

REACH Devices

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RD-MP

Digital melting point apparatus

Installation Qualification,
Operation Qualification,
and
Performance Qualification
Procedures
(Revision 1.01 06/13)

Company:

Location:

Instrument Model: RD-MP

Serial #:

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

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Comments: _____

REACH Devices representative _____ Verified by _____

Date:

1. Protocol Approval

This protocol is to be used for qualifying the installation, operation and performance of the RD MP point instrument identified on the title page of this document, located at the customer site also shown on the title page and specifically located at:

The definition of a system refers to the Installation Qualification for the system in question. Any changes to the content listed on the equipment record would constitute a change to the system and render the corresponding OQ no longer valid. Subsequent changes to the system should be covered in the customer change management system and SOP's.

Comments:

For REACH Devices: _____

(Print Name and title)

Signature: _____ **Date:** _____

For customer: _____

(Print Name and title)

Signature: _____ **Date:** _____

For customer: _____

(Print Name and title)

Signature: _____ **Date:** _____

For customer: _____

(Print Name and title)

Signature: _____ **Date:** _____

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

Protocol Approval

Protocol Acceptance/Approval by Customer

I, the undersigned, agree that the procedures described herein are applicable to the equipment defined on the title page of this document.

A per-page signoff area has been provided for those situations where an internal SOP requires review and acceptance of each page of the delivered document. If this not required, use the area to acknowledge deviations only. Acceptance of the entire document is considered to be complete when the Certification of System Qualification is reviewed and signed by the responsible parties.

For Customer: _____
(Print Name and title)

Signature: _____ **Date:** _____

For Laboratory Supervisor/Manager: _____
(Print Name and title)

Signature: _____ **Date:** _____

Protocol Acceptance/Approval by REACH Devices.

I, the undersigned, agree that the procedures described in this document assembled by REACH Devices Technical Support Services, are appropriate for the equipment defined in this protocol and reflect the current REACH Devices qualification procedure.

For (Executing Engineer): _____
(Print Name and title)

Signature: _____ **Date:** _____

Comments: _____

REACH Devices representative _____ Verified by _____

Date: _____

Scope of Document

This Installation, Operation and Performance Qualification protocol will be performed on the REACH Devices instrument described on the title page, located at the customer site also identified on the title page and specifically located at the building and room stated on the Protocol Approval page.

This protocol identifies the methods and documentation that will be used to evaluate this instrument for installation, operation and performance functions in accordance with the manufacturer's specifications.

On any page where a written entry is made, a direction is followed or data is gathered by a REACH Devices representative, that page must be signed and dated.

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

Instrument Description

Model # RD-MP
Serial #

Specifications

Operation

Temperature display :	Melting point & Melting point range.
Temperature range:	35°C to 270°C
Temperature resolution	0.1°C
Ramp rates	1.5, 3, 6 and 12°C/min
Heat-up time (fast mode)	~10 min
Cool- down time (from 270 to 45°C)	~15 min
Temperature accuracy	± 0.5°C (long term)
Reproducibility	0.2°C
Temperature sensor	two Pt RTD (built-in)
Oven Control	closed loop

General

Display	Back-lit 1.6" alphanumerical LCD
Capillaries	
Dimensions	1.4 mm to 2.0 mm outside dia., 100mm length
Capacity	up to 6 tubes simultaneously
Fill height	2 mm to 3 mm
Power ^a	120V or 220V, 20W, 50-60Hz
Operating temperature	0 °C to 40 °C, non-condensing.
Auto shutoff	after 20 min of idle mode
Protections	
Maximum measurement time	3h 20 min, unit shuts off if exceeded
Max. internal electronics temperature	120°C, one time thermal fuse
Weight	2 lbs
Dimensions	L:5.5", W:3.5", H:2.5"

^aLine voltage must be specified upon purchasing

Comments: _____

REACH Devices representative _____ Verified by _____

Date: _____

Description of Typical Use

RD-MP is a bench-top instrument designed to measure melting point of samples. It relies on the capillary method supported by virtually all pharmacopeia procedures for melting point determinations.

