

Title: Operating Procedure, Calibration and Preventive Maintenance

Document No: 730001799

Version No: 09

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1 PURPOSE

The purpose of this procedure is to outline the calibration and preventive maintenance (PM) program for assembly, measurement and test equipment.

2 SCOPE

The scope of this procedure is for assembly, measurement and test equipment used in the manufacture of Waters equipment, managed in the Milford calibration database, and requiring Calibration or Preventative Maintenance.

3 DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
Accuracy	The degree to which the result of a measurement, calculation, or specification conforms to the correct value or a standard.
Assembly Equipment	Equipment used to aid the assembly of manufactured product. This may include jigs, fixtures, alignment stations, hand or power tools.
Calibrate Before Use Label	A label placed on equipment that is currently in service, requiring calibration before each use.
Calibration	A process to ensure that equipment can produce accurate results. This includes verifying measurements and/or making adjustment(s) to ensure measurement accuracy.
Calibration / PM Database	Database used to manage the Calibration / PM program, including maintaining records
Calibration Not Required Label	A label placed on measuring equipment that does not require calibration or PM. Justification shall be captured in the Calibration/PM database, or stored in the equipment file.
DIR	Document Information Record - 'location/folder' for storing files within SAP
Due Date	Date that equipment is due for calibration or PM (must be performed by end-of-month)
IEC	International Electrotechnical Commission
Interval	The amount of time, in months, between calibration or PM cycles.
ISO	International Organization for Standardization
Measurement Equipment	Commercially-manufactured equipment used to take measurements (e.g. Digital Multi-Meter, Oscilloscope, Coordinate-Measuring Machine).
Out of Service / Do Not Use Label	A label placed on equipment that is currently out of service, but not obsolete e.g., items that require service, calibration, PM, setup or qualification.
Out-of-Scope Equipment	Devices which do not yield critical measurements or provide precise conditions/parameters do not require calibration or PM. Note that "Calibration Not Required" labels shall not be applied to these assembly aids. This type of equipment may include, but is not limited to: 1-2-3 blocks, V-blocks, angle plates, sine plates, parallels, holding fixtures (which do not wear/degrade), heat guns, soldering irons, air guns, ultrasonic cleaners, signature pads, bar code scanners, light sources, microscopes, printers/labelers, presses, non-critical pressure gauges (e.g. air/gas supply lines & tanks), non-critical power fastener drivers & dispensers, feeler gauges, rulers, tape measures, yardsticks and beakers.

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Term	Definition / Abbreviation
PM	Preventive Maintenance: The servicing, for the purpose of maintaining equipment in satisfactory working order, by performing systematic inspection, detection, and correction of potential failures. PM activities may include tests, measurements and parts replacement.
Precision	Refinement in a measurement, calculation, or specification, especially as represented by the number of digits given.
Reference Standard	An object with known and documented characteristics or values used in the calibration of Assembly, Measurement and Test Equipment. Reference standards shall be traceable to national or international standards, e.g., National Institute of Standards and Technology (NIST), where possible. Otherwise, independent, reproducible standards shall be used.
Remove Item	To remove equipment from production and stop periodic calibration and maintenance.
RG	'Release General' DIR Status in SAP
SAP	Systeme, Anwendungen und Produkte - Enterprise Resource Planning Software
TE	Test Equipment or Test Engineering
Test Equipment	Waters-manufactured equipment used to verify that manufactured product meets applicable specifications.

