

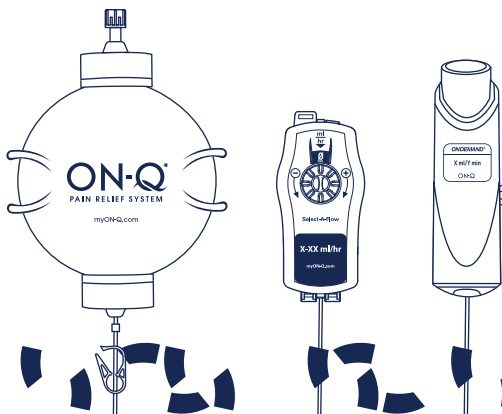


ON-Q Pain Relief System

ON-Q[®] PUMP

with SELECT-A-FLOW[®] VARIABLE RATE CONTROLLER
AND ONDEMAND[®] BOLUS BUTTON

Instructions for Use



Important Information

Please read the entire document before operating the ON-Q* device. Follow all instructions carefully to ensure the safety of patient and/or user.

User Information

- For 24-hour Product Support, call 1-800-444-2728 or +1-949-923-2400 (English only).
- Visit www.halyardhealth.com or contact your sales representative for the latest product information and Technical Bulletins, including but not limited to:
 - ON-Q* with SELECT-A-FLOW*, Drug Dosing Information
 - Use of ON-Q* Pump in Magnetic Resonance (MR) environment
 - Latex Sensitivity - ON-Q* Pump
 - Continuous Infusion in Pediatric Patients
 - Use of ON-Q* Pump in Hand and Foot Surgery Volume and Flow Rate Selection
 - What We Know About Chondrolysis Today
 - Use of ON-Q* with Perioperative Autologous Blood Transfusion Systems
 - USP 797
 - Effect of Storage Times on Flow Rate on Pre-filled ON-Q* Elastomeric Pumps
 - Patient Guidelines

⚠ Warning

Flow rate is adjustable and bolus is deliverable on demand. To reduce potential adverse effects, medication dosing should be based on the Total Flow Rate.

- **Total Flow Rate refers to bolus + basal rate. To reduce potential adverse effects, medication dosing should be based on the Total Flow Rate.**
- **To reduce potential adverse events:**
 - Medication dosing should be based on the maximum flow rate (7 or 14 ml/hr). Flow rate may vary \pm 20%.
 - Regardless of the prescribed flow rate, only fill pump with medication dosage that is appropriate to administer at the maximum flow rate.

- Refer to the drug manufacturers' package insert for complete information.
- Due to risk of ischemic injury, vasoconstrictors such as epinephrine are not recommended for continuous infusions for the following routes of administration: intraoperative site, perineural and percutaneous (excluding epidural).
- Medications or fluids must be administered per instructions provided by the drug manufacturer. Physician is responsible for prescribing drug based on each patient's clinical status (such as age, body weight, disease state of patient, concomitant medications, etc.).
- There is no alarm or alert when flow interruption occurs, therefore, life-supporting medications whose usage may cause serious injury or death due to stoppage or under-delivery are not recommended for infusion with the ON-Q* device.
- There is no indicator of pump infusion status, therefore, use caution where over-delivery of medications could result in serious injury or death.
- Epidural infusion of analgesics is limited to uses of indwelling catheters specifically designed for epidural delivery. To prevent infusion of drugs not indicated for epidural use, do not use IV set with additive ports. It is strongly recommended that devices used for administration of medication via epidural routes be clearly differentiated from all other infusion devices.
- To avoid complications, use the lowest flow rate, volume and drug concentration required to produce the desired result. In particular:
 - Avoid placing the catheter in the distal end of extremities (such as fingers, toes, nose, ears, penis, etc.) where fluid may build up as this may lead to ischemic injury or necrosis.
 - Avoid placing the catheter in joint spaces. Although there is no definitive established causal relationship, some literature has shown a possible association between continuous intra-articular infusions (particularly with bupivacaine) and the subsequent development of chondrolysis.
 - Avoid tight wrappings which can limit blood supply or fluid diffusion.



