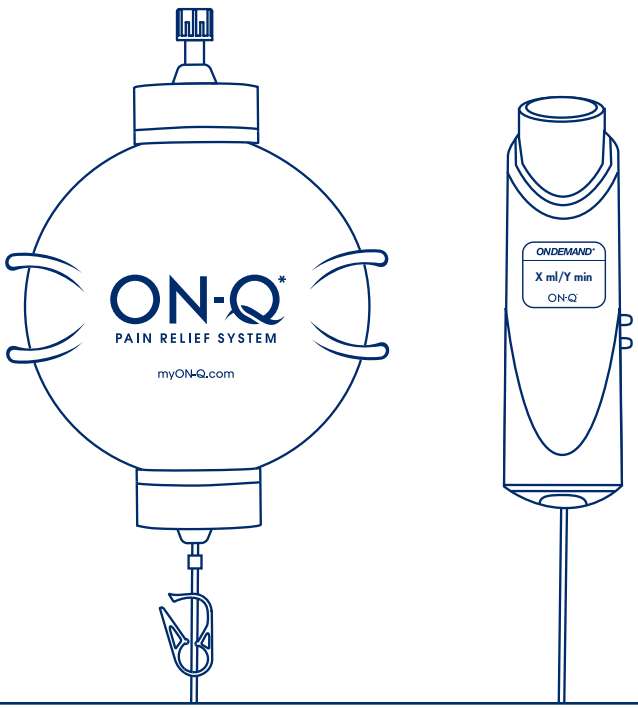
ON-Q*
PAIN RELIEF SYSTEM

Instructions For Use

ON-Q Pump with ONDEMAND* Bolus Button*



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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 800-444-2728 or +1-949-206-2700 (English only).
- Visit *www.iflo.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.
- PHT DEHP 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 pump and contact I-Flow* 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.)

Fill Volume (ml)	270	400
Refrigerator to Room Temp (hr)	12	15

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

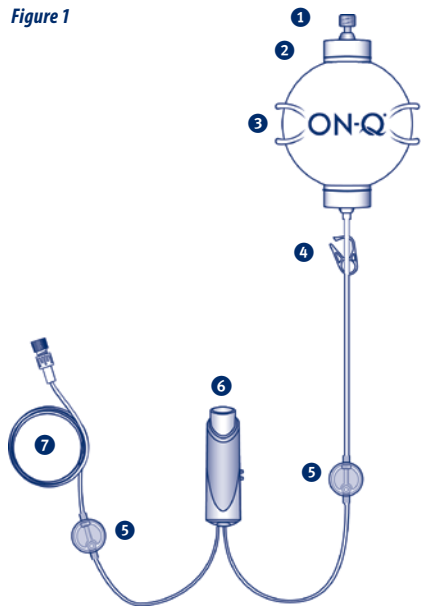


Figure 2A

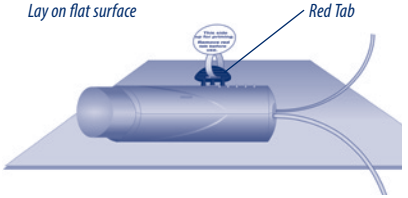


Figure 2B

Right Way

Figure 2C

Wrong Way

Figure 2D

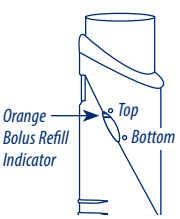
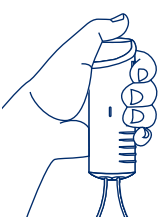


Figure 2E



INSTRUCTIONS FOR USE

Use Aseptic Technique

FILLING THE ON-Q* PUMP: ***(Figure 3)***

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%.

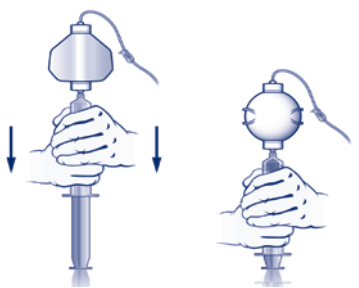
NOTE: Filling Extension Sets are provided with larger pumps (see product insert).

⚠ **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 3



⚠ **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.
270 ml	335 ml	≤ 9 ml
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

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 (Figure 2A).
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 2B). It is important to remove red tab completely and ensure it does not break (Figure 2C). The ONDEMAND* bolus device will begin to fill.

   ⚠ **WARNING: Do not pull the red tab upwards as breakage could occur (Figure 2C). 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).**

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 2D).

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.

BOLUS ACTIVATION

1. Press down on the ONDEMAND* button until it locks into place (Figure 2E).
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 2D).
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.

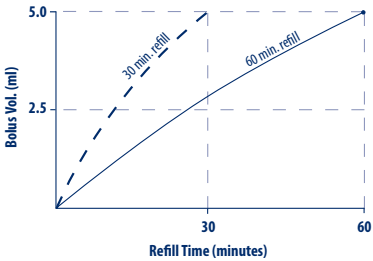
⚠ **WARNING: If the bolus button will not latch, close the clamp. Otherwise continuous medication delivery may be occurring. This delivery may be significantly greater than the Total Flow Rate.**

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.

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 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 I-Flow* for return product instructions at ifloproductcomplaint@kcc.com.

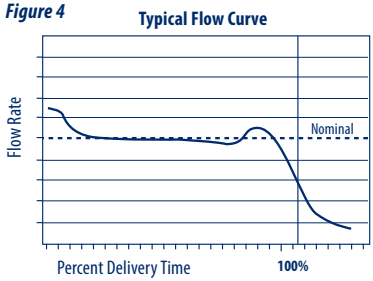
TECHNICAL SPECIFICATIONS

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.

TYPICAL FLOW CURVE

The flow rate may be higher or lower at the beginning and end of the infusion (Figure 4).

Figure 4



NOTES:

Latex is not in fluid pathway or in contact with human. Refer to ON-Q Pump Latex Sensitivity Technical Bulletin at www.iflo.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.

For more information, please call
+1.949.206.2700 · 1.800.448.3569
(English only) or visit *www.iflo.com* for the latest product information and Technical Bulletins.

To order additional Instructions for Use or Patient Guidelines please email or call:
***internationalorders@iflo.com* or +1.949.206.2688**

For Customer Service please call:

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