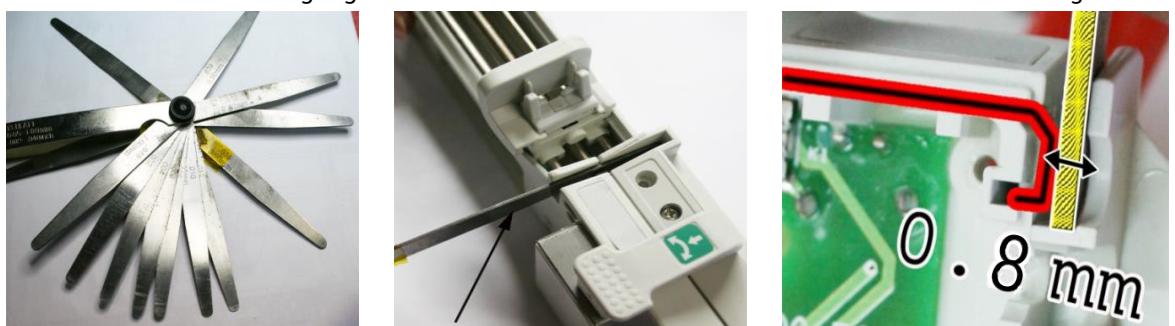


Figure 6-46. Metric Feeler Gauge (Right) – Measuring 0.8 mm (Left and Bottom)

- h. To correct the distance, if needed, bend the collar sensor contact's end that touches the button.

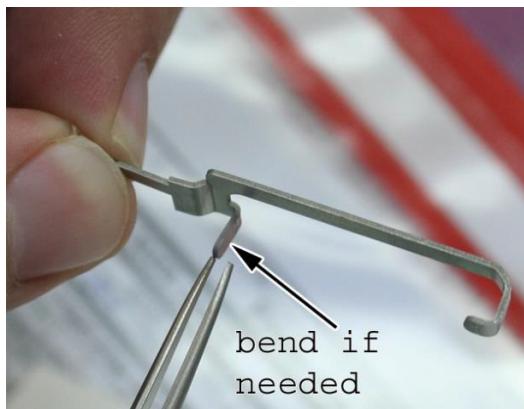


Figure 6-47. Adjusting the Collar Sensor Contact

Perform the PVP (refer to section *Appendix B. Performance Verification Procedure (PVP)* on page 71).

## 6.5. Restore Software Default Settings



NOTE: Software default settings should only be restored before beginning the last (PVP) after service has been completed.



NOTE: Pumps associated with a complaint will have software default settings restored only after notification of complaint closure.

1. Enter the Technician menu (refer to section *3.4.1. Technician Menu* on page 18).
2. Use the buttons to scroll to the **Factory Setting** option.
3. Press the button.
4. Press the button to reset the software factory settings to their default settings.
5. Select the **Restart Pump** option.
6. Press the button.
7. Verify that the factory default settings were reset to their default values.
8. Add the Software Default Settings Restored insert to the pump packaging. This notifies the customer that any desired customer-programmed setting must be reprogrammed prior to use.
9. Perform the PVP (refer to section *Appendix B. Performance Verification Procedure (PVP)* on page 71).

## 6.6. Pump Default Settings

The pump is programmed with a number of default parameters that can be changed using Change Set Up (and if applicable to the specific version, the **Rate** setting) in the **Info** menu, and using the Technician menu. Changing these default parameters requires the use of access codes.

Table 6-1. Pump Default Settings

Parameter	Purpose	Default	Range
<b>Info</b> menu; accessed by pressing the  key. The display shows the <b>Info</b> menu and enables you to select the following parameters:			
Battery Level	Current battery level.	Empty through Full, in %.	
Exit	Exits Info mode.	Press the  key.	
Rate Setting (Access code 5)	In case the pump is set Volume over Rate. Use this setting to lock the rate.	5 ml/h	0.1 ml/h – pump max ml/h rate. Maximum rate can be configured in Maximum Rate (Technician menu).
Event Log	Last 512 events.	Press the  key for full disclosure.	
Change Setup	Changes default parameters.	Enter the access code.	
Change Setup mode; accessed with code 99.			
Language	Changes the language.	English	English, local language.
Time & Date	Ensures that all events in the log are stamped with the correct date and time.		Day, month, year, hours, minutes.
Key Operation	Limits the forward movement of the actuator caused by pressing the  key during syringe loading.	5 mm	0.1 – 100 mm.
Backlight Duration	Limits backlight duration to help preserve battery life.	5 seconds	0 – 60 seconds.
Info Duration	Limits the length of time the Info screen displays	5 seconds	1 – 20 seconds.
Bolus Dose Rate	Enables to set the bolusing dose rate. NOTE: This setting is available only if bolus delivery is enabled on Technician menu.	300 ml/h	1 – 650 ml/h

