Commercial name of the affected product: Q-stress 6 and Xscribe 6
FA Number: FA-2023-055
Manufacturer: Welch Allyn Inc, Skaneateles
Authorized Representative: Welch Allyn Ltd. (SRN: IE-AR-000000768)
Type of Action: Correction

ARBOR MEDICAL KORPORACIJA, SIA
BIR. MEISTARU IELA 7, VALDLAUCI KEKAVA DISTR. KEKAVAS NOVAD
LV-1076 Riga
Latvia

December 12, 2023

Dear Sir, Madam

Problem Description

Baxter Healthcare Corporation is issuing a Correction for the Q- Stress and XScribe Cardiac Stress Testing Systems (Q-Stress version 6 or higher and XScribe version 6 or higher) due to a potential change in the QRS amplitude identified in electrocardiogram (ECG) readings when the Source Consistency Filter (SCF) is enabled. The SCF is a configurable feature with multichannel recordings, which aims to reduce noise and remove inconsistent signals without distorting the ECG signal associated with stress testing.

Baxter performed internal testing using patient ECG data through the SCF algorithm, which showed an average QRS amplitude change of 5.4% reduction during pre-exercise and 7.1% reduction during peak heart rate (see Figure 1). The maximum QRS amplitude changes observed were a 39.7% reduction during pre-exercise and a 71.0% reduction during peak heart rate.

When the SCF is enabled, QRS amplitude changes may be observed in the displayed ECG waveform on the on-screen real-time display, live ECG printouts, and final reports. The average beat display and all calculations (e.g., heart rate, ST level, ST slope) are not based on SCF-filtered data; therefore, they are not affected. Algorithm-detected events (e.g., PVC, VRUN) are also not based on SCF-filtered data and therefore unaffected.

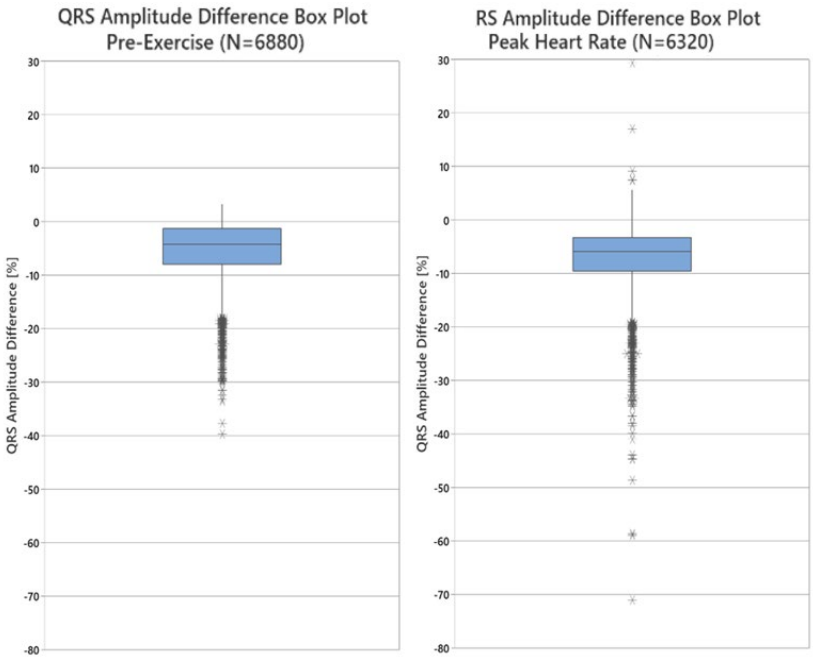

Figure 1 *Distributions of QRS amplitude difference measurements evaluated in the 10-beat segments of Pre-Exercise (left) and Peak Heart Rate (right). Dataset includes 102 real stress exams before and after the application of the Source Consistency Filter (SCF). Records were typically 10-15 minutes long and consisted of 8 leads (I, II, V1-V6). The analysis focused on two segments of data: Pre-Exercise and Peak Heart Rate. Pre-Exercise consists of the first 10 beats following SCF activation during the Pre-Exercise phase of the stress exam. Peak Heart rate consists of 10 beats associated with the maximal patient exercise stress so is considered worst case.*

Affected Product

Product Code	Product Description	Lot	UDI Number
See Attachment A	XScribe version 6 or higher	All	See Attachment A
	Q-Stress version 6 or higher		

Hazard Involved

If the QRS amplitude displayed is changed and is unrecognized by the clinician, medical intervention may be omitted, delayed, or provided that is contradictory to the patient's true condition.

When the SCF is enabled, diagnoses that require accurate representation of the QRS amplitude in the waveform may be incorrect when made based on the ECG waveform as displayed on the (1) on-screen real-time display, (2) live ECG printouts, and (3) final reports.

There are no clinically significant changes to other aspects of the waveform or displayed content / final report (e.g., the ST segment, calculated measurements, average beats); therefore, diagnoses based on these are not affected.

Baxter identified one customer complaint which indicated low amplitude, small, or incorrect QRS measurements. No complaints were associated with injury or death.

Actions to be taken by Baxter

Due to the potential impact on the QRS complex, Baxter is developing a software update for Q-Stress version 6 or higher and XScribe version 6 or higher to resolve the issue. Baxter will contact you when the software update is available.

