

07T2H 24326

Stryker Instruments

CMP CHANGE ORDER

Change Order #:

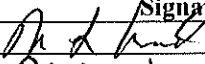

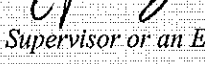
CMP Number:	CMPE-0009	Current Revision:	A
CMP Title:	Approvals Lab Gages	New Revision:	B

CALIBRATION DUE DATE EXTENSIONS

Note: Use this section for due date extensions only. The New Revision should be the same as the Current Revision. Justification for the extension must be provided in the Change Description.

Gage ID Number:		Current Due Date:	
Current Calibration Interval:		Extend Calibration Until (List Date):	

APPROVALS

Title	Printed Name	Signature	Date
Originator	Morgan Macomber		10-16-07
Calibration Technician	Jeff Novotny		10/16/07
Engineering Review*	Jim Pomeroy		16 OCT 2007

**Note: Engineering Review should be signed by the AQE Supervisor or an Engineering Manager, as appropriate.*

CHANGE DESCRIPTION

Add: under section

1.0 Preparation

Note: All Gages for the Approvals Lab must be labeled with the letters "AP" at the beginning of the gage number. Ex. AP1234. This designates the gage as an approvals laboratory gage.

OCT 16 2007 PM 12:51

	SIGNATURE	DATE
AUTHOR:	S/M. MACOMBER	2/12/07
CALIBRATION TECHNICIAN:	S/J. NOVOTNY	2/12/07
CALIBRATION SUPERVISOR:	S/M. MACOMBER	2/12/07
ENGINEERING REVIEW:	S/J. POMEROY	2/12/07

EXTERNAL CALIBRATION MAINTENANCE PROCEDURE (Approvals Lab Gages)

DEVICE DATA

Device Description:	All gages in the Approvals Lab
Number of Gages:	
<p>Note: Each gage associated with the device must have a separate GAGE DATA table and procedure.</p>	

GAGE DATA

Gage Description:	Calibration Interval:
Gage ID Number:	<input type="checkbox"/> 1 Month <input type="checkbox"/> 3 Months <input type="checkbox"/> 6 Months <input checked="" type="checkbox"/> 12 Months* <input type="checkbox"/> 24 Months <input type="checkbox"/> Other (Specify):
Gage Type: <input checked="" type="checkbox"/> Variable <input checked="" type="checkbox"/> Fixed	

CALIBRATION PROCEDURE

- add* → **1.0 PREPARATION:**
- Note! ALL gages for the Approvals Lab must be labeled with the letters "AP" at the beginning of the gage number. Ex. AP1234. This designates the gage as an approvals laboratory gage.*
- 1.1 Electrical Gages
 - 1.1.1 Ensure the equipment is packaged to avoid problems from BSD if applicable. The gage(s) must be packaged to avoid damage for the anticipated type of shipment.
 - 1.2 Mechanical Gages
 - 1.2.1 The gage(s) must be packaged to avoid damage for the anticipated type of shipment.
 - 1.3 Anticipated types of shipment may include vendor pickup or shipment through a package delivery service. Gages being sent through a package delivery service will require the use of a speedy pack machine, bubble wrap or other materials to avoid damage from shipping. When the gage is returned from the external calibration vendor the gage must be examined for damage from shipping. If damage has occurred the gage will be sent back to the external calibration supplier for evaluation.
 - 1.4 Handle the instruments with care. If an instrument is damaged, return it to the manufacture for repair and recalibrate before use.

2.0 SPECIAL CONSIDERATIONS:

- 2.1 All suppliers must be ILAC or ISO 17025 certified for the Approvals Lab.

- 2.2 This CMPE must be used for all of the gages from the Approvals Lab.
- 2.3 The certification received for each gage from the ILAC or ISO 17025 certified vendors must contain the following information.
- 2.3.1 Measurement uncertainty and the measurement uncertainty statement.
 - 2.3.2 Must have a link to a primary standard or to a natural constant realizing the International System of Units (SI) by an unbroken chain of calibrations.
 - 2.3.3 Must contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. Before and after results are required if applicable.
 - 2.3.4 Must contain the title Calibration Certificate.
 - 2.3.5 The name and address of the Calibration Vendor and location where the calibration was performed.
 - 2.3.6 Must contain a unique identification number that can be linked to the gage. The Stryker Instruments gage identification number will be used.
 - 2.3.7 Must contain Stryker Instruments and Stryker Instruments address.
 - 2.3.8 Identification of the methods used.
 - 2.3.9 A description of, the conditions of, and unambiguous identification of the item being calibrated.
 - 2.3.10 The date of receipt of the calibration item where this is critical to the validity and application of the results, and the date of performance of the calibration.
 - 2.3.11 Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity of the results.
 - 2.3.12 The name(s), function(s), and signature(s) or equivalent identification or person(s) authorizing the calibration certificate.
 - 2.3.13 Where relevant, a statement to the effect that the results relate only to the item being calibrated.
 - 2.3.14 The conditions (e.g. environment) under which the calibrations were made that have an influence on the measurement results.

3.0 **DATA REVIEW:**

- 3.1 Review calibration results for any Out of Calibration or Out of Service conditions. For this CMPE, usable and calibration limits are the same as the manufactures limits. Reference 11ti006 for any gages that fail the usable limit.
- 3.1.1 Review the certification received from the Calibration Vendor for calibration data to evaluate if the gage has passed calibration.
- 3.2 Record either Pass or Fail in the calibration software.

