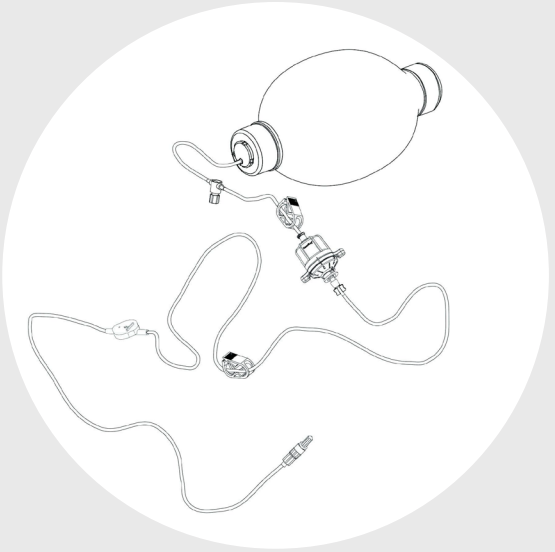
PHYSICIAN GUIDELINES AND INSTRUCTIONS



Ambu

Ambu® ACTion™ Block Pain Pump

Disposable Pain Management System

Rx Only

ACTion™ Block Pain Pump
Standard Version

DESCRIPTION

The ACTion™ Block pump provides continuous delivery of local/regional anesthetic solution.

ACTion™ BLOCK CONTENTS

- Compression Unit (the pumps' reservoir)
- Regulating Set (infusing set)
- Flow Splitter (optional)
- 50/60 cc luer-lock syringe
- Surgical dressing (optional)
- Antimicrobial dressing (optional)
- Medication stickers
- Pump stickers
- Flow Splitter (optional)
- Carrying pouch
- Combination lock (for the carrying pouch)
- Sealed male/female cap (optional – when supplied, is loose in the regulating set sterile pouch)

  In the "Closed System" configuration, the compression Unit and the Regulating Set are connected and bonded and can't be set apart.

NOTES

- Intended for use for patients under the care of a physician or licensed health care provider.
- **The ACTion™ Block is for single patient use only. Do not re-sterilize**
  1. Re-use might result with patient contamination.
  2. Re-sterile will result with poor device performances that do not meet the declared tolerances.
- Medication used with this system should be administered in accordance with the instructions provided by the drug manufacturer.
- Patients should be advised to contact their physician or licensed health care provider if any of the system connections become disconnected or the catheter exits the insertion site
- The ACTion™ Block is a latex free device.
- Avoid dropping the pump. In the event of damage or leakage; advise patients to contact their physician or licensed health care provider.
- In case of emergency, advise patients to close the clamp on the administration set in order to stop the flow of medication immediately.

CONTRAINDICATION

- ACTion™ Block is not intended for intravenous, intra-arterial use.
- ACTion™ Block is not intended for delivery of blood, blood products or lipids.

FILLING THE PUMP

For the ***Closed System configuration;*** start at below sub-clause #2.
For the **Modular configuration:** the Compression Unit (the pump) is packed in a sterile pouch located in the main box or container. It can be filled away from the patient, i.e. in the pharmacy or other approved location.

1. Remove the compression Unit from the sterile package.
2. Close the "c" clamp positioned closed to the exit port (Figures 1a, 1b).
3. Remove the **colored** cap and fill the Compression Unit through the check valve using the 50/60 cc syringe included in the set.
4. Place the cap back on the inlet port of the check valve.
5. Complete the medication sticker and attached it to the tubing. Place the other medication sticker in the patient record or implant log.

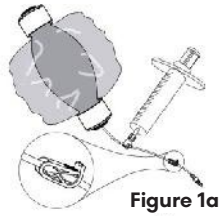


Figure 1a

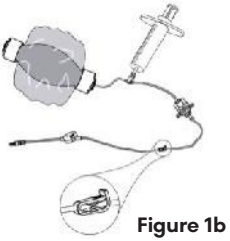


Figure 1b

NOTES

Maximum volume

1. For pumps of nominal volume, 200ml is 330ml.
2. For pumps of nominal volume, 400ml is 550ml.
3. For pumps of nominal volume, 650ml is 650ml.
4. For pumps of nominal volume, 1000ml is 1100ml.

WARNING

- Use aseptic technique to fill the pump.
- After use, handle and discard in accordance with standard medical protocol.

The following two sections referring ONLY to the "Modular" configuration

CONNECTING THE REGULATING SET

1. Remove the ACTion™ Block regulating set from the sterile packaging.
2. Remove the caps off the compression unit exit port and the regulator inlet port and connect the tube to the Regulator (luer connector) (see Figure 2a).

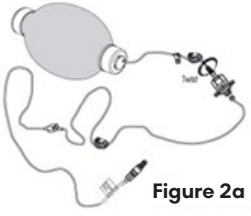


Figure 2a

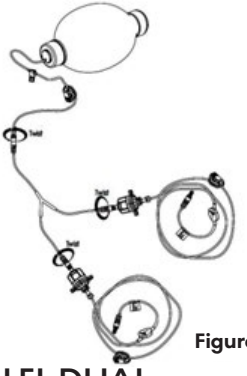


Figure 2b

WHEN PUMP SET IS USED FOR A PARALLEL DUAL FLOW-RATE ADMINISTRATION

1. Connect the luer-lock connector of the Compression Unit to the luer-lock connector of the Y-Tubing set (included in the second Regulating Set packing when available).
2. Then connect each luer-lock connector on the Y-Tubing to each Regulator inlet port (see Figure 2b)

NOTES Close the luer-lock connectors tightly to avoid leaks.