Parameter	Purpose	Default	Range
Bolus Maximum Volume	Availability depends on the pump version. Enables the user to set the bolus maximum volume.  NOTE: This setting is available only if bolus delivery is enabled on Technician menu.	0 ml (Disabled)	0 (Disabled)- 20 ml
Titration Option	Enables the user to change the operation rate during programming.	Disabled	In case the default duration is set to zero (00:00).
Default Duration	When a new program is confirmed, the pump resets to this default (setting to zero 00:00 skips the duration step during programming). When the Program Lock is ON (see below), cannot be set to zero.	24:00 hours	00:01 to 99:00 hours. With default duration set to 0:00 hours, pump runs as an ml/h infusion. Otherwise when default duration is set nonzero, the pump runs as a volume over time infusion.
Occlusion Pressure	Indicates the setting at which an occlusion alarm is activated.	720 mmHg	200 – 1,500 mmHg.
Program Lock	Prevents alteration of either the duration or rate during setup. When the Program Lock is ON, the Default Duration cannot be set to zero.	ON	ON/OFF.
<b>Technician Mode:</b> accessed with code 123.			
Serial Number/ Production Date	Pump serial number and production date of the pump. (Week No., Month and Year.)		
Main Self-Test (follow display prompt)	Automatically proceeds in sequence through the following tests: Keypad, Display, Acoustic Alarm, Back-up alarm, Mic level, LEDs test, Syringe Sensors, Diameter, Syringe Travel Test and Power Voltage.		
Manual Tests	Enables manual selection of the tests listed in the row above.		
Syringe Setup	Adds or deletes syringes from the default list.	Refer to procedure <i>Enabling and Disabling a Predefined Syringe Type in the Pump Menu</i> on page 19.	
Pressure Calibration	Performs a Pressure Calibration routine using the calibrated force gauges.	Refer to section <i>3.4.3. Occlusion Pressure Calibration</i> on page 21.	
Factory Press. Test	Test routine to fine-tune the pressure calibrations, using a 5 ml and 50 ml syringe. (Only relevant for UK and IE pumps.)	Refer to section <i>3.4.3. Occlusion Pressure Calibration</i> on page 21.	
Pressure Test	Test routine to ensure that pressure calibration is within specifications.		
Syringe Travel	Sets up the Volume Sensing system by ensuring that the CPU knows the position of the actuator.	Refer to section <i>3.4.4. Syringe Travel Calibration</i> on page 28.	
Diameter Calibration	Sets up the syringe recognition system.	Refer to section <i>3.4.5. Syringe Diameter Calibration</i> on page 29, which requires three points (8 mm, 19 mm, and 30 mm).	
Syringe dead space	11 mm	10-12 mm	
Volume Test	Can be set to any volume at any flow rate. This test is performed by visually comparing between the actual volume in the syringe and the volume displayed on the pump screen.		
Factory Settings	Resets all settings to their defaults.		
Operating Hours	Number of hours in use.	Can be reset by pressing the <b>□</b> key.	
Service Interval	A warning can be set for when a preset number of operating hours has been reached.	0 – 50,000 hours. or 0 -12 Months	

Parameter	Purpose	Default	Range
Access Codes	Sets the three access codes of the pump for Technician, Change Setup, and Rate. (Defaults: 123, 99, 5, respectively).		The codes can be changed by the user.
Purge Vol.	Sets maximum purge volume	0 ml	0 – 2 ml.
Maximum Rate	Maximum flow rate at which the pump operates.	5 ml/h	0.1 – 650 ml/h.
Microphone Level	Microphone sensitivity. Check in silent room.	numeric value is displayed whilst buzzer beeps	Making noise or gently tapping pump will activate microphone and numeric values will rise. Value must be higher than 50. It is possible to adjust the microphone sensitivity if required. This can be done in Technician Menu.
Bolus enable/disable	Enables bolus.	Disable	Disable/Enabled

# Appendix A. Service Center Recommended Part List

Service center recommended parts may be ordered from a BD authorised distributor.

