Urgent Field Safety Notice (FSN)

FSN number: FSN012024

FSCA number: FSCA012024

Issue Date: 28th May 2024

Issued by: Paola Franciosi

Title: Quality Assurance and Regulatory Affairs Manager (PRRC)

Attention: Distributors and users of the Aqualine family of tubing sets for Aquarius System

To whom it may concern,

Our company's products are subject to continuous and rigorous surveillance to ensure ongoing safety and reliability while being used.

As part of our product surveillance, we have identified a potential problem that could affect the performance of the product.

We would therefore like to provide you with the following information within this document:

- Affected Product
- Problem Description
- Hazard Identified
- Associated Risk to patient/users
- Recommended Action

We would like to apologize for any inconvenience.

Sincerely,

Paola Franciosi

Quality Assurance and Regulatory Affairs Manager (PRRC)

This document contains important information for the continued safe and proper use of your medical device.

Affected Product:

Tubing set

REF	Product code	Unique Device Identification	Manufacturing date
AQUALINE	1500000006	(01)08033718000019	Between 1st January 2022 (2022-01) and 30th April 2024 (2024-04)
AQUALINE S	1500000106	(01)08033718000026	
AQUALINE RCA	1500009006	(01)08033718000033	
AQUALINE (China Market)	1500000007	(01)080033718000521	
AQUALINE S (China Market)	1500000107	(01)080033718000712	
AQUALINE D (China Market)	1500000207	(01)080033718000705	
AQUALINE RCA (China Market)	1500009007	(01)080033718000736	
AQUALINE RCA D (China Market)	1500009207	(01)080033718000729	

Kits (tubing set + filter)

REF	Product code	Unique Device Identification	Manufacturing date
AQUASET 03 LV	4500030106	(01)18033718000399	Between 1st January 2022 (2022-01) and 30th April 2024 (2024-04)
AQUALINE S	1500001906	(01)08033718000217	

AQUASET 07P	4500071006	(01)18033718000405	Between 1st January 2022 (2022-01) and 30th April 2024 (2024-04)
AQUALINE	1500000906	(01)08033718000200	

AQUASET 07P LV	4500071106	(01)18033718000412	Between 1st January 2022 (2022-01) and 30th April 2024 (2024-04)
AQUALINE S	1500001906	(01)08033718000217	

AQUASET 12	4500120006	(01)18033718000429	Between 1st January 2022 (2022-01) and 30th April 2024 (2024-04)
AQUALINE	1500000906	(01)08033718000200	

AQUASET 19	4500190006	(01)18033718000436	Between 1st January 2022 (2022-01) and 30th April 2024 (2024-04)
AQUALINE	1500000906	(01)08033718000200	

CITRASET RCA 12	4500129906	(01)18033718000443	Between 1st January 2022 (01-2022) and 30th April 2024 (04-2024)
AQUALINE RCA	1500009906	(01)08033718000224	

CITRASET RCA 19	4500199906	(01)18033718000450	Between 1st January 2022 (2022-01) and 30th April 2024 (2024-04)
AQUALINE RCA	1500009906	(01)08033718000224	

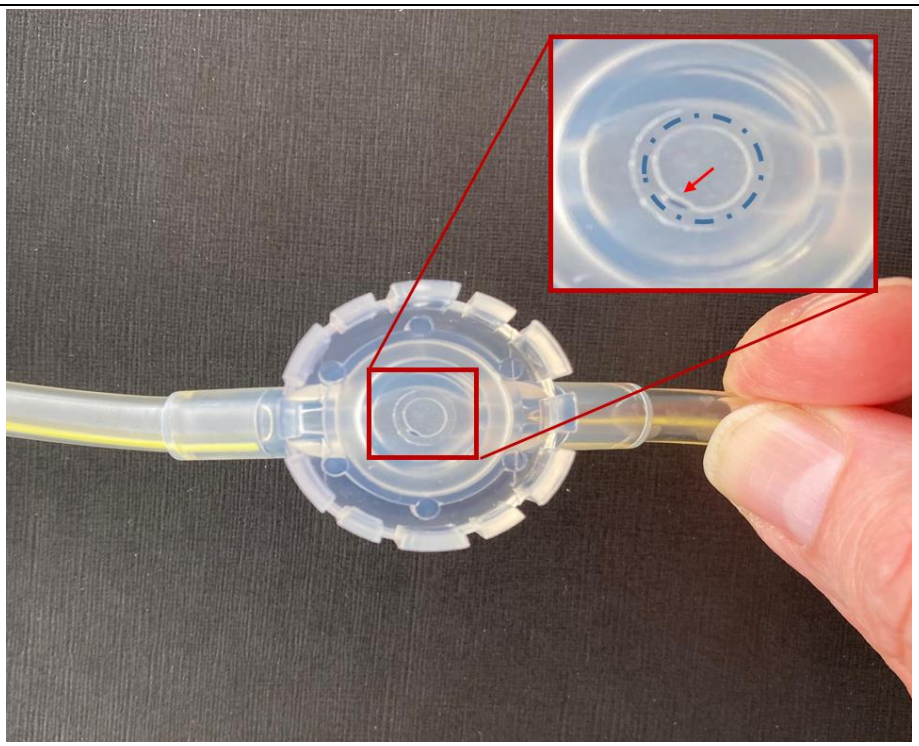
Problem Description:

