



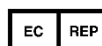
# ***BodyGuard 121 Twins***

## **Infusion System Operator Manual**

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**NOTE:** To assure proper use of the BodyGuard 121 Twins, C.M.E urges all users to read this manual carefully, become familiar with the procedures and system functions, and follow all recommendations herein.



***When Air Sensor is OFF – Use administration set with Hydrophobic filter (which expels air from the administration set). The use of any other set can cause severe damage to the patient and is strictly forbidden. Using the pump with air in line detector off may cause an embolism resulting in death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary. Please contact your technician in order to enable the air sensor if disabled with no need.***



U.S.A. federal law restricts this device to sale by or on the order of a physician.

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# 1- Introduction

## Overview

The *BodyGuard* 121 Twins provides the following features:

- 2 Channels pump
- Small, light, and compact pump.
- Multi Program:

Continuous	Continuous program. Infusion Rate: 0.1 to 1200 ml/hr. Volume: 0.1 to 9999 ml. Bolus Volume: 0-100ml Bolus Rate: 0.1-1200 ml/hr
TPN	Rate Taper program, with programmable up and down times.
DOSE	Dose program Dose: 0.1 to 250 kg in 0.1kg units. Volume: 0.1 to 99.9 ml in 0.1ml units 100 to 9999 ml in 1 ml units Concentration: 0.1 to 1000 mg/ml in 0.1 mg/ml units Dose: 0.1 to 1000 µg/kg/min in 0.1 µg/kg/min units
PCA	Optional Patient Control Analgesia: Continuous delivery plus /or programmed boluses. Bolus Volume: 0-25.5 ml Clinician Bolus Volume: 0.1-100ml Bolus Rate: 0.1-1200 ml/h
Intermittent	Optional A set dose delivered in set intervals. Between Intervals the pump will keep vein open (KVO Mode).
25 Steps	Optional Operator can design a specific protocol for drug delivery which contains up to 25 steps. Infusion Rate: 0.1 to 1200 ml/hr Volume: up to 9999ml, for each step Accumulated Volume for all steps – up to 10 liters.

- 
- Highly accurate fluid delivery on either or both channels.
  - Operated with a customized safe administration set.
  - Rechargeable internal lit-on battery.
  - Can be latched into a Charger, which is mounted on an IV pole.
  - Anti-free flow protection valve on the administration set.
  - A.B.S. Anti-Bolus System.
  - Silent operation.
  - Drop sensor control (optional on both channels).
  - RS232 data collection.
  - Bolus Cable (optional).

# Keypad Description and Functions

Front of BodyGuard 121 Twins Infusion Pump



## 1. Display Screen

A screenshot of the LCD display showing the following text: 'C|Rate 500ml/h', 'O|VolumeLeft 2000ml', 'N|Infused 4571.8ml', and 'T|Press OK to start'.

- Displays pump/infusion status
- Displays programming choices & instructions

## 2. Up Arrow



- Scrolls up through options

## 3. START/ OK



- Starts infusion.
- Confirms selection and setting.

## 4. STOP/NO



- Stops infusion.
- Silences an alarm condition.
- Pauses priming.
- Zeroes the displayed value during programming
- Erases the last digit during programming.
- Returns to previous screen



## 5. Prime Bolus

- Pressing Prime/Bolus key followed by Start/OK key *during data setting*: Enable Priming procedure. A graph appears on the display screen showing the priming volume with the current value increasing until reaching the set volume. Priming default volume: 20 ml.
- Pressing Prime/Bolus key during operation enables the user to see an infusion of a piggyback bag.



## 6. Power ON/OFF

- Turn the system on, by pressing and holding the button until the self-test screen appears.
- Turn the system off, by pressing and holding the button until the graph is black and a beep is generated.



## 7. Select Channels key

Allows the user to move between channels



## 8. Two Operation LED ( one for each channel)

- Green Indicator
  - Lights during system self-test
  - An intermittent green light indicates infusion delivery on the selected channel and lights continuously on the other channel.
- Red Indicator
  - Indicates an alarm state with a continuous red light
  - Blinks when the pump is in a stand-by mode during programming, on the selected channel or when the pump indicates low battery.



## 9. INFO

- Supplies information about the pump and its programs (see info mode chapter).
- Pressing continuously locks and unlocks the keypad to prevent accidental or deliberate change to pump operation.



## 10. Down Arrow

- Scrolls down through options



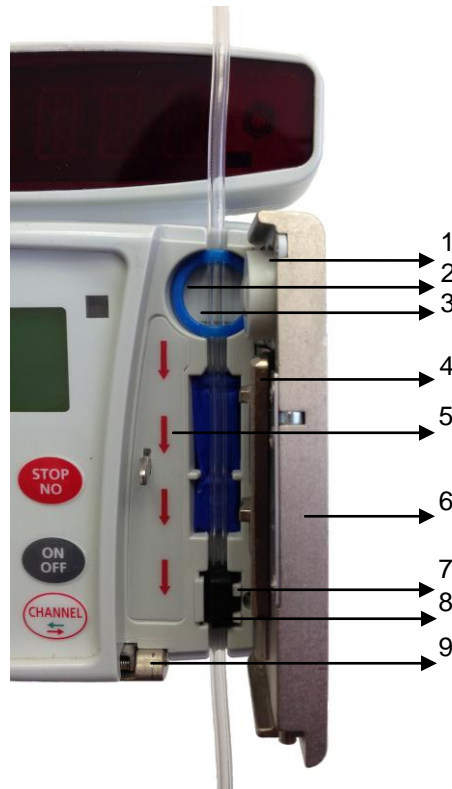


## 11. Numeric Keys

- Enters numeric parameters during programming

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## BodyGuard 121 Twins Pump with one Door Open



#	Area	Function
1.	Anti-stretch key	Prevents incorrect tube stretching and locates the IV set correctly in conjunction with the Keyway
2.	Air sensor – front	Ultrasonic air detector, which is mounted on the front housing.
3.	Air sensor - door	Mounted on the door.
4.	Pressing Plate	Connected to the door by two springs.
5.	Pump door	Covers the pressing plate.
6.	Flow Direction	Shows direction of pump operation.
7.	Pressure sensor	Detects downstream tubing restriction and occlusion. Alarm level can be adjusted to suit patient needs.
8.	Keyway	Guides the IV set in conjunction with the Anti-stretch key
9.	Latch holder	Holds the door closed when latch is in vertical position.

# The Charger



#	Area	Description
1.	Pump channel one led	Green when channel I is infusing, Red when channel I is being programmed or under alarm, idle when channel II is on display.
2.	Battery charging led	Red when the battery is empty and being charged
3.	Battery charged led	Red when the battery is fully charged
4.	Channel one charger display	Displays channel I data
5.	Channel two charger display	Displays channel II data
6.	Mains led	Red when the pump is connected to mains
7.	Channel two pump led	Green when channel II is on display, Red when channel II is being programmed or under alarm, idle when channel I is on display.

---

# System Safety Checks

The following details outline the safety checks designed into the *BodyGuard 121 Twins* infusion system in order to minimize the possibility of under or over infusions.

## Free Flow Protection

The system's customized IV lines (on each channel) are equipped with an anti-siphon valve that prevents free-flow towards the patient when the IV line is not attached to the pump. When the pump is attached to the IV line and delivering fluid, the pressure delivered by the pump opens the valve. The one way valve also prevents one channel infusing in the other channel.

## Anti-Bolus Function

The anti-bolus function is designed to reduce the bolus that may occur upon the release of an occlusion following a downstream occlusion alarm. Upon the detection of a downstream occlusion, the alarm is activated and the pump returns the IV line pressure to neutral within 15 seconds. Neutral line pressure is achieved by the reverse operation of the pumping mechanism, and measurement of the IV line pressure through the in-line pressure detection system.

## Air-in-Line Accumulation

To improve the detection of air in the IV line, the BodyGuard 121 Twins Infusion system utilizes an air-in-line accumulation system in addition to the standard single bubble detection. This feature monitors the volume of air that passes through the IV line by accumulating the volume of individual bubbles of 1 ml over a moving window of 15 minutes. The limit is not configurable. Although an individual bubble may not exceed the pre-programmed threshold, the cumulative volume of bubbles of 1-milliliter volume may exceed the limit during the 15 minutes window and initiate an air-in-line alarm. This accumulation feature is particularly useful with infusions for patients who are highly sensitive to air (i.e. infants, neonates, children) or when infusing products that create significant volumes of small air bubbles.

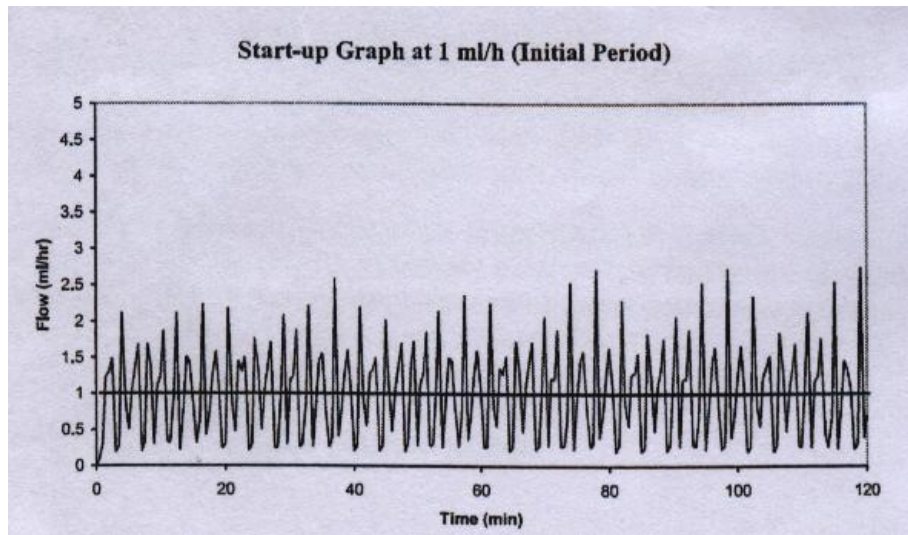
# Pump Accuracy

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

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## Start-up Curves

The Start-up curves represent continuous flow versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical complexity and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed according to IEC 60601-2-24 standard.



## Trumpet and Flow Rate

With the *BodyGuard 121 Twins*, as with all infusion systems, the action of the pumping mechanism and variations cause short – term fluctuations in rate accuracy.

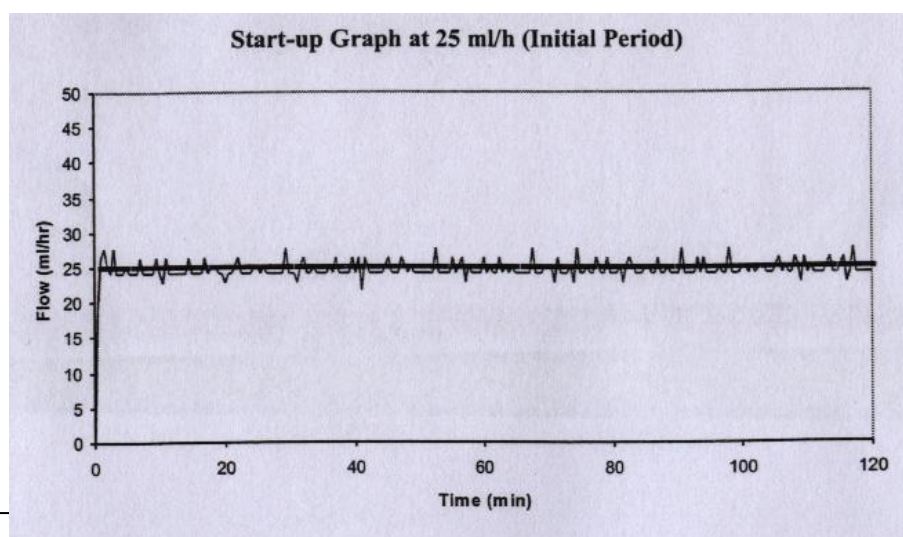
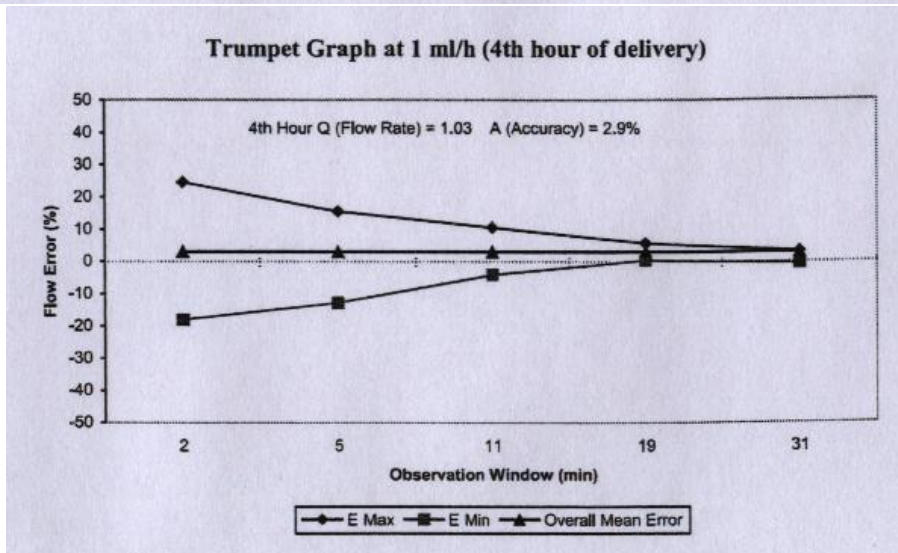
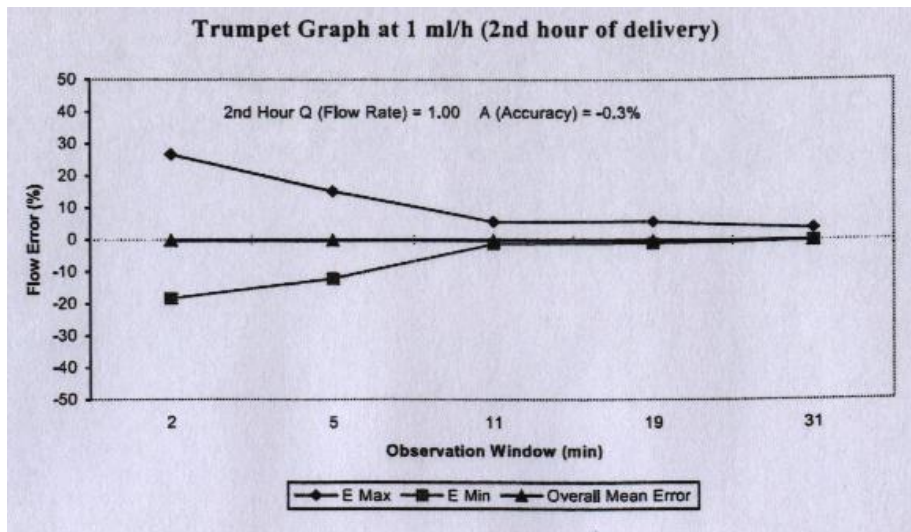
The following curves show typical performance of the system in two ways:

1. The accuracy of fluid delivery over various time periods is measured (trumpet curves).
2. The delay in onset of fluid flow when infusion commences is measured (start up curves).

Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods, "Observation windows", as opposed to continuous data versus operating time. Over long observation windows, short-term fluctuations have little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effect as represented by the "mouth" of the trumpet.

Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short-term fluctuations in rate accuracy may have clinical impact depending on

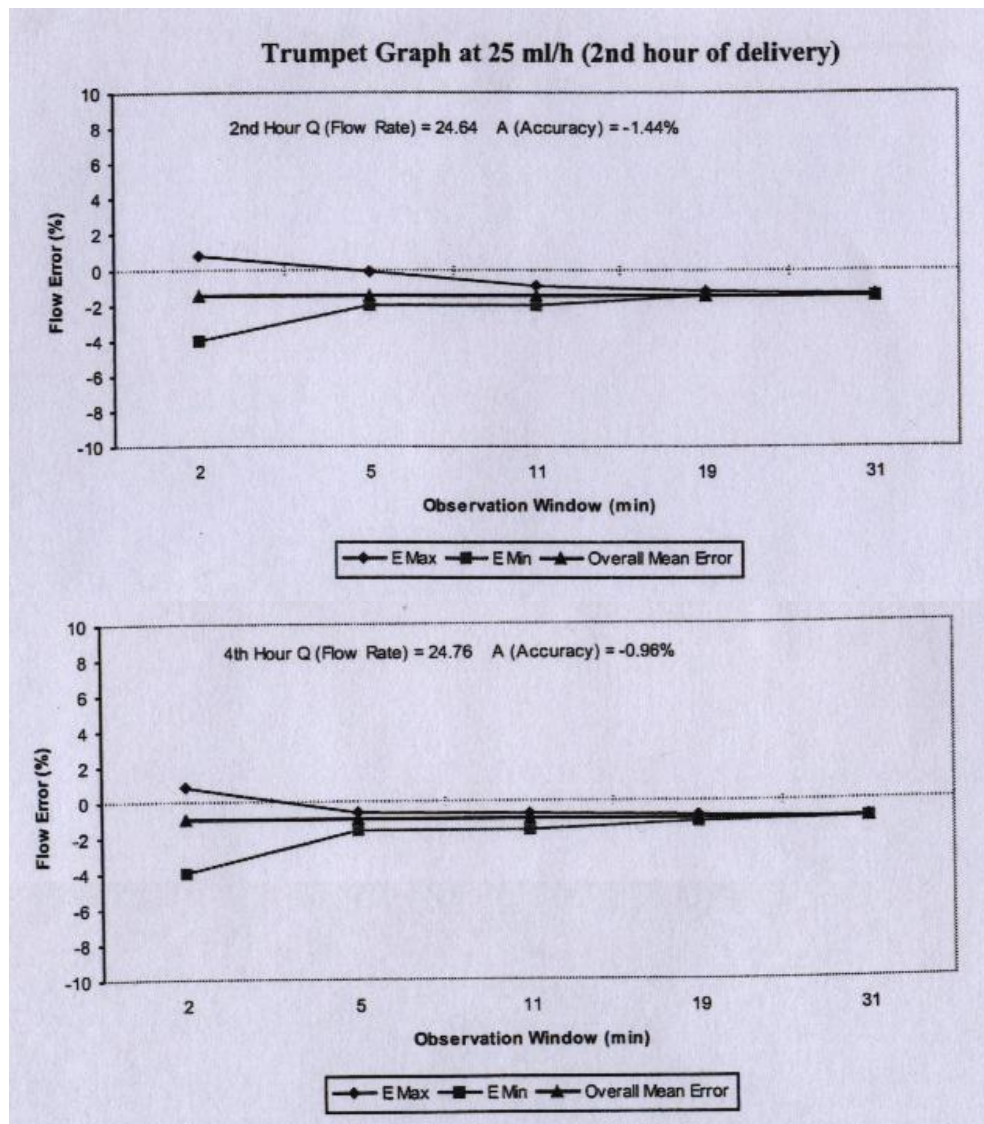
the shelf life of the drug being infused and the degree of inter-vascular integration; the clinical effect cannot be determined from the trumpet curves alone.



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## 2 – Symbols, Warnings, and Cautions

### System Symbols

The following symbols are used with the *BodyGuard 121 Twins* Infusion System and components. Labels on the system or statements in this manual preceded by any of the following words and/or symbols are of special significance intended to help you operate the pump in a safe and successful manner.



Attention, consult accompanying Instructions.



CSA mark



CE mark indicates conformance to Medical Device Directive 93/42/EEC.



Do not dispose of in municipal waste. Symbol indicates separate collection for electrical and electronic equipment. (WEEE Directive 2002/96/EEC). **NOTE:** Does not apply to the battery.



Do not dispose of battery in municipal waste. Symbol indicates separate collection for battery is required.



The use of single-use disposable components on more than one patient is a biological hazard. Do not reuse single-use disposable components.



Type CF applied part.



Date of Manufacture



Serial Number



Expiry Date of disposable

LOT

Lot Number

STERILE

EO

Sterilized with Ethylene Oxide



**Warning:** Indicates that the information is a warning. Warnings advise you of circumstances that could result in injury or death to the patient or operator. Read and understand this manual and all warnings completely before operating the *BodyGuard 121 Twins* Infusion System.



**Caution:** Indicates that the information is a caution. Cautions advise you of circumstances that could result in damage to the device. Read and understand this manual and all cautions completely before operating the *BodyGuard 121 Twins* Infusion System.



**NOTE:** Indicates that the information that follows is additional important information or a tip that will help you operating the *BodyGuard 121 Twins* Infusion System.

## Intended Use

The *BodyGuard 121 Twins* infusion Pump system is designed for infusion of medications or fluids requiring continuous or intermittent delivery at precisely-controlled infusion rates through clinically acceptable routes of administration, including intravenous, subcutaneous, percutaneous, intra-arterial, epidural, enteral, 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, PCA therapy, parenteral and enteral nutrition fluids, chemotherapeutic agents, blood or blood products infusion and general fluids therapy in hospital and home care environments.

## Warnings

To avoid possible personal injury or loss of life, observe the following:



***When Air Sensor is OFF – Use administration set with hydrophobic filter (which expels air from the administration set). The use of any other set can cause severe damage to the patient and is strictly forbidden. Using the pump with air-in-line detector off may cause an embolism resulting in death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary. Please contact your technician in order to enable the air sensor if disabled with no need.***



Read the entire Operation Manual before using the pump, since the text includes important precautions.



The maximum volume that may be infused under SINGLE FAULT CONDITION is 0.1 ml



Voltage present in internal components may cause severe shock or death upon contact. Disconnect the Charger from the mains prior to opening the casing. Only trained service personnel should open the pump cover.



Blown fuses could pose a fire hazard. Replace blown fuses on the charger only with fuses of the same type and rating (see fuse values on the Charger PCB).



The equipment is not suitable for use in the presence of flammable anesthetic-air/oxygen/nitrous oxide mixture. Do not use the system in the presence of these gases.



Make sure the pump is securely attached to the Charger, which is connected firmly to an IV pole.



A kinked or occluded IV line may impair the operation of the pump and the accuracy of the infusion. Before operation, verify that the IV line is not kinked or occluded.



The *BodyGuard 121 Twins* should be operated only with the *BodySet/MicroSet* IV lines. Use of IV lines other than the *BodySet/MicroSet* may impair the operation of the pump and the accuracy of infusion.



Drugs must not be administered to the epidural space unless the drugs are indicated for this purpose and are administered in accordance with the indications included in the manufacture's package. Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient. For epidural administration of drugs use *MicroSet* only.



Any adjustments, maintenance, or repair of the uncovered pump may impair the operation of the *BodyGuard 121 Twins* Infusion System and/or the accuracy of infusion. Any adjustments, maintenance, or repair of the uncovered pump should be performed by authorized skilled technicians. Any adjustments, maintenance, or repair of the uncovered pump while connected to mains should be avoided.



The *BodyGuard 121 Twins* Infusion System should be operated within a temperature range of 15°C (59°F) to 45°C (113°F) and up to 85% humidity. Operating the pump at temperatures and/or humidity outside that range may affect accuracy.



Use of improper accessories represents unsafe operation. Use only accessories and options designed for this system.



Disposables must be compatible with the medicine delivered.



Battery charging is enabled as long as the charger cord is connected to the mains and the pump is in the charger. Switching the pump off does not disconnect it from the mains. To disconnect from mains, remove the charger cord from the power outlet. To disconnect pump from mains, remove it from the charger.



Dropping the *BodyGuard 121 Twins* Infusion System could cause damage to components. If the pump is dropped, return the pump for inspection by qualified service personnel.



Use 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 IV sets.



Watch your fingers / nails when opening the pump door.



Do not operate the pump near high-energy radio-frequency emitting equipment, such as electro-surgical cauterizing equipment, and cellular telephones. False alarm signals may occur.

## Cautions

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



Leaving the battery in a discharged state for a long period of time may damage the battery. Connect the pump to the mains via the charger whenever possible to recharge the battery.



Do not store the pump with the battery fully depleted.



Xylene, Acetone, or similar solvents could cause damage to components. Do not clean the pump with these chemicals. Clean solution spills on the pump immediately. Use a damp cloth or sponge. A mild detergent may be used. Wipe thoroughly with a dry cloth.



Immersing the *BodyGuard 121 Twins* Infusion pump into liquid could cause damage to components. Do not immerse the pump into any type of liquid.



Battery damage could occur if left in a temperature higher than 50°C (122°F).



Infusion of blood or blood products should be restricted to maximum rate of 600ml/h.

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# 3 – Bodyguard 121 Twins-Installation and Setup

## Unpacking

1. Carefully remove the pump and Charger from the box.
2. Make sure no items were damaged during shipment
3. Make sure you have the following items:
  - *BodyGuard 121 Twins* Infusion Pump
  - Charger
  - Operation Manual

If any items are missing or damaged, contact your *BodyGuard 121 Twins* dealer.

## Charging the Pump



**NOTE:** The pump is protected against overcharging. Connect the pump to the mains via the charger whenever possible to be sure that the battery is fully charged at all times.



**Warning:** If the battery is damaged during operation, while pump and charger are disconnected from mains, the pump will turn off.

1. Connect the charger unit to AC power, and verify that the AC indicator is lit (charger right side above channel II).
2. Put the pump into the charger and tighten the safety screw. Please see drawing on the charger.
3. The battery is charging when the red battery LED on the front of the charger is lit. (charger lower left side above channel I) The battery is fully charged when the full battery LED symbol turns red (charger upper left side above channel I).
4. Remove the pump from the charger by releasing the safety screw and lifting the pump out of the charger.



**Caution:** Leaving the battery discharged for a long period of time may damage the battery.


# 4 – Operation

## Before Operating the Pump

Before attaching the system to a patient, run the following tests to verify that all indicators and alarms work properly. Perform the test on both channels.


When an alarm is activated the following occurs:


- An alarm message appears on the pump and charger display. Each channel has its own display. The alarm message will be shown on the display relevant to the channel in which the alarm occurred.
- An audible alarm sounds.
- Infusion ceases.
- The operation LED changes from green to red.

 NOTE: All tests should be performed in the Continuous program on both channels.


## Pump Operation Test (Channel 1)

1. Click the pump into a Charger connected to AC power. Verify that the CHARGE Red LED on indicator is on (on charger) the charger
2. Insert a BodySet / MicroSet administration set, on left (green) channel, and close the pump door. Press the door until a click is heard.

 NOTE: For instructions on how to load and prime an administration set refer to sections “Loading the Administration Set” & “Priming the Line”.

3. Press  key until the self-test screen appears. The pump will enable setting data of channel 1. Press the Start/Ok key to confirm channel 1 or press Channel key to enter channel 2 data.

4. After switching the pump on, Channel 1 and the program selected will be displayed on the screen. During the self-test a long beep will be heard. This procedure verifies that the pump’s acoustic and visual features are working properly. After overview, press Start/Ok key to display


the last set rate. If air sensor is off, Press  to confirm.

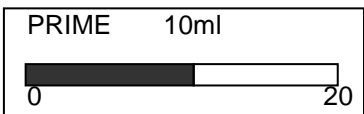
5. Press  to prime the IV line.

PRIME  
DISCONNECT PATIENT  
Press OK to Start





**Warning:** Ensure the set is not connected to a patient!!









6. Press  to start priming. The screen shows the progress bar of the priming operation.
7. When priming has completed, wait 2 minutes without pressing any key. After two minutes the screen displays “Pump Unattended” and an alarm will sound.



Pump Unattended  
Press Start key

8. Press  to silence the alarm.
-  **NOTE: Same tests should be performed for channel 2.**




## Air in Line – Alarm Test ( Channel 1)

1. Insert a BodySet administration set in Channel 1 and close the pump door. Press the door until a click is heard. Switch the pump on.
-  **NOTE:** For instructions on how to load and prime an administration set refer to sections “Loading the Administration Set” & “Priming the Line”.
2. The pump will display channel 1 and the program selected. In order to edit channel 2 press the CHANNEL key once.
  3. The pump displays Channel 1 and the program selected. Press  to show the last rate
  4. setting. If air sensor is off, Press  to confirm.  
Set/change the infusion rate at 500ml/hr, using the numeric keypad and press  to confirm setting. Verify that the charger’s display shows 500.
- Rate 500 ml/h  
 Press OK for Volume
5. Set Volume at 20 ml. press  key.
  6. The pump display will show the accumulation screen where all set data is shown, check the settings, if correct, press  to start operation
- Volume 20 ml  
 Press OK Key
- |                   |          |
|-------------------|----------|
| Rate              | 500 ml/h |
| Volume left       | 20 ml    |
| Infused           | 0 ml     |
| Press Ok to Start |          |
7. Disconnect the IV line from the IV bag or turn the drip chamber upside down (applicable to the BodySet only) to allow an air bubble greater than 5 mm to enter into the administration set.
  8. Air-in-line alarm will be activated as soon as the air bubble enters the set segment located behind the pump door.
  9. Press  to turn the alarm off.
-  **NOTE: Same tests should be performed for channel 2.**


## Down Occlusion – Alarm Test (Channel 1)

1. Insert a BodySet administration set in channel 1 and close the pump door. Press the door until a click is heard.
2. Make sure room temperature is 21-23 °c.