- **ONDEMAND* device:** To prevent continuous over delivery of medication significantly greater than the Total Flow Rate, close the clamp if any of the following conditions occur:

- The red tab is not removed or breaks while removing.
- The orange bolus refill indicator is not near the top at all times except within 60 minutes of pressing the bolus button.
- The bolus button will not latch except within 30 minutes of pressing the bolus button.


ONDEMAND* device - If the bolus button does not pop back up within 30 minutes of pressing it, check position of orange indicator:

- If orange indicator is in the bottom position, close the clamp. Continuous medication delivery may be occurring significantly greater than the Total Flow Rate.
- If orange indicator is in the top position: something may be impeding the flow. Check for tubing kinks, closed clamp or patency of connected devices such as catheter or unvented filter (verify patency) according to your standard protocol.
- It is the responsibility of the healthcare provider to ensure patient is educated in the proper use of the system.
- It is the responsibility of the healthcare provider to modify Patient Guidelines provided with pump as appropriate for your patients' clinical status and medication prescribed.

⚠ Caution

-  Do not use if package is open, damaged or a protector cap is missing.
-  Single use only. Do not sterilize, refill or reuse.

Reuse of the device could result in the following risks:

- Improper functioning of the device (i.e., inaccurate flow rate)
- Increased risk of infection
- Occlusion of the device (i.e., impedes or stops infusion)
- The pump is sterile and non-pyrogenic.
-  Product uses Di (2-ethylhexyl) phthalate (DEHP) plasticized PVC:
 - DEHP is a commonly used plasticizer in medical devices. There is no conclusive scientific evidence to date that exposure to DEHP has a harmful effect on humans. However, the risk and benefit of using medical devices with DEHP for pregnant women,

breastfeeding mothers, infants and children should be evaluated prior to use.

- Certain solutions may be incompatible with the PVC material used in the administration set. Consult drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
- Do not underfill pump. Underfilling pump may significantly increase the flow rate.
- Do not exceed maximum fill volume. (Table 1)
- Clamp is provided to stop the infusion. Do not remove or break clamp. Do not use clamp as an intermittent delivery device.
- Roll tubing between fingers to promote flow if clamped for extended time.
- The fill volume, infusion rate, bolus dose and bolus interval is labeled on the fill port.
- Avoid contact of cleansing agents (like soap and alcohol) with the filter because leakage may occur from the air eliminating vent.
- Do not tape over filter(s) as this could block the air vent and impede the infusion.
- Do not immerse pump in water. Take care to protect pump during any activities, which could cause pump and filter to get wet, such as showering.
- In the event of any leakage from pump or administration set, close tubing clamp. Replace pump if necessary.
 - Do not discard pump and contact Halyard Health for product return instructions.
- Do not add unvented filter to end of the administration set as this may impede or stop the flow rate.
- ONDEMAND* device: do not remove the red tab until the tubing is completely primed. Up to 5 ml bolus of air may be delivered if not primed correctly.
- SELECT-A-FLOW* device: flow rate is unpredictable if it is dialed between rate settings.
- **Flow rates may vary due to:**
 - Fill volume**
 - Filling pump less than the labeled volume results in faster flow rate.
 - Filling pump greater than the labeled results in slower flow rate.
 - **Viscosity and/or drug concentration**
 - **Pump position** - position pump at approximately the same level as the catheter site:
 - Positioning pump above this level increases flow rate.
 - Positioning pump below this level decreases flow rate.

Temperature

- SELECT-A-FLOW* and ONDEMAND* devices should be worn outside clothing and kept at room temperature.
- To ensure flow rate accuracy, do not place heat or cold therapy in close proximity to the flow controller.
- Temperature will affect solution viscosity, resulting in faster or slower flow rate.
- SELECT-A-FLOW* and ONDEMAND* devices have been calibrated using Normal Saline (NS) as the diluent and room temperature (22°C, 72°F) as the operating environment. Flow rate will increase approximately 1.4% per 1°F/0.6°C increase in temperature and will decrease approximately 1.4% per 1°F/0.6°C decrease in temperature.
- If refrigerated, allow pump to reach room temperature before using.
 - It may take approximately 15 hours for a pump to reach room temperature.