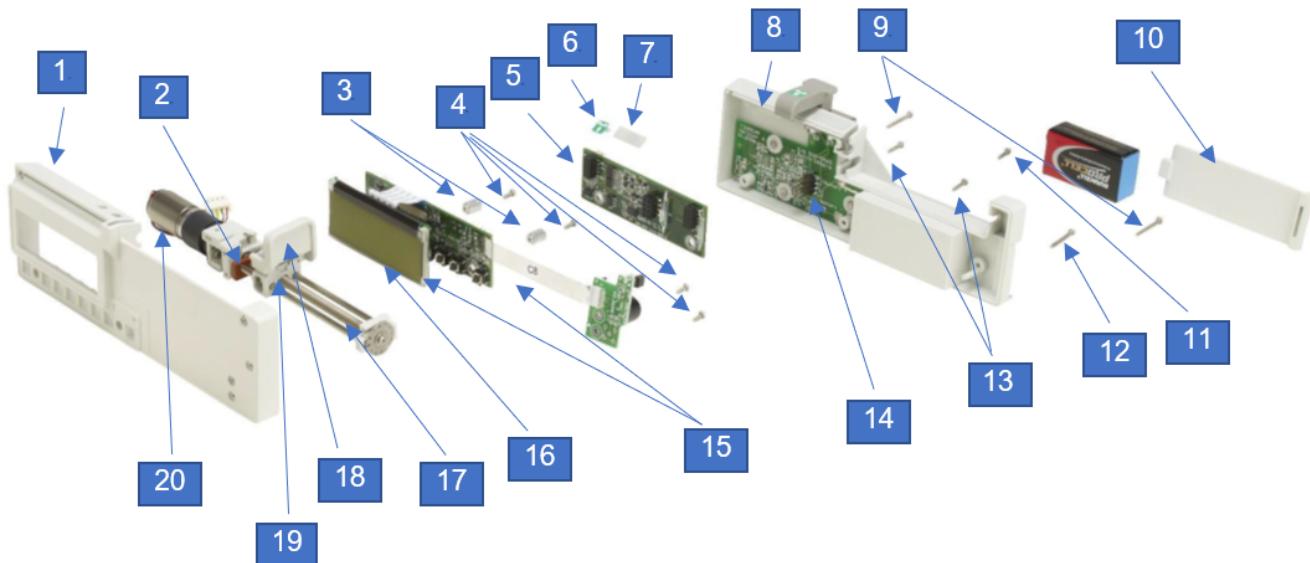


Figure A-1. Diagram of Pump Components

Table A-1. Spare Parts Assemblies

Part Number	Description	Comments	Diagram Ref.
100-190SM	KIT, GASKETS, SPARE PART, T34		
230-010S	ASSEMBLY, PCB, SYRINGE ACTUATOR		19
300-100S	ASSEMBLY, FRONT, T34, SPARE PART	Please consider ordering spacer foam (600-001S).	1
400-031S	ASSY, REAR, T34, 3.1ED		8
500-309XV	DISPLAY TRNS122X32NEWCSTMVER		16
ASSY000043	ASSY, BLOCK, PUMPING, T34, 3.1ED - GAI PROJECT	Replaced ASSY34BKS and 200-000S.	17
230-018PS	KIT, ACTUATOR AND COVER		18
CBA00075	ASSY, TH, REAR, T34, 3.1ED		14
CBA00076	ASSY, TH, SYRINGE MOTOR, T34,3.1ED		5
FW-{software name}	FIRMWARE, {software name}	Including latest SW flashed on PCB.	
MSC00238	ASSY, PCB + DISPLAY, T34, 3.1ED	Main PCB + encoder PCB + display	15
MTA0001	ASSY, MOTOR, T34		20



NOTE: Firmware includes a main PCB, display and matching software.

Table A-2. Pump Individual Components

Part Number	Description	Comments	Diagram Ref.
100-006X	NUT, M2, A2, DIN934		
100-195S	SEAL, FINAL, T34 AND T34L, SILIC, ADH, TRAN, 0.53 WID		
200-012	SCREW, M2x8, CYLINDER, PHILLIPS, SS, DIN 7985		11
200-070	SCREW, M2X5, CYLINDER, SS, PHILLIPS		4
200-101SX	SCREW, M3X5, DIN 913, ZINC		
200-102S	SCREW, M2X5, DIN912, ISO 4762, SS		
200-103S	NUT, SQUARE, M2, DIN 562, SS		
250-154	MAGNET, DOOR, N48, NICKEL, PLATED, NDF100, D4X2 mm		
250-196S	GASKET, SILICON RUBBER, 2.5 mm, 60 SHORE, RED		2
300-570X	SCREW, M2X20, SS, DIN7985, PHILLIPS		9
300-580X	SCREW, M2X10, CYLINDER, SS, DIN 7985, PHILLIPS		13
400-002S	INJECTION, COVER, BATTERY, T34		10
400-005S	BENDING,SENSOR 1,T34/T34L		
500-549S	TAPE, ISOLATION, ADHESIVE		
600-001S	SPACER, SOFT		
600-003T	SCREW, M2x18, DIN 7985, A2, PHILLIPS		12
MAP0016	CNC SPACER FRONT T34		3