- ☞ **NOTE:** For instructions on how to load and prime an administration set refer to sections “Loading the Administration Set” & “Priming the Line”.

3. Press  until the self-test screen appears. The pump displays Channel 1 and the program selected. Press the Start/OK key to display the last rate setting. If air sensor is off, press  to confirm.
4. Set the infusion rate at 500ml/hr, using the numeric keypad and press  to display last volume set.

Rate 500 ml/h
Press OK for Volume
5. Set Volume at 20 ml.

Volume 20 ml
Press OK to Start
6. The pump display will show the accumulation screen where all set data is shown, check the setting, if correct, press  to start operation.

Rate	500 ml/h
Volume left	20 ml
Infused	0 ml
Press Ok to Start	
7. Wait 5 minutes and connect a pressure gauge at a distance of 1 meter from the exit of the pump. Place both the pump and the pressure gauge at the same level (on a table)
8. Wait 5 more minutes and occlude the IV line downstream of the pump (between the pump and the patient).
9. The Down Occlusion alarm occurs at the time and rates listed below (time is measured from actual occlusion time to alarm, with accuracy of +30%-20%):
  - 500 ml/h up to 20 seconds
  - 60 ml/hr up to 1 minute
  - 1 ml/hr up to 80 minutes
  - 0.1 ml/hr up to 11 hours

- ☞ **NOTE:** The pressure threshold can be changed to suit patient need (refer to section on changing the current Default Pressure Limit).

10. Depending upon the set flow rate and pressure threshold, the Down Occlusion alarm will be activated.

DOWN OCCLUSION
Press STOP to mute


11. Press  key to mute the alarm.

- ☞ **NOTE: Same tests should be performed for channel 2.**




## Door Open – Alarm Test (Channel 1)


1. Insert a BodySet /MicroSet administration set in channel 1 and close the pump door. Press the door until a click is heard.


- ☞ **NOTE:** For instructions on how to load and prime an administration set refer to sections “Loading the Administration Set” & “Priming the Line”.

2. Press  until the self-test screen appears.




3. The pump displays Channel 1 and the program selected. Press  to change the display to
  - show the last rate setting. If air sensor is off, press  to confirm.
  4. Set the infusion rate at 500ml/hr, using the numeric keypad and press  to display the last set volume.
 






Rate 500 ml/h
Press OK for Volume
  5. Set Volume at 20 ml. Press the  key.
 

Volume 20 ml
Press OK key
  6. The pump display will show the accumulation screen where all set data is shown, check the setting, if correct, press  to start operation.
 



Rate	500 ml/h
Volume left	20 ml
Infused	0 ml
Press Ok to Start	
  7. Open the pump door.
 

DOOR OPEN
Close Door
  8. "Door Open" alarm will be activated at once.
  9. Close the door. The display will show STOP.
-  **NOTE: Same tests should be performed for channel 2**

## Battery Test

1. Insert a BodySet /MicroSet administration set in both channels and close both doors. Press the doors until a click is heard in both channels.
-  **NOTE:** For instructions on how to load and prime an administration set refer to sections "Loading the Administration Set" & "Priming the Line".
2. Take the pump out of the charger.
  3. Press  until the self-test screen appears.
  4. The pump displays Channel 1 and the program selected. Press  to display the last rate
  - setting. If air sensor is off, press  to confirm.
  5. Set the infusion rate at 1200ml/hr, using the numeric keypad and press  for volume.
 


Rate 1200 ml/h
Press OK for Volume
  6. Set Volume at 9999 ml.
 

Volume 9999 ml
Press OK key
-  The pump display will show the accumulation screen where all set data is shown, check the setting, if correct, press  to start operation.
- |                   |          |
|-------------------|----------|
| Rate              | 500 ml/h |
| Volume left       | 20 ml    |
| Infused           | 0 ml     |
| Press Ok to Start |          |

- 
- Wait until pump displays the "low battery" message

Low Battery

Connect To Charger

- Press  to turn the pump off.
- Connect the pump to a charger.
- Verify that the red LED indicating an empty battery lights on (lower left side of the charger above channel one).
- Verify that the full battery LED lights red after 4-6 hours of charging (upper left side of the charger above channel one).

## Charger Indicator Test

- Click the pump into the charger and connect the charger to mains. Disconnect the power cord from the AC power outlet.
- Verify that the CHARGE LED indicator (in the charger right side above channel II) is off.
- Connect the power cord to the AC power outlet. Verify that the CHARGE LED indicator is on.

## Drop Sensor Function

- Connect the drop sensor to the pump charger as shown on picture:



- Check the pump display for Drop Sensor presence.  
The charger should show drop sign after recognizing that the drop sensor is connected (when the pump is operating) as shown on picture.



## Dedicated BodyGuard 121 Twins Administration Sets

The *BodyGuard* 121 Twins infusion System should only be operated with the *BodySet* or *MicroSet* dedicated Infusion sets.

The major difference between the two types of sets is the tubing diameter. The *MicroSet* administration set, with smaller tubing diameter, is designed for the administration of expensive drugs.



**Warning:** Do not operate the *BodyGuard* 121 Twins Infusion system with any administration set, other than the *BodySet* or *MicroSet*. The *BodySet/MicroSet* Infusion Sets are equipped with a free flow protection valve, to prevent a gravitational free flow hazard. Using a different set may essentially change the administration rate and expose the patient to free-flow.

## The *BodyValve*<sup>TM</sup>

The Anti free flow valve, *BodyValve*<sup>TM</sup>, enhances pump functioning by:

- Preventing free-flow in the event the set is detached from the pump.
- Preventing back-flow (reflux) in the event several infusion pumps are connected simultaneously to the same patient.
- Preventing free-flow in the event of a mechanical malfunction.
- Preventing pump operation if the set has been loaded incorrectly.



**Warning:** Replace the administration set every 72 hours to lessen the incidence of bacteria formation.



**Warning:** Disposables must be compatible with the medicine delivered.



**Warning:** Patient or operator injury may result if package is opened or damaged, or if damaged components are used. Visually inspect contents and package before each use.



**Warning:** Air embolism can cause serious injury or death to the patient. Do not connect a patient to the *BodyGuard* Infusion Pump until all trapped air has been cleared from the fluid path. Carefully read the instruction for loading an administration set. Punctured set components may cause air embolism as well.



**Warning:** Drugs must not be administered to the epidural space unless the drugs are specifically indicated for this purpose and are administered in accordance with the indications included in the manufacture's package insert accompanying the drugs. Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

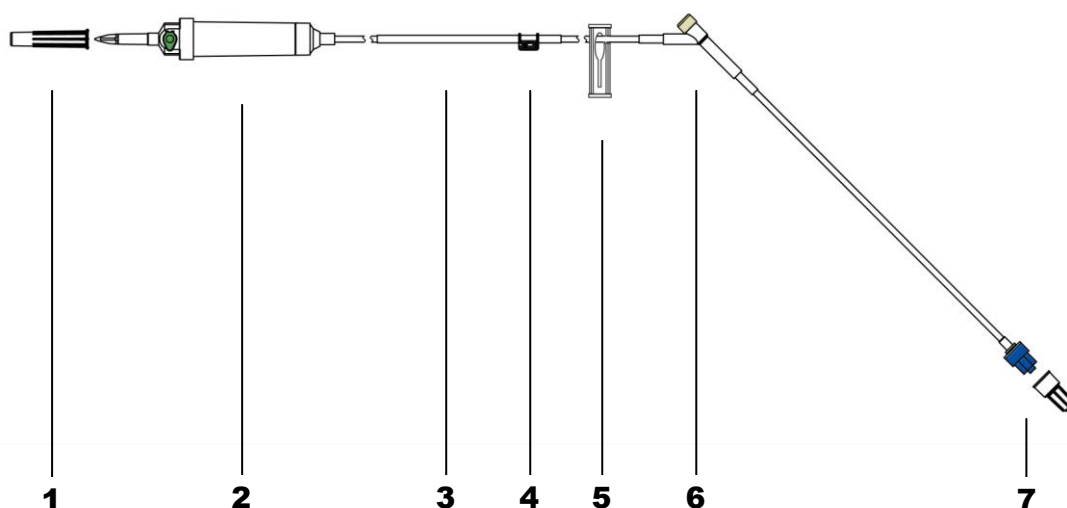


**Warning:** For epidural administration of drugs use *MicroSet* only.



**Caution:** Component damage may occur if not installed properly. Assure all connections are secure; do not over tighten. This will help minimize leaks, disconnection and component damage.

## MicroSet™ with Drip Chamber

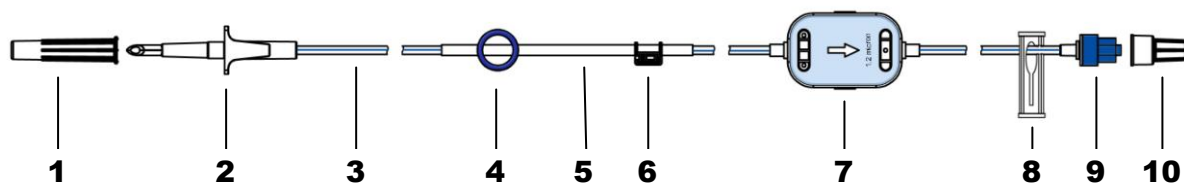


#	Area	Function
1.	Spike Cap	Connects the administration set to solution bag
2.	Drip Chamber with Spike	Displays infused drops from the administration bag to the patient
3.	Pumping Segment Tubing 3 x 4.1 mm	Transfers the solution
4.	Key	Locates the tube in the correct flow direction
5.	Slide Clamp	Can be used to occlude the tube
6.	Y Connector	Used to add drugs by syringe
7.	BodyValve™ With Cap	Anti free-flow valve

\* The set can be configured without the Y connector.

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## MicroSet™ with 1.2mic Filter




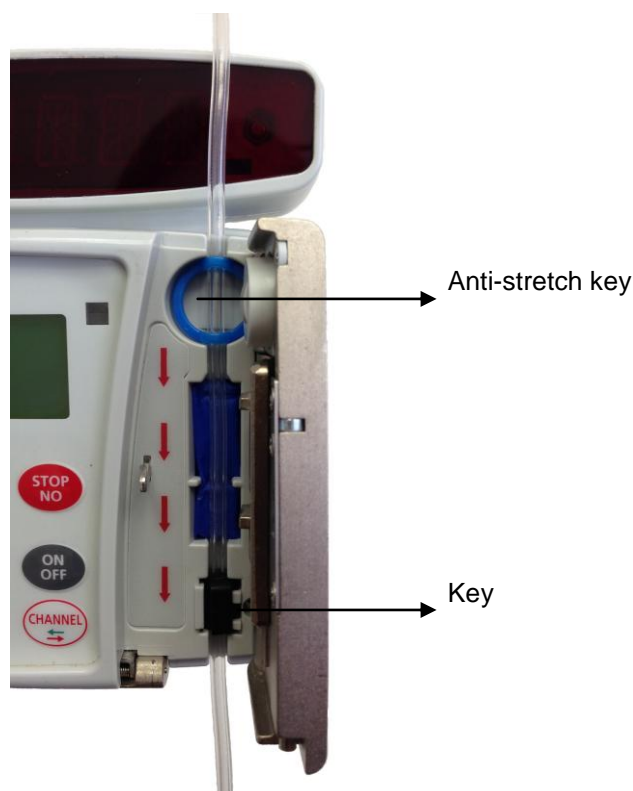
#	Area	Function
1.	Spike Cap	Keeps the set sterile
2.	Spike	Connects the administration set to solution bag
3.	Administration Tubing 1.5 x 3 mm	Transfers the solution
4.	Anti Stretch locator	Prevents incorrect tube stretching and locates the administration set correctly
5.	Administration Tubing 3 x 4.1 mm	Transfers the solution (pumping segment)
6.	Key	Locates the tube in the correct flow direction
7.	Filter 1.2 micron	Filters the fluid path from air and particles
8.	Slide clamp	Can be used to occlude the tube
9.	Anti-Siphon valve	Connects the administration set to the patient access device – prevent free flow
10.	Male luer lock Cap	Keeps the set sterile

---


# Loading the Administration Set

 NOTE: Follow the Instructions supplied with the individual administration set.


 **Warning:** Use of any administration set, other than the *BodySet/MicroSet*, may impair the operation of the pump and the accuracy of infusion.




1. Prepare the administration set by remove it from the sterile packaging leaving the end caps on the line.
2. Pull the door latch down (on the door's bottom surface) to open the *BodyGuard 121 Twins* pump door.
3. Hold the section of tubing with the black key and anti-stretch blue key on it and make sure the flow direction corresponds to the flow direction arrows inside the pump door.
4. Insert the IV tubing into the pump by placing the black key into the keyway and the blue key above the air sensor- door as shown by the arrows in picture 1. Insert the tubing from up down, and avoid stretching or pulling the tubing. Check that the keys located on the tube are located in its correct position.

 NOTE: The IV key can only be fitted into the keyway one way. If you are having trouble fitting it, do not force it in. Try to turn the line around to ensure you are correctly lined up with the direction of flow.


5. Ensure that the distal flow valve is on the right hand side of the pump.
6. Close the pump door until the latch clicks.

 **NOTE:** Ensure that the tubing is inserted completely into the pumping channel. Same procedure should be applied to both channels.



**Warning:** Use aseptic technique. Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components and only use single use consumables marked  once.

## Priming the Line (same for both channels)


 **NOTE:** Both *BodySet* and *MicroSet* administration sets contain a one-way Anti-Siphon valve also called Free-Flow valve. Therefore, the lines cannot be primed using gravity and must be primed using the *BodyGuard* 121 Twins priming function.

Prime function must be used:

1. Before starting a program
2. After air in line alarm







**Warning:** Always disconnect IV tubing from patient before starting priming procedure.

-  **NOTE:**
- The priming should be performed at a flow rate of 425 ml/hr or lower in order to remove the entire air in set. During priming the air in line alarm is disabled.
  - The priming volume is adjustable from 0-60 ml (see “Change set up” section) with an initial default setting at 20 ml.

## Priming Operation – before starting a program

1. Insert a BodySet administration set in Channel 1 and close the pump door. Press the door until a click is heard. Switch pump on.



 **NOTE:** For instructions on how to load and prime an administration set refer to sections “Loading the Administration Set” & “Priming the Line”.