Storage

- Storage of a filled ON-Q* Pump for more than 8 hours prior to starting infusion may result in a slower flow rate.

External pressure

- External pressure such as squeezing or laying on pump increases flow rate.

Indications for Use

- The ON-Q* Pump is intended to provide continuous delivery of medication (such as local anesthetics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and/or pain management. Routes of administration include: intraoperative site, perineural, percutaneous and epidural.
- ON-Q* Pump is indicated to significantly decrease pain and narcotic use when used to deliver local anesthetics to or around surgical wound sites, or close proximity to nerves, when compared to narcotic only pain management.

Contraindications

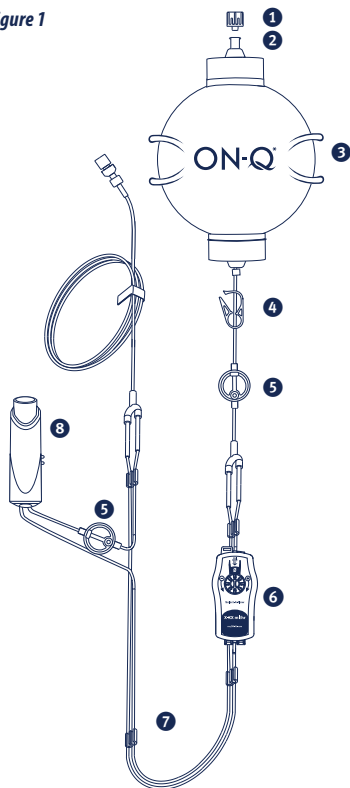
- ON-Q* Pump is not intended for blood, blood products, lipids, fat emulsions, or Total Parenteral Nutrition (TPN).
- ON-Q* Pump is not intended for intravascular delivery.
- The ON-Q* Pump with SELECT-A-FLOW* and ONDEMAND* devices are not intended for use with ON-Q* SOAKER* and SILVERSOAKER* catheters because they could prevent the proper functioning of the ONDEMAND* device.

Description of Device: (Figure 1)

The ON-Q* Pump with SELECT-A-FLOW* and ONDEMAND* devices allows user to set the desired flow rate and to activate a bolus dose on demand.

- 1 Fill Port Cap
- 2 Fill Port
- 3 ON-Q* Pump
- 4 Clamp
- 5 Air Eliminating Filter
- 6 SELECT-A-FLOW* Variable Rate Controller
- 7 Tubing
- 8 ONDEMAND* Bolus Device

Figure 1



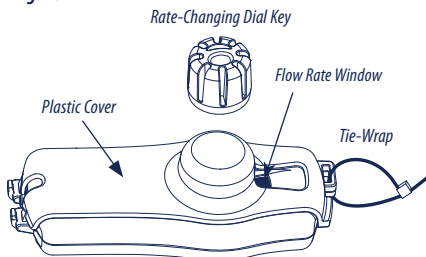
The ONDEMAND* Device Description

ONDEMAND* device is a bolus button. The ONDEMAND* device allows fixed boluses to be delivered on demand by patient or health care provider.

SELECT-A-FLOW* Device Description

SELECT-A-FLOW* device is a flow controller that allows the user to adjust the infusion rate by turning the rate-changing dial key on the device. The flow rate is within a predetermined range and is designated on each device.

Figure 2



To Discourage Tampering: (Figure 2)

1. Remove the dial key from the dial by pulling it straight out. Put the dial key in a safe place for later use, e.g., attached to a key ring.
2. Close the cover over the SELECT-A-FLOW* Variable Rate Controller.
3. For increased tamper resistance, the cover may be locked to the SELECT-A-FLOW* Variable Rate Controller using the tie-wrap.

Note: If desired, the cover may also be removed from the SELECT-A-FLOW* device by fully opening the cover and then pulling straight up on the plastic feet at the bottom of the cover.

⚠ Warning: Do not rely on the SELECT-A-FLOW* dial key or tie-wrap to prevent patient tampering.

