X-Cal™ Technology for Enhanced Patient Safety and Improved Clinician Efficiency

SUMMARY

> Masimo developed an innovative technology known as X-Cal to enhance clinical performance, patient safety, and clinician efficiency, and began implementing X-Cal in its sensors, cables, and technology boards in 2009.

> X-Cal technology enhances the ability for these three components to work as an integrated system, permitting reliable measurements under challenging conditions such as patient motion and low perfusion while also enhancing patient safety.

> Masimo is dedicated to enhancing our patient-focused solutions when technology permits us to more effectively address customer needs. Using insights and customer feedback obtained since X-Cal was deployed, we have added several enhancements that are discussed in this bulletin.

X-CAL OVERVIEW

Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry consists of three monitoring components that are designed to work as an integrated system:

1) The sensor that connects to the patient

2) The patient cable that connects the sensor to the Masimo technology board in the monitor

3) The Masimo technology board installed in a multi-parameter patient monitor or Masimo pulse oximeter (each referred to as the "host monitor" hereafter)

❶ Sensor   ❷ Cable   ❸ Host Monitor

Patient Monitor   or   *Masimo Oximeter*

When all three system components are fully functioning and comply with Masimo's design requirements, the system works as intended. However, when any <u>one</u> of the system components is compromised, unrecognised, erroneous measurements may occur that can impact patient safety.

MASIMO

BACKGROUND

As noted above, X-Cal technology is incorporated into Masimo technology boards, patient cables, and sensors to enhance the ability for these related system components to communicate with each other so that they can work as an integrated system. The origin of the "X-Cal" name comes from "calibration", since X-Cal sensors store unique characteristics of individual sensors that permit X-Cal enabled Masimo technology boards to adapt to the specific sensor in use. In addition to facilitating improved performance, the X-Cal design permits sensors designed in the future to be compatible with an X-Cal enabled board installed in a host monitor years before the sensor is developed.

It is understood that all cables and sensors eventually wear out and fail, in turn preventing physiological signals from being transmitted from the patient to the technology board. It is also understood that the longer any brand of cable or sensor is in service, the more likely it is to reach that point of failure. A less recognised fact is that as cables and sensors become worn, they may experience intermittent failures which can cause erroneous signals to be sent to the monitor that can affect measurement accuracy.

Inaccurate measurements caused by these types of intermittent failures may lead to false alarms or even mask true alarm events such as hypoxemia. Furthermore, this type of failure can only be discovered during active monitoring, which represents a patient safety issue while also creating work-flow inefficiencies for clinical and biomedical staff. To minimise the likelihood of unknown, intermittent cable and sensor malfunctions, some hospitals try to replace their cables and sensors before their expected life is exhausted. X-Cal helps users replace Masimo sensors and cables when they should be replaced.

HOW X-CAL WORKS

X-Cal technology is designed to work with host devices equipped with X-Cal enabled technology boards and will only operate with X-Cal enabled cables and sensors. This system design helps prevent measurement inaccuracy and patient safety risks that may be caused by imitation cables and sensors that use components and manufacturing processes that do not meet the Masimo quality and performance specifications—specifications which are required to provide consistent performance during challenging monitoring conditions. When an imitation sensor or cable is connected to an X-Cal enabled host monitor, a message will be displayed to alert the user that the cable or sensor is defective.

To address the reliability risks associated with intermittent failures that can occur in cables and sensors used beyond their expected life, X-Cal technology automatically tracks the aggregate time that individual cables and sensors are used for active patient monitoring. X-Cal detects when a specific cable or sensor has been used beyond its expected active monitoring time and notifies the user. This reduces the likelihood that intermittent, unknown sensor failures will affect measurement accuracy and patient safety.

RECENT X-CAL FEATURE ENHANCEMENTS*

User Notification Prior to Expiration: The Masimo technology board will notify the host monitor when a cable or sensor reaches 90% of its expected active monitoring time. The notification will indicate which of these accessories (the cable or sensor) is nearing expiration. When the host monitor receives this indication from the Masimo technology board, the host monitor will display a message such as "Cable Near Expiration" or "Sensor Near Expiration."

Enhanced Functionality and User Notification Upon Expiration of Cable / Sensor Active Monitoring Time: The Masimo technology board will alert the host monitor when a cable or sensor reaches the end of its expected active monitoring time, and the host monitor will display a user notification message such as "Replace Cable" or "Replace Sensor".

* X-Cal feature enhancements, including user notification messages described herein, may vary between different brands or models of third-party monitors as noted on last page of this bulletin.

