

TECHNICAL BULLETIN

Factors Affecting Flow Rate - ON-Q* Pain Relief System with Fixed Flow Rate

HOW THE PUMP WORKS

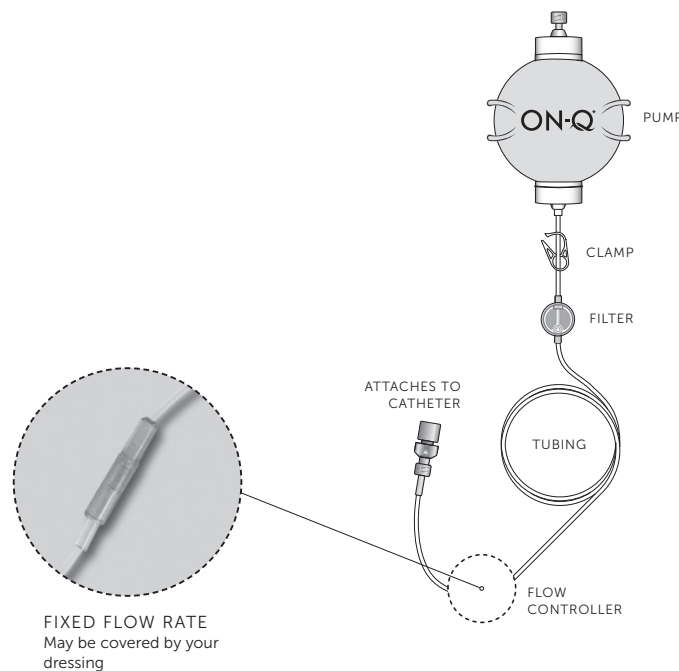
The ON-Q* pump consists of a dual layer elastomeric membrane with a soft outer protective cover. The pressure that pumps the fluid is generated by the strain energy of the elastomeric membranes that are forced to expand when the pump is filled.

Flow control is achieved with a flow restrictor comprised of a fixed diameter and length in conjunction with the pressurized reservoir. The flow restrictor is a precision bored glass orifice and is located at the distal end of the pre-attached pump tubing.

Elastomeric pumps are calibrated to specific operating conditions. Flow rate accuracy for the ON-Q* pump with fixed flow rate is determined under the following conditions: When filled to the labeled volume, ON-Q* flow accuracy is $\pm 15\%$ of the labeled infusion rates when infusion is started within 0-8 hours after fill and delivering normal saline as the diluent at 88° F (31° C) against a back pressure of 16 inches (40 cm).

FACTORS AFFECTING FLOW RATE

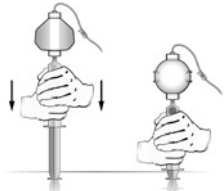




A variety of factors such as fill volume, temperature, pump position, and storage times affect the flow rate accuracy of elastomeric pumps. These factors may result in an increase or decrease in flow rate from the labeled flow rate and impact the delivery time. The information presented on the attached table outlines the factors affecting flow rate and presents information to help ensure accurate delivery times.



ON-Q* PAIN RELIEF SYSTEM WITH FIXED FLOW RATE

FACTORS AFFECTING FLOW RATE

When filled to the labeled volume, ON-Q* flow accuracy is $\pm 15\%$ of the labeled infusion rates when infusion is started within 0-8 hours after fill and delivering normal saline as the diluent at 88° F (31° C) against a back pressure of 16 inches (40 cm).

	FLOW RATE FACTOR	GUIDELINES
Fill Volume	 <p>Flow rate accuracy specification is based on filling the pump to the labeled fill volume</p> <ul style="list-style-type: none"> Filling the pump <u>less</u> than the labeled fill volume \uparrow <u>increases</u> flow rate Filling the pump <u>more</u> than the labeled fill volume \downarrow <u>decreases</u> flow rate 	<p>Refer to the Delivery Times Table in the product Instructions for Use</p> <ul style="list-style-type: none"> Do not fill less than the minimum fill volume listed on the Delivery Times Table Do not exceed the maximum fill volume
Temperature	 <p>The flow controller should be in direct contact with the skin (88° F, 31° C). Temperature will affect fluid viscosity:</p> <ul style="list-style-type: none"> Flow rate will \uparrow <u>increase</u> approximately 1.4% per 1° F/0.6° C increase in temperature Flow rate will \downarrow <u>decrease</u> approximately 1.4% per 1° F/0.6° C decrease in temperature 	<ul style="list-style-type: none"> Tape flow controller to the patient's skin Do not place ice, cold therapy or heat in close proximity to the flow controller If ON-Q* is refrigerated, allow the pump to reach room temperature prior to use Instruct patient not to place pump underneath bed covers where it may become too warm
Pump Position	 <p>The pump should be positioned approximately 16 inches (40 cm) below the level of the catheter site</p> <ul style="list-style-type: none"> Positioning the pump above this level may \uparrow <u>increase</u> the flow rate Positioning the pump below this level may \downarrow <u>decrease</u> flow rate 	<ul style="list-style-type: none"> Do not place the pump on the floor or hang from a bed post or IV pole Use E-clip to clip to the patient's dressing or clothing or place the pump in the carrying case
Storage Time	 <p>Flow rate accuracy specification is based on starting the infusion within 0-8 hours after filling</p> <ul style="list-style-type: none"> Pumps stored for more than 8 hours prior to starting infusion may \downarrow <u>decrease</u> flow rate 	<ul style="list-style-type: none"> When a filled pump is stored beyond 8 hours before use, the pressure in the reservoir will decrease due to stretch of the elastomeric membranes, which may result in a reduction in flow rate below the labeled rate Technical Bulletin (Effect of Storage Times on Flow Rate of Pre-Filled ON-Q* Elastomeric Pumps) available at www.halyardhealth.com
External Pressure	 <ul style="list-style-type: none"> Squeezing or laying on the pump may \uparrow <u>increase</u> flow rate 	<ul style="list-style-type: none"> Do not squeeze the pump. The pump has sufficient force to infuse the medication Instruct patient to place the pump on a bedside table or other location when sleeping, to help prevent laying on the pump for extended periods of time

Note: If the ON-Q* device did not perform as expected, do not discard. Contact Halyard Health for product return instructions.

There are inherent risks in all medical devices. Please refer to the product labeling for **Indications, Cautions, Warnings and Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to www.halyardhealth.com for additional product safety **Technical Bulletins**.

Please contact the Clinical Services Department at **800-444-2728** or **949-923-2400** if you have any questions regarding this information.

Rx only.

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