

Customer Technical Bulletin

CTB-00579 Rev 002

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Product: Selenia Subsystem: Compression Assembly

Dimensions/3Dimensions

Subject: Pass/Fail Criteria for Manual Compression Force on Selenia

Dimensions-3Dimensions Systems

Revision History

Rev 002 – Updated revision level of MAN-03706 from 008 to 009.

<u>Purpose</u>

To provide information on the pass-fail criteria for the manual compression force on Selenia Dimensions/3Dimensions systems outlined in the Hologic Quality Control (QC) manual, MAN-03706, Revision 009 and below.

Scope

This information applies to Selenia Dimensions and 3Dimensions systems.

Resolution

When performing the Compression test, per Section 4.12 of MAN-03706, Revision 009 and below, the record form used by the technologist located in Appendix B erroneously states a range of 25-45 lbs for the Manual Compression entry in the form. Manual compression must provide at least 25 lbs of force, and the system is capable of providing up to a maximum manual compression force of 67 lbs.

Please disregard the 45 lb limit placed on manual compression in the QC record form and use 25 lbs minimum as the pass-fail criteria for manual compression. This shall be corrected in the next revision of the Hologic QC Manual.

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