Table A-3. Pump Labels

Part Number	Description	Comments	Diagram Ref.
130-005S	LABEL, BATTERY, T34		
250-013S	LABEL, ACTUATOR, T34/L, LEX 125, GL 3M468, RAL7035		
250-014S-103	LABEL BODYGUARD T FRONT NARROW	For BD BodyGuard™ T pumps	
300-041-103	LABEL, KEYPAD BD BODYGUARD T	For BD BodyGuard™ T pumps	
300-041S	LABEL, DISPLAY, T34		
300-041S-103	LABEL, DISPLAY , BD BODYGUARD T	For BD BodyGuard™ T pumps	
300-042-103EN	LABEL, INSTRUCTIONS, BD BODYGUARD T, ENGLISH	For BD BodyGuard™ T pumps	
300-043S	LABEL, SCREW, 34		7
300-045S	LABEL, SYRINGE HOLDER, POLYE GR, WH ALC RES PR, 7.5x7.5		6
LBL00104	LABEL, REAR, T34, 3.1ED	Can be ordered for T34 pumps (without a S/N)	
LBL00105	LABEL, KEYPAD, T34, 3.1ED		
LBL00106	LABEL, INSTRUCTIONS, T34, 3.1ED		
LBL00111	LABEL, T34 GRAY, LEXAN,GLUE 3		
LBL00112	LABEL, QC APPROVED, T34, 3.1ED		
LBL00141	LABEL, SEAM SEAL, T34		
LBL00221	LABEL, REAR, BODYGUARD T	For BD BodyGuard™ T pumps	
PRL00131	LABEL, UDI, MEDICAL DEVICE\ACCESSORY		

Table A-4. Service/Test Tools

Part Number	Description	Comments
100-405PX	KIT, BURNING STATION, CABLES INCLUDED	
100-406X	CABLE, BURNING STATION, T34	
150-312S	COMMUNICATION STATION, BODYCOMM, BG T & T34	Used for connecting the pump to BD BodyComm™ Software Utility Tool and PumpMaster Software Utility Tool).
197-000X	CABLE, BODYCOMM (RS232-RS232)	
197-100X	CABLE, BODYCOMM, USB to SERIAL, U-224	
334S	GAUGE, DIAMETER, SYRINGE PUMPS, 19 mm	
336S	GAUGE, DIAMETER, SYRINGE PUMPS, 8 mm	
338S	GAUGE, DIAMETER, SYRINGE PUMPS, 30 mm	
T000355	BD BODYGUARD T DIGITAL SYRINGE OCCLUSION TEST GEAR	The syringe force gauges (included in kit 900-000) are no longer available to order. If you still have a set, reach out to your BD representative for guidance.

# Appendix B. Performance Verification Procedure (PVP)

Pump/Serial Number Hospital Name/Reference	Service Order/Inventory Number Pump Software Version	
<b>INSPECTION</b>	<u>Physical inspection*</u> and <u>clean.</u> <u>Replace damaged labels.</u>	
	<u>Perform the Test Verification Workflow.</u>	
	<b>Test:</b>	<b>Pass Criteria:</b> FAIL would not allow to continue to next step.
	Main Self-Test - access Technician menu (code 123)	
	Keypad	All keys must be pressed without fail.
	Display	Verify operation of all display pixels.
	Acoustic Alarm Test (Buzzer) + back-up alarm test + MIC level test	Test passes on first two screens if alarms are heard. Test passes on MIC level screen if values are over 50.
	LEDs Test	Checks green, red and yellow/orange LEDs.
	<u>Syringe Sensors Test</u>	Loading and removal of random syringe should display PASS.
	<u>Syringe Diameter Test</u>	Detection of syringe diameter within specification (3 diameter gauges – 8 mm, 19 mm, and 30 mm).
<b>MANUAL and SELF TESTS</b>	<u>Syringe Travel Test**</u>	PASS displayed when successful Auto Travel has completed. Results being <b>67 mm ± 1.0 mm</b> .
	Power Voltage Test	Voltmeter reading of 9 V battery to be <b>±0.2 V</b> from pump display (battery in pump).
	Syringe Holder and Actuator Movement	Verify smooth operation.
	<u>Battery Operation Test</u>	Load new battery. Verify 95–100% in Info mode.
	<u>Restore Software Default Settings</u>	If main PCB was replaced, verify that software and settings are correct, including syringe macro. When in doubt, refer to a clinician.
	<u>Occlusion Pressure Calibration.</u>	
	Pass/Fail	
	<u>Set/Confirm Time and Date</u> – info/set up/more/99/set Time & Date.	
	<input type="checkbox"/>	
	<u>Reset Hours Counter – Tech mode/Tech Code/123/</u> /Hours Counter.	
	<input type="checkbox"/>	
	<u>Volume Accuracy</u> ( $\pm 5\%$ ) 15 ml at 100 ml/h = 9 min NOTE: Set Pump back to client settings (or restore default settings) as per request.	
<u>Performed By</u> Print:		Sign: _____ Date: / /
Schedule: Perform this procedure at least every 12 months or as required. * pump must be internally inspected for fluid ingress if suspected (customer report or external evidence such as residue). ** make sure that actuator is located halfway between both ends		

