



1 Introduction

The SonoTT™ aQuila System is the newest addition to em-tec’s medical portfolio. An independent Class Im* flow measurement system, under MDR**, it measures and displays the volumetric flow rates in extracorporeal tubing circuits. Consisting of the evaluation device—also referred to as flow meter—and a compatible sensor, the system is quick to setup, intuitive and easy to use, and provides an additional layer of safety during various medical applications — for patients and clinicians alike.



Figure 1: SonoTT™ aQuila System

1.1 SonoTT™ aQuila

The SonoTT™ aQuila is a compact device that is used either mounted to a device stand or a pole holder via a standard VESA mounting (75 x 75 mm). With its glove-suitable 10.1” touch display and intuitive user interface, it displays the current flow values as numbers or graph and offers the option record data in form of a screenshot or recording. All recorded data can either be opened and viewed on the device or be exported via USB. The system can be used with one or two flow sensors, meaning it allows for up to two flow points.



Figure 2: SonoTT™ aQuila mounting options (right: pole holder; left: device stand)

1.2 SonoTT™ Clamp-On SL



Figure 3: SonoTT™ Clamp-On SL

The SonoTT™ Clamp-On SLs are non-invasive and easy-to-install flow measurement sensors. Their function is based on the transit time method and they are available for all commonly used tube sizes. They are made for long-term use and ideally suited for strict hygienic requirements.

2 Applications

In general terms, the SonoTT™ aQuila System enables additional flow measurement in extracorporeal clinical applications. By doing so, it helps detect possible complications or anomalies such as clogged filters, inadequate blood flow, or changes in the flow rate that might indicate the deterioration of the circulation condition as early as possible. In addition to displaying the current flow values during the surgery or medical treatment, the device also allows for recording the data. After, all recordings can be transferred to the patient file to ensure a detailed and easily accessible patient documentation. As flow measurement is important whenever extracorporeal blood flow plays a role, there are various applications where the use of the SonoTT™ aQuila System can be beneficial. The following chapters will introduce some of the more common ones.

2.1 Heart-Lung Machine (HLM)

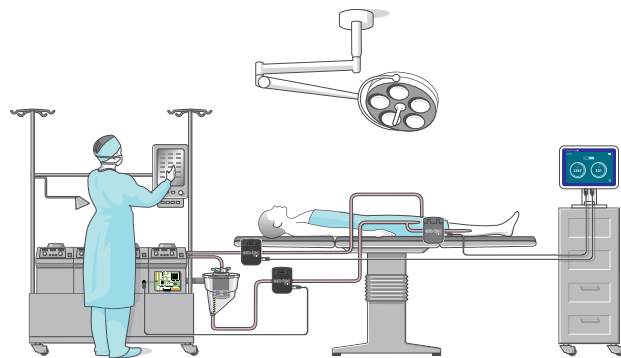


Figure 4: SonoTT™ aQuila usage example: Heart-Lung Machine

Heart-lung machines (HLM), also known as Cardiopulmonary Bypass Machine (CBM), are used to assume the functions of the heart and/or lungs during medical procedures such as open-heart surgery or aortic prosthesis, i.e. during procedures where the heart must be stopped (cardioplegia) or when the patient’s own heart and/or lungs fail.

In many cases, the number of flow sensors on a HLM is limited which contrasts with the rising demand for data and the comprehensive requirements regarding clinical safety procedures and assurance.



By using the SonoTT™ aQuila, this gap can be filled as the additional flow measurement data provides more safety for both patients and clinicians and supplies valuable information regarding the overall procedure and treatment.

2.2 Dialysis

During dialysis treatments, a patient's blood is filtered and 'cleaned' of toxins, waste products, and excess fluids. For hemodialysis, the most common form of dialysis, this is done by a dialysis machine that circulates the blood through a filter membrane before returning it to the body.

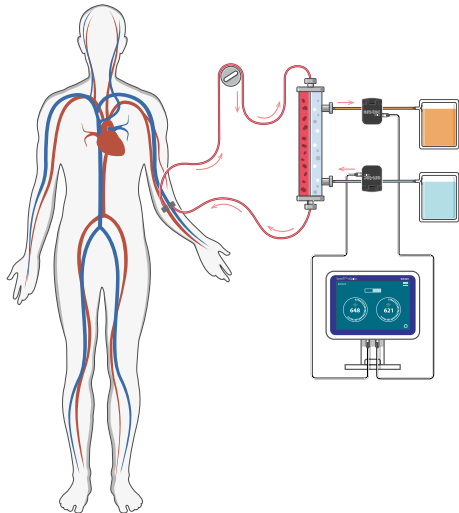


Figure 5: SonoTT™ aQuila usage example: dialysis

Right now, the majority of dialysis machines do not feature a flow measurement function, i.e. they do not include any flow measurement sensors. Yet, knowing the current flow rates as well as having an overview over their development can serve as an indicator of how effective the treatment is and what condition the shunt is in and thus increases the overall safety and comfort for both patients and staff.

