

February 16, 2018 (2/16/2018)

## **URGENT: MEDICAL DEVICE RECALL**

Cc: Chairman of Medical Board and relevant Head of Departments

Dear Customer:

Transonic Systems Inc is conducting a voluntary product recall of two lots of ADT1018 Flow QC Tubing – hemodialysis blood tubing set. Transonic has discontinued the ADT1018 product line and has ceased purchasing product from this supplier entirely. The ADT1010 tubing set replaces ADT1018 Flow QC tubing.

### **Reason for the Voluntary Recall:**

The sterility of ADT1018 Flow QC Tubing cannot be assured. Because of this, there is a potential for an increased risk of infection.

- We are aware of no complaints related to the problem.
- No adverse events have been reported for this issue.
- Data quality is unaffected.
- Transonic is replacing ADT1018 Flow QC Tubing with ADT1010 tubing. ADT1010 tubing is made by a different manufacturer.

### **Risk to Health:**

Transonic is not aware of any actual products that are not sterilized; however, there is a small risk that unsterilized product may have been released. Given this, if the ADT1018 Flow QC Tubing were to be used without being sterilized, this would increase the risk of infection. The risk for patients who have come in contact with any unsterilized product would be 24—48 hours post use.

### **Actions to be taken by the Customer:**

1. Immediately review your inventory for the specific catalog number and lot numbers listed in the table below, and quarantine product subject to the recall. Immediately discontinue the use and distribution of the affected product.

If it appears that any of your patients have had contact with the ADT1018 Flow QC tubing set in the last 24—48 hours, please observe these patients for infection and report to us if any such events take place.

2. Complete the Medical Device Recall Return Response form and fax it back to Transonic at +1 607-257-7256 or email the completed form to [regulatory@transonic.com](mailto:regulatory@transonic.com). Upon receipt of the completed form, Transonic will issue product replacement.

3. Return all affected products with the completed Recall Response Card form following the instruction on the enclosed packing instruction.

NOTE: If you do not have any of the affected lots in your inventory, please complete the Recall Response Card form indicating you have zero (0) quantity and fax the completed form back to Transonic at +1 607-257-7256 or email the completed form to [regulatory@transonic.com](mailto:regulatory@transonic.com).


**Product and Distribution Information Table:**

Catalog Number	Lot Number	Distribution Dates (MM/YYYY)	Expiration Date (MM/DD/YYYY)
ADT1018	B151130E2	02/2016 – 10/2017	11/30/2018
	B161115E0	12/2016 – 10/2017	11/15/2019
ADT1018-40	B151130E2	02/2016 – 10/2017	11/30/2018
	B161115E0	12/2016 – 10/2017	11/15/2019

If you have any questions or require assistance with the return of the recalled product, please contact +1 800-353-3569 (within USA, Canada) or +1 607-257-5300 (from other locations) between 8AM and 5PM ET Monday through Friday.

The safety and well-being of patients and healthcare workers is the primary objective for Transonic and we aim to ensure that only the highest quality product is used by our customers. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,



David E. Johnson, Ph.D.  
VP, Quality and Regulatory Affairs



**MEDICAL DEVICE RECALL RETURN RESPONSE**  
**Acknowledgement and Receipt Form**  
**Response is Required**  
**TRANSONIC ADT1018 and ADT1018-40 Flow-QC Tubing Sets**

**DISTRIBUTOR SECTION:**

Distributor Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
Town, State and Zip Code: \_\_\_\_\_  
Contact Number: \_\_\_\_\_

I have read and understand the recall instructions provided in the date of 2/16/2018. Yes\_\_\_ No\_\_\_

Any adverse events associated with recalled product? Yes\_\_\_ No\_\_\_

If YES, please explain:

\_\_\_\_\_  
\_\_\_\_\_

I have checked my stock and quarantined inventory consisting of \_\_\_\_\_ (units/cases).

I have either:

Identified and notified my customers that were shipped or may have been shipped this product  
by: \_\_\_\_\_  
\_\_\_\_\_

(Specify Date and Method of Notification). *Send customer form (see next page) to your customers and have this returned to Transonic as soon as possible OR fill it out for your customers and return to Transonic.*

**Or:**

Attached is a list of customers with address, phone, email who may have received this product. I have NOT contacted them and wish for Transonic to notify my customers. \_\_\_Yes \_\_\_No

I have questions and wish to have Transonic's Quality Dept. contact me: Yes \_\_\_ No\_\_\_

Signature of Recipient: \_\_\_\_\_

Name & Title: \_\_\_\_\_

Please Fax or Email completed Response Form to: 607-257-7256 or [regulatory@transonic.com](mailto:regulatory@transonic.com)  
or Mail

Attn: David Johnson, Quality  
Transonic Systems  
34 Dutch Mill Road  
Ithaca, NY 14850

**MEDICAL DEVICE RECALL RETURN RESPONSE**  
**Acknowledgement and Receipt Form**  
**Response is Required**

**CUSTOMER SECTION**

Institution Name: \_\_\_\_\_  
Customer Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
Town, State and Zip Code: \_\_\_\_\_  
Contact Number: \_\_\_\_\_

I have read and understand the recall instructions provided on the date of 2/16/2018. Yes\_\_\_ No\_\_\_

Any adverse events associated with recalled product? Yes\_\_\_ No\_\_\_

If YES, please explain:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Affected Product Information Table				
Product Name:	Product Number:	Lot/Serial# Enter one of two lot codes below B151130E2 B161115E0	Quantity in Inventory	Quantity Returned/ Destroyed
Flow-QC Clear Advantage	ADT1018/ADT1018-40			
Flow-QC Clear Advantage	ADT1018/ADT1018-40			

I have questions and wish to have customer service contact me: Yes \_\_\_ No\_\_\_

Signature of Recipient: \_\_\_\_\_

Name & Title: \_\_\_\_\_

Please Fax or Email completed Response Form to: 607-257-7256 or [regulatory@transonic.com](mailto:regulatory@transonic.com) or Mail to:

Attn: David E. Johnson, Ph.D.

Transonic Systems

34 Dutch Mill Road

Ithaca, NY 14850