2. The pump will display channel 1 and program selected. Press the  key to confirm channel 1 or press the channel key to enter channel 2 data.
3. The pump displays Channel 1 and the program selected. The display will automatically change and display the last rate setting. If air sensor is off, Press  to confirm.
4. When the display screen shows the existing program press  key to prime the administration set.

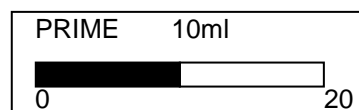
PRIME  
DISCONNECT PATIENT  
Press OK to Start



**Warning:** Ensure the set is not connected to the patient!!!

5. Press  to start priming. You may stop priming at any time by pressing .

6. The display screen will show a progress bar indicating the priming operation.



7. Once the priming has completed, the display will change back to the previous screen the pump was in before priming.



Make certain that all air is removed from the IV line before connecting to the patient. To perform another priming operation, in case all air was not cleared from the set, open a door and close it, then follow the same instructions to prime the set once more until no air is left in the set.

## Prime Operation – After Air in Line Alarm



1. Press  to mute the alarm.
2. Disconnect IV tubing from patient.

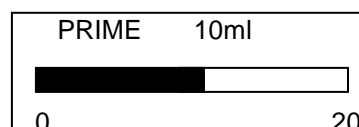
PRIME  
DISCONNECT PATIENT  
Press OK to Start

3. Press  once.




**Warning:** Ensure the set is not connected to the patient!!!

4. Press  to start priming. You may stop priming at any time by pressing .
5. The display screen will show a progress bar indicating the priming operation.



6. When priming has completed make certain that all air is removed from the IV line.

7. Connect IV line to the patient and press  to resume program.



**NOTE: Same tests should be performed for channel 2.** To change the display to

channel 2, use the Channel select key . User may prime channel one while setting program data on channel two.



## Operation steps

As follows are the steps for starting infusion procedure. For detailed instructions regarding each step refer to the relevant sections in the Operation chapter.



---

## Pump Mounted on IV Pole

1. Connect the *BodySet/MicroSet* to the medication bag; for each channel a bag (if necessary). Mount the bag on an IV pole.
2. Attach the pump into the charger. Mount the charger on an IV pole.
3. Connect the charger via a standard power cord to a grounded AC outlet.
4. Open channel 1 pump door and load the administration set into the pump's tubing canal. Repeat, same operation, if necessary, for channel 2.
5. Turn on the *BodyGuard 121 Twins* pump, by pressing  key until the self-test screen appears.
6. The display will show Channel 1 and the program selected. Press the  key to display the last rate setting.
7. Prime the administration set.






**Warning:** Make sure patient is not connected to the pump during priming!!! Repeat the same operation for channel 2 if necessary.

8. Set the required program and continue as described for every program setting.



**Warning:** Verify that infusion proceeds normally before leaving the pump unattended.

## Portable Connection

1. Connect the *BodySet/MicroSet* to the medication bag, for each channel, if necessary.
2. Open the door of channel one and load the administration set into the pump's tubing canal. Do the same for channel two.
3. Turn on the *BodyGuard 121 Twins*, by pressing  until the self-test screen appears.
4. The display will show channel 1 and the selected program. Press the  to display the last program, rate setting. If air sensor is off, Press  to confirm.
5. Prime the administration set.



**Warning:** Make sure patient is not connected to the pump during priming!!! Perform the same procedure for channel 2, if necessary.

- 
6. Set the required program and continue as described for every program setting.



**Warning:** Verify that infusion proceeds normally before inserting the infusion bag and pump into the carrying bag.

## Programming

The *BodyGuard* 121 Twins infusion system features two different programming options:

- Dose Program
- Dose: 0.1 to 250 kg in 0.1kg units.
- Volume: 0.1 to 99.9 ml in 0.1ml units
- 100 to 9999 ml in 1 ml units
- Concentration: 0.1 to 1000 mg/ml in 0.1 mg/ml units
- Dose: 0.1 to 1000 µg/kg/min in 0.1 µg/kg/min units

### Continuous Program

- Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Total Volume to be Infused: 0.1 to 9999 ml
- Program as Rate Over Volume or Volume Over Time
- Secondary Infusion (Piggy) Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Secondary Infusion (Piggy) Volume: 0.1 to 9999 ml

### TPN Program

- Used for Total Parenteral Nutrition
- Volume: 1 to 9999 ml
- The program has a taper up/taper down pattern. The parameters to be set are: Total Volume, Time Up, Time Down and Total Time. The pump will calculate the ramping infusion rates.

### Intermittent Program (optional)

- Used for setting a dose protocol at set intervals from 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Volume: 0.1 to 9999 ml
- Interval Time: 0:01 minute to 20:00 hours

### 25 Steps Program (optional)

- Used for setting specific protocol that contains up to 25 steps
- Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Volume: 0.1 to 9999 ml for each step
- Accumulated volume for all steps is up to ten liters


### PCA Program (optional)

- Used for PCA applications. Combines basal rate and pre-programmed boluses
- Rate: 0.0 to 100 ml/hr in 0.1 ml increments
- Volume: 0.1 to 1000 ml

- Bolus Volume: 0 to 100 ml
- Bolus Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments


## Keep Vein Open Mode

The *BodyGuard* 121 Twins Infusion pump uses a Keep Vein Open (KVO) mode that runs automatically at the end of a program, if desired. KVO can also be set to run during a *delay* at the start of a program. The KVO rate can be set from 1-5 ml/hr with an initial default setting of five ml/hr. The KVO rate is adjustable through the "change setup" mode. To disable the KVO mode – set the KVO rate at 0ml/hr. If the programmed infusion rate is lower than the KVO rate, the KVO will run at the programmed infusion rate. KVO during *End Program* is limited to a volume of 5 ml.



 **NOTE:** To use the automatic KVO at the end of a protocol, make sure that the IV bag contains an additional dose over the volume to be infused.


## End Program Mode


When a protocol has completed, an audible alarm will sound continuously and the display will indicate END


PROGRAM – KVO (assuming KVO is enabled). To stop the alarm and enter a new program, press . If the stop key is not pressed before the first 4 beep have sounded, KVO will begin automatically. KVO will run for four minutes. The pump screen then displays it is in KVO mode and continues into 4 more minutes of KVO administration at the set preset rate.


## Changing Current Program

1. Turn on the BodyGuard Pump, by pressing  until the self-test screen appears and the screen will change to channel 1 and the set program. Press  to enter channel 1 and display the last set mode.

2. When the Rate screen is displayed, press  twice.

3. Scroll to "Change set up" option. Press .

4. Scroll to "More" and press .

5. Enter code 901, using the numeric keyboard and press .

6. Scroll to "Select Program" option. Press .

7. Scroll to the required program and press .

Volume Infused
View set up
> Change set up

Buzzer Level
> More ...
Change set up


Code	901
Technician	

Pressure Default
> Select Program
Priming Volume





Select Program
> CONTINUOUS
TPN

8. Press  to restart the pump.

History  
> Restart Pump  
Pressure Default

 NOTE: The selected program will remain in the pump's memory until changed by the operator.


## Changing Current Program – Shortcut



1. Turn on the BodyGuard Pump, by pressing  until the self-test screen appears. Press  key to enter channel 1 and display the program selected.
2. Immediately press and hold  for two seconds.
3. Scroll to the required program and press .

Select Program  
> CONTINUOUS  
TPN


## Continuous Infusion


### Rate over Volume (Channel 1)



 NOTE: Before operating the pump in *Rate Over Volume*, make sure that you are in the *Continuous* Program and that the IV bag contains an additional 5 ml of volume. This ensures adequate volume for KVO during *End Program*. If *Delay Before Start* is set, you must include enough volume for the delay period, in addition to the 5 ml KVO volume.

1. Turn the pump on by pressing and holding the  until the self-test screen appears.
2. Pump displays Channel 1 and the program selected.  
Press . Wait for the rate screen to display.

Channel I  
Continuous

 NOTE: If pump is not already in *Continuous* program refer to changing program section for instructions on how to change the program.



 NOTE: Whenever you decide to set a new program, follow instructions at the bottom of each screen.

3. Do one of the following:
  - Press  to confirm the existing parameters.
  - Enter the desired rate using the numeric keypad and  
Press .

Rate 500 ml/h  
Press OK for Volume

 NOTE: The screen will be blank upon initial setup.

4. The screen displays the last set volume.  
Do one of the following:



- Press  to confirm the existing parameters.
- Enter the desired volume using the numeric keypad and  
press  .

Volume 456 ml

Press OK Key

5. Enter delay time, if applicable. For further information regarding delay option – refer to delay program section.

6. Pump displays program accumulation screen.  
Do one of the following:

- Press  to confirm the existing parameters and start infusion.
- Press  to go back to rate setting screen.

Rate 500 ml/h

Volume 456 ml


Press OK to start

Press OK to Start

7. During program operation the charger displays the rate in which the program is operating. The pump displays the volume to be infused (vtbi) of each channel.




**NOTE:** -If one of the values is changed during the programming mode, the pump will not recall

the new value, unless changes are confirmed by pressing  within 10 seconds. If prime procedure is activated during data setting, the pump will return to the original (previous) screen, once priming has completed.

## Changing the Rate

The pump allows rate adjusting during the *Rate Over Volume* Program.

*To change the rate during the infusion:*


1. Use numeric keypad to enter the new desired rate, during operation and press  within ten seconds to confirm. The pump will bip once and the infusion will resume at the adjusted rate.

Rate 500 ml/h


Adjust & Press OK





**NOTE:** If the rate change is not confirmed within ten seconds, the pump will continue operation at the original rate and the display will return to the previous setting.


2. To stop the infusion press 

## To change the rate while in Stop mode:


1. Press  first during infusion.
2. Press any number on the keypad to return to the Continuous screen.

3. Press  to proceed to the rate screen.

4. Adjust the rate and press .

5. Adjust the volume and press .



NOTE: During programming you may backspace by using  :

Pressing **STOP/NO** once clears the last entered digit.

Pressing **STOP/NO** again clears the next number.

Pressing **STOP/NO** when the value is empty displays the original value or the previous screen.


## Volume over Time




NOTE: Before operating the pump in *Volume Over Time*, make sure that you are in the *Continuous* Program and that the IV bag contains an additional 5 ml of volume to be infused. This ensures adequate volume for KVO during *End Program*. If *Delay Before Start* is set, you must include enough volume for the delay period, in addition to the 5 ml KVO volume.

To set *Volume Over Time* enable the time function by following the steps below (while pump is "stopped"):


1. Press  twice.

2. Scroll to "Change set up", then press .

Volume Infused  
View set up  
> Change set up

3. Scroll to "More" and press .

Buzzer Level  
> More  
Change set up

4. Enter code 901, using the numeric keypad and press .

Technician  
Code      XXX

5. Scroll to "Time Option" and press .

Operation Led  
> Time Option  
Delay Before Start



6. Press  or , to turn Time Option ON.

Resume Press OK  
Repeat Press NO



7. Press  twice.

8. If the previous program was not completed, the pump displays the following screen:

9. Do one of the following:

- To resume this program, press . The accumulation screen will display the remaining Volume.
- To restart the program and /or set new parameters press  and continue as follows:

10. The screen displays the last set volume.  
Do one of the following:


- Press  to confirm the existing parameters.
- Enter the desired volume using the numeric keypad and press .


Volume 500 ml

Press OK key

 **NOTE:** The screen will be blank upon initial setup.


11. The screen displays the last set total time.  
Do one of the following:

- Press  to confirm the existing parameters.
- Enter the desired total time using the numeric keypad using the format HH:MM (for example, enter 0-2-0-0 for



two hours) and press .

Total Time 2:00


Press OK key

 **NOTE:** First two digits represent hours and last two digits represent minutes. Use digital point to move from hours to minutes.

12. The pump calculates the rate based on the time and volume entered, the accumulation screen is then displayed. Do one of the following:

- Press  to confirm the existing parameters and start infusion or enter delay time, if applicable. For further information regarding delay option – refer to delay program section.
- Press  to go back to volume setting screen.



13. During program operation pump displays the time left for the current program in each channel. The charger will display operation rate on each channel.

 **NOTE:** If one of the values is changed during the programming mode, the pump will not recall

the new value, unless changes are confirmed by pressing .




If prime procedure is activated during data setting, the pump will return to the original (previous) screen, once priming has completed.



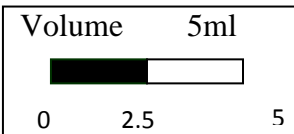
NOTE: Whenever required to stop infusion, press . Stop displayed on screen. Stop mode is limited for two minutes. After two minutes alarm is sounded. Press  to mute. The specific channel will show the rate on the charger's display.

## Bolus During Continuous Operation

The pump allows additional Bolus dose during Continuous operation.

1. Press on .
2. Set Bolus volume and press  to start Bolus infusion.
3. After bolus is completed, the pump will return to Basic program.
4. User can stop the bolus infusion at any time by pressing .

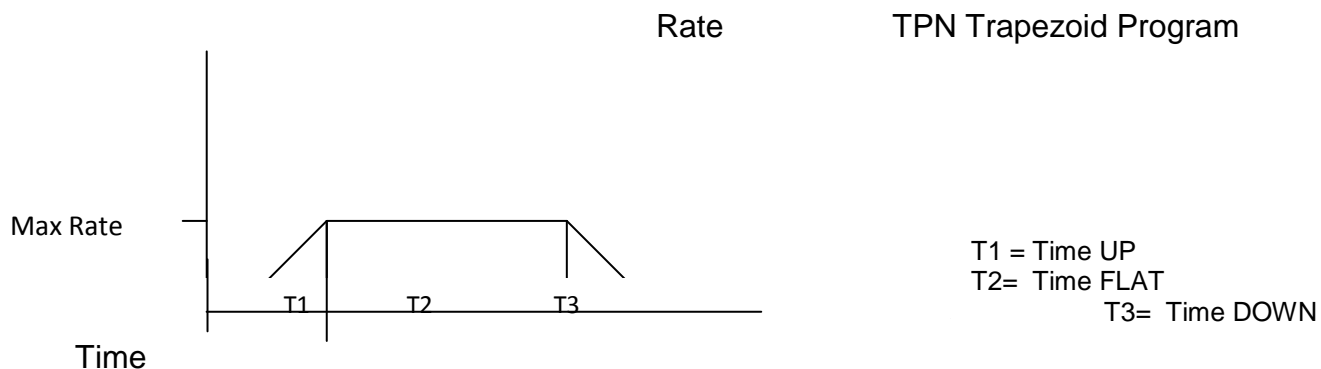
Clinical Bolus  
Volume 5 ml  
Press OK to start





## TPN Infusion

**Total Parenteral Nutrition** - This mode delivers an infusion while automatically tapering up and down. The pattern of the program is a trapezoid.