2.3 Distal Perfusion

The distal perfusion cannula (DPC) is inserted into the distal superficial femoral artery to ensure adequate blood flow during life-sustaining applications where a temporary support of the respiratory and pulmonary system is needed. To prevent limb

ischemia or a blockage of the blood flow that might damage the extremities, i.e. the legs or feet, ensuring and maintaining a sufficient blood flow is essential. This, in turn, is only possible through an accurate and reliable flow measurement.

2.4 Apheresis

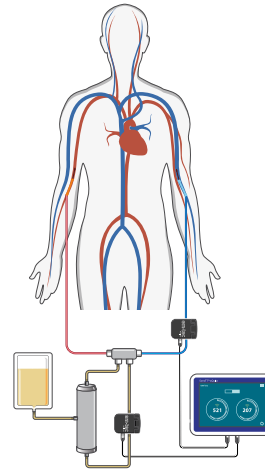


Figure 6: SonoTT™ aQuila use example: apheresis

Similar to dialysis, apheresis treatments filter the blood of unwanted components by passing it through an apheresis device before returning it to the patient. While the blood flow plays a central role in this acute treatment, it mostly does not include a flow measurement function due to a lack of sensors. Using the SonoTT™ aQuila System during apheresis

means being able to measure and document the flow rates, which helps evaluate and improve the overall treatment.

2.5 ECMO (=ExtraCorporeal Membrane Oxygenation)

As is the case with heart-lung machines, ECMO devices take over the function of the heart and/or lungs when they are unable to work in a life-sustaining manner. Other than heart-lung machines, which are commonly used only temporarily, i.e. during surgery, or if the heart and/or lungs do not resume their full function after an intervention, ECMO treatments tend

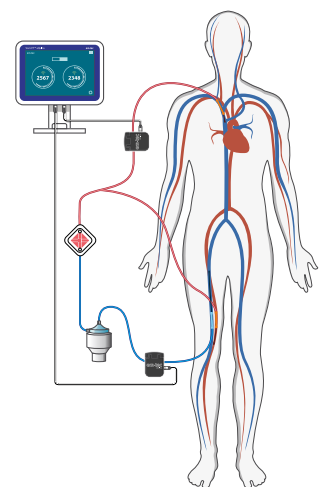


Figure 7: SonoTT™ aQuila usage example: ECMO



to be longer and can span several days, weeks, or, in rare cases, even months. Typically, ECMO devices come with only one flow sensor. This means that for venovenous (VVA) ECMOs, it is not possible to measure the flow rates on all access points. With the SonoTT™ aQuila System, clinicians gain two additional flow measurement points and therefore another layer of safety, more information, and a certain degree of comfort.

3 Benefits

No matter the specific application, among the main benefits of the SonoTT™ aQuila System are:

- the fact that it adds a flow measurement function,
→ improves the overall safety for both clinicians and patients
- the fact that having several measurement points and being able to see their current flow rates,
→ makes it possible to detect any complications and anomalies early and to intervene accordingly
- the option to visualize the flow rates,
→ can indicate a deterioration of the circulation condition
→ are particularly well visible when displayed as graph
→ can be caught, and therefore rectified, as quickly as possible
- and the option for data recording and export.
→ adding to the patient documentation
→ providing a comprehensive display and evaluation of flow rates

Of course, the applications described here represent only part of the possible areas of use, since the SonoTT™ aQuila System can basically be used whenever blood flow plays a role.

4 Additional Information

* Class Im

Medical devices are grouped into risk classes with Class I being the lowest and Class III being the highest. Consequently, Class I is for low risk devices, i.e. devices whose malfunction or failure has no impact on the patient safety. Class Im further specifies that it is a medical device with measurement function.

**MDR

The MDR (= Medical Device Regulation) is the currently active regulation according to which manufacturers must admit their medical devices. It came into force in May 2017 and replaces the MDD (Medical Device Directive).

5 Contact

If you have any questions regarding the new SonoTT™ aQuila System or any of the information in this document, please do not hesitate to contact us at:

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