

## Instruments

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To:	Valued Customer
Cc:	N/A
From:	Stryker Instruments
Subject:	Malis Generator Operational Performance Testing

All Malis Generators, 6700-313-500, have been inspected to the specifications provided by the Quality Inspection Procedure prior to shipping and passed all functionality, performance, and safety test requirements.

There are no annual maintenance requirements for the Malis Generator. The device should be inspected upon initial receipt and before each use, as described within the Instructions for Use, 6700-313-716, supplied with the console upon purchase.

Operational Performance Testing may be performed on the device, as described in Appendix A within the Instructions for Use, 6700-313-716. Additional information on test setup are as follows:

- Testing should be performed in both the CUT setting and COAG setting and outputs should match values in the “Typical Output versus Power Setting” table in Appendix A of the Instructions for Use.
- All BC Biomedical analyzers used for testing must be set to pulse waveform.
- All analyzers must be set to continuous operation, with a set load of 400  $\Omega$  for CUT outputs and 50  $\Omega$  for COAG outputs.
- If required, recommended analyzer delay settings are 900 - 1000 milliseconds for CUT and COAG outputs.
- The Forceps Testing Biomed Cord, 6700-313-538, should be used during all test setups.

We at Stryker Instruments appreciate your support of our products. We are committed to continuously improving our products by monitoring their performance in the field. If we can be of further assistance, please contact your sales representative.

Sincerely,

**Stryker Instruments**