Safety Precaution

Safety Instructions and Warnings

- Safety instructions must be strictly followed during all stages of installation, operation and service of this product. Failure to comply with these precautions and warnings violates the safety standards expected of users of this product.
- The Operations Manual is a component of the product and must remain readily available to all laboratory personnel with access to the RD-MP Melting Point System.
- If you have any doubts about how to use this product safely, contact REACH Devices using the contact information provided in the manual.
- Do not use this product for any purpose other than its intended usage.
- Retain these safety and operating instructions for future reference.
- Identify and adhere to all warnings posted on the product and throughout the manual.
- Failure to comply with these instructions may result in serious personal injury, including death, as well as significant property damage.
- The instruction manual should form the basis of any training requiring the use of this product.
- Wear protective garments such as lab coat and goggles at all times.
- Refer servicing to qualified personnel only.

Electrical Shock Risks

- It is your responsibility to install and operate this product in full conformance with local electrical codes. Consult an experienced electrician if necessary.
- If the power cord becomes damaged, replace it immediately.
- Dangerous voltages capable of causing injury are present during the operation of this product. Do not remove the covers while the unit is plugged into a live outlet.
- Do not use this product if it has unauthorized modifications. Unauthorized modifications may result in fire, electric shock and other hazards.
- Do not install substitute parts or perform any unauthorized modifications to this instrument.
- The line fuse is internal to the instrument and may not be serviced by the user.
- Always use an outlet which has a properly connected protective ground. Consult with an experienced electrician if necessary.
- GFCI (Ground Fault Circuit Interrupter) protected outlets are often available in laboratory environments, particularly in proximity to water sources. GFCI's are generally regarded as an important defense against electrocution. However, the use of a GFCI in conjunction with the RD-MP must NOT be regarded as a substitute for proper grounding and careful connections. GFCI's must also

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

be tested regularly to verify their functionality. Always consult an electrician when in doubt.

- Do not use accessories not recommended in the manual as they may be hazardous.
- Keep all electrical wiring on your laboratory benches neatly organized and in good working conditions. Label and color-code all high voltage cables. Inspect all HV wires periodically for problems as part of your safety checkups.
- Use tie downs and cable channels to hold all electrical wiring in place (i.e. no dangling cables).
- Keep all electronic instrumentation neatly organized, and remove unconnected cables, power supplies and connectors from your laboratory benches and shelves.
- Do not push objects of any kind into this product through openings as they may come in contact with dangerous voltage points or short out parts that could result in a fire or electric shock.
- Operation of this product with line voltages other than those accepted by the power supply can cause damage to the instrument and injury to personnel.

Burn Risks

- Do not touch the heater block while hot.
- Check that the temperature reading is below 55°C before removing or inserting capillaries.

Explosion Risks

- This product is not compatible with application environments requiring: explosion proof equipment, or compatibility with samples which may explode or ignite by heat, friction or spark.
- Do not use this product to analyze samples of unknown composition or contamination.

Product Placement Requirements

- Place this product on a stable, clean, level and even surface.
- Place the product away from water sources (i.e. faucets, safety showers, eyewashes, rain, etc.) Do not allow the product to become wet.
- No containers, chemicals or other appliances should be placed behind the product.
- Always operate the unit in its proper orientation. Do not operate the unit on its side.
- To prevent damage to the product and ensure sufficient cooling in the electronic compartment, place the sidewalls of the unit at least 10 cm away from walls or other objects.
- Your RD-MP may produce some smoke the first time it is heated. The smoke is caused by residual oils coating the metal surfaces of the heater and surrounding areas. Once the oils burn away, the smoke will permanently cease.

Comments: _____

REACH Devices representative _____ Verified by _____

Date: _____

Documentation

RD-MP melting point system includes the following documents:

(Note any discrepancies below.)

Document	Present?
Instruction Manual	
Certificate of Calibration	

There may also be additional enclosures containing promotional or educational material.

Warranty and Maintenance Policy

Warranty

RD-MP melting point systems are precision built with quality materials and are fully guaranteed for one year from date of purchase against defects in materials and workmanship. They are certified against primary melting point standards traceable to WHO International Pharmacopoeia.

Should service be required during the warranty period there will be no charge for parts or service labor. Shipping charges for “return to factory” repairs are the responsibility of the customer.

Maintenance

To assure many years of reliable operation REACH Devices. recommends that C&CS (Calibration and Certification Service) be performed at least annually. This service consists of an inspection for temperature offset and slope calibration, removal of broken capillaries, cleaning the unit’s exterior. Your instrument is then calibrated and certified in writing to be performing within Instrument specifications. This certification states that your instrument has been calibrated against standards which are traceable to the WHO International Pharmacopoeia .

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

Installation Checklist and Qualification

Ordering Information:

Customer Order Number _____

Supplier Invoice Number _____

Check to be sure that all components are received and that there is no shipping damage. Note any missing parts and notify REACH Devices immediately. Shipping damage must be reported to the carrier.

