

Center for Clinical and Translational Research Standard Operating Procedure



Section: Clinical Research Center Date Created: November 1st, 2010

Title: Equipment Calibration and Maintenance Version Date: April 18th, 2025

SOP Number: CO21

<u>PURPOSE:</u> The purpose of this standard operating procedure (SOP) is to outline the Clinical Research Center's (CRC) monitoring and calibration of equipment used for clinical research studies to ensure that all equipment is operating precisely and with accuracy.

SCOPE: This procedure applies to all CRC equipment used in clinical research studies that requires routine calibration or maintenance.

PERSONNEL RESPONSIBLE: All CRC study personnel are responsible for proper use and handling when using CRC equipment. Study staff are responsible for requesting the initial BioMed calibration and preventative maintenance of all sponsor-provided machines. Designated CRC staff are responsible for ensuring that calibration occurs annually, equipment maintenance oversight, and retaining appropriate documentation for specified equipment. Sodexo personnel responsible for planned and unplanned maintenance as needed.

PROCEDURES:

- Newly acquired machines all newly acquired research related machines, both CRC sponsored, and sponsor provided, will be serviced by Sodexo before use. It is the responsibility of the study staff to ensure that all sponsor-provided machines are ready for use upon drop-off to the CRC. This includes but is not limited to the study intake IT assessment and initiating the request with BioMed for annual preventative maintenance.
- Annual maintenance all research machines, including those owned by the CRC, and study specific machines, will be monitored and calibrated annually by Sodexo. This maintenance incurs a fee through Sodexo. Annual maintenance for study specific machines will be charged to the appropriate study account.
- Maintenance as needed if a research machine requires unplanned maintenance, a service ticket will be submitted to Sodexo for the maintenance. If the request is for a sponsor-provided machine, the study team will first be notified to see if sponsor approval is required. Unplanned maintenance will be charged to the appropriate study account if it is performed on a study specific machine.
- Calibration documentation will be stored electronically on Sodexo site and available for study sponsor or CRO representatives review upon request.
 - o Go to https://mmwa.mysodexo.com/tnmc/default.aspx
 - Hover your mouse over the "Device Info" tab and then press "Advanced Device Lookup."



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- Three different fields should show up now under the "Additional Search Criteria" title. Press the drop-down menu on the first field from the left and change it from "Manufacturer" to "Department Name" Then press the drop-down menu on the second field and change it from "Equal to" to "Contains." Finally, type the number "Clinical Research Center" into the third field and press "search." OR change Manufacturer" to "Cost Center." Then press the drop-down menu on the second field and change it from "Equal to" to "Contains." Finally, type the number "7525" into the third field and press "search" for CRC maintained machines.
 - If a study specific machine is used, search for the study cost center.
- This should bring up all the devices in the CRC that are monitored by Biomed. To pull up the calibration logs or submit a work order for a certain device, find the description and model of the device and scroll to the far-left column with the title "CTM Tag #."
- For Work Orders: Click on the number in the column, this should bring you to the device details tab. On the right of your page under "WO Summary" you will see a button that reads "Create a WO" should there be any issues with the device, you would click this button and fill out the details of the problem and then submit the work order to BioMed.
- o <u>For Calibration Logs</u>: Click on the number in the column, this should bring you to the device details tab. Next to the device details tab there should be a tab named "Work Order History" click on this tab. This will show you all the documented work that has been completed to the device.
 - The calibration data is a part of the annual or six-month inspection and the inspection reads as "PM-Scheduled" under the "Type" column. Find the most recent PM-Scheduled work order and click on the work order number in the far-left column under the "WO #" title.
 - This will bring you to the details of the work order. In the details tab there is a print button toward the bottom. Click the print button and print the work order, which includes the calibration and maintenance data.
 - After the forms have been printed, email the forms to yourself and then forward them to the requestor.

RESOURCES:

Nebraska Medicine:

• EC01 Medical Equipment



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- IC08 Refrigerator, Freezer and Ice Machine Monitoring, cleaning and Maintenance
- EC03 Electrical and Electronic Equipment Safety

Department Approval

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Signed Serena Maines	Signed: 4/25/2025	
Research Nurse Manager		
Signed	Signed:	
Assistant Vice Chancellor for Clinical Research		