Instructions for Use
ON-Q* Pump with 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:
  • Use of ON-Q* Pump in Magnetic Resonance (MR)
environment
  • Latex Sensitivity
  • 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
  • Perioperative Autologous Blood Transfusions
  • USP 797
  • Effect of Storage Times on Flow Rate on Pre-filled
ON-Q* Elastomeric Pumps
  • Patient Guidelines

⚠️ Warning
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.
• 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.
• 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.
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 on the proper use of the system.
- It is the responsibility of the healthcare provider to modify Patient Guidelines provided with the pump as appropriate for your patients’ clinical status and medication prescribed.

⚠️ Cautions

- Do not use if package is open, damaged or a protector cap is missing.
- Single use only. Do not resterilize, 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 the 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 the 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.
- 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.

- 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
    - The ONDEMAND* device 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.
    - ONDEMAND* device 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 12 or 15 hours (depending on model) for a pump to reach room temperature. (See table below.)

<table>
<thead>
<tr>
<th>Fill Volume (ml)</th>
<th>270</th>
<th>400</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator to Room Temp (hr)</td>
<td>12</td>
<td>15</td>
</tr>
</tbody>
</table>

**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**

- 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 ONDEMAND* device is 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 ONDEMAND* device incorporates a bolus device. The ONDEMAND* device delivers a continuous infusion (basal) and allows fixed boluses to be delivered on demand by patient or healthcare provider.

1. Fill Port Cap
2. Fill Port
3. ON-Q* Pump
4. Clamp
5. Air Eliminating Filter
6. ONDEMAND* Bolus Device
7. Tubing

**Figure 1**
**Instructions for Use**

**Use Aseptic Technique**

**Filling the ON-Q® Pump:** *(Figure 2)*

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

1. Close clamp.
2. Uncap the fill port.
3. Attach filled syringe to fill port. Invert pump as shown.
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 ±4%.

*Note: Filling Extension Sets are provided with larger pumps (see product insert).*

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

6. Remove syringe from fill port.
7. Replace fill port cap. Label with the appropriate pharmaceutical and patient information.

*Note: The ON-Q® Pump contains a Carry Case for holding pump.*

**Figure 2**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>270 ml</td>
<td>335 ml</td>
<td>≤ 9 ml</td>
</tr>
<tr>
<td>400 ml</td>
<td>550 ml</td>
<td>≤ 15 ml</td>
</tr>
</tbody>
</table>

**Total Flow Rate Dosing**

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

<table>
<thead>
<tr>
<th>Bolus Dose</th>
<th>Refill Time</th>
<th>Total Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 ml</td>
<td>30 min</td>
<td>10 ml/hr + Basal Rate</td>
</tr>
<tr>
<td>5 ml</td>
<td>60 min</td>
<td>5 ml/hr + Basal Rate</td>
</tr>
</tbody>
</table>

**Priming The Administration Set**

**Use Aseptic Technique**

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

1. Lay the ONDEMAND® device on flat surface with the red tab label side up.
2. Open clamp and remove tubing cap to begin priming. Do not discard tubing cap.
3. When all air has been removed from the entire tubing and fluid is observed at end of Luer lock (approximately 4 minutes), the administration set is primed.
4. Replace tubing cap until ready for use.
5. Remove the red tab by pulling straight out *(Figure 3-A)*. It is important to remove red tab completely and ensure it does not break *(Figure 3-B)*. The ONDEMAND® bolus device will begin to fill.
Warning: Do not pull the red tab upwards as breakage could occur (Figure 3-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).

Starting Infusion

Use Aseptic Technique

1. Connect tubing to patient’s catheter. Make sure connection is secure.
2. 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.

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 3-C).

6. 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 3-C).

Bolus Activation

1. Press down on the ONDEMAND* button until it locks into place (Figure 3-D).
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 3-C).
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. Otherwise 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.
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 the pump may not be evident during the first 24 hours after start of infusion.
- As medication is delivered, the 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, basal flow rate accuracy is ±15% and bolus dose accuracy 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°C/72°F.
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.

*Registered Trademark or Trademark of Halyard Health, Inc. or its affiliates. © 2015 HYH. All rights reserved.

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.