PRIMING AND SETTING THE ADMINISTRATION SET

1. For priming purposes, the regulator is packaged with the Lock Guard key inserted and flow rate is set to the maximum flow rate (over 6 ml/hr or over 15 ml/hr depends on the set version) (See Figure 3). Verify the regulator is set to the highest level.
2. Remove all cap off the regulating set exit port and ensure both c-clamps are open (one on compression set tubing, one on regulating set tubing). Wait until medication flows through the regulating set exit port. Make sure most of the air bubbles have drained from the set and from the tubing (Note: the in-line filter automatically drains out any air bubbles remaining in the set tubing).
3. Set the desired flow rate:
   a. Pull the Clamp of the Lock-Guard from the red locking ring and pull the Adjusting Ring out of the hub (see Figure 4).
   b. Select the desired flow rate by dialing the Adjusting Ring clockwise and aligning the digit on Ring with the black line. Push the adjusting ring toward the regulator to secure the selected flow rate (See Figure 5).
4. To avoid locking of the flow rate in error and to better secure the selected flow rate place the Clamp of the Lock-Guard between the red locking ring and the white adjusting Ring (See Figure 6a).
5. To permanently lock the flow rate prior to the patient being released; remove the Lock Guard from the regulator, push the red locking ring toward the regulator body (See Figure 6b). You will hear an audible click response once permanently locked.
6. Once the red locking ring has been pressed, attempting to unlock the red ring will cause damage to the regulator and could affect the flow rate.

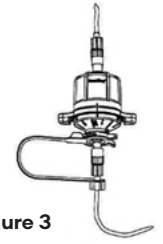


Figure 3

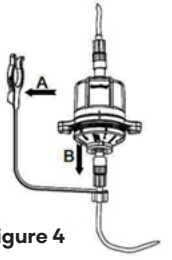


Figure 4

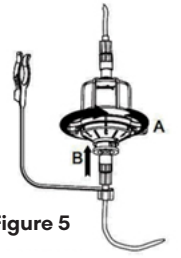


Figure 5

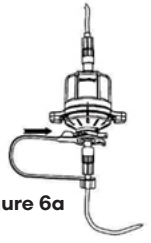


Figure 6a

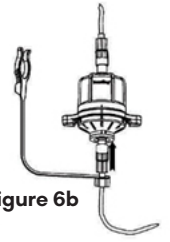


Figure 6b

NOTES

If applicable you may use the Red sealed cap to seal the exit port of the regulating set after priming when the pump is being pre-filled in advance;

a. Close the clamp on the reservoir tubing (see Figure 1).
b. Place the sealed cap at the exit port.

NOTES

- Approximate priming time for a 1-6 ml/hr set without bolus is 13 to 17 minutes
- Approximate priming time for a 5-15 ml/hr set without bolus is 6 to 8 minutes.

NOTES

- The digits on the Regulator represents flow rate in ml/hr.
- As long as the red locking ring is in its original up and unlocked position the flow rate can be reset multiple times as needed; simply pull out the white adjusting ring, dial to the desired flow rate and push the adjusting ring in to secure. Replace the blue Lock Guard to avoid accidental engagement of the red locking ring.

ORGANIZING THE SYSTEM

Place the compression unit and the regulator in the carrying pouch and close it. Verify that the tubing is free and no kinks have occurred (See Figure 7).

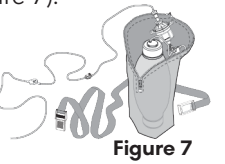


Figure 7

CONNECTING THE PUMP

1. Remove the cap off the system exit port and connect it to the inlet port of the catheter (luer-lock connector) (See Figure 8).
2. When two catheters need to be fed by the same pump, remove the Flow Splitter from the sterile packaging and connect it to the system exit port (See Figure 9).
3. Then remove the caps off the Flow Splitter exit port and connect the catheters (luerlock connector).

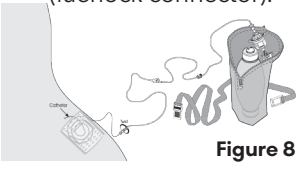


Figure 8

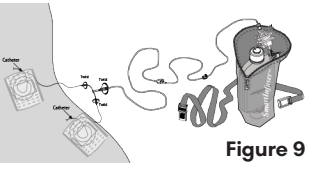


Figure 9

WARNING

- Prior to connecting the regulation set exit port to the catheter verify that there is a slow drip from the exit port.
- The reservoir must not be connected directly to the catheter, as this can result in free flow of the anesthetics to the patient. Excessive anesthetics can result in a life-threatening condition.

NOTES

- Close the luer-lock connectors tightly to avoid leaks.
- Infusion is complete when the pump is no longer inflated (the compression unit body will feel hard when touched in the middle) (See Figure 10).