# Appendix C. Drawings

## Front Assembly

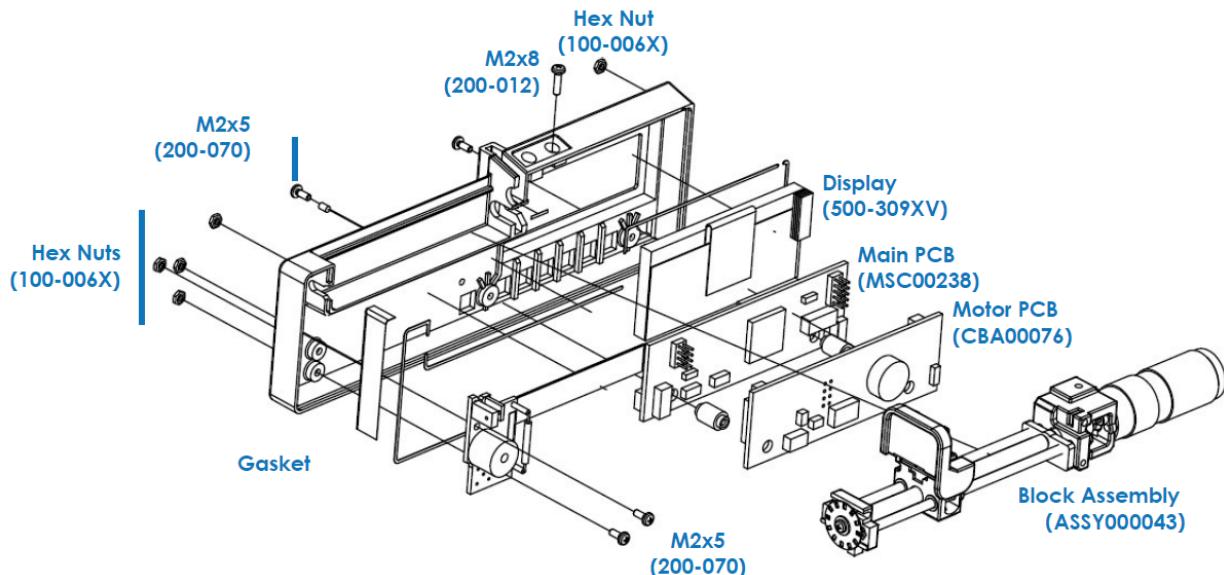


Figure C-1. Front Assembly

## Block Assembly (ASSY000043)

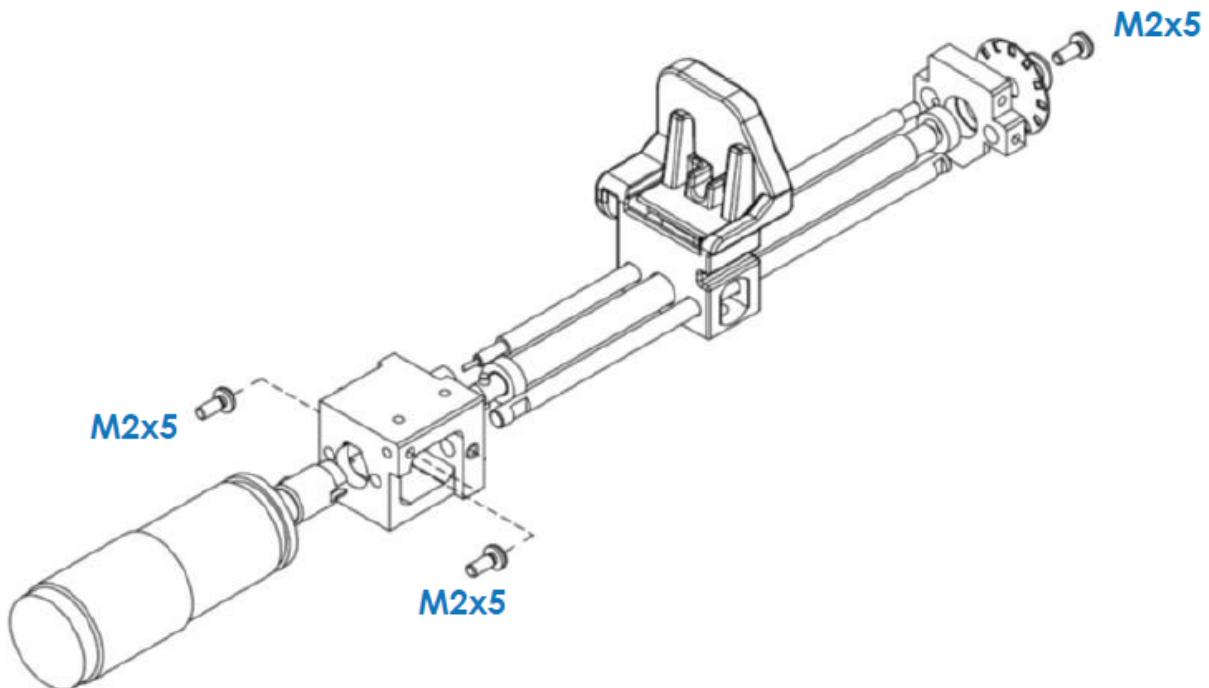


Figure C-2. Block Assembly (ASSY000043)