In addition to the enhanced user notification messages upon cable or sensor expiration, several key functionality enhancements have been added, which are described below:

<u>Patient Cables:</u> Although the host monitor will display a "Replace Cable" message after the cable's expected active monitoring time has been reached, <u>the cable will not stop functioning due to this expiration</u>. However, the user should replace the cable to reduce the potential occurrence of undetected, intermittent failures.

<u>Sensors:</u> Sensors will continue to operate for a defined period of time (as described below) after sensors have exceeded their expected active monitoring time and the host monitor notifies the user to "Replace Sensor." Furthermore, sensors will not stop functioning after reaching this expiration <u>until active monitoring is stopped</u> and the following additional conditions are encountered:

> "Post-Expiration Grace Period": Reusable and disposable sensors include a post-expiration grace period to provide users with a substantial window of time after the sensor's expiration, and the cessation of active monitoring, to replace the sensor. For reusable sensors, this post-expiration grace period is 72 hours, and for disposable sensors, it is 12 hours. The host monitor will continue to display "Replace Sensor" or a similar message during the post-expiration grace period.

> Once the post-expiration grace period is exhausted, the monitor will display "Sensor Failure" (or similar message), but the sensor will not stop functioning until one of the following conditions is encountered:

- the sensor has been removed from the patient ("probe-off" condition) for at least <u>two (2) continuous hours</u>; *or*

- the sensor is disconnected from the cable, or the cable is disconnected from the monitor; *or*

- the Masimo technology board is reset (for example, such as when the monitor is turned off).

X-CAL EXPECTED PATIENT MONITORING TIMES

The X-Cal expected active monitoring time for each type of cable and sensor is shown below and will be indicated in its applicable DFU (Directions For Use).

Sensor or Cable	Active Patient Monitoring Limit	Duration if Monitoring 24 Hours Per Day	Duration if Monitoring 12 Hours Per Day	Duration if Monitoring 8 Hours Per Day
Single-patient-use SpO2 Sensors with Replaceable tape[1]	336 hours	14 days	28 days	42 days
Single-patient-use SpO2 Sensors without Replaceable tape	168 hours	7 days	14 days	21 days
Reusable SpO2 Sensors (DCI, DCIP, YI, TC-I, TF-I, and DBI)	8,760 hours	12 months	2 years	3 years
Patient Cables[2]	17,520 hours	24 months	4 years	6 years

[1] Sensors with replacement tapes may not be available in all markets.

[2] NOTE: As noted earlier, the patient cable will not stop functioning despite exceeding its expected active monitoring time. However, Masimo recommends replacement of the patient cable when a "Replace Cable" or a persistent "Low Signal IQ" message is displayed to reduce the likelihood of unknown, intermittent cable failures.

NO INTERRUPTIONS DURING PATIENT MONITORING

It is important to note that even when a sensor has exceeded both its expected active monitoring time as well as the additional "Post-Expiration Grace Period" described above, <u>the sensor will not stop functioning until active monitoring is stopped</u>. Furthermore, if monitoring is stopped by removing the sensor from the patient—rather than by turning the monitor OFF or disconnecting the cable or sensor from the monitor—the sensor must be off of the patient for two continuous hours before the X-Cal system considers monitoring to have stopped. This two-hour period allows for temporary interruptions in monitoring due to sensor-site inspection and/or repositioning, or when inadvertent "probe off" conditions may occur.

X-CAL FUNCTIONALITY IN THIRD-PARTY, MULTI-PARAMETER PATIENT MONITORS

X-Cal functionality and the associated user notifications provided by third-party multi-parameter patient monitors may vary by company and/or the vintage of a specific patient monitor model, and in particular, whether the software in the Masimo technology board in the patient monitor and the software in the host monitor incorporate the X-Cal enhancements described herein. Please check with the patient monitoring manufacturer for details pertaining to any specific monitor model or vintage. Please contact Masimo Technical Services with any remaining questions you may have.

CONCLUSION

Masimo's innovative X-Cal technology enhances clinical performance, patient safety, and clinician efficiency by allowing the sensor, patient cable and Masimo technology board to operate as an integrated system. Masimo is pleased to offer new enhancements to the prior version of X-Cal. These include additional messaging, extended post-expiration monitoring periods, extended cable operation and more. This allows the X-Cal system to further address some of the common factors, such as the use of imitation cables and sensors, as well as Masimo cables and sensors used beyond their expected monitoring life, that can impact measurement accuracy, patient safety and reliability.

QUESTIONS

Please contact the Masimo Technical Services Department in your local area with any questions or assistance you may need regarding this notice.

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