4 ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Management	It is the responsibility of Management to ensure implementation of this procedure. Review and approve Out of Calibration Notice (730005742). Test Engineering Management: Review/approve request to remove and/or Deactivate test equipment. If necessary.
Calibration Coordinator	Oversee Calibration/PM activity and maintain the Calibration/PM database. Communicate upcoming calibration schedule to equipment owners. Issue Out of Calibration Notice (730005742).
Calibration/PM Technician	Execute Calibration or PM per procedure or standard. Ensure that documentation is properly completed; provide documentation to Calibration Coordinator. Calibration or PM activities may be performed by Calibration Coordinators, technicians, engineers or ISO/IEC 17025 accredited vendors.
Operator/User(s)	Operators using equipment shall verify that it has been calibrated or maintained. Otherwise; stop using the equipment and notify Calibration / PM technician.
Equipment Change Request Originator	Complete the Equipment Change Request (730005738) and provide it to the Calibration Coordinator.
Calibration Coordinator, Supervisor, and/or Engineering	Determine (individually and/or collaboratively) equipment calibration and/or PM requirements. These may be documented in a calibration/PM procedure.
Planner	Ensure that there is no demand for the part(s) tested by custom test equipment prior to equipment removal or deactivation.

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Roles	Responsibilities
	Approve request to remove and/or obsolete test equipment.
Product Manager	Ensure that there is no anticipated demand for the part(s) tested by equipment prior to equipment obsolescence. Approve request to obsolete test equipment, approval may be obtained via email or other communication, and is not a required signature on the Equipment Change Request.
Quality	Review/Approve Out of Calibration Notice (730005742).

5 REFERENCES / RELATED DOCUMENTS

N/A

6 FORMS

Document No:	Document Title
730005738	Form, Equipment Change Request
730005741	Form, Calibration/PM, Record
730005742	Form, Calibration/PM, Out-of-Calibration Notice
730006638	Form, Equipment Add Request

7 RECORDS

All updates will be captured in the Calibration/PM database. Records/Forms/Certificates may be stored in the Calibration/PM database, the calibration vendor's database, or filed as hardcopy.

8 HEALTH & SAFETY

No Health & Safety-specific considerations

Should anyone following this instruction identify a health and safety hazard which has not been highlighted in this section and/or within the body of the text, they should notify their Manager/ Supervisor immediately.

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9 PROCEDURE

9.1 ADDING EQUIPMENT TO THE PROGRAM

Roles	Tasks/Instructions
Calibration/PM Equipment Add Request Originator	9.1.1 Provide information about the device to be added to the calibration coordinator, using the Equipment Add Request (730006638). For equipment received directly by calibration coordinator, it is not necessary to complete an Equipment Add request.
Calibration Coordinator	9.1.2 Review Equipment Add Request for completeness if provided. Obtain any missing necessary information. 9.1.3 Assign Equipment ID Number and inscribe or label ID number on equipment. 9.1.4 Update Calibration/PM database. 9.1.5 Update the database or equipment file with calibration certificate, test record or other calibration/PM evidence, and Equipment Add Request form as appropriate. See Appendix - Labels for label examples.

9.2 CALIBRATION / PREVENTIVE MAINTENANCE

Roles	Tasks/Instructions
Calibration Coordinator	9.2.1 Generate list of equipment due for calibration or PM monthly from the Calibration/PM database and distribute to the appropriate departments. 9.2.2 Prioritize items designated as Reference Standards to be calibrated/maintained first, to ensure their availability for use on other equipment by end-of-month.
Operator/User	9.2.3 Verify equipment is in calibration / PM before use by verifying the calibration or PM sticker affixed to the equipment or referencing the Measuring Equipment Calibration Status Report by ID number. 9.2.4 Do not use equipment that is not in calibration or over-due for PM. Remove equipment that is not within calibration or PM date from use, label "Out Of Service, and notify calibration / PM technician.