## Actuator Assembly (ASSY000045)

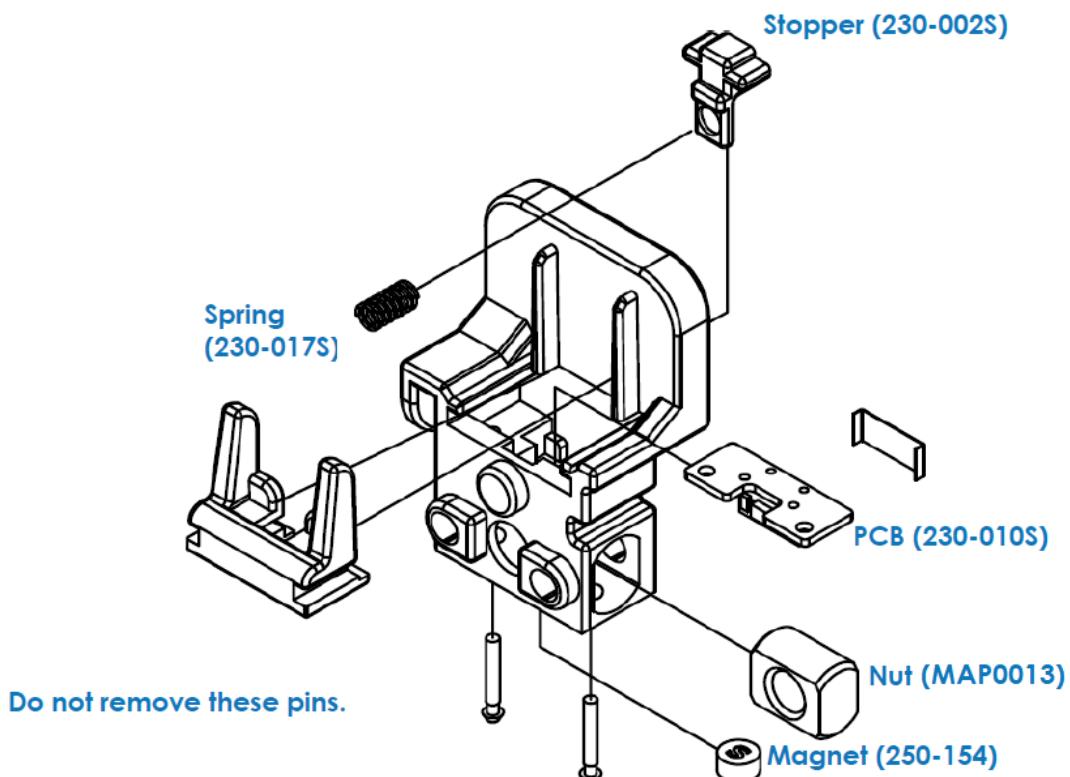


Figure C-3. Actuator Assembly (ASSY000045 - You can order 230-018PS, which includes the cover)

## Rear Assembly (400-031S)

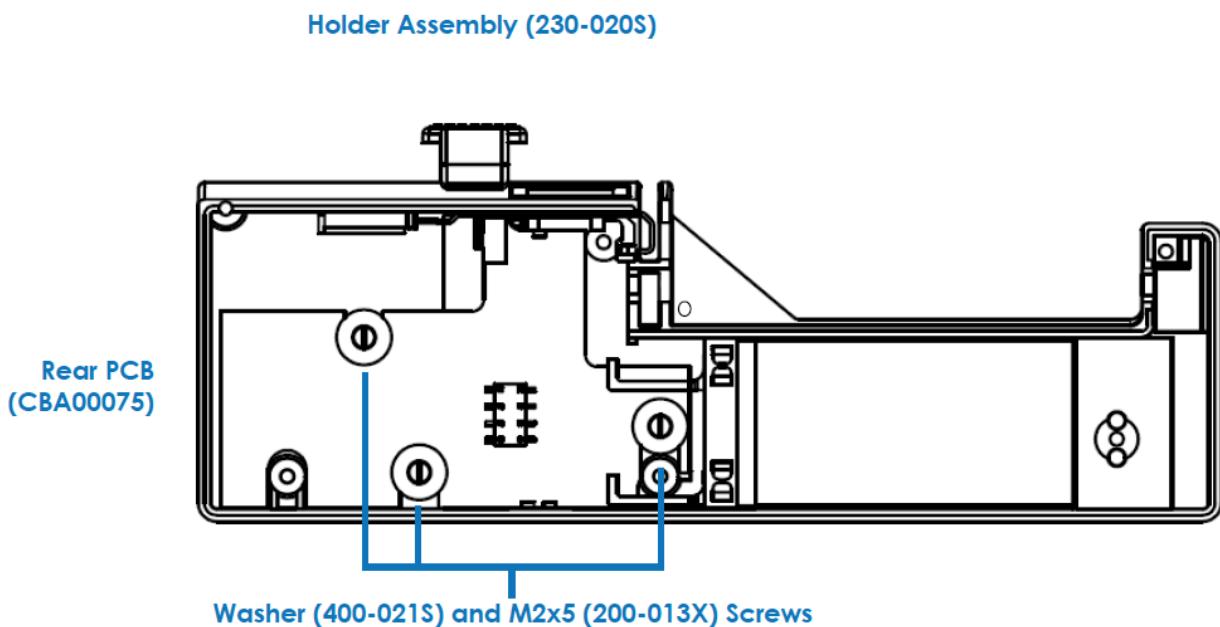


Figure C-4. Rear Assembly (400-031S)