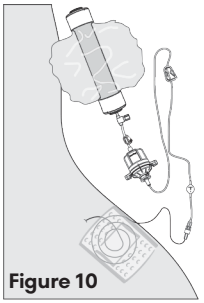


Figure 10

CAUTION

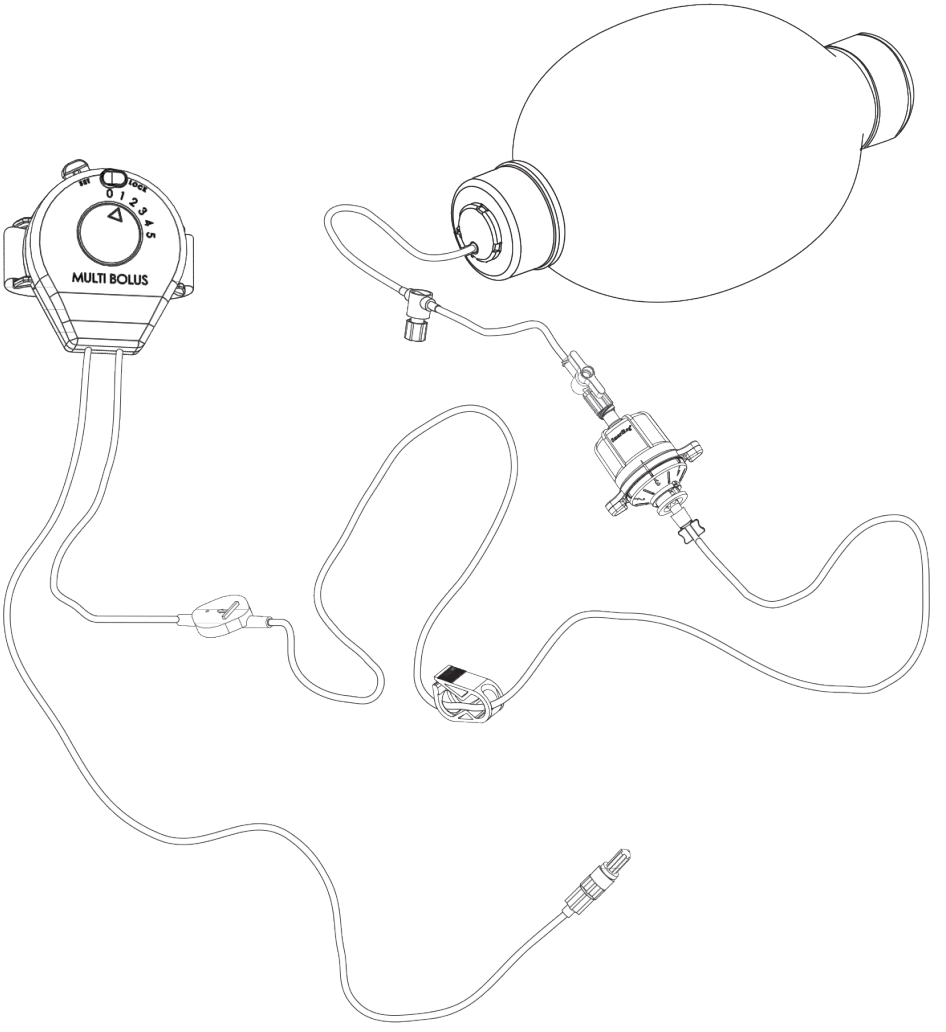
- Close the luer-lock connectors tightly to avoid leaks.
- Infusion is complete when the pump is no longer inflated (the compression unit body will feel hard when touched in the middle) (See Figure 10).

NOTES

- The position of the regulator's adjusting ring determines the nominal infusion flow rate.
- When saline liquid is used at 22° C, the regulator maintains an accuracy of ±15% of the selected flow rate and stability of ±5% throughout the entire therapy. The viscosity of the solution affects the actual flow rate.
- Actual infusion time may vary due to differences between the nominal and actual flow rate and tolerances in the actual medication volume.
- The product is sterile if indicated with symbol on product pouch - STERILE R: Sterile by Radiation. STERILE EO: Sterile by Ethylene Oxide.

ACTion™ Block Pain Pump

MultiBolus™ Version



DESCRIPTION

The ACTion™ Block pump provides continuous delivery of a local/regional anesthetic solution. The MultiBolus™ enables the patient to activate the bolus at the expense of the continuous basal flow.

ACTion™ BLOCK CONTENTS

- Compression unit (pump)
- Regulating set (Infusing Set)
- 50/60 cc luer-lock syringe
- Surgical Dressing
- Medication stickers
- Pump stickers
- Carrying pouch
- Carrying pouch combination lock
- Antimicrobial dressing (optional)
- Flow Splitter (optional)
- Lock-Guard (optional- is pre-assembled on the regulating set)
- Sealed male/female cap (optional - when supplied, is loose in the regulating set sterile pouch)

NOTES

- Intended for use for patients under the care of a physician or licensed health care provider.
- **The ACTion™ Block is for single patient use only. Do not re-sterilize.**
  1. Re-use might result with patient contamination.
  2. Re-sterilize will result with poor device performances that do not meet the declared tolerances.
- Medications used with this system should be administered in accordance with the instructions provided by the drug manufacturer.
- Patients should be advised to contact their physician or licensed health care provider if any of the system connections become disconnected or the catheter exits the insertion site.
- The ACTion™ Block is a latex free device.
- Avoid dropping the pump. In the event of damage or leakage, advise patients to contact their physician or licensed health care provider.
- In case of emergency, advise patients to close the clamp on the administration set in order to stop the flow of medication immediately.