On a TPN Program the operator may set the total volume which corresponds to the size of the bag to be infused, the total time, and the up and down time. Program operation will start from 2 ml/h and will increase to the maximal rate. During the flat session (T2) the rate will not change. During the last part of the program (T3), the program will start to decrease the infusion rate according to the set taper down time.

Up and down time can be set to zero. A TPN program with up and down time set to zero, is a **continuous** program.

**NOTE:** Before operating the pump in *TPN program*, make sure that the IV bag contains an additional 5 ml to total volume to be infused. This ensures adequate volume for KVO during *End Program*. If *Delay Before Start* is set, you must include enough volume for the delay period in addition to the 5 ml KVO volume.

1. Turn the pump on by pressing and holding the until the self-test screen appears. The pump display will show channel 1 and the selected program. Press to display the first TPN screen – “Total Volume”.

2. Press . Wait for the Volume screen to display.

Channel 1 TPN PROGRAM
Total volume __ml



**NOTE:** If pump is not already in *TPN Program* refer to changing program section for instructions.

**NOTE:** Whenever you decide to set a new program, follow instructions at the bottom of each screen.

3. If the previous program was not completed, the pump displays the following screen:



Resume Press OK Repeat Press NO
------------------------------------

4. Do one of the following:

- To resume this program, press . The accumulation screen displays. The Volume remaining will be infused.
- To restart the program and /or set new parameters press  and continue as follows:

5. Pump displays the last set volume (volume for the TPN bag). Do one of the following:



Volume 1500 ml  
Press OK key

- Press  to confirm the existing parameters.
- Enter the desired volume using the numeric keypad and press .



NOTE: The screen will be blank upon initial setup.

6. The screen displays the last set time (total time for the



program to run). Press  to confirm the existing parameters or enter the desired time using the numeric keys and press .

Total Time 12:30  
Press OK key





NOTE: First two digits represent hours and last two digits represent minutes in the format HH:MM (for example, enter 0-2-0-0 for 2 hr.). Use digital point to move from hours to minutes.

7. The screen displays the time for rate to taper up. Press

 to confirm the existing parameters or enter the desired value (up to 4:15 h) and press .

Up Time 01:00  
Press OK key



8. The screen displays the time for rate to taper down. Press

 to confirm the existing parameters or enter the desired value (up to 4:15 h) and press .

Down Time 0:30  
Press OK key

9. The pump calculates the set data and displays the accumulation screen, including the maximal rate for the program (to be infused during flat period). Do one of the following:

Volume 1500 ml  
Maximal Rate: 127 ml/h  
Press OK to start

- Press  to confirm the existing parameters and start infusion or enter delay time, if applicable. For further information regarding delay option – refer to delay program section.
- Press  to go back to volume setting screen.


10. During program operation pump displays the time left for the current program and program direction (Up/Flat/Down).

U P	Rate
	2 ml/h

### Early Taper Down



If the program must be interrupted early, and the planned taper down time must commence immediately, do as follows:



1. During TPN program press Stop/NO key the display will show STOP.



2. Press  continually (2 sec) to stop the pump operation and display Taper Down screen.



Taper Down: 0:30 Press OK key
----------------------------------


3. Do one of the following:



- Press  to start the taper down process immediately with the existing parameters.
- Set time for taper down, using numeric keys and press  to start the taper down process.


 NOTE: Pressing  from taper down screen will start the taper down process immediately.


 NOTE: If one of the values is changed during the programming mode, the pump will not recall the new value, unless changes are confirmed by pressing . If prime procedure is activated during data setting, the pump will return to the original (previous) screen, once priming has completed.

 NOTE: Whenever required to stop infusion, press . Stop message is then displayed on the screen. Stop mode is limited for two minutes. After two minutes an audible alarm sounds.

Press  again to mute the alarm.

 NOTE: During programming you may backspace by using  :









Pressing  once clears the last entered digit.

Pressing  again clears the next number.

Pressing  when the value is empty displays the original value or the previous screen.

 NOTE: user may set TPN PROGRAMS on both channels.

## Setting Down Occlusion

1. Turn the pump on by pressing and holding the  until the self-test screen appears.
2. Pump displays channel 1 and the program selected.  
Press . Wait for the Rate screen to display.
3. Press  twice.
4. Scroll to "Change set up", then press .
5. Scroll to "Pressure Level" and press .
6. Press  or  to adjust the level (high, normal, low).
7. Press  to store the parameter in memory.

Volume Infused  
View set up  
> Change set up

Change set up:  
> Pressure Level  
  Buzzer Level

Pressure Setting  
High                      10 psi  
Adjust ↑↓ & press OK




### NOTE:


- The following pressure parameters can be set:
  - Low - 5 psi (0.3 bar)
  - Normal - 7.5 psi (0.5 bar)
  - High - 10 psi (0.7 bar)
- The selected pressure level will remain in memory until it is changed or the pump is turned off.
- In the event a down occlusion situation occurs, the patient is protected by an anti-bolus feature, which prevents bolus delivery to the patient when the downstream occlusion is released.
- When turning the pump on, the pressure default will be recalled and not the pressure level.
- After down stream occlusion, infusion will restart from the stop point.

## Program Delay


The option to delay the program before start can be set in *Continuous* program, *TPN* and *25 steps* programs.

**Turning the delay option ON:**


1. Press  twice from STOP or settings mode.

2. Scroll to "Change set up" option. Press .


Volume Infused  
View set up  
Change set up

3. Scroll to "More" and press .



Buzzer Level  
> More  
Change set up


4. Enter code 901, using the numeric keypad and press .

Technician  
Code **901**

5. Scroll to select "delay before start" and press .

Time option  
> Delay before start  
Language

6. Turn delay option ON by pressing  or .

7. Press  and the screen displays Restart Pump

8. Press  to continue.

### Setting delay before start

1. After setting the program data pump enables setting the delay (if applicable).

Volume 456 ml  
  
Press OK for delay

2. Use numeric keypad to set delay time (up to 20 hours).



NOTE: pressing  without setting delay time will start infusion immediately.

3. During delay time, pump will operate in KVO mode. Time left will count down until 00:00.



NOTE: After delay time infusion will start automatically.

## Dose Program

The *Dose* program is the second program in the BodyGuard software, behind the *Continuous* program. Programming the pump using ml/hr in Continuous mode is a standard default setting, yet an operator is able to quickly select the *Dose* program in the event that this mode is desired.


The ability to program and adjust medication administration based on dose ( $\text{mcg/kg/min}$ ), and not only flow rate, provides flexibility for the medical staff and a higher level of safety and care for the patient.

### Operating the Dose Program

1. After power on and Self Test the following screen is appears:

C	<b>Continuous</b>
O	Program
N	Press No to Change
T	

- 2.

Press and hold the  key to enable the program selection menu. Use one of the **arrow keys** to scroll to **Dose**

➤	Continuous Dose
---	--------------------

**option** and press .

3. In the following four screens the user will have to set the patient's weight, the concentration of the drug, the actual dose, and the volume to be delivered. The first three are the parameters required to calculate the flow rate in ml/hr. Use **numeric keys** to set parameters and press **Start/OK** to confirm each input parameter.

- ☞ NOTE: Patient Weight is configurable from 0.1 to 250 kg in 0.1 kg increments.

D	<b>Patient weight?</b>
O	<u>10</u> kg
S	
E	Press OK for Conc.

- ☞ NOTE: Concentration is configurable from 0.1 to 1000 mg/ml.:

D	<b>Concentration?</b>
O	<u>10</u> mg/ml
S	
E	Press OK for Dose

- ☞ NOTE: Dose is configurable from 0.1 to 999 mcg/kg/min.

To program in mg/kg/min, press  while the cursor is blank, and the screen will display the following:

D	<b>Dose?</b>
O	<u>100</u> mcg/kg/min
S	
E	Press OK for Volume

- ☞ NOTE: At this point, if the rate calculated by the pump is outside the pump's flow rate range, which will be .1 to 1200 ml/hr, the pump will deny the user from proceeding to the next screen.



- ☞ NOTE: As a safety feature, especially in pediatric care, the pump can be configured to have a Flow Rate Limit option in the Adjust Settings menu. The operator can set the rate so that under no circumstances can any infusion be programmed over 100 ml/hr, for example.

NOTE: Volume is configurable from 0.1 to 9999 ml (0.1 increments to 99.9 ml, and 1 ml increments from 100 to 9999 ml.)


D	<b>Volume?</b>
O	<u>60</u> ml
S	
E	Press OK to Review

4. After inserting the patient's weight, drug concentration, dose, and volume to be delivered, two confirmation screens are displayed. The rate, displayed on the second screen, is a confirmation number, which is a result of all data parameters (*Note: 6ml/hr is the flow rate calculated by the pump based on the input parameters*).

D	<b>Weight</b>	<b>10 kg</b>
O	Conc	10mg/ml
S	Dose	100mcg/kg/min
E	Press OK to Continue	

Press  to confirm and start the infusion, or  to return to the previous screens and change the input parameters.

<b>D</b>	<b>Volume</b>	<b>60 ml</b>
<b>O</b>	<b>Rate</b>	<b>6 ml/hr</b>
<b>S</b>		
<b>E</b>	Press OK to Start Infusion	

5. After pressing , the pump would begin the infusion and would display the screen below. The LED would blink green and the battery icon would be displayed on the right side of the display screen.

Dose	100 mcg/kg/min
Weight	10 kg
Rate	6 ml/hr

NOTE: Pressing the “Info” key during the infusion will display the following:

- Volume Infused (in ml)
- Battery Level
- Concentration (in mg/ml)
- Tube Temperature
- Time Left
- Actual pressure in psi, that is a bar starting from 0 to 10 showing the actual pressure

6. **Dose Adjustment:** The pump allows dose changing during infusion. Use numeric keys to set the new dose value and press **Start/OK** within 10 seconds. The pump will briefly alarm and the infusion will resume at the adjusted dose. For example, the infusion below is running at 100 mcg/kg/min. If the operator wishes to change to 200 mcg/kg/min, he would press “200”, and press **Start/OK** within 10 seconds. The second screen below would then be displayed. Note that the pump displays the new dose and the new flow rate.

**Before Change:**

Dose	100 mcg/kg/min
Weight	10 kg
Rate	6 ml/hr

**After Change:**

Dose	200 mcg/kg/min
Weight	10 kg
Rate	12 ml/hr


7. **Bolus operation:** In order to program a bolus during the infusion, perform the following steps:
- Press the orange key containing a syringe (this key operates the priming function prior to programming an infusion and when the pump activates the “Air in Line” alarm).
  - The screen will appear as indicated below. Use numeric keys to set the volume of the bolus.


- ☞ NOTE: Bolus volume is configurable from 0.1 to 99.9 ml in 0.1 increments

Bolus Volume?  
 \_\_\_\_\_ ml  
 Press OK to Start

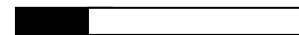
- ☞ NOTE: As a safety feature, especially in pediatric hospitals, the pump can be configured to have a Max. Bolus Limit option in the Adjust Settings menu.

- ☞ NOTE: The rate at which the bolus is infused is configurable in the **Adjust Settings** menu – it will not be adjustable every time a bolus is initiated.

- After programming the Bolus Volume, press  within ten seconds to initiate the bolus. (If the **Start/OK** is not pressed the infusion will remain at the

normal rate.) Upon pressing  within ten seconds, an audible alarm would sound and the following screen would be presented, which shows the progression of the bolus injection. After the bolus is completed, the screen would revert back to the normal infusion screen (see Step 5). At any time, user can press **Stop/No** to stop the bolus injection.

Bolus Running




Press No to Stop

## Intermittent Infusion (Optional)

The Intermittent Infusion program is a special program which enables the design of a dose delivery protocol at set intervals. Each dose is given at a set time. The pump will “Keep Vein Open” between the doses. The infusion program continues until the total volume to be infused is delivered.

### Rate over Volume

1.

Turn the pump on by pressing and holding the  until the Self-Test screen appears. If air sensor is off, please contact your technician in order to enable the air sensor. Using the pump with air in line detector off may cause an embolism resulting in death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name.

Channel I  
Intermit

- ☞ NOTE: When pump is in *lock out mode*, parameters can be viewed, but cannot be changed.

- ☞ NOTE: If pump is not already in *Intermittent* Program, refer to Changing Program section.



- ☞ NOTE: Whenever you decide to set a new program, follow instructions at the bottom of screen.

- ☞ NOTE: When returning to a program, the screen will display the last set program.



3. **Bag Volume Screen**



Do one of the following:

- Press  to confirm the existing parameters.
- Enter the Bag Volume and press .

Bag Vol: \_\_\_\_ ml  
Enter & press OK

4. **Dose Volume Screen**



Do one of the following:

- Press  to confirm the existing parameters.
- Enter the Dose Volume and press .

Dose Vol: \_\_\_\_ ml  
Enter & press OK

5. **Dose Rate Screen**



Do one of the following:

- Press  to confirm the existing parameters
- Enter the Dose Rate and press .

Dose Rate: \_\_\_\_ ml/h  
Enter & press OK

6. **Interval Time Screen**

Do one of the following:

- Press  to confirm the existing parameters
- Enter the time between the each dose and press .



Interval Time: \_\_:\_\_\_\_  
Enter & press OK



NOTE: Interval time is counted from starting time of one bolus until starting time of the following bolus.

7. **KVO Rate Screen**



Do one of the following:

- Press  to confirm the existing parameters
- Enter desired KVO rate (from .1 to 5 ml/h), press .

KVO Rate: \_\_\_\_ ml/h  
Enter & press OK


8. **Accumulation Screen**


Do one of the following:

- Press  to confirm the existing parameters and start infusion.
- Press  to go back and adjust program parameters.

Dose Vol: 200 ml/h  
 Dose Rate 200 ml/h  
 Interval Time 1:00  
 KVO Rate 0.2ml/h

Bag Vol: 200 ml/h  
 VolumeLeft 200 ml/h  
 Infused 1:00  
 Press OK to continue



 **NOTE:** If pump is in **Delay Mode**, enter Start Time (24 Hour Clock) and Start Date. For further information regarding the Delay Option, refer to Delay Program section.


9. Press  to Start Infusion. Delay time option is disabled, screen will show start time as “Immediate”.



Next Dose  
 Start Time: Immediate  
 Press OK to start

10. During program operation, the pump displays the rate in which the program is operating.

Rate  
**25 ml/h**

 **NOTE:** If one of the values is changed during the programming mode, the pump will not recall the new value unless changes are confirmed by pressing .

 **NOTE:** If prime procedure is activated during data setting, the pump will return to the original (previous) screen once priming has completed.




