
FAQ for the Obsolescence of Flow QC set and related HD03-CO Accessories (May 2022 Rev.A.)

Why are the DTM's being discontinued (MDR countries)?

The Data transfer Modules (DTM) save patient data, including PHI data; but the DTM cybersecurity measures do not comply with new MRD requirements. Therefore, Transonic can no longer sell the DTM version after Jan 2023 into the following MDR-requiring locations:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Italy, Latvia, Lithuania, Hungary, Ireland, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden

What is the difference between the DTM and PMM?

The Patient-less Measurement Module (PMM) does not require patient data (PHI) to make a measurement, and the measurement data is not saved. Thus, there are no cybersecurity issues regarding PHI, the MRD regulations, or country-specific privacy requirements.

Do I need to replace my DTM-CO or PMM-CO?

The DTM-CO or PMM-CO can still be used for measuring Delivered Flow, Recirculation, and Access Flow. The Cardiac Output measurements can only be used with your unexpired supply of Flow-QC set. Once the supply has been exhausted, and no additional sets are available, the CO measurement will no longer be a functioning protocol. Any historical CO measurements made on a DTM-CO will remain visible in the patient's record.

Can I still make a CO measurement without the use of a Flow-QC set?

No. The Transonic HD03 Monitor was validated for Cardiac Output measurements with the Flow QC-set. Only the Flow QC has an injection post at the precise location required for saline dilution.

Will historical CO measurements display on the DTM-CO and the Administrative Software?

Yes, the previous measurement will still display in the historical data.

Why are Cardiac Output and the related accessories being discontinued if the issue is just the availability of the Flow-QC sets?

The Flow-QC set is required for CO measurement, therefore, the CO modules (DTM-CO & PMM-CO) and the saline bag warmer are no longer applicable accessories.

Can I remove the Flow-QC sets from the tubing list?

The Transonic Flow-QC set ADT1010 tubing name is used when the HD03 meter is calibrated, so the Flow-QC Set must remain the default tubing. However, the default tubing list on the HD03 will display the top three tubings used by your facility, so as other tubings are added, the least used tubing will be removed from display. The tubing can still be picked from the Tubing Library if needed.

Can I still use the HD03 for measurements with Pediatric patients?

Please check for the current tubing list (you can download the list from the Transonic website www.transonic.com) and review it for the tubing you are currently using. If the exact tubing is listed, you can continue the use on pediatric patients. If the exact tubing is not listed, please contact Transonic Customer Service. An unopened, non-expired package of the tubing can be sent to Transonic to determine if the diameter is sufficient for calibration and inclusion in our tubing list.

If my HD03 is an HD03-E and can only be used with a Flow-QC set, what do I do?

If your HD03E is less than 10 years old, it can be converted to an HD03. Transonic will work with you to have your HD03-E Monitor shipped to our service center. The service team will then convert your Monitor into an HD03, and you can then select the bloodlines you routinely utilize from the tubing list. The HD03 sensors will be placed directly on the hemodialysis bloodlines instead of the Flow QC set. Transonic can provide an updated Operator's Manual and instructions for applying the sensor to the hemodialysis bloodline instead of the Flow QC-set. Customer service will assist you with the logistics, such as shipping and service timeframe. The conversion from the HD03-E to an HD03 with PMM will occur at no cost to your institution. If you have calibration planned in the near future for an HD03-E, conversion and calibration can be completed during the same service.

What else is impacted by the removal of the Cardiac Output measurements?

This obsolescence removes all parameters based on CO, including the following:

Cardiac Index (CI), Stroke Volume Index (SVI), Total Ejection Fraction (TEF), Systemic Vascular Resistance (SVRI), Total End Diastolic Volume Index (TEDVI), Central Blood Volume Index (CBVI), Active Circulation Volume Index (ACVI), Oxygen Delivery Index and Access Flow / Cardiac Output (AF/CO) % or ratio.

Delivered Flow, Recirculation, and Access Flow will remain active measurements with the HD03.

When must I stop using the Flow-QC sets at my institution?

You can continue to use the Flow-QC sets for Cardiac Output measurements until your current inventory of Flow-QC sets expire. The HFW1000 Saline Bag Warmer and the ADT1010 Flow-QC tubing will continue to be available for purchase until the end of January 2023, and can be used prior to the expiration date on the sets.

What if I recently purchased a HD03CO?

If you recently purchased (< 12 month) an HD03CO, you may return it to Transonic for a refund or we can refund the difference between the cost of the HD03CO and the HD03. Please contact Transonic Customer Service or your local representative to discuss these options.