Actions to be taken by Customers

1. Until a software update becomes available and is installed, clinicians should evaluate the potential impact of the SCF as described to determine if it should be enabled or disabled during stress testing.

2. Enable or disable the SCF prior to stress testing by:
   - Navigating to the “Modality Settings” menu (see Figure 2).

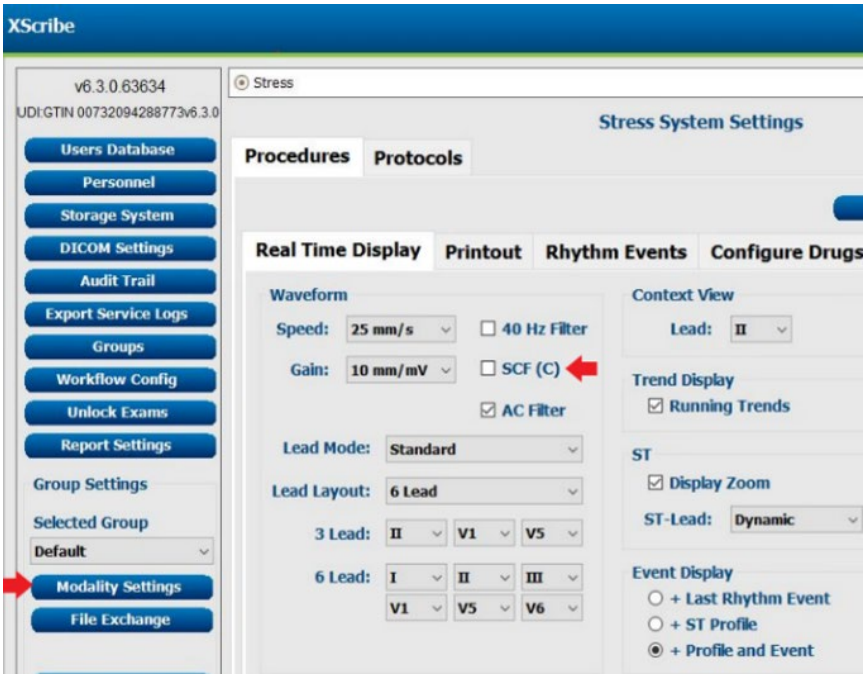

Figure 2 *Modality Settings menu*

   - It can also be enabled/disabled by left-clicking anywhere in the real-time ECG window which opens a “Waveform Control” window, allowing the user to set displayed ECG leads, filters (including the SCF), display gain and display speed (see Figure 3).

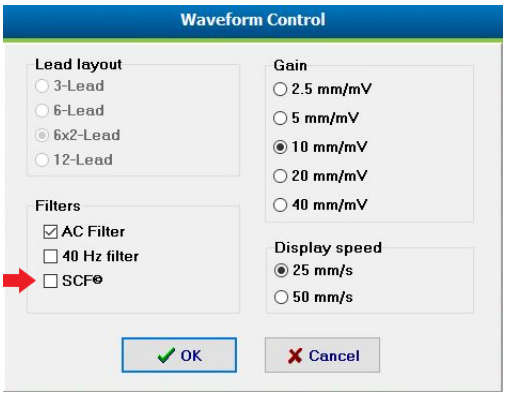

Figure 3 *Waveform Control window*

   - When the filter is on, the “SCF©” mark appears in the lower right-hand border of the real-time ECG display (see Figure 4).

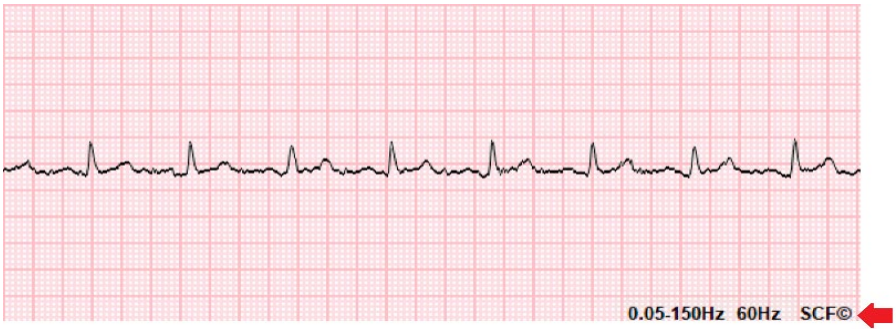

Figure 4 *Real-time ECG Display*

3. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them, informing them of the requirement to evaluate the potential impact of the SCF during stress testing.
4. If you received this communication directly from Baxter, complete the enclosed Baxter Customer Reply Form and return it to Baxter by e-mailing it to the initial email address. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Correction in accordance with your customary procedures.
6. If you purchased this product from a distributor, please note that the Baxter reply form is not applicable. If a response is requested by your distributor or wholesaler, please return it to your distributor/wholesaler according to their instructions.

Further information and support

For general questions regarding this communication, contact Baxter representative.

We apologize for any inconvenience this may cause you or your staff.

Sincerely,

Ági Zag
CQA Specialist, FA coordinator
Baxter d.o.o., Ljubljana
Letališka cesta 29A
1000 Ljubljana
Slovenia
T: +38614201692
M: +386 40 456 096

Agi Zag
Digitally signed by Agi Zag
Date: 2023.12.12 15:57:04 +01'00'

Enclosure: Reply Form
Attachment A: List of Affected Products