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Roles	Tasks/Instructions
Calibration/ PM Technician	9.2.5 Obtain procedure or standard for equipment being calibrated or maintained. Note: Waters manufactured equipment may have a custom calibration / PM procedure, may be maintained and tested per current product test procedure, or may be maintained and tested by the Waters System Support Group using appropriate procedures per the product being calibrated or maintained. 9.2.6 Perform calibration or PM (including making necessary adjustments and/or repairs) so all specified results/tolerances (calibration) are met or so that required verification testing (PM) is complete. If accuracy and precision are not defined in a calibration / PM procedure or documented standard: - one data point will be verified for hard gauges such as pins and gauge blocks - two data points, one at the approximate minimum, and one at approximate maximum values will be verified for gauges producing variable results such as micrometers, calipers and indicators. 9.2.7 Complete appropriate record of calibration performed and provide to the calibration coordinator. This record can be: - A "Calibration/ PM Record" (730005741). - A report or certificate as provided by a calibration vendor, documenting the results. - A custom record as required by a custom calibration / PM procedure. - Data entered directly into the calibration database. 9.2.8 When calibration or PM is complete, remove any expired or "Out of Service/ Do Not Use" labels and then affix the appropriate completed label on the equipment. This will include ID number, initials, date and next due date. Some items are unfit for labels (e.g. too small or used in harsh environments), or labels may fall/wear off. Information for these items may be found in the department's Measuring Equipment Calibration Status Report by ID number.
Calibration Coordinator	9.2.9 Update the Calibration/PM database. File Records/Forms/Certificates in the Calibration/PM database, the calibration vendor's database, or as hard copy. 9.2.10 Issue Out of Calibration Notice (730005742) as needed to supervisor (Management) of department where the equipment is used.
Management and Quality Representative	9.2.11 Review/approve Out of Calibration Notice. 9.2.12 Return completed Out of Calibration Notice to the Calibration Coordinator.
Calibration Coordinator	9.2.13 File Out of Calibration Notice, in the Calibration/PM database, the calibration vendor's database, or as hard copy.

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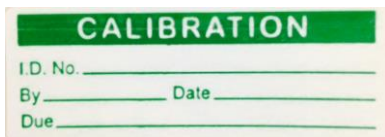
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9.3 CHANGING OR REMOVING EQUIPMENT FROM THE PROGRAM

Roles	Tasks/Instructions
Calibration/PM Change Request Originator	9.3.1 Complete "Form, Equipment Change Request" (730005738) and obtain appropriate approvals. All Changes require equipment owner approval, Custom test equipment (TE prefix) also requires production planner and Engineering approval in addition to the equipment owner.
Engineering Manager	9.3.2 Review/approve request to deactivate custom test equipment.
Production Planner	9.3.3 Review/approve request to deactivate custom test equipment
Calibration/PM Change Request Originator	9.3.4 Submit Equipment Change Request to Calibration Coordinator.
Calibration Coordinator	9.3.5 Review change request: Verify that change is appropriate: Interval may be changed, considering history, performance, measurement criticality and frequency of use. Deactivation of equipment requires appropriate approval, and verification that equipment is no longer required or has been replaced. 9.3.6 Update Calibration/PM database and/or file as appropriate.
Test Engineer	9.3.7 For deactivation of test equipment (with Test Equipment Design Documents in SAP); create an Engineering Change Request (ECR) to add the completed "Equipment Change Request" to the DIR and to change the DIR status from RG to OBS. For other test equipment, add the completed "Equipment Change Request" to the equipment file.
Calibration Coordinator	9.3.8 Add the completed Equipment Change Request to the equipment file.
Equipment Owner Calibration Coordinator	9.3.9 Store or dispose of equipment being removed as appropriate, considering possible reuse and/or need for spare parts.

10 APPENDIX - LABELS



CALIBRATION

I.D. No. _____

By _____ Date _____

Due _____

Calibration Labels (or equivalent)




PREVENTIVE MAINTENANCE

I.D. _____

BY _____ DATE _____

DUE _____

PM Label (or equivalent)



OUT OF SERVICE

DO NOT USE

Comments _____

OESR: ☐ _____

Eng. Eval: ☐ _____

Service: ☐ _____

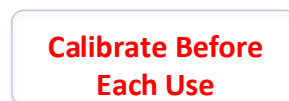
Other: ☐ _____

T.E.# / ID# _____

Out of Service / Do Not Use Label



Calibration Not Required Label



Calibration Before Use Label

Note: Other labels may be used (e.g. vendor-supplied or printed), if they meet the minimum data requirement (ID/Serial Number, Date & Due Date).