SELECT-A-FLOW* device is available in two flow rate ranges and distinguished by color on the face of device:

Blue (1-7 ml/hr)

- Flow rate: 1, 2, 3, 4, 5, 6, 7 ml/hr

Purple (2-14 ml/hr)

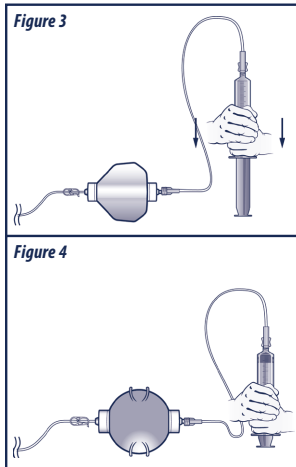
- Flow rate: 2, 4, 6, 8, 10, 12, 14 ml/hr

Instructions for Use

Use Aseptic Technique

Filling ON-Q* Pump: (Figure 3-4)

Note: Follow hospital protocols and applicable regulations for filling pump.



⚠ Warning

- Flow rate is adjustable and bolus is deliverable on demand. To reduce potential adverse effects, medication dosing should be based on the Total Flow Rate. (Table 2)
- Medication dosage should be based on maximum flow rate. Pump is preset at 7 ml/hr or 14 ml/hr (Table 3)

1. Close clamp.
2. Uncap the fill port.
3. Attach filled syringe to Filling Extension Set. (Figure 3)
4. Grasp syringe with both hands.
5. Push down on plunger continuously until volume is dispensed. Do not handle pump while filling, as the syringe tip may break. Repeat as necessary. (Syringe accuracy is $\pm 4\%$) (Figure 4)

Note: Filling Extension Set is provided with pump (see product insert for further information).

⚠ Caution: Do not underfill pump. Underfilling pump may significantly increase the flow rate. Do not exceed maximum fill volume. (Table 1)

- Remove filling extension set from fill port.
- Replace fill port cap. Label with the appropriate pharmaceutical and patient information.
Note: ON-Q* Pump contains a Carry Case for holding pump.

⚠ Caution: Do not fill less than the labeled fill volume or exceed the maximum fill volume. (Table 1)

Table 1: Fill Volume

Labeled Fill Vol.	Maximum Fill Vol.	Retained Vol.
400 ml	550 ml	≤15 ml

Total Flow Rate Dosing

Total Flow Rate refers to bolus + basal, which is the infusion rate per hour. (Table 2)

Table 2: Total Flow Rate

Bolus Dose	Refill Time	Total Flow Rate
5 ml	30 min	10 ml/hr + Basal Rate
5 ml	60 min	5 ml/hr + Basal Rate

Table 3: 24-Hour Dosing Reference Chart (Basal Rate)

Select-A-Flow* Model	Drug Concentration (mg)		
	0.2%	0.25%	0.5%
7 ml/hr Max. Flow Rate	336	420	840
14 ml/hr Max. Flow Rate	672	840	1,680

Formula:

$ml/hr \times \% \text{ drug concentration} \times 10 \times 24 \text{ hr} = 24\text{-hour dose (mg)}$

⚠ Caution: Calculations based on the labeled flow rate. Flow rate accuracy varies.

Priming the Administration Set

Use Aseptic Technique

⚠ Caution: Do not remove the ONDEMAND* red tab until the tubing is completely primed. Up to a 5 ml bolus of air may be delivered if not primed correctly.

Note: Please refer to the ONDEMAND* figures for reference.

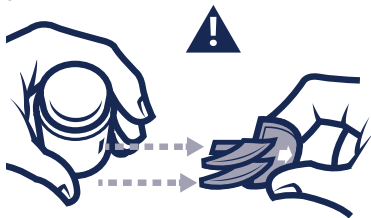
- There are two channels to prime. The ONDEMAND* device is primed first, followed by the SELECT-A-FLOW* device.

⚠ Caution: Do not add unvented filter to end of the administration set as this may impede or stop flow rate.

- Open the plastic cover of the SELECT-A-FLOW* device and set dial on face of device to 0, off position. The tactile feel will allow the user to ensure selected flow rate is set (Figure 6-A, 6-B).
- Lay ONDEMAND* device on flat surface with red tab label side up.
- Open the clamp and remove tubing cap to begin priming. Do not discard tubing cap.
- When all air is removed from the ONDEMAND* device and fluid is observed at the luer lock (approximately 4 minutes), the ONDEMAND* channel is primed.
- To begin priming the SELECT-A-FLOW* device, set dial on face of the SELECT-A-FLOW* device to highest flow rate setting to minimize priming time. Make sure the selected flow rate is within the window and aligned below the ml/hr ▼ mark (Figure 6-C, 6-D).
 - The tactile feel will allow the user to ensure selected flow rate is set.
- Open the clamp.
- When all air has been removed from the entire tubing and fluid is observed at end of luer lock, the SELECT-A-FLOW* device channel is primed.
- Set the SELECT-A-FLOW* device dial back to 0, off position and replace tubing cap until ready for use (Figure 6-A).
- Remove the ONDEMAND* device red tab by pulling straight out (Figure 5-A). It is important to remove red tab completely and ensure it does not break (Figure 5-B). The ONDEMAND* bolus device will begin to fill.

Figure 5-A

RIGHT WAY



⚠ Warning: Do not pull the red tab upwards as breakage could occur (Figure 5-B). If red tab is not removed or breaks while removing, continuous delivery will occur. This delivery may be significantly greater than the Total Flow Rate (bolus + basal).

Figure 5-B



11. The device is now ready to use; however, a complete bolus dose won't be available until the labeled refill time has elapsed. The orange indicator should be at the top level (Figure 7-A).

Starting Infusion

Use Aseptic Technique

1. Connect tubing to patient's catheter. Make sure connection is secure.
2. Select the appropriate flow rate by turning the dial on the SELECT-A-FLOW® device until the flow rate setting is within the window and aligned with the ml/hr ▼ mark on the face of the SELECT-A-FLOW® device (Figure 6-C, 6-D).
 - The tactile feel will allow the user to ensure selected flow rate is set.
3. Open clamp.
4. The patient or clinician should give a bolus as soon as possible after the infusion has started to ensure the bolus device is working properly. The bolus button should pop up within a few minutes and the orange indicator should begin to move towards the top.

Figure 6-A

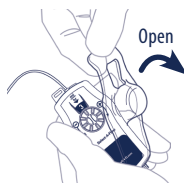


Figure 6-B

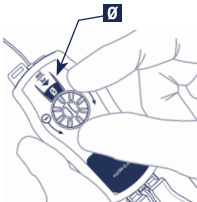
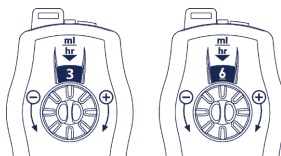


Figure 6-C



Figure 6-D

Examples of flow rate settings
3 ml/hr 6 ml/hr



⚠ Caution: Flow rate setting must be within window and aligned with ml/hr ▼ mark to ensure accurate flow rate. Do not dial between numbers. Flow rate is unpredictable if dialed between numbers (Figure 6-E).

Figure 6-E

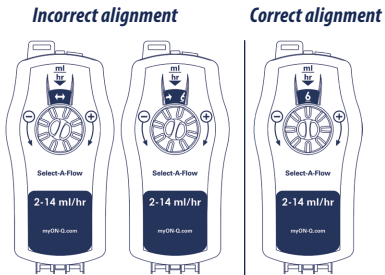
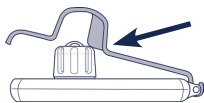


Figure 6-F



Note: Cover will not close if dialed between numbers (Figure 6-F).

Changing the Flow Rate During an Infusion

1. Insert the dial key into the dial of the SELECT-A-FLOW* device.
2. Turn the dial until the new flow rate is selected. Make sure the selected flow rate setting is within the window and aligned with the ml/hr ▼ mark on the face of the SELECT-A-FLOW* device. (Figure 6-C, 6-D)
 - The tactile feel will allow the user to ensure selected flow rate is set.
3. Remove the dial key from the device and put in a safe place for later use.