Inventory:

Item	PN	Qty	Present?
Melting Point Apparatus	RD-MP	1	
Power cord		1	
User Manual		1	

Setup:

Instruction	Completed?
Place your RD-MP on a stable, clean, level and even surface. Always operate the unit in its proper orientation. Do not operate the unit on its side. Place the side walls of the unit at least 10 cm away from walls or other objects.	
Check that quartz plate is firmly installed over the heating block. Check that there is no foreign material in capillary slots.	
Check if it is comfortable to observe the heating block through the lens. If not, flip out the bracket on the unit bottom. This will allow RD-MP to be observed from an angle.	
Connect the power cord to the socket on the back panel of the instrument and plug it into the appropriate AC line	

Comments: _____

REACH Devices representative _____ Verified by _____

Date: _____

Operation Checklist and Qualification

Verify that all functions operate normally as indicated.

Function	Operation	Condition
Connect the power	Connect RD-MP to a grounded outlet using the power cord provided	
Turn on power	Press ON button. The unit should produce a beep, turn on heating block light, LCD back-light and a fan. LCD should show a heating block temperature (usually close to room temperature), word "idle" and 6°C/min heating rate. Heating element is off during this phase.	
Insert the sample capillaries	Insert up to six capillary sample tube(s) into the oven	
Start temperature	If the desired starting temperature is more than 10°C higher than current temperature reading press FASTER button repeatedly until word "fast" appear on the screen. Press RUN button and wait until the temperature reading became about 5 to 10°C below the desired starting temperature.	
Adjust the heating rate	Press SLOWER button to select the the heating rate from the 12°C/min, 6°C/min, 3°C/min and 1.5°C/min. <i>Note: newer use "fast" mode for melting point determination.</i>	
View the Melt	Visualization of the melt during the heating ramp is accomplished via the observation window located on the front panel of the RD-MP. Heating rate can be changed any time by pressing FASTER or SLOWER buttons. The measurement may be aborted any time by pressing RUN button.	
Cool off the unit	After the highest desired temperature was reached press RUN button to initiate the rapid cool-off. Note, unit will automatically turn to cool off mode after 250°C is reached. The message "idle" will appear.	
Auto shutoff	The unit will shut off after 20 minutes idle mode.	

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

Performance Checklist and Qualification

Acceptability test

Procedure	Result	Met?
<p>Check the appropriate legal, company and laboratory regulations to see if provided indium and tin standards are appropriate.</p> <p>If they are appropriate, use a pair of provided standards (capillaries with blue and red marks).</p> <p>If the provided standards are unacceptable, two appropriate USP-certified melting point standards should be obtained. Pay attention to the information on sample pretreatment, drying procedures, grinding, capillary tube dimensions, sample loading and rated melting points .</p> <p>For best results, the melting points of these two standards should lie below and above the expected melting point(s) of the the substance(s) of interest. Note that the standards chosen should differ in melting points at least 50°C</p>	<p>For provided indium and tin standards:</p> <p>Melting points should lie within 156.1°C to 157.1°C for indium (blue) 231.4°C to 232.4°C for tin (red) (at 1.5°C/min ramping rate)</p> <p>For USP-certified melting point standards:</p> <p>1. Melting point range (clear point minus onset point) must be less than 2°C for each capillary (at 1.5°C/min ramping rate)</p> <p>2. Temperature Offset Correction values of should remain within $\pm 0.5^\circ\text{C}$</p>	

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

Performance Checklist and Qualification (cont'd)

Acceptability test procedure:

Step	Comments?
<p>If using the provided standards then load one indium containing capillary (blue) and one tin containing capillary (red). Use central slots for these capillaries.</p> <p>If using USP-certified melting point standards, load four capillaries with the two chosen standards, one standard per two capillaries.</p>	
<p>Prepare a sheet of paper and a pen to record the observed melting points.</p>	
<p>Turn on RD-MP by pressing ON button. Press FASTER button until word “fast” appears on display. Press RUN to start heating the aluminum block.</p>	
<p>Watch the temperature rise. When the temperature is about 5 to 7 degrees below the lowest melting point of the standard set press SLOWER button until the message “1.5°C/min” appears on LCD</p>	
<p>Watch the melting process of the first standard. Record the melting point (if indium and tin standards are used) or melting point range (if USP-certified melting point standards) are used.</p>	
<p>Press FASTER button until word “fast” appears on display. Watch the temperature rise. When the temperature is about 5 to 7 degrees below the higher melting point of the standard set press SLOWER button until the message “1.5°C/min” appears on LCD</p>	
<p>Watch the melting process of the second standard. Record the melting point (if indium and tin standards are used) or melting point range (if USP-certified melting point standards) are used.</p>	
<p>Press RUN button. The “idle” message will appear on the screen. The unit will switch itself off in about 20 minutes.</p>	