## Pump Assembly

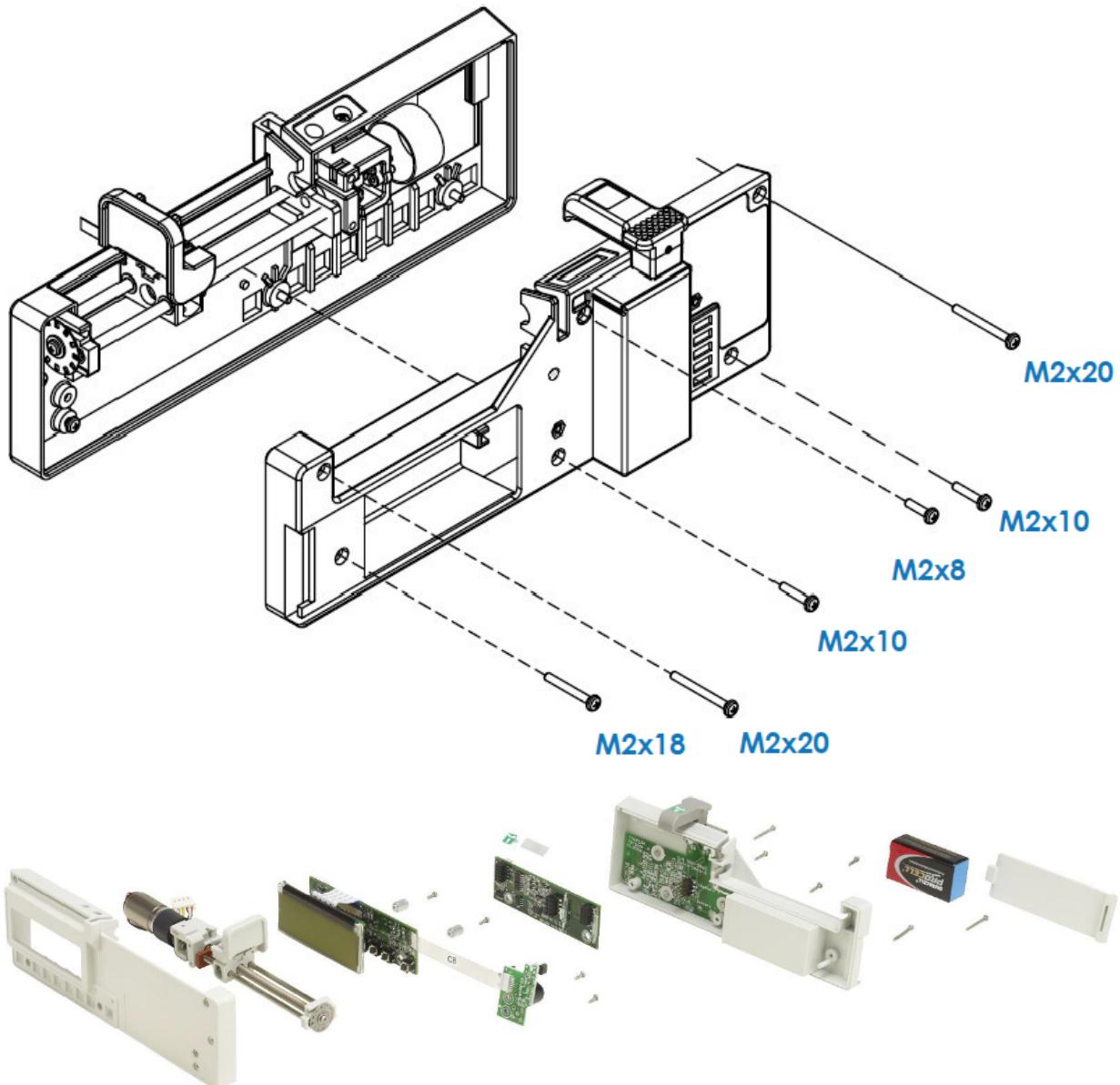


Figure C-5. Pump Assembly

# Appendix D. 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.	<ul style="list-style-type: none"> <li>0.1-10 ml/h in 0.01 ml/h increments;</li> <li>10-29.9 ml/h in 0.1 ml/h increments;</li> <li>30-49.5 ml/h in 0.5 ml/h increments;</li> <li>50-299 ml/h in 1 ml/h increments;</li> <li>300-650 ml/h in 5 ml/h increments.</li> </ul>							
Bolus parameters	Bolus flow rate 1-650 ml/h: <ul style="list-style-type: none"> <li>1-10 ml/h in 0.01 ml/h increments;</li> <li>10-29.9 ml/h in 0.1 ml/h increments;</li> <li>30-49.5 ml/h in 0.5 ml/h increments;</li> <li>50-299 ml/h in 1 ml/h increments;</li> <li>300-650 ml/h in 5 ml/h increments.</li> </ul>	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.								
Accuracy	<p>±5% system accuracy (pump and set combined) by volume under nominal conditions, defined as follows:</p> <ul style="list-style-type: none"> <li>Flow rates: 1 ml/h and 5 ml/h;</li> <li>Tested with extension set model M100-172SB;</li> <li>Needle: 18 gauge;</li> <li>Solution Type: Distilled water;</li> <li>Temperature: 22°C ± 3°C;</li> <li>Back Pressure: 0 ± 10 mmHg;</li> <li>Syringe size and brand: BD Plastipak™ 20 ml.</li> </ul> <p>Accuracy measured using the trumpet curve test method defined in EN/IEC60601-2-24.</p>								
Occlusion pressure	200-1500 mmHg configurable (10 mmHg increments).								
Battery	9 V alkaline, IEC 6LR61 type.								
Operating time	<table border="1"> <thead> <tr> <th>Rate</th><th>Approximate battery life</th></tr> </thead> <tbody> <tr> <td>1 ml/h</td><td>&gt; 50 hours</td></tr> <tr> <td>5 ml/h</td><td>&gt; 35 hours</td></tr> </tbody> </table>			Rate	Approximate battery life	1 ml/h	> 50 hours	5 ml/h	> 35 hours
Rate	Approximate battery life								
1 ml/h	> 50 hours								
5 ml/h	> 35 hours								
Indicators	4 line LCD display (122 x 32 pixels), dual color operation LED.								
Alarms	<p>When a problem is detected, the pump displays the following alarm messages, sounds an audible alarm and the LED lights red:</p> <ul style="list-style-type: none"> <li>Occlusion or Syringe Empty</li> <li>End Program</li> <li>End Battery</li> <li>Syringe Displaced during infusion</li> <li>System Error</li> </ul>								
Dimensions	167 x 68 x 39 mm								