CONTRAINDICATION

- ACTion™ Block is not intended for intravenous, intra-arterial use.
- ACTion™ Block is not intended for delivery of blood, blood products' or lipids.

FILLING THE PUMP

The Compression Unit (the pump) is packed in a separate sterile pouch located in the main box or container. It can be filled away from the patient, i.e. in the pharmacy or other approved location (see Figure 1).

1. Remove the Compression Unit from the sterile package.
2. Close the “c” clamp (Figure 1) at the exit port.
3. Remove the cap and fill the compression unit through the check valve using the 50/60 cc syringe included in the set.
4. Place the cap back on the check valve inlet port.
5. Complete the medication sticker and attach it to the
6. tubing. Place the other system sticker in the patient record or implant log.

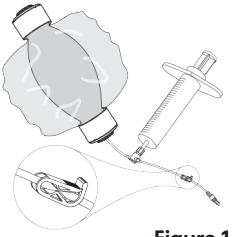


Figure 1

NOTES

Maximum volume

1. For pumps of nominal volume 200ml is 300ml
2. For pumps of nominal volume 400ml is 500ml
3. For pumps of nominal volume 650ml is 650ml
4. For pumps of nominal volume 1000ml is 1100ml

WARNING

- Use aseptic technique to fill the pump.
- After use, handle and discard in accordance with standard medical protocols.

CONNECTING THE REGULATING SET

1. Remove the ACTion™ Block regulating set from the sterile packaging.
2. Remove the caps off the compression exit port and the regulator inlet port and connect the tube to the Regulator (luer-lock connector) (see Figure 2).

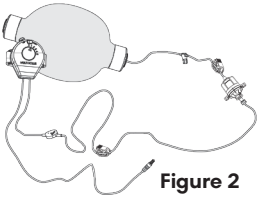


Figure 2

NOTE

Close the luer-lock connectors tightly to avoid leaks.

PRIMING AND SETTING THE ADMINISTRATION SET

1. For priming purposes, the regulator is packaged with the Lock Guard key inserted and flow rate is set to the maximum flow rate (over 6 ml/hr or over 15 ml/hr depends on the set version) (See Figure 3). Verify the regulator is set to the highest level.
2. Place the compression unit and the bolus so that exit port positioned facing up and the bolus's tubes are positioned upwards (use the bolus's strap to hold it to the unit) and wait until medication flows through the catheter and most of the air bubbles have drained from the set and from the catheter (Note: the set in-line filter automatically drains out any air bubbles remaining in the set tubing) (See Figure 4)
3. Select the desired flow rate:
   a. Pull the Clamp of the Lock-Guard from the red locking ring and pull the Adjusting Ring out of the hub (see Figure 5).
   b. Select the desired flow rate by dialing the Adjusting Ring clockwise and aligning the digit on Ring with the black line(See Figure 6A). Push the adjusting ring toward the regulator to secure the selected flow rate (See Figure 6B).
4. To avoid locking of the flow rate in error and to better secure the selected flow rate place the Clamp of the Lock-Guard between the red locking ring and the white adjusting Ring (See Figure 7a).
5. To permanently lock the flow rate prior to the patient being released; remove the Lock Guard from the regulator, push the red locking ring toward the regulator body (See Figure 7b). You will hear an audible click response once permanently locked.
6. Once the red locking ring has been pressed, attempting to unlock the red ring will cause damage to the regulator and could affect the flow rate.

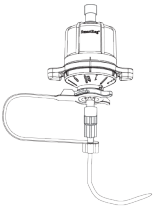


Figure 3

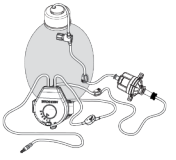


Figure 4

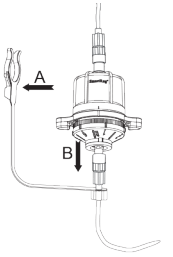


Figure 5

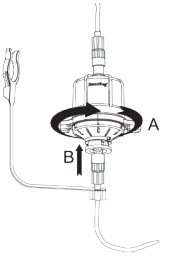


Figure 6

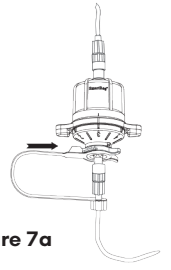


Figure 7a

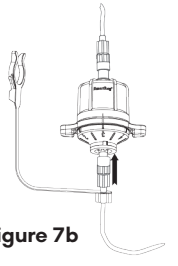


Figure 7b

NOTE

If applicable you may use the Red sealed cap to seal the exit port of the regulating set after priming when the pump is being pre-filled in advance;

a. Close the clamp on the reservoir tubing (see Figure 1).
b. Place the sealed cap at the exit port.

NOTES

- Approximate priming time for a 1-6 ml/hr set without bolus is 13 to 17 minutes
- Approximate priming time for a 5-15 ml/hr set without bolus is 6 to 8 minutes.
- Approximate priming time for a 1-6 ml/hr set with bolus is 65 to 75 minutes.
- Approximate priming time for a 5-15 ml/hr set with bolus is 35 to 40 minutes.