Figure 7-A

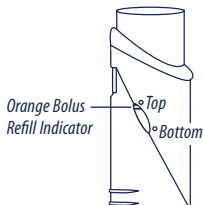


Figure 7-B



Bolus Activation

1. Press down on the ONDEMAND* button until it locks into place (Figure 7-B).
2. Bolus will be delivered and ONDEMAND* device will begin to refill.
3. The orange indicator shows how much medication is in the bolus device (Figure 7-A).
4. The next full bolus will be available when orange indicator is at the top level.
5. Pressing the bolus button prior to the end of the refill time will result in a partial bolus dose.

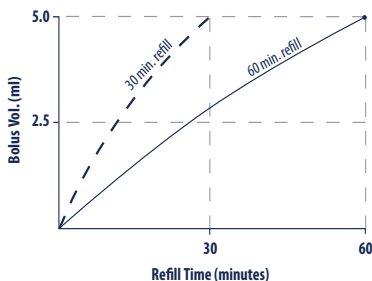
⚠ Warning: If the bolus button will not latch, close the clamp. Continuous medication delivery may be occurring. This delivery may be significantly greater than the Total Flow Rate.

Note: It is normal that it will not latch within 30 minutes of pressing the bolus button.

⚠ Warning: If the ONDEMAND* button does not pop back up within 30 minutes, check position of orange indicator.

1. If orange indicator is in the bottom position, close the clamp. Continuous medication delivery may be occurring which can be significantly greater than the Total Flow Rate.
or
2. If orange indicator is in the top position, something may be impeding the flow. Check for tubing kinks, closed clamp or patency of connected devices such as catheter or unvented filter (verify patency) according to your standard protocol.

ONDEMAND* Device Refill Chart



The ONDEMAND* device is available in 30 or 60 minute refill times as labeled on the device. Refill time is approximately linear.

During the Infusion

- A change in appearance and size of pump may not be evident during the first 24 hours after start of infusion.
- As medication is delivered, pump will gradually become smaller.
- Make sure:
 - Clamp is open.
 - There are no kinks in the tubing.
 - Filter vent is not taped or covered.
 - Heat, ice or cold therapy is placed away from the flow controller.

End of Infusion

- Infusion is complete when pump is no longer inflated.
- Close clamp, disconnect and dispose of pump according to your institution's protocol.

Note: If pump did not perform as expected do not discard. Contact Halyard Health for product return instructions at: HalyardIrvineProductComplaint@hyh.com or 1-800-448-3569.

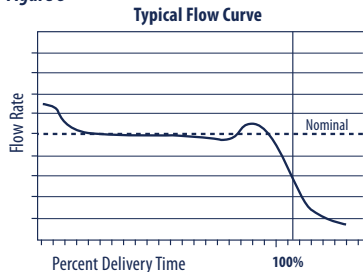
Technical Specifications

Delivery Accuracy: When filled to the labeled volume, SELECT-A-FLOW* device delivery accuracy is $\pm 20\%$ while ONDEMAND* bolus dose is $+10\%/ -20\%$ of the labeled rates when infusion is started 0-8 hours after fill and delivering normal saline as the diluent at $22^{\circ}\text{C}/72^{\circ}\text{F}$.

Typical Flow Curve

The flow rate may be higher or lower at the beginning and end of the infusion (Figure 8).

Figure 8



Notes:

Latex is not in fluid pathway or in contact with human. Refer to Latex Sensitivity Technical Bulletin at www.halyardhealth.com.

Storage Conditions

Store under general warehouse conditions. Protect from light sources and heat. Keep dry.

Rx only = Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Additional U.S and Foreign Patents may be issued and/or pending.

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For more information, please call +1.949.923.2400 • 1.800.448.3569 (English only) or visit www.halyardhealth.com for the latest product information and Technical Bulletins.

To order additional Instructions for Use or Patient Guidelines please email or call: HalyardIrvine.ProductInquiry@hyh.com or +1.949.923-2400.

For Customer Service please call:

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