Classification	<p>Type CF Equipment (degree of protection against electrical shock). IP22 protection against ingress of water and solid objects.</p> <p>Definition of code: I = Ingress P = Protection 2 = Protection from solid objects ≥12.5 mm 2 = Protection from dripping water (15° tilted)</p>								
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	<p>Designed and manufactured in accordance with ISO 13485, IEC 62304, IEC 62366-1, ISO 14971, IEC 60529, ISO 8536-8 and UL 94.</p> <p>CE marked in accordance with the Medical Devices Directive 93/42/EEC.</p>								

EMC Specifications:	<p>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).</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Reorient or relocate the receiving antenna.</li> <li>• Increase the separation between the equipment and receiver.</li> <li>• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.</li> <li>• Consult the dealer or an experienced radio/TV technician for help.</li> </ul> <p>The BD BodyGuard™ T Syringe Pump has been tested to comply with the requirements of IEC 60601-1-2:2014.</p>		
<b>EMC – Emissions Compliance</b>	<b>EMC Standard</b>	<b>Range</b>	<b>Compliance</b>
Radiated emissions	CISPR 11:2015	30 MHz - 1 GHz	Class B, Group 1
<b>EMC – Immunity Compliance</b>	<b>EMC Standard</b>	<b>Test level</b>	<b>Compliance</b>
Electrostatic Discharge (ESD) Immunity	IEC 61000-4-2	Contact discharge ± 2 kV, ± 4 kV, ± 6 kV Air discharge ± 2 kV, ± 4 kV, ± 8 kV	No degradation of performance
	IEC 60601-2-24	Contact discharge ± 8 kV Air discharge ± 15 kV	Operator intervention may be required as pump may intermittently reset, requiring user to restart the infusion.
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	<ul style="list-style-type: none"> <li>• 3 V/m 0.15 MHz - 80 MHz</li> <li>• 6 V/m in ISM and amateur radio bands between 0.15 MHz and 80 MHz</li> <li>• 80% AM at 1 kHz</li> </ul>	Yes
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009	30 A/m 50 Hz	Yes
Environmental specifications	<p><b>Operating Environment Range:</b></p> <ul style="list-style-type: none"> <li>• Ambient temperature: 5°C to 40°C.</li> <li>• Relative humidity: 15% to 90%, non-condensing.</li> <li>• Ambient pressure: 70 kPa to 106 kPa.</li> </ul> <p><b>Transport and Storage Conditions</b></p> <ul style="list-style-type: none"> <li>• Ambient temperature: -25°C to 70°C.</li> <li>• Relative humidity: 0% to 90%, non-condensing.</li> <li>• Ambient pressure: 48 kPa to 110 kPa.</li> </ul>		