



Technical Release Bulletin

REFERENCE 2 (REF2) Acceptable Reference Range

Issue date: June 2022

Background: The SQA line of automated Sperm Quality Analyzers have acceptable reference limits for all key service parameters, including the Reference 2 (REF2) value. Acceptable ranges are published in the SQA user guide and service manual and displayed by the system each time an automated calibration and self-test is completed. If any parameter is out of range, the SQA system will not pass the calibration or self-test, and an error notice with recommended troubleshooting steps will be displayed.

Passing Range vs. Ideal Range: Like most parameters, the REF2 value is dynamic and will change from day-to-day. When the system performs its auto-calibration it may adjust its levels to meet the required target values. If the REF2 parameter is between the range of 2,500 and 3,500, the system will pass the self-test and the system is ready for testing. Any deviation between 2,500 and 3,500 will not influence the system's accuracy or performance and there is no clinical impact associated with a REF2 value in this range.

While a REF2 range of 2,500 to 3,500 is passing and acceptable from the manufacturer's perspective, Medical Electronic Systems also recommends an "Ideal Range" of 2,800 to 3,200 to avoid unexpected troubleshooting during routine use. A REF2 value between 2,500 and 2,800 or 3,200 and 3,500 will not impact the accuracy of the reported results, but it does leave the system closer to the acceptable limits. Proper maintenance procedures are recommended daily and weekly to keep the system in the **Ideal Range**, but all results in the **Passing Range** are acceptable for reliable semen analysis assessment using the SQA line of sperm quality analyzers.

For additional questions, please e-mail service@mes-llc.com.

"Remember, it All Started with a Sperm"

Compliance Date: Effective June 2022.

Authority: Eric Carver, eric@mes-llc.com

Distribution: MES LLC, all MES Ltd. Distributors.