7. Select the MultiBolus volume by aligning the arrow with the digit by moving the lever (See Figure 8), secure the selected volume by turning the lock 180° (See Figure 9).
8. To permanently lock the bolus volume prior to the patient being released; push the lock downward (See Figure 10).

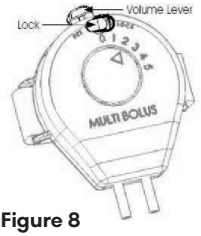


Figure 8

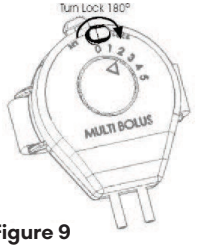


Figure 9

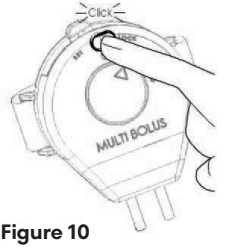


Figure 10

NOTES

- The digits on the Regulator represents flow rate in ml/hr.
- As long as the red locking ring is in its original up and unlocked position the flow rate can be reset multiple times as needed; simply out the adjusting ring, dial to the desired flow rate and push the adjusting ring in to secure.
- The digits on the MultiBolus™ represent volume in ml.

ORGANIZING THE SYSTEM

Place the compression unit and the regulator in the carrying pouch and close it. Verify that the tubing is free and no kinks have occurred (See Figure 11).

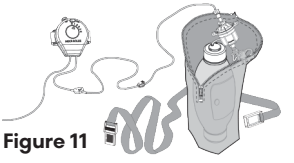


Figure 11

CONNECTING THE PUMP

Remove the cap off the system exit port and connect it to the inlet port of the catheter (luerlock connector) (See Figure 12).

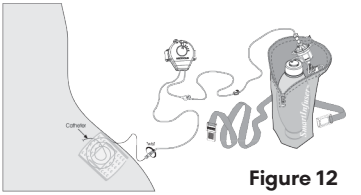


Figure 12

WARNING

- Prior to connecting the regulation set exit port to the catheter verify that there is a slow drip from the exit port.
- The reservoir must not be connected directly to the catheter, as this can result in free flow of the anesthetics to the patient. Excessive anesthetics can result in a life-threatening condition.

NOTES

- Close the luer-lock connectors tightly to avoid leaks.
- The MultiBolus™ isn't applicable when using administration with Flow Splitter.
- DO NOT remove the blue check valve from the system exit port when using the ACTion™ Block with a MultiBolus (See gure 13).
- Infusion is complete when the pump is no longer inated (the compression unit body will feel hard when touched in the middle) (See Figure 14).

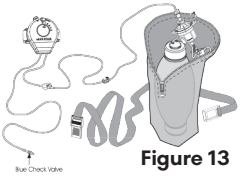


Figure 13

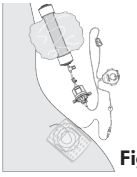


Figure 14

CAUTION

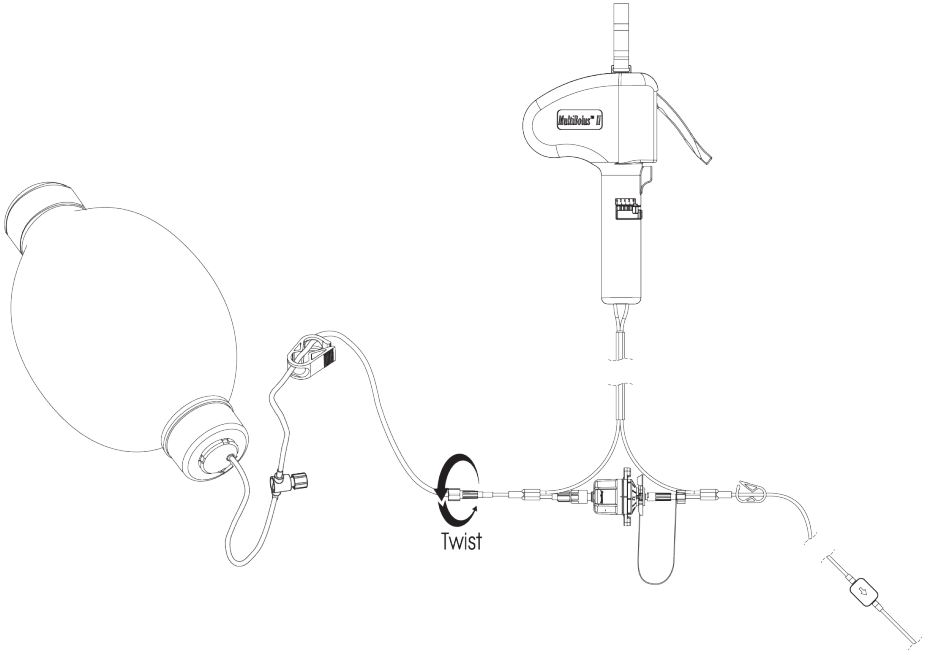
- Do not cover the lter of the ACTion™ Block.
- Sterile, unless sterile packaging is broken. Do not use the product if any damage has occurred to the sterile packaging.

NOTES

- The position of the regulator's adjusting ring determines the nominal infusion flow rate.
- When saline liquid is used at 22° C, the regulator maintains an accuracy of ±15% of the selected ow rate and stability of ±5% throughout the entire therapy.
- The viscosity of the solution affects the actual flow rate.
- Actual infusion time may vary due to differences between the nominal and actual flow rate and tolerances in the actual medication volume.
- The product is sterile if indicated with symbol on product pouch -

STERILE R : Sterile by Radiation- STERILE EO : Sterile by Ethylene Oxide.

Ambu® ACTion™ Block Pain Pump
MultiBolus II™ Version



DESCRIPTION

The ACTion™ Block pump provides continuous delivery of a local/regional anesthetic solution. The MultiBolus™ II enables the patient to activate the bolus in addition to the continuous basal flow.

- By adding standard regulating set to the pump administration you create a dual flow-rate administration while the bolus feature is available only to one site.
- By adding a FlowSplitter™ at the regulating set exit port you can create a dual catheter administration with bolus feature (the volume of the basal and the bolus equally split between the catheters).

ACTion™ BLOCK CONTENTS

- Compression unit (pump)
- Regulating set (Infusing Set)
- 50/60 cc luer-lock syringe
- Surgical Dressing
- Medication stickers
- Pump stickers
- Carrying pouch
- Carrying pouch combination lock
- Antimicrobial dressing (optional)
- Flow Splitter (optional)
- Lock-Guard (optional- is pre-assembled on the regulating set)
- Sealed male/female cap (optional - when supplied, is loose in the regulating set sterile pouch)

NOTES

- Intended for use for patients under the care of a physician or licensed health care provider.
- **The ACTion™ Block is for single patient use only. Do not re-sterilize.**
  1. Re-use might result with patient contamination.
  2. Re-sterilize will result with poor device performances that do not meet the declared tolerances.
- Medications used with this system should be administered in accordance with the instructions provided by the drug manufacturer.
- Patients should be advised to contact their physician or licensed health care provider if any of the system connections become disconnected or the catheter exits the insertion site.
- The ACTion™ Block is a latex free device.
- Avoid dropping the pump. In the event of damage or leakage, advise patients to contact their physician or licensed health care provider.
- In case of emergency, advise patients to close the clamp on the administration set in order to stop the flow of medication immediately.

WARNING

- In order to avoid nerve injury do not use the MultiBolus II™ with catheters with open distal end.
- The catheter placement is the ultimate decision of the physician. However, MFS – Medical Flow Systems recommends not to place catheters intraarticularly after orthopedic surgery in order to avoid chondrolysis or necrosis of the local tissue due to continuous infusion of local anesthetics.

CONTRAINDICATION

- ACTion™ Block is not intended for intravenous, intra-arterial use.
- ACTion™ Block is not intended for delivery of blood, blood products or lipids.

FILLING THE PUMP

The Compression Unit (the pump) is packed in a separate sterile pouch located in the main box or container. It can be filled away from the patient, i.e. in the pharmacy or other approved location (see Figure 1).

1. Remove the Compression Unit from the sterile package.
2. Close the “c” clamp (Figure 1) at the exit port.
3. Remove the cap and fill the compression unit through the check valve using the 50/60 cc syringe included in the set.
4. Place the cap back on the check valve inlet port.
5. Complete the medication sticker and attach it to the tubing. Place the other system sticker in the patient record or implant log.

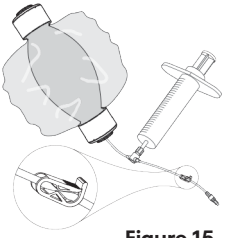


Figure 15

NOTE

Maximum volume

1. For pumps of nominal volume 200ml is 300ml
2. For pumps of nominal volume 400ml is 500ml
3. For pumps of nominal volume 650ml is 650ml
4. For pumps of nominal volume 1000ml is 1100ml

WARNING

- Use aseptic technique to fill the pump.
- After use, handle and discard in accordance with standard medical protocols.

CONNECTING THE REGULATING SET

1. Remove the ACTion™ Block regulating set from the sterile packaging.
2. Remove the caps off the compression exit port and the regulator inlet port and connect the tube to the Regulator (luer-lock connector) (see Figure 2a).

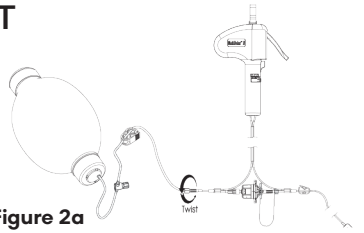


Figure 2a

WHEN PUMP SET IS USED FOR A PARALLEL DUAL FLOW RATE ADMINISTRATION

1. Connect the luer-lock connector of the Compression Unit to the luer-lock connector of the Y-Tubing set (included in the second Regulating Set packing when available).
2. Then connect each luer-lock connector on the Y-Tubing to each Regulator input port (See Figure 2b).

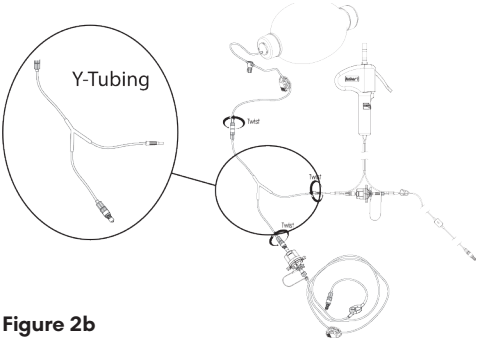


Figure 2b

WHEN PUMP SET IS USED FOR A PARALLEL DUAL CATHETER ADMINISTRATION

Connect the male FlowSplitter™ to the male luer connector at the administration exit port.

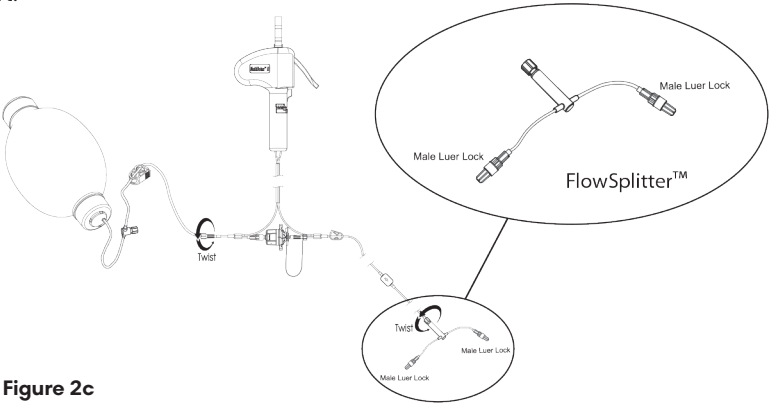


Figure 2c

NOTE
Close the luer-lock connectors tightly to avoid leaks.

PRIMING AND SETTING THE ADMINISTRATION SET

1. For priming purposes, the regulator is packaged with the Lock Guard key inserted and flow rate is set to the maximum flow rate (over 6 ml/hr or over 15 ml/hr depends on the set version) (See Figure 3). Verify the regulator is set to the highest level.
2. Remove the caps off the regulating set exit port and ensure both c-clamps are open (one on compression set tubing, one on regulating set tubing). Wait until medication flows through the regulating set exit port. Make sure most of the air bubbles have drained from the set and from the tubing (Note: the in-line filter automatically drains out any air bubbles remaining in the set tubing).

SETTING THE BASAL FLOW RATE

3. Select the desired basal flow rate:
   a. Pull Lock-Guard from the red locking ring and lift the white Adjusting Ring out of the regulator's hub (see Figure 4).
   b. Select the desired flow rate by dialing the Adjusting Ring clockwise and aligning the digit on Ring with the black line. Push the ring toward the regulator to secure the selected flow rate (See Figure 5).
4. To avoid locking of the flow rate in error and to better secure the selected flow rate replace the Lock-Guard between the red locking ring and the white Adjusting Ring (See Figure 6a).
5. To permanently lock the flow rate prior to the patient being released; remove the Lock-Guard from the regulator, push the red locking ring toward the regulator body (See Figure 6b). You will hear an audible click response once permanently locked.
6. Once the red locking ring has been pressed, attempting to unlock the red ring will cause damage to the regulator and could affect the flow rate.

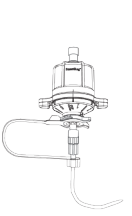


Figure 3

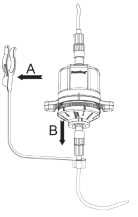


Figure 4

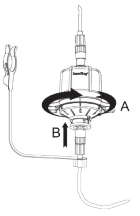


Figure 5

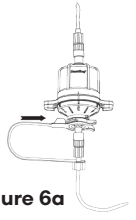


Figure 6a

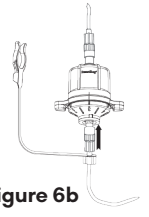


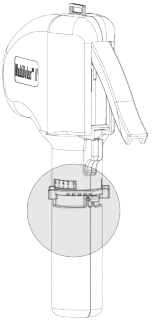
Figure 6b

NOTES

- Approximate priming time for a 1-6 ml/hr set is 13 to 17 minutes
- Approximate priming time for a 5-15 ml/hr set is 6 to 8 minutes.
- The actual volume of the first activated bolus will be about 1 ml less than normal.

SETTING THE MULTIBOLUS II™

1. Verify that the Locking-Pin is at horizontal position (Figure 7a) and dial the MultiBolus II™ to any volume in the range 3ml to 6ml as detailed in clause #9 below.
2. No special procedure is required for priming the bolus device; when first activated the in-line filter will automatically drain out any air from the bolus reservoir.
3. Depending on the selected volume, the bolus' reservoir will be filled within approximately one hour.



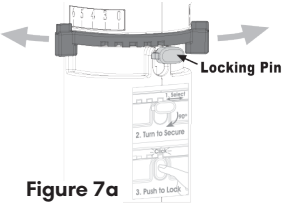


Figure 7a

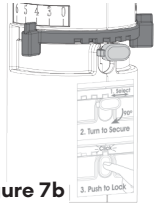


Figure 7b

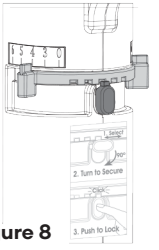


Figure 8

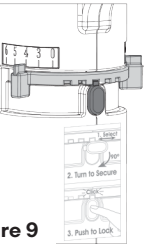


Figure 9

3. Select the desired volume of the bolus device before activation;MultiBolus II™ to any volume in the range 3ml to 6ml as detailed in clause #9 below.
   a. Align the digit on the bolus's adjusting ring with the desired volume (See Figure 7a, 7b).
   b. Turn the Lock Pin vertical wise to secure the selected volume (See Figure 8).
   c. To permanently lock volume prior to the patient being released, push in the Lock Pin toward the device body (See Figure 9).

NOTE

Dialing of the Adjusting Ring should be performed right before priming and setup or after the bolus trigger has been squeezed and has reset. If you wish to change the bolus rate at a later time, you may need to fully squeeze the bolus trigger in order to change the selected volume.

ACTIVATING THE MULTIBOLUS II™

The MultiBolus II™ is a semi-automatic mechanical device; once loaded it is automatically in active delivery mode

1. Activating Bolus mode of the device is established by squeezing the Activating Lever with your ngers till the device “clicks” (See Figures 10, 11). Then, release the Lever.
2. Depending on the selected volume and the catheter diameter, within approximately 30 seconds to one minute the bolus device will “click” again; notifying the end of the loading phase.

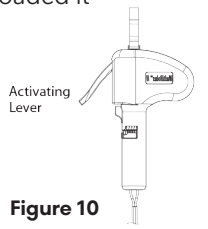


Figure 10

NOTE

- The Activating Lever must be squeezed all the way down till it “clicks” to deliver the entire selected bolus amount. When the Activating Lever is only partially squeezed the device will only delivery a partial bolus and will stop delivery of the bolus medication immediately once the Activating Lever has been released. i.e. once the lever is released, no more medication will leave the MulitBolus II until it is squeezed again.
- The resistance to movement of the Activating Lever is signicantly easier when the device is in automatic activating mode.
- When not activated, the resistance to movement of the Activating Lever is normal (relatively high).

Figure 11

WARNING

- Prior to connecting the regulation set exit port to the catheter verify that there is a slow drip from the exit port.
- The reservoir must not be connected directly to the catheter, as this can result in free flow of the anesthetics to the patient. Excessive anesthetics can result in a life-threatening condition.

CONNECTING THE PUMP TO THE CATHETER

Once the ACTion™ Block has been primed, the basal ow rate has been selected and secured/locked (if applicable) and the bolus volume has been selected and secured/locked; connect the tubing set exit port to the catheter inlet port using the male luer-lock connector.

ORGANIZING THE SYSTEM

Place the compression unit and the regulator in the carrying pouch (supplied in box) and close it. Using the clamp, attach the bolus device to the designated eyelet positioned on the external side of the carrying pouch. Verify that the tubing is free and no kinks have occurred (See Figure 12).

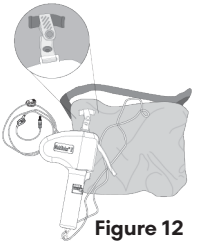


Figure 12

CAUTION

- Do not cover the filter of the regulating set.
- Do not tape in-line filter to patient's skin.
- Sterile, unless sterile packaging is broken. Do not use the product if any damage has occurred to the sterile packaging.

NOTES

- The digits on the regulator represents flow rate in ml/hr.
- As long as the locking red ring is in its original up position the flow rate can be reset multiple times as needed; simply pull out the Lock-Guard, pull up on the white Adjusting Ring, dial to the desired flow rate and push the white Adjusting back in and replace the Lock-Guard to secure.
- The digits on the MultiBolus II™ represent bolus volume in ml,
- The actual bolus volume may vary from the selected volume by +0ml /-0.8ml at semi-automatic and +5%/-10% at manual.
- The bolus reservoir is filled at a flow rate of 6ml/hr ±20%.
- As long as the Locking Pin has NOT been pushed in, the bolus volume can be reset multiple times when the semi-automatic bolus delivery has ended.
- To adjust bolus volume turn the Lock Pin to horizontal position, dial to the desired volume and turn back the Lock Pin to vertical position.
- The position of the regulator's white Adjusting Ring determines the nominal infusion flow rate.
- When saline liquid is used at 22° C, the regulator maintains an accuracy of ±15% of the selected flow rate and a consistency rate of ±5% throughout the entire therapy.
- The viscosity of the solution affects the actual flow rate and the actual bolus filling time.
- Actual infusion time may vary due to differences between the nominal and actual flow rate and tolerances in the actual medication volume.
- The maximum flow rate refers to bolus + basal rate. To reduce potential adverse effects, medication dosing should be based on the maximum flow rate.
- The average velocity of the bolus dose when set to 6ml and connected to a 21Gcatheter is 5 to 6 ml/minute.
- The catheter diameter affect the bolus dose velocity; higher diameter =higher velocity, lower diameter = lower velocity.
- The MultiBolus II™ is 100% mechanical device that requires about 4 Kg (~8.8 lb) during activation.
- **It is up to the physician to determine whether or not the individual patient is capable of activating it.**
- Patient should be trained in accordance with the Patient Guidance And Instructions.

Ambu

Ambu, Inc.
6230 Old Dobbin Lane
Columbia, MD 21045
Tel. 800 262 8462
Fax 800 262 8673
ambuUSA.com

US: Rx only