 **NOTE:** Whenever required to stop infusion, press . Stop displays on the screen. Stop mode is limited to two minutes. After two minutes an audible alarm sounds. Press

 again to mute the alarm or press STOP/NO until the pump powers off.


## Rate Adjustment


It is necessary to stop infusion in order to change any or all parameters of the current infusion program


### To change the rate while in Stop mode:

- Press any number on the keypad and then press .
- Adjust the rate and press .
- Adjust all other parameters and press  to restart infusion.



NOTE: During programming, you may backspace by using  :

Pressing  once clears the last entered digit.

Pressing  again clears the next number.




Pressing  when the value is empty displays the original value or the previous screen.

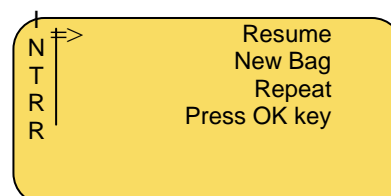
## Resume Infusion, Start New Bag, or Reprogram Infusion

When an Intermittent infusion is stopped and the pump is re-started, the operator has the following options:

- (1) **Resume:** Resume the original infusion exactly where it left off
- (2) **New Bag:** Resume the original infusion with a new bag
- (3) **Repeat:** Repeat or re-program the infusion

### 1. Intermittent Stop Screen

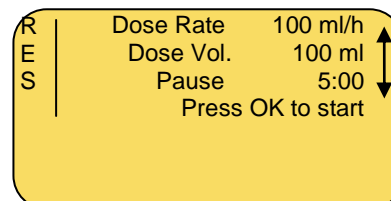
Press  or  to scroll to the appropriate selection and press .



### 2. Resume – New Bag – Reprogram Screen

Display shows a summary of the current infusion to be started. User can scroll through the details by pressing


 or . Press  to start infusion.



## Program Delay


The option to Delay Program Before Start can only be used in the Intermittent Mode.

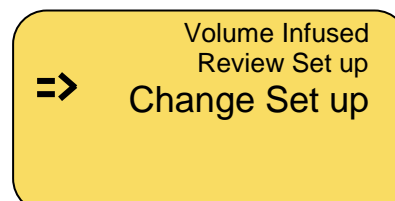
## Turning the Delay Option ON


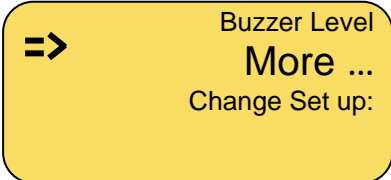



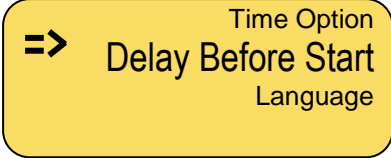




1. Press  twice from STOP or setting mode.



**Warning:** If air sensor is off, please contact your technician in order to enable the air sensor. Using the pump with air in line detector off may cause an embolism resulting in death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.


2. Scroll to "Change Set up" option and press .





3. Scroll to "More ..." and press  .  

4. Enter *Change Set up* level 1 code, using the numeric keyboard and press  .  

5. Scroll to "Delay Before Start" option and press  .  

6. Turn delay option ON by pressing  or  .
7. Press  and the screen displays Restart Pump
8. Press  to continue.

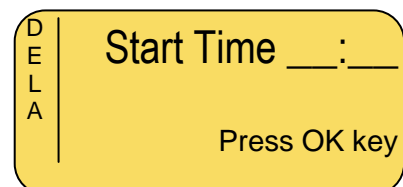
## Setting the Time for “Delay Before Start”

After entering the program data, the pump enables setting the Delay Before Start time (when *Delay Before Start* is turned ON).

- ☞ NOTE: The delay time format is a 24 hour clock. This means that hours are viewed as follows 10:00, 11:00, 12:00, 13:00, 14:00, 15:00 etc.
- ☞ NOTE: The pump automatically displays the current time and date. To start pump immediately, press  to confirm the existing time and date and start infusion.
- ☞ NOTE: If the time and/or date automatically displayed by the pump are incorrect, go to the *Settings Menu* and select “*Set Time & Date*” to reset the clock in the pump.

### 1. **Start Time Screen**

To change the Start Time, type the desired start time using the numeric keypad and press  . To start pump immediately, do not change the time and press  .




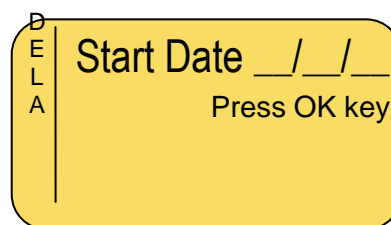
- ☞ NOTE: To start pump at **9:30 AM**, enter **0-9-3-0**. To start the pump at **9:30 PM**, enter **2-1-3-0**.

2. **Start Date Screen**

To change the Start Date, type the desired start date using

the numeric keypad and press . To start pump on

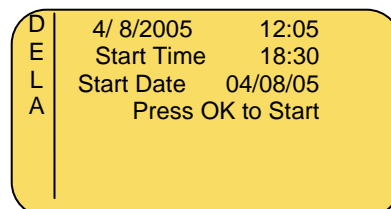
the same day, do not change the date and press .



DELA Start Date \_\_/\_\_/\_\_  
Press OK key

3. **KVO During Delay Screen**

During delay time, pump will operate in KVO mode. Time left will count down until 00:00 and will then automatically start the programmed infusion. During the delay, this screen will be displayed showing when the infusion will start.



DELA 4/ 8/2005 12:05  
Start Time 18:30  
Start Date 04/08/05  
Press OK to Start



**NOTE:** After delay time, pump will beep once then infusion will start automatically.

## Turning Pump Off During an Intermittent Infusion

When the pump is turned off during an intermittent infusion, the internal clock in the pump will continue to monitor the timing of the infusion.


**If the pump is stopped during a dose**, the operator will be able to resume the dose if the infusion is resumed before one third of the interval time has elapsed. For example, if the interval is 3 hours, then the operator can restart the infusion within 1 hour, the remainder of the dose will be administered as well as the future scheduled doses. If the operator restarts the infusion after one third of the interval time has elapsed, the operator will not receive the remainder of the dose. The pump will automatically begin KVO until the next scheduled dose. The purpose of this “One Third” rule is to allow the operator to turn their pump off during a dose without changing the scheduled dose times.


**If the pump is turned off during a dose and restarted after the next scheduled dose time has passed**, then the pump will start that the next dose immediately from the beginning followed by a complete interval as set by the operator. For example, if the patient restarts the infusion an hour past the scheduled dose time, then the patient will receive a complete dose followed by a complete interval.

**If the pump is turned off during the interval period**, the patient can restart the pump anytime before the next scheduled dose without impacting the timing of the delivery of the next dose. If the pump is not restarted until after the next scheduled dose was scheduled, then the pump will start the next dose immediately followed by a complete interval.

## 25 Steps Protocol (Optional)

This protocol permits programming of up to twenty-five different steps. Each step has its own rate and volume. Step accumulation is limited to a Volume of ten (10) liters. Protocol steps are delivered sequentially until all steps are completed.

-  **NOTE:** Before operating the pump in *25 Steps Protocol*, make sure that the IV bag contains an additional 5 ml of total volume to be infused. This assures adequate volume for KVO during *End Program*. If *Delay Before Start* is set, you must include enough volume for the delay period, as well as the post program period.




1. Turn the pump on by pressing and holding the  until the Self-Test screen appears.





**Warning:** If air sensor is OFF, please contact your technician in order to enable the air sensor. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name.

25 - Steps  
Program  
Press NO to Change



-  **NOTE:** If pump is not already in *25 Steps Protocol*, refer to changing program section for instructions.
-  **NOTE:** Whenever you decide to set a new program, follow instructions at the bottom of screen.
-  **NOTE:** The screen will be blank upon initial setup.

3. **Rate Screen – Step 1**  
Do one of the following:

- Press  to confirm the existing parameters.
- Enter the desired rate and press .

Step 1 Rate  
\_\_\_\_ ml/h  
Press OK for Volume


4. **Volume Screen – Step 1**  
Do one of the following:

- Press  to confirm the existing parameters.
- Enter the desired volume and press .

Step 1 Volume  
\_\_\_\_ ml  
Press OK to Continue

5. **Rate Screen – Step 2**  
Pump displays the rate for step 2. Repeat the same instructions for step 1 and repeat until the required number of steps is entered.

Step 2 Rate  
\_\_\_\_ ml/h  
Press OK for Volume



6. After entering the last required step, press  without entering a rate.

This indicates that all required data has been set. All programs following the last set program will be automatically cleared.

☞ NOTE: If pump is in **Delay Mode**, enter KVO rate.

7. **Accumulation Screen**


Do one of the following:

- Press  to confirm the existing parameters.
- Press  to go back to rate setting screen.



☞ NOTE: If pump is in **Delay Mode**, enter Start Time (24 Hour Clock) and Start Date. For further information regarding the Delay Option, refer to Delay Program section.


8. Press  to Start Infusion.


9. During program operation, the display identifies which step is currently running, as well as the rate.


☞ NOTE: If one of the values is changed during the programming mode, the pump will not recall the new value unless changes are confirmed by pressing .


If prime procedure is activated during data setting, the pump will return to the original (previous) screen once priming has completed.

☞ NOTE: Whenever required to stop infusion, press . Stop displays on the screen. Stop mode is limited to two minutes. After two minutes an audible alarm sounds. Press  again to mute the alarm.

☞ NOTE: During programming you may backspace by using .

Pressing  once clears the last entered digit.

Pressing  again clears the next number.

Pressing  when the value is empty displays the original value or the previous screen.

## PCA Infusion (Optional)

Patient Control Analgesia is a program used for patients who require IV pain management or epidural analgesia. Pain management is administered through a continuous basal rate, in combination with pre-programmed boluses. The pump will deliver only the boluses corresponding to the preset time intervals. All bolus features are stored in the pump memory. The physician can read these statistics and adjust the settings as needed.

Step 5 Rate  
\_\_\_\_ ml/h  
Press OK for Volume

Steps Total 5  
Volume Total 500 ml  
Press OK to Start

Start Infusion?

Rate Step 1 of 5  
25 ml/h



**Warning:** When operating the pump on PCA program with a rate of 0.0 ml/h there is a hazard of blood clot forming. Connect saline infusion in parallel to avoid this problem.

## PCA Menu


Due to the sensitive nature of PCA infusion, the BodyGuard 323 offers a specific menu to enhance the operator's experience while programming PCA infusions. The menu organizes the infusion information centrally while maintaining the same programming format as the other infusion modes of the pump.

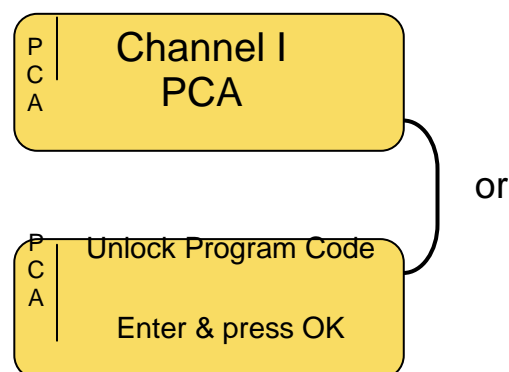
1. Turn the pump on by pressing the  until the Self-Test screen appears.



**Warning:** If air sensor is off, please contact your technician in order to enable the air sensor. Using the pump with air in line detector off may cause an embolism resulting in death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name.

Press . If the pump is unlocked, the PCA Menu will display. If the pump is locked, enter the "Unlock Program Code"



- NOTE: The PCA program automatically locks upon completion of programming.
- NOTE: If pump is not already in *PCA* Program refer to Changing Program section for instructions.
- NOTE: Whenever you decide to set a new program, follow instructions at the bottom of each screen.

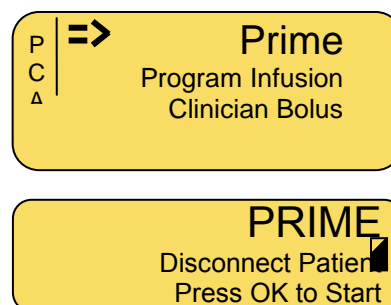
## Priming

- NOTE: Priming is disabled during PCA operation. Always prime the set before starting a program.




**Warning:** Always disconnect IV tubing from patient before starting the priming procedure.

1. Selecting the **Prime** option from the PCA menu, the screen will show the priming screen.
2. Press OK to program priming procedure.



**Warning:** Ensure the set is not connected to the patient!!

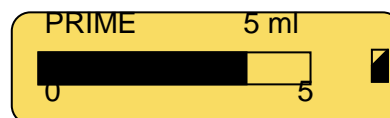


3. Enter the volume to prime the set and press  to begin priming procedure. You may stop priming at any time by

pressing .

4. The display screen will show a graph indicating the prime operation.

Prime Vol \_\_\_\_ ml  
Press OK to Continue



5. Once the priming has completed, the display will change back to the previous screen the pump was in before priming. If more priming is needed, repeat procedure.


## Program Infusion

1. **Volume Screen**

Enter the infusion Volume and press .

Volume \_\_\_\_ ml  
Enter & press OK


2. **Rate Screen**

Enter the Rate in ml/hr and press  or follow step 3 to change to concentration format.

Rate \_\_\_\_ ml  
Enter & press OK

3. **Rate/Concentration Selection Screen**

- To program *Concentration in Milligrams per Milliliter*

(mg/ml), press  once.

- To program *Concentration in Micrograms per Milliliter*


(mμ/ml), press  once again.

ml/hr  
Press OK to Continue  
NO for Concentration

4. **Rate or Concentration Screen**

Do one of the following:

- Press  to confirm the existing parameters.

- Enter the desired rate or concentration and press .



Rate \_\_\_\_ ml/h  
Adjust & press OK

Concentration \_\_\_\_ mg/ml

Concentration \_\_\_\_ micrograms/ml

or

or


-  **NOTE:** To change from *Concentration* back to *Rate*, enter 0 (zero) for Concentration and press .

5. **Concentration Rate Screen**

(Only When using Concentration Format)

Do one of the following:

- Press  to confirm the existing parameters.


- Enter the desired rate or concentration and press .

PCA  
Rate \_\_\_\_ mg/h  
Adjust & press OK

6. **Bolus Screen**

Do one of the following (Bolus can be ml, mg, or mcg depending on the program selected):

- Press  to confirm the existing parameters.


- Enter the desired bolus dose and press .

PCA  
Bolus Vol. \_\_\_\_ ml  
Press OK to Continue

7. **Lock Time Screen**

The lock time is the amount of time between patient boluses. Do one of the following:


- Press  to confirm the existing parameters.

- Enter the desired lock time in minutes and press .

Lock Out \_\_\_\_ min  
Enter & press OK

8. **Limit in XXX Hours**

To enable this feature go to the Change Set up menu and


set a time limit (window), then press . In the following screen choose either the amount of max “Dose at Time Window” or the max Boluses Number during the time limit. Once Limit has been set, the screen on the right will appear while programming a PCA program. Set the limit (in volume) to be administered during the preset timeframe.

Limit in 2 Hours  
\_\_\_\_ml  
Enter & press OK

9. **Locking Screen**

The pump automatically locks before a PCA infusion program can be completed. Do one of the following:

- Press  to lock the PCA program and proceed.

- Press  to scroll through and review the program or adjust parameters.



PCA  
Lock: Press OK  
Review: Press NO

## 10. Accumulation Screens

The pump displays the accumulation screen with a summary the program entered. User can scroll through the entire

program by pressing  or .





Do one of the following:

- Press  to confirm parameters and proceed..
- Press  to go back and adjust parameters.

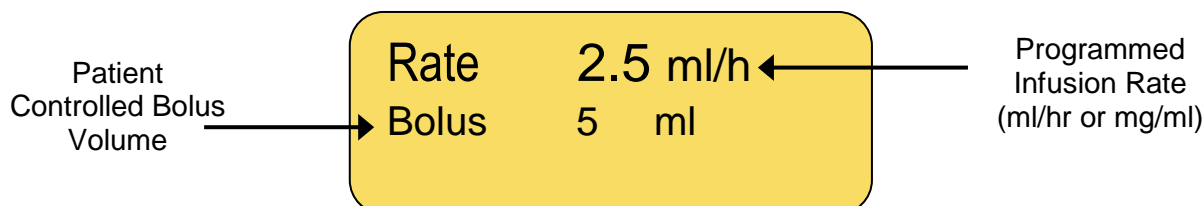
Bag Vol: 200 ml  
Vol. Left 200 ml  
Infused 0ml  
Press OK to start

Rate ml/hr  
Bolus Vol: ml  
Press OK key

Bolus Rate ml/hr  
Lock Out: Min  
Limit Off  
Press OK to start

-  NOTE: Operator can confirm that pump is infusing by checking that the LED light is blinking green on the pump and that a spinning logo is showing on the charger display.
-  NOTE: LED indicator can be turned off in the main settings menu to save battery power.
-  NOTE: The *BodyGuard* is capable of continuous infusion (basal) rates of up to 100 ml/h. However you may use the pump for the delivery of only one drug protocol and the maximum safe ceiling for this regime could be, for example, 30ml/h. operators can set a maximum rate in 'Change Set Up' using the Technician Access Code to assure other operators do not accidentally program the pump to deliver above a preset ceiling. See section for 'Change Set Up'.
-  NOTE: The *BodyGuard* is capable of delivering the bolus dose at up to 1000ml/h. The default setting of 600ml/h is designed to deliver any bolus at an optimal speed. The operator can adjust the bolus to be delivered over a shorter/longer period in 'Change Set Up' using the Technician Access code.

## Interpreting the Display Screen During PCA Infusion



### Infusion Rate

The first line of the display shows the current infusion rate. Depending if the operator programmed the current protocol in ml/hr, mg/ml/hr or mcg/ml/hr this line will display the current format being used.

### Bolus Volume

When administering a bolus dose using Prime/Bolus button, the bolus volume is displayed in place of the infusion rate screen until the bolus is completed. As with infusion rate, the bolus format will be displayed in ml/hr, mg/hr or mcg/hr depending on how the current program is set up.

### Battery Status


In the right hand margin, you can see the battery and infusion status indicator. The battery symbol will be visible when the pump is not connected to the mains charger. Operator can check the charge level by monitoring the black fill inside the symbol (i.e. completely black symbol indicates a fully charged battery).

## Patient Activated Bolus

A PCA infusion can (optionally) be programmed to allow the patient to request boluses of a specified volume within predetermined time intervals. The patient can request the bolus by one of the following two methods:



1. **Using Bolus Cable – Assuming Pump is Equipped with Bolus Connection + Cable**


Press the button on the end of the bolus cable. The bolus cable plugs into the side of the pump where a label reads “Bolus”

 **NOTE:** Administering boluses via a bolus cable is dependent on a bolus connection and cable. Not all BodyGuard 121 Twins are equipped with such devices.

2. **Using Keypad**

Press the  button on the keypad.

 **NOTE:** User can stop a bolus at any time by pressing .

 **NOTE:** If patient requests more boluses than are allowed, the pump will display “Bolus Locked” and will continue to track the amount of boluses requested by the operator. The bolus history can be reviewed by a physician/clinician by scrolling the Info Menu. See “Using History Functions” section of the manual.

## Clinician Activated Bolus

A Clinician Activated Bolus can be performed *before* starting the PCA infusion or *during* the PCA infusion.

To infuse a Clinician Activated Bolus **before** starting the PCA infusion, perform the following steps:

1. From one of the program parameter screens, Press the  button.

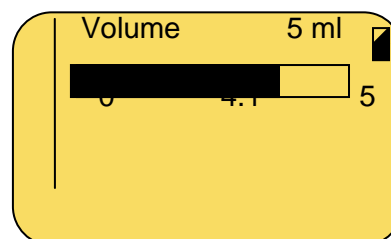
2. Enter Priming Code and press .

Priming Code  
XXX  
Enter & press OK

3. Enter the volume of the Clinician Bolus and press  to begin priming procedure. You may stop the bolus at any time by pressing .

The Volume for the Bolus will be in ml, mg or µg depending on the settings of the existing protocol entered for the PCA infusion. To change, go to Program Infusion in the PCA menu and follow the steps until the selection can be made for ml, mg or µg.

- The display screen will show a bar indicating the Bolus is being infused. The progress bar displays the amount of the bolus to be infused (clear) and the amount infused (dark).



Once the bolus is completed, the display will change back to the PCA menu.



User can stop a bolus at any time by pressing

STOP  
NO



**Warning:** Boluses will be infused up to the full volume that is requested unless the operator stops the bolus manually by pressing **STOP NO**. This is true even when the volume infused is less than the specified Hour Limit for Volume (e.g. 4 Hr Limit) at the beginning of a bolus and goes over the limit during the bolus.

To infuse a Clinician Activated Bolus during a PCA infusion, perform the following steps:

- During operation, press **STOP NO** and then press **PRIME BOLUS** to stop the current infusion and initiate the Clinician Bolus.

- Enter Level 2 Technician Code and press **START OK**.

CA Bolus Code  
XXX  
Enter & press OK

- Enter the volume of the Clinician Bolus and press **START OK** to begin priming procedure. You may stop the bolus at any time by pressing **STOP NO**.

The Volume for the Bolus will be in ml, mg or  $\mu$ g depending on the settings of the existing protocol set up for the PCA infusion.

Clinician Bolus  
Volume \_\_\_\_ ml  
Press OK to Start

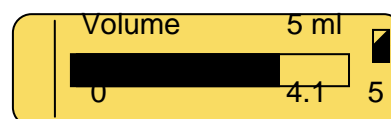
Clinician Bolus  
Volume \_\_\_\_ mg  
Press OK to Start

Clinician Bolus  
Volume \_\_\_\_ mcg  
Press OK to Start

or

or

- The display screen will show a graph indicating the Bolus is being infused. The graphical bar displays the amount of the bolus to be infused (clear) and the amount infused (dark).



Once the bolus is completed, the pump will resume the original PCA infusion.



operator can stop bolus at any time by pressing

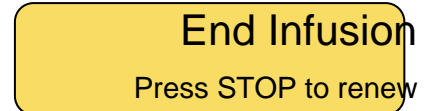
STOP  
NO

---

## End of Infusion, Restart Infusion, or Bag Change

### 1. **End Infusion Screen**

Once infusion has reached its end (pre-set volume was infused), an alarm sounds and the display will show:



### 2. **KVO Display**

The alarm will stop after 4 beeps. The pump will show the pre-set KVO rate. The alarm will sound again every 4 minutes until the user changes the bag or stops the pump.



### 3. **PCA Restart Menu**

This screen displays when:

(1) The pump is turned OFF and back ON in PCA mode.

(2) Infusion is stopped by pressing and holding



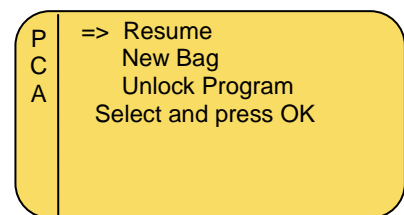
User can scroll through the following options by pressing



or



- **Restart** – Starts infusion exactly where it left off previously.
- **New Bag** – Restarts infusion exactly where it left off previously and updates bag volume to be equal to the bag volume originally programmed.
- **Unlock Program** – Brings operator back to the PCA Menu. When asked for a code, enter the Unlock Code.



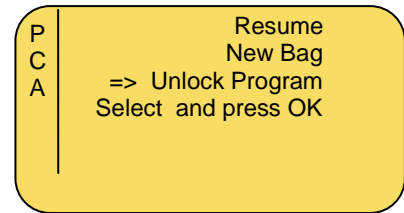
**NOTE:** If using an infusion set with drip chamber, change to a new infusion bag, but make sure that the drip chamber is half filled and there is no air in the administration set. If using an ambulatory IV, PCA or Epidural set without a drip chamber, priming the line may be needed.  
**Disconnect the set from patient before priming!!!**

---

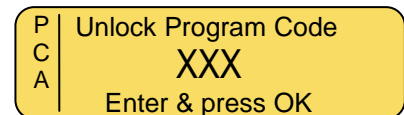
## Return to PCA Programming Screens

### 1. *PCA Restart Menu*

Scroll to "Menu" using  and press .



### 2. Enter Level 1 Technician Code and press .




## Lock Mode

The *BodyGuard* provides two different levels of locking:

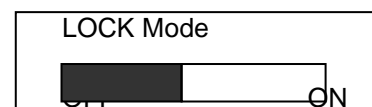
- **Level 1: Keypad Locking**  
During operation all keys are disabled excluding the **STOP/NO** and the **INFO** key.  
During programming all keys are disabled excluding the **START/OK** and the **INFO** key.
- **Level 2: Maximal Rate Locking**  
This feature enables the operator to set a maximal rate for the pump to accept. The program rate then can be adjusted only up to a preset limit.


## How To Lock

### Level 1 – Keypad locking


Press and hold  until the entire bar is black and a beep is heard. The beep indicates that the locking program is turned ON.


- The keys are locked in memory until they are unlocked or until entering *Change set up* mode.

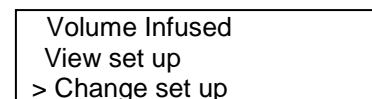



To unlock the keys Press and hold  until the entire graph is cleared and a beep is heard. The beep indicates that the locking program is OFF. The number one is no longer displayed in the upper-right corner of the screen and the keys are unlocked.

### Level 2 – Maximal Rate locking

1. Press  twice from STOP or setting mode.

2. Scroll to "Change set up" option. Press .



3. Scroll to "More" and press .

4. Enter code 901, using the numeric keypad and press



Technician  
Code **902**

5. Scroll to "Maximum Rate " option. Press





Bolus Rate  
> Maximum Rate  
KVO Rate

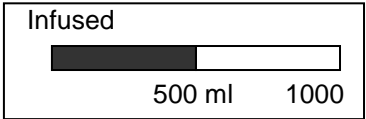
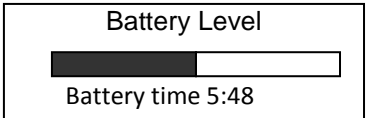
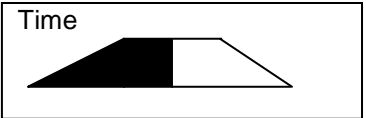
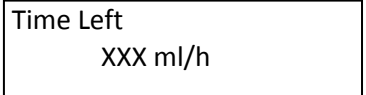
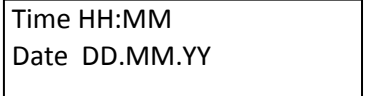
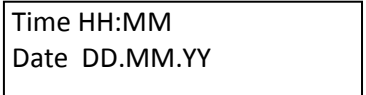


Use numeric keys to set desired rate and press




## Info Mode


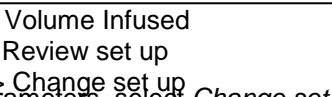
Access the info mode by pressing  during operation, data setting or while in the Stop mode.

Pressing  during *program operation* will display the following:

Number of button presses	Infusion Mode	Information	Screen
1	All programs	Infused Volume  Total Volume to Be Infused	
2	All programs	Battery Status	
3	TPN	Program Status in a graphic illustration	
3	Continuous/ Dose/PCA	Time remaining for the end of the program	
3	25 Steps	Time and Date	
4	Cont/TPN/ Dose/PCA	Time and Date	
4	25 Steps	Actual Pressure	
5	Cont/TPN/ Dose/PCA	Actual Pressure	






Pressing  during *data setting* or in the *stop mode*, will display the following:

Number of button presses	Information	Screen
One	Infused Volume Total Volume to Be Infused	<div data-bbox="956 443 1321 562">  </div> Pressing <b>STOP/NO</b> will clear Volume Infused.
Two	Option Selection screen	<div data-bbox="922 721 1287 817">  </div> To change parameters, select <i>Change set up</i> , press <b>Start/OK</b> and follow instructions in the Change set up section.  To view current pump settings, select <i>Review set up</i> , press <b>Start/OK</b> and follow instruction in View set up section.







#### NOTE:

- If no selection is made within ten seconds after pressing , the screen will exit the information mode and display the previous screen.
- To exit the information mode after making a selection in Review set up, press  once to return to the original screen.
- To exit the information mode after making a selection in Change set up, press .
- Depending on software version, Info button may display slightly different data.

## Review set up

The Review set up feature is designed to allow you to view the programmable options and other important information about the pump. In View set up, the current setting can be viewed, but cannot be changed.

1. Press  twice.
2. Press  to scroll to "Review set up" option. Press  and the current settings are displayed, but cannot be changed.
3. To view the setting for a particular option, select the desired option and press .

Volume Infused > Review set up Change set up
--

View set up: > Battery Level Lock Out
---



Screen No.	Screen Display	Information
1	Battery Level	Current battery level (Empty >>> Full)
2	Display Time and Date	Time and date
3	Show Power Voltage	Battery and power specifications
4	Buzzer Level	Current buzzer volume setting
5	Pressure Level	Current pressure level setting
6	Pressure Defaults	Current pressure default setting
7	Select Program	Current Slected Program
8	Volume Option	Option currently ON or OFF
9	Priming Volume	Current Priming volume setting
10	Priming Rate	Current rate of priming procedure
11	Maximum Bolus Volume	Maximal Bolus Volume
12	Bolus Rate	Current bolus rate setting
13	Maximal Rate	Current maximal rate setting
14	KVO Rate	Current KVO rate setting
15	Flow Control	Flow Control
16	Air-in-Line-Limit	Current air bubble size setting
17	Operation LED	Option currently ON or OFF

18	Time option	Option currently ON or OFF
19	Delay before start	Option currently ON or OFF
20	Language	Current pump messages language
21	Serial Number	Pump Serial Number
22	Production Date	Pump production date
23	Operation time	Hours since last Service Calibration
24	Software Version	Pump Software Version
25	Volume Calibration	Volumetric Calibration value
26	Pressure Delta	Pressure Calibration – Delta value
27	Pressure CAP	Pressure Calibration – Cap value
28	EXIT	EXIT

## Change Set up







The “Change Set up” mode allows you to make changes to various parameters.

### To access Change Set up:

1. Press  twice.
2. Scroll to "Change set up" option. Press .

Volume Infused  
Review set up  
> Change set up

### To adjust Pressure Level or Buzzer Level:







1. Press  or  to select an option and press .
2. Make adjustment by pressing  or  and press .

Change set up:  
> Pressure Level  
Buzzer Level

### To adjust other parameters:

1. Scroll to select "More" and press .


Buzzer Level  
> More  
Change set up

2. Use numeric keypad to enter Code 901 and press .
3. Scroll to select a desired parameter and press .
4. Adjust the parameter by pressing  or  or by using the numeric keypad.
5. Press  and the screen displays Restart Pump.
6. Press  to continue.

The table below indicates the adjustable parameters

Screen No.	Screen Information	Action
1	Pressure Level	Choose pressure level (High 10 psi, Normal 7.5 psi, Low 5 psi).
2	Buzzer Level	Adjust the buzzer level. Note: the buzzer cannot be muted for safety reasons.
3 Code 901	Restart pump	Restart pump
4	Pressure Default	Select pressure default (High 10 psi, Normal 7.5 psi, Low 5 psi).
5	Select Program	Select the infusion program
6	Volume Option	ON by Default. Can be turned OFF in some modes to enable operator to work indefinitely until operator stops or changes the it.
7	Priming Volume	Set the priming volume from 0-60 ml.
8	Priming Rate	Optimal: 600ml/h (adjustable up to 1200ml/h)
9	Max. Bolus Volume	Set the Max. bolus volume from 0-100 ml.
10	BOLUS rate	Set the bolus rate from 0-1200 ml/hr.
11	Maximal Rate	Set the maximal rate from 0.1-1200 ml/hr
12	KVO rate	Set the KVO rate from 0.1-5.0 ml/hr
13	PCA Limit Setting	Set a time window in which a limit of drug administration can be set.
14	Flow Control	0-20 drops per ml.

15	Air-in-Line Limit	Set detectable air bubble size from 0.1-1.0 ml.
16	Operation led	Turn operation led ON/OFF
17	Time option	Turn time option ON/OFF. While time option is ON, continuous program will be set to Volume over Time.
18	Delay before start	Turn option ON/OFF
19	Language	Enable changing the language of pump messages (only for models, in which the software includes more than one language).
20	Set Time & Date	Set actual time and date
21	Event Log Channel I	Indicates injection history.
22	Event Log Channel II	Indicates injection history.
23	Restart Pump	Reboots the Pump and returns to opening screen



 **NOTE:** While the pump is in programmable mode, all parameters can be set, or parameters used in last program can be confirmed. The memory hold capability is available for the life of the internal battery.

## 5 – Alarm State and Troubleshooting

### Alarm State


When the infusion pump detects a problem, the following occurs:


- The infusion stops.
- An audible alarm sounds.
- A message appears on the display screen indicating the cause of the alarm, and:
- The LED indicator will change from green to red.


 **NOTE:** Pressing  during an alarm, mutes the alarm for two minutes.

The conditions listed in the following table activate an alarm:

## Troubleshooting (on the relevant channel)

Description	Result	Possible Cause	Required Action
Air in Line <div>             Air in Line              Press stop to mute           </div>	Infusion stops and an alarm is activated.	Air is present in administration set.	Disconnect line from patient, press  . Remove the air, as described on priming section.
	The operation led for the relevant channel will blink red.	The roller or clip on the administration set is closed upstream of the pump.	Open clamp/clip.
	The Charger display will show: "AIR"	The line was not loaded correctly.	Re-load the IV line.
Down occlusion <div>             Down Occlusion              Press Stop to mute           </div>	Infusion stops and an alarm is activated.	The roller or clip on the administration set is closed downstream of the pump.	Open clamp/clip.
	The operation led for the relevant channel will blink red.	Administration set is kinked	Straighten the Set.
	The charger display will show: "PRES" for Pressure	Cannula is blocked	Change or clear the Cannula
		Administration set loaded incorrectly	Re-load the IV line
		NOTE: operator may change pressure setting	Refer to Setting Down Occlusion secn

Pump Unattended	Alarm is activated	Two minutes had elapsed without pressing a button	 Press to resume
<div>Pump Unattended</div> <div>Press Start key</div>	The operation led for the relevant channel will blink red.	Pump left in STOP state for more than two minutes	
Door Open	Infusion stops and an alarm is activated.	The door of the pump was not closed properly prior to operation.	Close the Door of the pump.
<div>Door Open</div> <div>Close Door</div>	The operation led for the relevant channel will blink red.	The door has accidentally opened during operation.	
Low Bttery	Pump will only run for another 30 minutes if it will not be connected to mains.	30 Minutes of battery life remaining.	Place the pump in charger and connect to mains.
<div>Low Battery</div> <div>Connect To Charger</div>	The operation led for the relevant channel will blink red.		
End Bttery	Pump operation stops. The pump cannot be used unless connected to mains.	Battery is depleted.	Place the pump in charger and connect to mains. Wait at least 2 minutes before operating.
<div>End Battery</div> <div>Connect To Charger</div>	The operation led for the relevant channel will blink red.		
Fatal Error	Infusion stops.	Fatal internal error has occurred.	Restart the pump. If the alarm does not stop press Info and record the error number (if possible). Pack the pump properly, in its original packaging, and contact your service provider.
<div>Error xx (number)</div> <div>Send for service</div>	The operation led for the relevant channel will blink red.		

End Program	Program ends, pump will start KVO mode automatically if enabled in settings menu.	Current infusion program has completed.	Press  to restart a new program or turn the pump OFF.
End Program KVO			
Press stop to			
	The operation led for the relevant channel will blink red.		
Missing Key	Pump will not start	Administration set loaded incorrectly – the key was not located in its place correctly.	Reload the set into the pump as per as instructions.
Missing Key			
Set key & Close Door	The operation led for the relevant channel will blink red.	A set, different than the Bodyset/ Microset was loaded in the pump.	Change the set to a BodySet/ Microset.
		Attempt was made to operate the pump/channel without an administration set.	Load a set in the desired channel.



Lock Out	Setting cannot be changed.	Lock Out mode is turned on.	No action required. If changing program is required – unlock the pump – refer to lock section for further instructions.
Locked	The operation led for the relevant channel will blink red.		
Lock mode	Kepad does not function	Lock mode is turned on.	No action required. If changing parameters is required – unlock the keys using Info button– refer to lock section for further instructions.
Lock Mode	The operation led for the relevant channel will blink red.		
Wrong TPN data	Program will not start operating.	The set parameters are impossible to perform. Volume or time parameters are incorrect	Check data and change accordingly.
Wrong TPN data Check Data	The operation led for the relevant channel will blink red.		

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## 6 – Specifications

Channels	Two independent channels.
Pumping Mechanism:	Piston Pump
Flow Rate:	0.1 to 100 ml/hr in 0.1ml , 100 to 1200ml/hr in 1 ml increments.
Priming Rate:	600 ml/hr
Total Infused Volume:	0.1-9999 ml
Total Time Setting:	100 hours
Accuracy:	± 5 %.
KVO rate:	0.1 to 5 ml/hr. (to be set)
Air Sensor:	Ultrasonic, adjustable air bubble size
Maximum Pressure:	60, 90, 150, 240, 360, 480mmHg Adjustable
Power Supply:	110-240 VAC, 50/60 Hz. 0.3A max.
Battery:	Rechargeable Li-Polymer 7.4V, 1800mAh. (Typical)
Battery Operation at 125 ml/hr:	7.5 hours
Battery Charging:	Automatic when clicked into the Charger that is connected to an AC power source. Four hours needed to charge a fully-depleted battery.

**Alarms:** When a problem is detected, the *BodyGuard* displays the following alarms:

- Air in line
- Down Occlusion
- Pump Unattended
- End Program
- Low Battery
- End Battery
- Door Open
- Fatal Error
- Lock Mode
- Lock Out Mode
- Missing Key



**NOTE:**



When this symbol is seen, consult accompanying documents.

<i>BodyGuard</i> Dimensions:	146 x 84 x 40 mm. (L x w x h).
Classification	Type CF Equipment (degree of protection against electrical shock)
Housing:	ABS (fire retardant)

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Weight (without charger)	<ul style="list-style-type: none"> <li>• 390 gr. without battery</li> <li>• 450 gr. with battery</li> </ul>
Weight (with standard charger)	<ul style="list-style-type: none"> <li>• 600 gr</li> </ul>
Electrical Safety	Complies with: <b>EN 60601-1</b> (Medical Electrical Equipment Safety), <b>IEC 60601-2-24</b> (Infusion pumps and controllers), <b>IEC 60601-1-4</b> (Programmable Electrical Medical System), <b>UL 2601- 1</b> and <b>CAN/CSA C22.2</b> No 601.1.
Standards	Manufacture in accordance to <b>ISO 13485</b> . <b>CE marked</b> (In accordance with the Medical Devices Directive 93/42/EEC)
EMC	The <i>BodyGuard</i> Infusion System is designed to be in compliance with EN 60601-1 (safety) and IEC 601-1-2 (EMC).
<b>Environmental Specifications</b>	<p><b>Non Operating Conditions</b> (Transportation and Storage):</p> <p>Temperature: -25°C to 50 °C (-13 °F to + 122 °F)</p> <p>Humidity: 5 % to 100% R.H., non-condensing</p> <p>Air pressure: 48kPa to 110kPa</p> <p><b>Operating Conditions:</b></p> <p>(The system may not meet all performance specifications if operated outside of the following conditions)</p> <p>Temperature: +15°C to +40 °C (+59 °F to + 113 °F)</p> <p>Humidity: 20 % to 90% R.H. at +40 °C, non-condensing</p> <p>Air pressure: 70kPa to 110kPa</p>
<b>IV Administration set</b>	<p>Dedicated IV administration sets with anti-siphon valve.</p> <p><i>BodySet</i>  Diameter: 3 X 4.1 mm  Length: approximately 1.5 m  Priming Volume: approximately 16 ml.</p> <p><i>MicroSet</i>  Diameter: 1.5 X 3 mm  Length: approx. 2 m  Priming Volume: approximately 4 ml.</p>
<b>Accessories</b> (optional)	<ul style="list-style-type: none"> <li>• Bolus cable</li> <li>• Charging cable</li> <li>• Small bag</li> <li>• Large back bag</li> </ul>

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# 7 – Service and Maintenance

## Cleaning

Before connecting the pump to a patient, and periodically during use, clean the unit using a lint-free cloth lightly dampened with warm water and a mild detergent or disinfectant.



**Warning:** Always turn the pump off, and remove the battery before cleaning.



**Warning:** Always unplug the charger from AC power before cleaning.



**Caution:** Do not clean the pump or charger with chemicals such as Xylene, Acetone or similar solvents. These chemicals can cause damage to plastic components and paint. Use a lint-free cloth dampened with warm water and a mild detergent or disinfectant.



**Caution:** Do not soak or immerse any part of the pump or charger in water.

## Storage

If the pump is to be stored for an extended period it should be cleaned and the battery fully charged. Store in a clean, dry atmosphere at room temperature and, if available, in its original packaging for protection.

**Perform functional tests and ensure that battery is fully charged once every three months.**

# Battery Operation

The *BodyGuard* pump can operate on battery power, enabling operation when the patient is being moved or during electrical power failure. When the pump operates on battery power, the AC icon is off. At full charge, the battery provides 7 hours of operation at an infusion rate of 125 ml/hr.



**Warning:** Do not operate the pump on AC power if the battery is not loaded in the pump for back up.



**Note:** When the pump is not in use, click the pump into the Charger and plug the system into an AC wall outlet (if possible) to charge battery.



**Note:** After the “end battery” signal has been activated or following long periods of storage, wait 2 minutes after the pump has been connected to an AC power supply before operating.



**Caution:** Leaving the battery in a discharged state for a long period of time may damage the battery.



**Note:** Whenever possible, use the pump connected to an AC power supply via the charging unit. This preserves the battery power supply for emergency use or for situations where the AC power is not available.



**Note:** Replace the battery once every two years.

# LIMITED WARRANTY

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The *BodyGuard* Infusion Pump has been carefully manufactured from the highest quality components.

*Caesarea Medical Electronics Ltd. (CME)* guarantees the pump against defects in material and workmanship for twelve (12) months from date of purchase by the original purchaser.

*CME's* obligation, or that of its designated representative under this Limited Warranty, shall be limited, at *CME's* option, or that of its designated representative, to repairing or replacing pumps, which upon examination, are found to be defective in material or workmanship. The repair or replacement of any product under this Limited Warranty shall not extend the above-mentioned Warranty period.

All repairs under this Limited Warranty should be undertaken only by qualified, trained service personnel. In the event that a pump is found to be defective during the warranty period, the purchaser shall notify *CME* or its designated representative within thirty (30) days after such defect is discovered.

The defective pump should be sent immediately to *CME* or its designated representative for inspection, repair or replacement. Shipping costs are the purchaser's responsibility.

Material returned to *CME* or its designated representative should be properly packaged using *CME* shipping cartons and inserts. Inadequate packaging may result in severe pump damage.

This Limited Warranty shall not apply to defects or damage caused, wholly or in part, by negligence, spilt fluids, dropping of the pump, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel; or to damage resulting from inadequate packaging in shipping the pump to *CME* or its designated representative.

If, after inspection, *CME* or its designated representative is unable to identify a problem, *CME* or its designated representative reserves the right to invoice purchaser for such inspection.

This Limited Warranty is the sole and entire warranty pertaining to *CME's* products and is in lieu of and excludes all other warranties of any nature whatsoever, whether stated, or implied or arising by operation of law, trade, usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purpose. Purchaser expressly agrees that the remedies granted to it under this limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Limited Warranty.

*Managing Director*