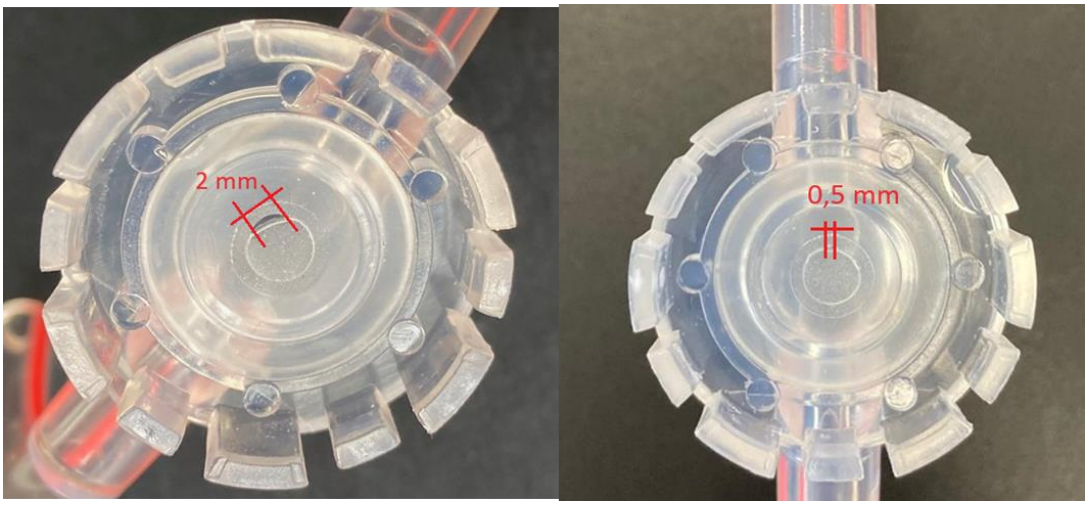
The membrane of the 4 pressure domes (access pressure dome, pre-filter pressure dome, return pressure dome and filtrate pressure dome) may have a visible hole (pointed in red) in the surface in a core position.

The hole could have different dimensions but is always placed on the INNER CIRCLE (blue dotted circle) (Figure 1).

To identify the pressure domes of the blood line please refer to Figure 2.

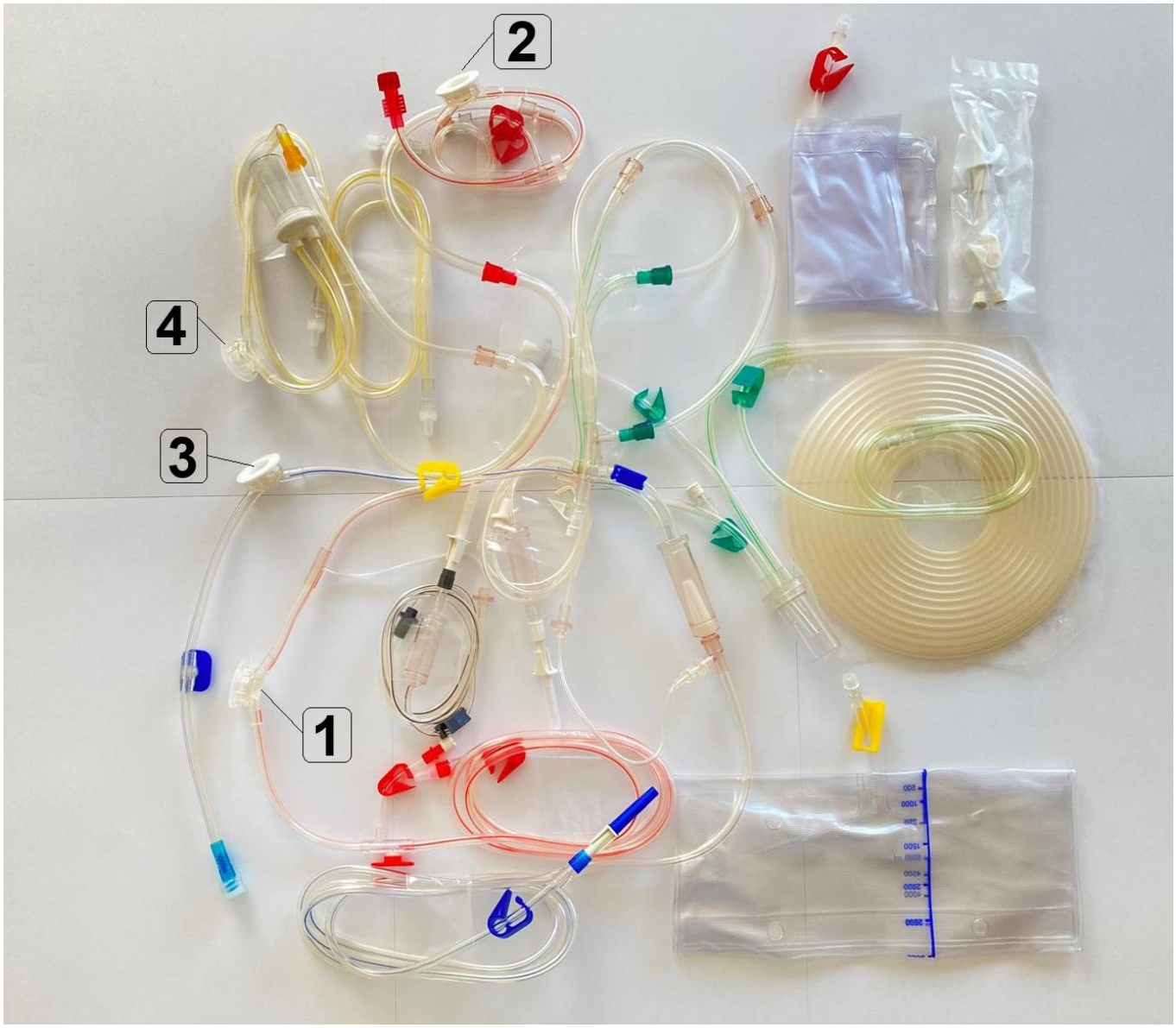
Figure 1





Aqualine tubing line – pressure dome identification

Figure 2



1 = ACCESS PRESSURE DOME
2 = PRE-FILTER PRESSURE DOME
3 = RETURN PRESSURE DOME
4 = FILTRATE PRESSURE DOME

Hazard Identified:

The presence of the hole may cause:

- liquid leaking during priming
- blood leaking during treatment
- air in the circuit

Associated Risk to patient/users:

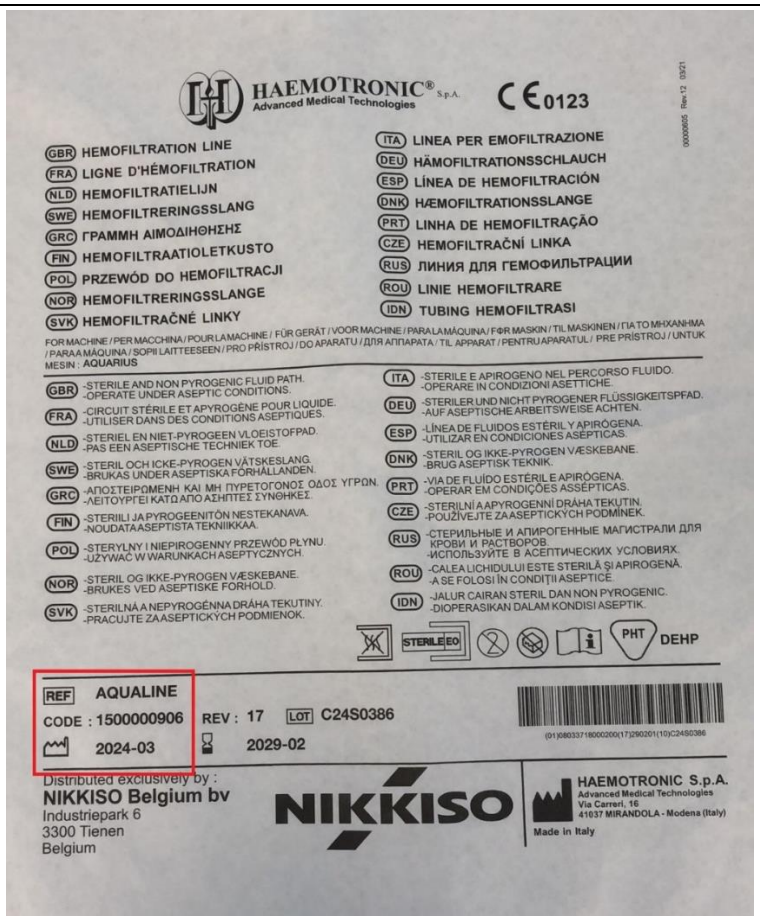
The following risks have been highlighted and could occur due to the presence of the identified hazard:

- delay of treatment due to change of the tubing set
- reduced therapy effectiveness
- blood loss during treatment
- contamination of the patient and/or user

Recommended Actions:

1) All users of the affected products shall read and take into consideration all instructions and information provided in this Field Safety Notice (FSN).
2) Identify the tubing set to check by the "REF", the "CODE" and the manufacturing date ( ) reported on the primary packaging (Figure 3).

Figure 3



3) Open the primary packaging and take out the tubing set.

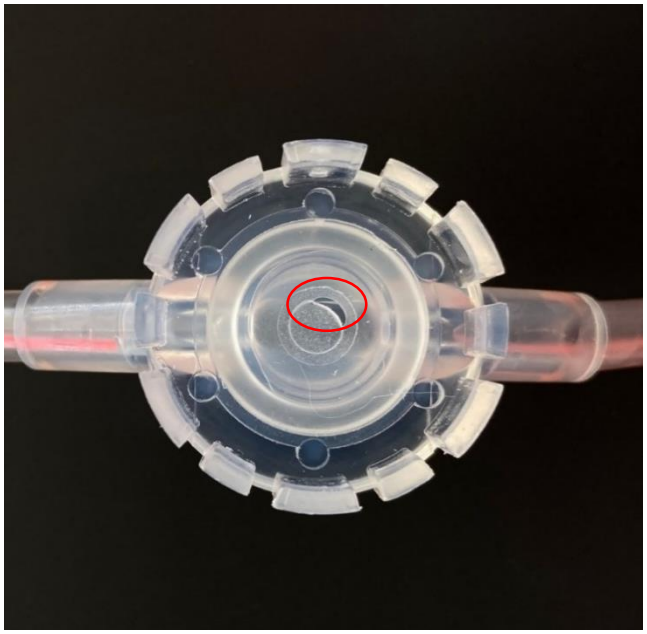
4) Remove the protective caps from each pressure dome.

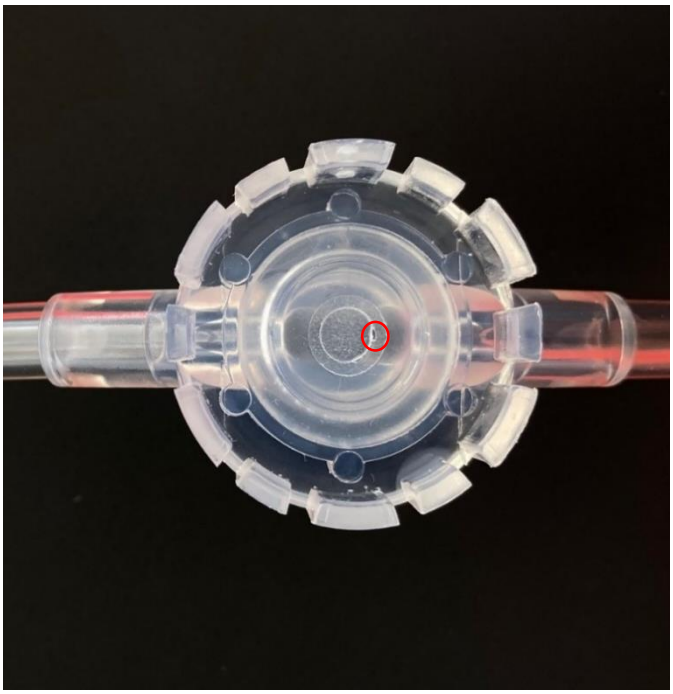
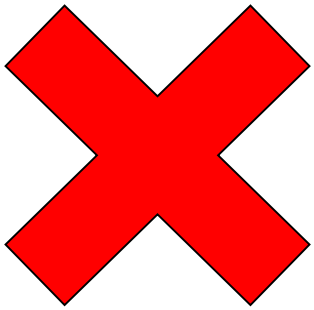
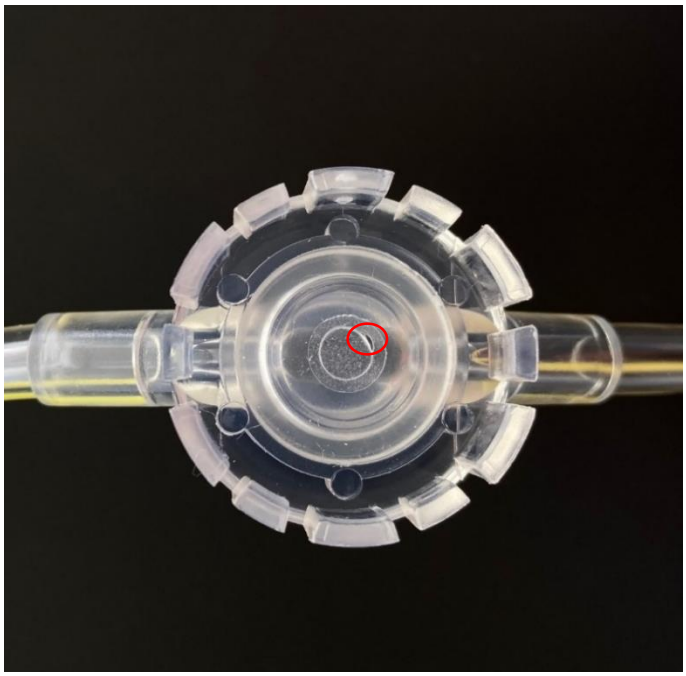
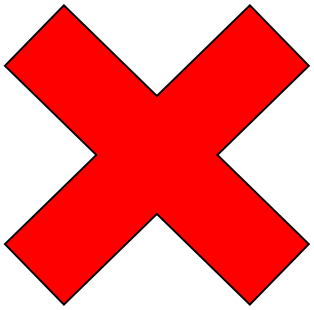
5) Carry out the visual check of each membrane surface, under a light source. The identification of the hole can be easier by the use of a dark background (Figure 4).

Figure 4

Membrane without the hole→USE IT

Membrane with the hole→RETURN



Membrane with the hole→RETURN	
	
	

6) If the hole is detected, the affected tubing set should not be used. A new tubing set should be used, following the same visual checks performed in steps 2-5 above.

7) All affected unused tubing sets should be returned for further investigation (As per defects highlighted in Figure 4). Used tubing sets may be contaminated and should not be returned. Unused haemofilters from an affected kit should be retained. Please contact your local Nikkiso representative for tubing set return and replacement details.

8) If you observe leakage while in treatment contact the physician immediately.
   a) Follow your local institutions guidance.
   b) Follow on screen instructions for ***End Treatment*** and safe disposal.

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

For Further Information and Support:
Contact your local Nikkiso representative
Or
Haemotronic SpA – Paola Franciosi / Quality Assurance and Regulatory Affairs Manager (PRRC)
Email paola.franciosi@gvs.com
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URGENT FIELD SAFETY NOTICE CUSTOMER REPLY FORM

FSN number: FSN012024

FSCA number: FSCA012024

URGENT FIELD SAFETY NOTICE Aqualine family of tubing sets for Aquarius System
[Name and address of the Distributor /Hospital]
Dept:
Date:

I hereby acknowledge receipt of the urgent field safety notice.

In addition, I confirm that I have forwarded the contents of the attached field safety notice to all the departments and to all those who need to be aware within my organisation or to any organisation where the potentially affected devices have been transferred.

I commit to follow the instructions carefully.

First and Last Name:_____

Position:_____

Signature:_____

Send the completed and signed customer reply form **without undue delay** to: quality@nikkisomedical.com.