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DOCUMENT HISTORY

(Note: Complete Document History may be obtained via the Document Management System.)

VERSION:	07	ORIGINATOR:	Michael Cotter	Change ID:	N/A
SUMMARY OF CHANGE: CLARIFIED SCOPE: ADDED TEXT CLARIFYING THAT THE SCOPE INCLUDES EQUIPMENT RESIDING IN MILFORD, MA PRODUCTION AREAS THAT REQUIRE CALIBRATION AND/OR MAINTENANCE. IN SECTION 8, ADDED IMAGE OF SMALL, ROUND CALIBRATION LABEL COMMONLY USED IN MACHINING OPERATIONS. IN SECTION 9.2, SHORTEN THE DATE REQUIREMENT (MMM YYYY TO MMM YY) TO BETTER FIT THE SMALL, ROUND LABELS, ABOVE IN SECTION 9.2.7, ADD REFERENCE TO MACHINING OPERATIONS MEASURING EQUIPMENT CALIBRATION STATUS REPORT LOG BOOKS. ON APPENDIX 2, CALIBRATION/PM RECORD, 'CALIBRATION ADJUSTMENTS MADE: YES ☐ No ☐ , ADD N/A ☐ . ON APPENDIX 2, CALIBRATION/PM RECORD, REMOVE REQUIREMENT TO APPLY EXPIRED DECAL.					
VERSION:	08	ORIGINATOR:	Michael Cotter	Change ID:	N/A
SUMMARY OF CHANGE: SECTION 3: Added non-critical pressure gauges to list of out-of-scope equipment. SECTION 4: Added "Operators using equipment shall verify that it has been calibrated or maintained." SECTION 5: Added 730000523 Good Documentation Practices (GDP) Added 730005738, 730005740, 730005741, 730005742 Calibration/PM forms. SECTION 9: Added "and inscribe or label ID number on equipment." to (9.1.5). Consolidated (9.1.7) & (9.1.8) for better clarity. Added to Operator/User responsibility, "Verify equipment is in calibration before use." (9.2.3) Removed Notes from 9.2.7 and incorporated statements within (9.2.8) APPENDIX: Remove Calibration/PM forms from Appendix Section.					
Version:	09	Originator:	Matt Brule	Change Id:	N/A
Description of Change: Update to version 09, using current template 730000483 V07, remove all "Δ" from previous revision. Repaginate and renumber to support updated template and other changes. Changes as follows: Section 2 SCOPE: Change to equipment that is tracked in the Milford Calibration Database. Section 3 DEFINITIONS AND ABBREVIATIONS: include definition / usage of calibration status labels, and definitions of accuracy and precision. Remove definitions of OBS, Obsolete Item, and OESR. Section 4 ROLES AND RESPONSIBILITIES: Add Equipment Change Request originator. Section 5 REFERENCES and RELATED DOCUMENTS: Remove associated forms. Add Section 6 FORMS. Update references throughout the document. Add Section 7 RECORDS, update references to records throughout document. Section 8 HEALTH & SAFETY: Update per template. Section 9 EQUIPMENT/MATERIALS OF USE REQUIRED: to an Appendix and add picture of Calibrate Before Use label. Update all references to point to new appendix. Section 10 Procedure: Update 10.1 ADDING EQUIPMENT TO THE PROGRAM to include the new Equipment Add Request Form 730006638 and speak to its usage. Update 10.2 CALIBRATION / PREVENTATIVE MAINTENANCE Add explanation of different procedures used to calibrate waters equipment. Add accuracy and precision statement and reword required number of data points. Describe how records can be stored, removing reference to "physical folders" Update 10.3 CHANGING OR REMOVING EQUIPMENT FORM THE PROGRAM This section completely rewritten in support of revised form 730005738, Form, Equipment Change Request. To detail how all equipment information is changed or removed from the system.					