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

Performance Checklist and Qualification (cont'd)

Acceptability test results and interpretation for provided indium and tin standards:

Melting point observed	Test passed? ^A
Within 156.1°C to 157.1°C range for indium (blue)	
Within 231.4°C to 232.4°C range for tin (red)	

^ASee *failed test remediation* chapter below if test failed

Acceptability test results for USP-certified melting point standards:

Standard's name	Batch No	MP standard value	Values obtained from RD-MP		
			Capillary	Onset point	Clear point
			1		
			2		
			3		
			4		
			3		
			2		

Interpretation of Calibration Test Results for USP-certified melting point standards:

1) Clear point for three capillaries must fall within $\pm 0.5^\circ\text{C}$ of each other

Standard's name	Batch No	MP standard value	Clear point values obtained from RD-MP		Criteria met?
			Capillary 1	Capillary 2	
			Capillary 3	Capillary 4	

Comments: _____

REACH Devices representative _____ Verified by _____

Date:

Performance Checklist and Qualification (cont'd)

2)MP Range (clear point temperature minus onset point temperature) must be less than 2°C for each capillary (at 1.5°C/min ramping rate)

Standard's name	Batch No	MP standard value	Melting point range values obtained from RD-MP		Criteria met?
			Capillary 1	Capillary 2	
			Capillary 3	Capillary 4	

3)Temperature Offset Correction (TOC) values of should remain within limit given below :^A

Batch No	MP standard value	Clear point values obtained from RD-MP			TOC (MP _{standard}) - (MP _{measured})	Accuracy limit	Criteria met?
		Capillary 1	Capillary 2	Average			
						± 0.5°C	
		Capillary 3	Capillary 4	Average		± 0.5°C	

^ASee *failed test remediation* chapter below if test failed

Comments: _____

REACH Devices representative _____ Verified by _____

Date: _____

Performance Checklist and Qualification (cont'd)

Failed test remediation

In some cases indicated above the RD-MP unit can be recalibrated by using the procedure below:

1. Calculate offset and slope as follow:

$$\text{slope} = (A2 - A1) / (M2 - M1)$$

$$\text{offset} = A1 - (M1 * \text{slope})$$

where:

A1 is actual standard 1 clear point

A2 is actual standard 2 clear point

M1 is measured average standard 1 clear point

M2 is measured average standard 2 clear point

There is also a calculator at www.reachdevices.com/MPoint/MPGeneral.html to simplify these calculations.

2. Switch the unit to calibration mode. To achieve this the unit must be unplugged, then plugged back in. Depress the FASTER button and then the ON button, and then release both. The message “Offset. RUN → slope” will be displayed. The value of offset can be adjusted in 0.1°C increment by pressing FASTER or SLOWER buttons.

After the desired value of offset is entered, press RUN button. The message “Slope. RUN → done” will be displayed. The value the slope can be adjusted in 0.001 increment by pressing FASTER or SLOWER buttons. Press the RUN button when the desired value of offset is reached. The unit will switch to normal mode of operation. The entered offset and slope values are saved to the unit's permanent memory.

The entire Performance Checklist and Qualification procedure must be repeated one more time. If any test fails again the unit should be sent in for servicing.

Comments: _____

REACH Devices representative _____ Verified by _____

Date: _____

Protocol Certification

**Installation, Operation and Performance Qualification of the
RD-MP melting point apparatus**

Certification

The Installation, Operation and Performance Qualification final report for the REACH Devices instrument, Model # _____, Serial # _____, has been reviewed and the instrument was found to meet the requirements necessary to be used in the customers' laboratory.

Final Report

Authorized REACH Devices representative:

Reviewed by _____ Signature _____ Date _____
Name and Title

Authorized Customer representative:

Reviewed by _____ Signature _____ Date _____
Name and Title

Customer QA representative: (if applicable)

Reviewed by _____ Signature _____ Date _____
Name and Title

Comments: _____

REACH Devices representative _____ Verified by _____

Date: