INDIANA CTSI Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR DRÄGER PAC 5500 PERSONAL O_2 MONITOR

CHAPTER: 3-Equipment

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1. REVISION
   1.1. Significant changes incorporated in this version include:
      1.1.1. SOP renamed to include model name "Dräger Pac 5500" to differentiate equipment and directives from new Sensit P100 personal O_2 monitors (per SF-3-3).
      1.1.2. Revised Step 2.1 to enhance clarity of purpose.
      1.1.3. Specify throughout SOP that the Dräger Pac 5500 Personal O_2 Monitor is utilized in R3-C156.
      1.1.4. Separated Error code management into a separate Step 2.2 to improve readability.
      1.1.5. Section order reconfigured to align with SOP SF-1-01, which defines that equipment SOPs have sections describing procedures for operation, cleaning, function verification, maintenance, and calibration. Section and step references corrected throughout document.
      1.1.6. Clarify that Step 6.5.1 directives apply to receipt of new equipment and equipment returning after span-calibration / repair.
      1.1.7. Corrected Steps 6.5.1.1 and 6.5.1.2 directives regarding documentation of Manufacturer Serial Number on Appendix A at equipment intake.
      1.1.8. Section 9 revised to include Appendix D.
      1.1.9. Added Collaborating Biobank Personnel (CBP) Training Section 10 to align with SF-1-01.
      1.1.10. Appendices A-C revised to reflect new SOP title.
      1.1.11. Added Collaborating Biobank Personnel Training Appendix D to facilitate training of CBP personnel.

2. PURPOSE
   2.1. This Standard Operating Procedure (SOP) defines the procedures for using a Drager Pac 5500 portable personal O_2 monitor unit in the Indiana CTSI Specimen Storage Facility (SSF) to monitor the oxygen level in the R3-C156 Liquid Nitrogen Freezer Room. This procedure defines equipment operation, function verification, maintenance, and cleaning procedures and serves to address potential discrepancies in the alarms generated via this unit compared to the stationary oxygen monitoring units installed in the SSF R3-C156 Liquid Nitrogen Freezer room.

2.2. Additionally, this procedure provides a mechanism for SSF staff to resolve specified error codes via the Dräger Communication Module and CC-Vision software. The Communication Module hardware enables the unit to interface with CC-Vision software on a PC, allowing firmware settings to be adjusted and data-logging files to be exported. Use of the Communication Module and CC-Vision software is not required for operation or standard maintenance of this unit. This procedure satisfies guidance set forth in ISBER.

3. PRINCIPLE
   3.1. Personal O_2 monitors are utilized when entering the R3-C156 Liquid Nitrogen Freezer Room for personal safety measures. This is necessary because oxygen in the atmosphere may be displaced by liquid nitrogen, thus creating an environment that is dangerously low in oxygen. The use of personal monitors along with the permanently installed devices serves two purposes: (1) there is a high propensity for false alarms with low oxygen monitors and, if determined that the stationary models are in false alarm by appropriate safety personnel, the personal O_2 monitor may be used to manage that condition and still assure that personnel are not in an unsafe environment and (2) the stationary alarms are not in the immediate vicinity of the employee and, thus may not detect a pocket within the room that has a dangerously low oxygen level. The personal O_2 alarms are pre-set to alarm at levels below 19.5% and above 23.5% O_2.

4. SCOPE
   4.1. The SOP applies to SSF Staff and trained Collaborating Biorepository Personnel (CBP) entering the R3-C156 Liquid Nitrogen Freezer Room as well as non-SSF staff and untrained CBP as directed by SSF Staff and trained CBP.

5. MATERIALS
   5.1. Personal O_2 Monitor – Dräger Pac 5500
   5.2. 123 or 123A Lithium 3V batteries (or compatible)
   5.3. Dräger CC-Vision software v7.4.6
   5.4. Dräger Communication Module (Pac Series) and PC cable (USB to micro USB)
   5.5. Cleaning Cloth

6. PROCEDURE
   6.1. **Use of the personal O_2 monitor: Refer to SOP SF-2-2** <u>LIQUID NITROGEN SYSTEM AND LIQUID NITROGEN FREEZER ROOM OPERATIONS</u> **for when personnel are required to wear a personal O_2 monitor.**
      6.1.1. Before entering the Liquid Nitrogen room, retrieve a personal O_2 monitor. Select a unit that is on, if available.
         6.1.1.1. Confirm the unit is displaying an O_2 value between 19.5% and 23.5%. A typical value is 20.9%.
         6.1.1.2. Confirm the notification icon [!] is not displayed.
         6.1.1.3. Confirm the low battery icon is not flashing.
         6.1.1.4. Documentation of these actions is not required.
         6.1.1.5. If the unit does not meet these criteria:
            6.1.1.5.1. Notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.
            6.1.1.5.2. Select a different unit for use, and repeat the actions above.
      6.1.2. If no powered-on units are available, select a unit and turn the unit on as follows:
         6.1.2.1. Press and hold the green OK button as the display counts down 3, 2, and 1.

6.1.2.2. Proceed only when the following are confirmed. (Summary of these items is included in Appendix B and is posted with the personal O_2 monitor). Documentation of each action is not required.
6.1.2.2.1. The LED, Audible Alarm and the Vibrating Alarm activates in respective sequence.
6.1.2.2.2. The Audible and Vibrating Alarm levels display.
6.1.2.2.3. A countdown of approximately 1 minute has been completed and the notification icon [!] is no longer lit. The O_2 sensor needs approximately 1-minute warm up time for every activation.
6.1.2.2.4. The low battery icon is not flashing.
6.1.2.2.5. The % Vol of O_2 is displayed and is greater than 19.5% and less than 23.5%.
6.1.2.2.6. If the unit does not meet these criteria, notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.

6.1.3. Clip personal O_2 monitor onto clothes so as to not obstruct the monitor's air intake before entering the Liquid Nitrogen Room.

6.1.4. To indicate functional operation, the unit emits a low volume click approximately every 60 seconds; however, the high volume of background noise in the lab may render the low volume click inaudible. Do not consider the unit to be non-functional if the click is not audible, as long as all other requirements are met.

6.1.5. After exiting the Liquid Nitrogen Freezer Room, turn off personal O_2 monitor, if desired, as follows:
6.1.5.1. Press and hold the green OK button and the blue + button simultaneously.
6.1.5.2. Observe for the following:
6.1.5.2.1. The display counts down 3, 2, and 1.
6.1.5.2.2. The LED and Audible Alarm activate momentarily.
6.1.5.2.3. The display becomes blank.
6.1.5.3. Remove from clothing and return to storage area.
6.1.5.4. If the unit fails to perform as described above, notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.

6.2. **Alarms**

6.2.1. Follow directives in SOP SF-2-2: Liquid Nitrogen System and Liquid Nitrogen Freezer Room Operations for response to Personal O_2 Monitor Alarms and Stationary Alarms.

6.2.2. Please note: A personal O_2 monitor will sometimes alarm for the reasons listed below. **If these reasons listed below are not applicable or if the wearer is unable to immediately determine applicability, vacate the LN_2 room.**
6.2.2.1. The monitor has been engulfed by LN_2 vapor (e.g. a monitor suspended from around the neck which accidently descends into an LN_2 freezer will cause an alarm)
6.2.2.2. The monitor's gas opening has been obstructed.
6.2.2.3. The wearer is exhaling into the gas opening.

6.2.3. Relocating to another area in the room and readjusting the monitor's position on the wearer's person will ensure that the monitor is cleared of the temporary issue.

6.2.4. If an O_2 monitor is deemed faulty, notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.

6.3. Cleaning:
- 6.3.1. As needed, wipe surface of the device with a clean damp cloth.
  - 6.3.1.1. Do not use abrasive cleaning agents, which may damage the optical lens.
  - 6.3.1.2. Do not wipe the gas opening. The gas opening is protected by a dust and water filter which can be damaged by pressure or excess moisture.
- 6.3.2. Documentation of cleaning is not required.

6.4. Function Verification: Perform Quality Control Test as directed per Section 6.5.2.2.

6.5. **Management and Maintenance**:
- 6.5.1. Upon receipt of new equipment and equipment returning after span-calibration / repair, the following information is recorded on the Personal O_2 Monitor Maintenance Log (Appendix A):
  - 6.5.1.1. For new equipment, document Manufacturer Serial Number on a new Appendix A.
  - 6.5.1.2. For existing equipment returning from span-calibration / repair, confirm Manufacturer Serial Number on existing Appendix A or create a new Appendix A, documenting Manufacturer Serial Number of new equipment, if needed.
  - 6.5.1.3. Date in Service, which is defined as the date span calibration testing documentation was received and QC check of unit was performed and deemed successful per Section 6.5.2.2. If receipt of documentation and QC check have different dates, enter whichever date is later.
  - 6.5.1.4. Confirmation of receipt of span calibration test report
    - 6.5.1.4.1. Calibration testing documentation must include, at minimum:
      - 6.5.1.4.1.1. O_2 monitor serial number
      - 6.5.1.4.1.2. Date of calibration
      - 6.5.1.4.1.3. Either date of next scheduled calibration or calibration interval in days
      - 6.5.1.4.1.4. Span calibration data must include:
        - 6.5.1.4.1.4.1. As found value (e.g. “actual value (prior)”, “Is value (before)”)
        - 6.5.1.4.1.4.2. As left value (e.g. “Is value (end)”, on X-dock certificates/reports only “set value” as listed under span calibration)
        - 6.5.1.4.1.4.3. Gas type (e.g. fresh air or Dräger CH4, O2, CO, H2S calibration gas)
        - 6.5.1.4.1.4.4. Concentration of oxygen
  - 6.5.1.5. Date of last span calibration/inspection
  - 6.5.1.6. Date for recommended Dräger span calibration/inspection (as stated on the calibration test report)
  - 6.5.1.7. Quality Control Check, which includes testing the personal O_2 monitor to ensure it is functioning properly (refer to Section 6.5.2.2.)
  - 6.5.1.8. The log is reviewed by SSF Management to ensure accuracy.
  - 6.5.1.9. File any documents produced by Dräger, including calibration test reports and service reports, in the Facility Manager’s office.

- 6.5.2. Routine Maintenance
  - 6.5.2.1. Identifying and changing low battery:
    - 6.5.2.1.1. Identifying low battery

6.5.2.1.1.1. Listen for audible alarm sounds and flashing lights for a pre-alarm.
6.5.2.1.1.2. There will be a low battery icon flashing on the monitor screen.
6.5.2.1.1.3. To acknowledge, push OK button.
6.5.2.1.1.4. After the pre-alarm has occurred, the battery will last from 1 hour to 1 week.
6.5.2.1.1.5. When the main alarm for the battery is activated, there will be repeating patterns of audible alarms with flashing lights.
6.5.2.1.1.6. Allow the device to cycle through the alarm until it automatically turns off after approximately 1 minute.
6.5.2.1.1.7. If monitor does not return to normal function, remove from use and notify SSF Management.

6.5.2.1.2. Changing the battery
6.5.2.1.2.1. Make sure that the personal O_2 monitor is off.
6.5.2.1.2.2. If it is not off, shut off device per Section 6.1.5.
6.5.2.1.2.3. Unscrew all 4 screws from the back case.
6.5.2.1.2.4. Open the front case to remove the depleted battery.
6.5.2.1.2.5. Insert the new battery in the proper orientation.
6.5.2.1.2.6. Replace the front case and fasten it back onto the monitor by tightening the 4 screws on the back.
6.5.2.1.2.7. Turn the device on per Steps 6.1.2.1 and 6.1.2.2, and allow 15 minutes for a sensor warm-up to be completed.
6.5.2.1.2.8. Once the warm-up is complete:
6.5.2.1.2.8.1. If the notification icon [!] is displayed, the monitor requires a bump test (a low-alarm function test using pressurized calibration gas) following battery replacement. The unit must be taken out of service and sent to Dräger for inspection per Section 6.5.2.3.
6.5.2.1.2.8.2. If the notification icon [!] is not displayed, the monitor is ready for use.
6.5.2.1.2.9. The device can be shut off per Section 6.1.5.

6.5.2.2. Annually, perform the Personal O_2 Monitor Quality Control Test as follows:
6.5.2.2.1. If the unit is on, follow Steps 6.1.1.1 – 6.1.1.4. If the unit is not on, follow Steps 6.1.2.1 and 6.1.2.2.
6.5.2.2.2. Place monitor over dry ice and confirm that a low oxygen alarm is triggered within approximately one (1) minute. Timing with a cell phone or wall clock is permitted. Start and stop times are not documented. Document Yes or No on Appendix A.
6.5.2.2.3. Place the personal O_2 monitor next to a wall O_2 monitor. Allow the reading on the personal O_2 monitor to stabilize up to approximately one (1) minute. Timing with a cell phone or wall clock is permitted. Start and stop times are not documented. Once the personal O_2 monitor reading stabilizes, record the personal O_2 monitor reading on Appendix A. Additionally, record the

reading from the O_2 wall monitor on Appendix A. Ensure that the O_2% from the personal monitor is within +/- 0.3 of the wall mounted monitor O_2%.

6.5.2.2.4. Annually, initiate a new copy of the Appendix A. Document and submit the completed version of Appendix A to SSF Management for review (lining out areas of the document that have not been used).

6.5.2.3. Dräger inspection:

6.5.2.3.1. The span calibration interval due date is defined by the instrument manufacturer. For inspections:

6.5.2.3.2. Contact Dräger as per Step 7.3. Provide unit serial number and request Return Material Authorization (RMA) number.

6.5.2.3.2.1. Request 730-day (2-year) calibration interval.

6.5.2.3.3. Remove unit to be inspected from service, documenting on Appendix A the date out of service and reason. The log is reviewed by SSF Management to ensure accuracy.

6.5.2.3.4. Clean the surface of the unit per Section 6.3.

6.5.2.3.5. Once the RMA letter is received by email, package the unit with the RMA letter and reference RMA number on packaging exterior.

6.5.2.3.6. Upon receipt, file any documents produced by Dräger, including new calibration test reports and service reports, in the SSF Management office.

6.5.2.3.7. Upon receipt, document per Section 6.5.1 and perform Personal O_2 Monitor Quality Control Test as specified in Section 6.5.2.2.

6.5.3. Non-Routine Maintenance

6.5.3.1. Correcting drift:

6.5.3.1.1. Drift from zero-point calibration presents as an atypical reading in a normal oxygen environment.

6.5.3.1.2. Move the device to a monitored normal oxygen environment (20.9% per a wall-mounted O_2 monitor) to confirm the reading is due to drift and not an indication of true room oxygen levels.

6.5.3.1.3. Confirm span calibration interval has not expired.

6.5.3.1.4. Perform fresh air calibration per Section 6.5.3.2.

6.5.3.1.5. If recalibration does not correct the drift, remove the unit from service, document on Appendix A, and notify SSF Management.

6.5.3.2. Performing a zero-point/fresh air calibration:

6.5.3.2.1. Zero-point/fresh air calibration sets the sensor to read room air as the “zero point”, or the standard percent of oxygen measured under normal conditions.

6.5.3.2.2. Perform fresh air calibration in a monitored normal oxygen environment (20.9% per a wall-mounted O_2 monitor).

6.5.3.2.3. Turn on the monitor per steps 6.1.2.1 and 6.1.2.2.

6.5.3.2.4. “-0-” will flash onscreen for approximately 5 seconds after the countdown.

6.5.3.2.5. While “-0-” is flashing, press the [OK] button once.

6.5.3.2.5.1. Note: If no button or the [+] button is pressed, the fresh air calibration is skipped and the device will enter measurement mode.

6.5.3.2.6. The monitor will complete a fresh air calibration.

6.5.3.2.7. The monitor will enter measurement mode upon completion.

6.5.3.2.8. Perform a QC check per Section 6.5.2.2 and document results on Appendix A (Personal O_2 Monitor Maintenance Log).

6.5.3.3. Notification icon and fault/warning codes

6.5.3.3.1. The personal O_2 monitor will display a notification icon [!] in the event of a fault or warning.

6.5.3.3.1.1. A fault indicates a calibration or hardware issue which impacts functionality of the device, and thus the safety of the user. (E.g., calibration failure, damaged sensor)

6.5.3.3.1.2. A warning indicates a firmware issue which does not impact the immediate safety of the user. (E.g., internal clock error, calibration interval reset)

6.5.3.3.2. To view fault/warning code, press [OK] button once.

6.5.3.3.3. To return to measurement mode, press [OK] button again.

6.5.3.3.4. Codes 210 and 160 may be corrected by SSF personnel. All other codes require the unit to be sent out for inspection by Dräger.

6.5.3.3.5. Fault Code 210 – Zero-point/Fresh Air Calibration Failed

6.5.3.3.5.1. Perform fresh air calibration per Section 6.1.3.2.

6.5.3.3.5.2. If calibration fails, remove the monitor from service, document on Appendix A, and notify SSF Management.

6.5.3.3.6. Warning Code 160 – Check Date and Time

6.5.3.3.6.1. Connect monitor to CC-Vision software per Steps 6.5.3.4.1 through 6.5.3.4.9.

6.5.3.3.6.2. Select “Data/Eventlogger” from the menu.

6.5.3.3.6.3. Click “Read Eventlogger”. (Figure 1, Appendix C)

6.5.3.3.6.4. When prompted, save file using the pre-populated file name and path.

6.5.3.3.6.4.1. Note: The Eventlogger files are not reviewed by the SSF and can be deleted. The procedure described in this section is used as a mechanism to export the log data from the monitor, thereby preventing the logfile from becoming full.

6.5.3.3.6.5. Select “Date & Time” from the menu. The current PC time and date will be displayed. (Figure 2, Appendix C)

6.5.3.3.6.6. Click “Receive” to gather data from the monitor. (Figure 3, Appendix C)

6.5.3.3.6.7. Once the device information populates, click “Send” to transfer the PC time and date to the monitor. (Figure 4, Appendix C)

6.5.3.3.6.8. Updating the time and date resets the eventlogger. Click "OK" on the pop-up warning. (Figure 5, Appendix C)
6.5.3.3.6.9. Proceed with Steps 6.5.3.4.10 and 6.1.3.4.11 to confirm success and generate report.
6.5.3.3.6.10. If the update fails, remove the monitor from service, document on Appendix A, and notify SSF Management.

6.5.3.4. Communication module and CC-Vision software
6.5.3.4.1. Use the communication (comm) module to connect the O_2 monitor to CC-Vision software on a PC.
6.5.3.4.2. Before connecting the monitor to the comm module, ensure the monitor's clip is closed and the clip loop is flipped up.
6.5.3.4.3. Insert the monitor into the comm module.
6.5.3.4.3.1. Align the optics. (Figure 6, Appendix C)
6.5.3.4.3.2. Slide the clip loop through the back of the comm module. (Figure 7, Appendix C)
6.5.3.4.3.3. Press the monitor firmly into the comm module. (Figure 8, Appendix C)
6.5.3.4.3.4. Connect the comm module to a computer using the PC cable.
6.5.3.4.3.5. Open CC-Vision.
6.5.3.4.4. Under "Communication", choose "Receive Data" from the drop down, and select "PAC". (Figure 9, Appendix C)
6.5.3.4.4.1. Alternatively, select the PAC 5500-shaped icon from the task bar. (Figure 10, Appendix C)
6.5.3.4.5. If unable to retrieve data, the comm module hardware or software may be faulty. Attempt to connect a different O_2 monitor. If still unable to establish a connection:
6.5.3.4.5.1. Update CC-Vision software, if an update is available.
6.5.3.4.5.2. Replace the PC cable with a new USB to micro USB cable.
6.5.3.4.5.3. If still unable to establish a connection:
6.5.3.4.5.3.1. Contact Manufacturer to troubleshoot.
6.5.3.4.5.3.2. Replace the communication module.
6.5.3.4.6. After data is received, a pop-up window will appear. If "Instrument Status" is red, a fault or warning needs to be resolved. (Figure 11, Appendix C)
6.5.3.4.7. Click on "Instrument Status" to view faults and warnings. A red checkmark indicates an error. (Figure 12, Appendix C)
6.5.3.4.8. Expand the tree next to the red check to view the error. (Figure 13, Appendix C)
6.5.3.4.8.1. Click the "Print" button to create a report of the findings.
6.5.3.4.8.2. Print, then initial and date the report.
6.5.3.4.8.3. File the report with the Dräger calibration and service reports.

6.5.3.4.9. If the error can be resolved, correct the issue per the applicable section of this SOP.
6.5.3.4.9.1. If the error cannot be resolved, remove the monitor from service, document on Appendix A, and notify SSF Management.
6.5.3.4.10. Click “Instrument Status”.
6.5.3.4.11. Click “Update”. “Instrument Status” will display black. (Figure 14, Appendix C)
6.5.3.4.11.1. Click the “Print” button to create a report of the updated findings.
6.5.3.4.11.2. Print a copy of the updated report on the reverse of the original report, or attach to the original report.
6.5.3.4.11.3. Initial and date the updated report.
6.5.3.4.11.4. File the reports with the Dräger calibration and service reports.
6.5.3.4.12. Click the “Exit” icon on the taskbar to close CC-Vision. (Figure 15, Appendix C)
6.5.3.4.13. When prompted, save file.
6.5.3.4.13.1. Add the date in ISO 8601 format (YYYY-MM-DD) to the end of the pre-populated file name.
6.5.3.4.13.2. Click “Save”.
6.5.3.4.14. Remove the monitor from the comm module.

6.5.3.5. Non-Routine Maintenance by Draeger
6.5.3.5.1. Remove unit to be inspected from service, documenting on Appendix A the date out of service and reason. The log is reviewed by SSF Management to ensure accuracy.
6.5.3.5.2. Clean the surface of the unit per Section 6.3, and bring the affected monitor to SSF Management Office, R3-C153.
6.5.3.5.3. Contact Dräger as per Step 7.3. Provide unit serial number and request Return Material Authorization (RMA) number.
6.5.3.5.4. Once the RMA letter is received by email, package the unit with the RMA letter and reference RMA number on packaging exterior.
6.5.3.5.5. Upon receipt, file any documents produced by Dräger, including test reports and service reports, in the SSF Management office.
6.5.3.5.6. Upon receipt of repaired unit, document per Section 6.5.1 and perform Personal O_2 Monitor Quality Control Test as specified in Section 6.5.2.2.

7. REFERENCES
7.1. ISBER Best Practices (current version)
7.2. Dräger 5500 Personal O_2 Monitor Operations Manual
7.3. Dräger customer service: (800) 437-2437

8. DOCUMENTATION
8.1. The maintenance log is submitted for review to SSF Management and maintained per SF-1-6 Controlled Document Management SOP.
8.2. The calibration reports and service documentation for each personal O_2 monitor are maintained per SF-1-6 Controlled Document Management SOP.

8.3. All Deviations are managed per the SF-1-9 Deviation Management SOP.

9. APPENDICES
   9.1. The current version of each of the following appendices is used to guide and/or implement this SOP:
   APPENDIX A – Personal O_2 Monitor Maintenance Log (1 Page)
   APPENDIX B – Components of the Personal O_2 Monitor (1 Page)
   APPENDIX C – Communication Module and CC-Vision Software Figures (7 Pages)
   APPENDIX D – Collaborating Biobank Training Directives (4 Pages)

10. COLLABORATING BIOBANK TRAINING DIRECTIVES
   10.1. CBP comply with Read and Understand training on SOP SF-3-15 (SOP for Dräger Pac 5500 Personal O_2 Monitor) by continuing to and reading Collaborating Biorepository Personnel Training, Appendix D, of this SOP.
   10.2. CBP comply with directives defined in Appendix D.

SSF Personal O_2 Monitor Maintenance Log

Year _____ Unit Serial Number _____ Page ____ of ____

Date in Service	Calibration / Service Documents Received and Filed *(Y or N)*	Date of Last Span Calibration	Span Calibration Due Date	QC Check Completed *(Y or N)*	Initials / Date	MGMT Reviewed *(Initials / Date)*

QC Check						
		A	B	C		
Reason for QC check	Dry ice triggers alarm Y or N *(Pass = Y)*	% O_2 reading from personal O_2 monitor *(record value)*	% O_2 reading from wall O_2 monitor *(record value)*	Pass / Fail *Pass if Absolute value of (A-B) ≤ 0.3*	QC Check Completed *(Initials / Date)*	Management Reviewed *(Initials /Date)*
☐ Return to service ☐ Fresh air calibration ☐ Annual maintenance						
☐ Return to service ☐ Fresh air calibration ☐ Annual maintenance						
☐ Return to service ☐ Fresh air calibration ☐ Annual maintenance						
☐ Return to service ☐ Fresh air calibration ☐ Annual maintenance						

Date out of Service	Reason for Maintenance Request	Initials / Date	MGMT Reviewed *(Initials / Date)*

Comments

Components of the Personal O_2 Monitor

Before use:

- Confirm the monitor is displaying an O_2 value between 19.5% and 23.5%. Normal room air averages 20.9% oxygen.
- Confirm the notification icon [!] is not displayed.
- Confirm the low battery icon is not flashing.
- If the above conditions are not met, bring the affected monitor to SSF Management Office, R3-C153, and select a different monitor for use.

During use:

- If the alarm is triggered due to a decrease of oxygen in the Liquid Nitrogen Room, immediately vacate the room.

1.0 LED

1.1 The LED responds when the monitor alarm is in alarm.
1.2 The LED is used as a visual alarm in dark or poorly lit conditions.

2.0 Audible Alarm

2.1 The audible alarm responds when the monitor is in alarm.
2.2 The horn is used for an audio alarm.

3.0 Vibrating Alarm

3.1 The vibrating alarm responds when the monitor is in alarm.
3.2 This is in parallel to the LED and Audible Alarms.

4.0 OK Button

4.1 Turns monitor On/Off.
4.2 Used to acknowledge alarms.
4.3 Used to view fault/warning codes.
4.4 Used to initiate fresh air calibration.

5.0 + Button

5.1 Turn monitor off in conjunction with the OK button.

6.0 % Vol of O2 Display Levels

6.1 The level of oxygen is displayed at all times when the monitor is in use.
6.2 During the activation sequence the low [A1] and high [A2] alarm levels are displayed, followed by the remaining number of days in the calibration interval [CAL].
6.3 During the warm-up period, the countdown in seconds flashes and the notification icon [!] is displayed.
6.4 After the warm-up period, "-0-" is displayed for approximately 5 seconds.

7.0 Gas Opening

7.1 The amount of oxygen available is measured through the gas opening

Communication Module and CC-Vision Software Figures

Figures referenced in 6.1.3.3: Notification icon and fault/warning codes

Figure 1. Eventlogger

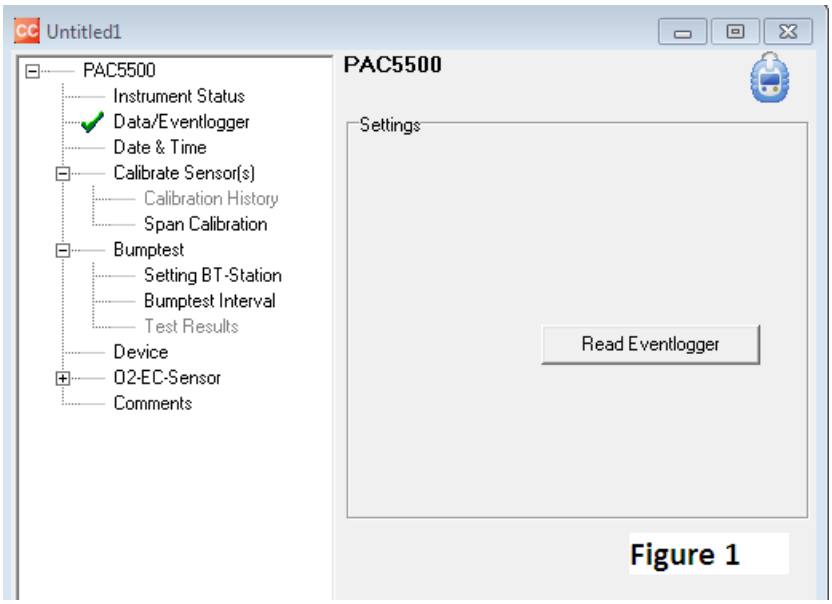


Figure 2. Date and Time

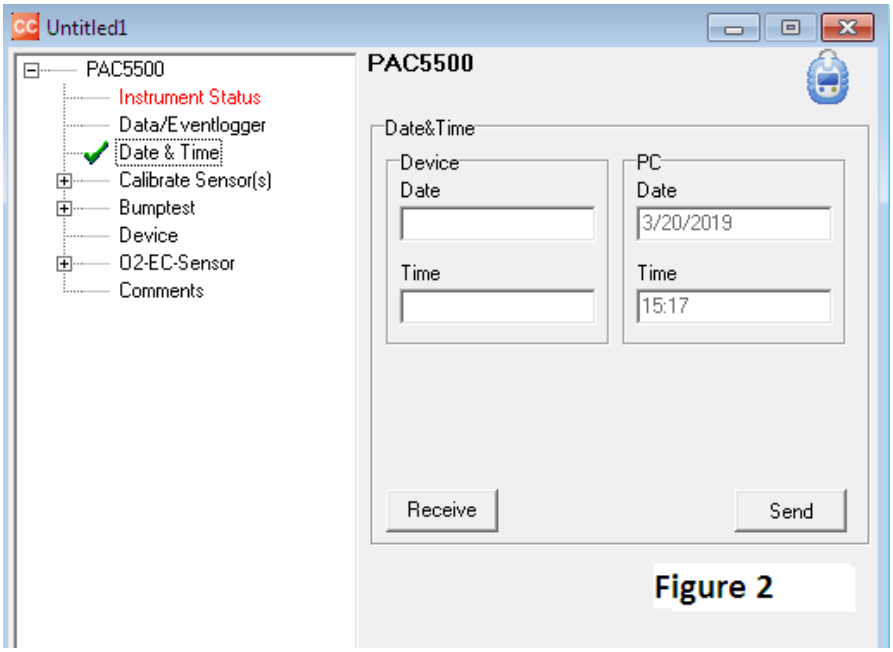


Figure 3. Date and Time, receive

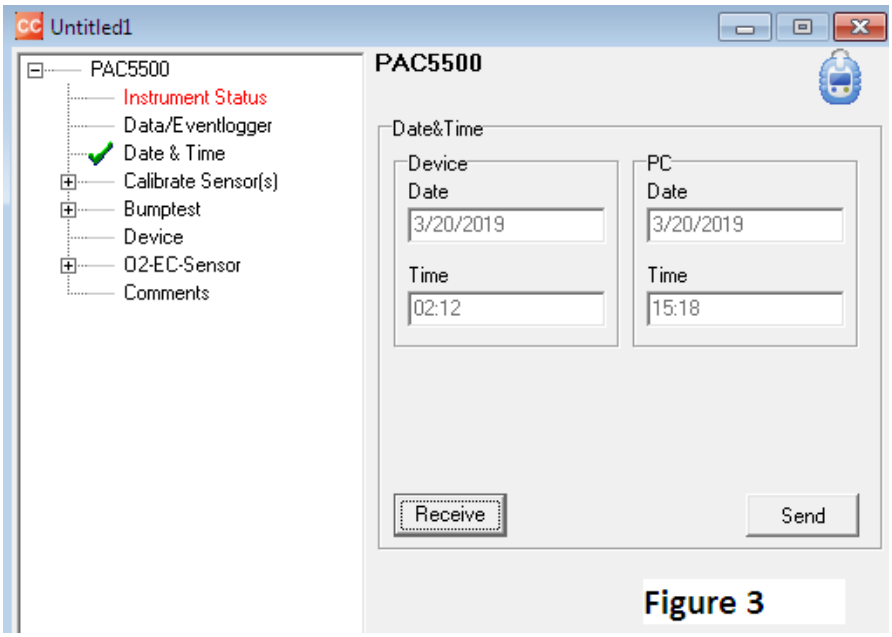


Figure 4. Date and Time, send

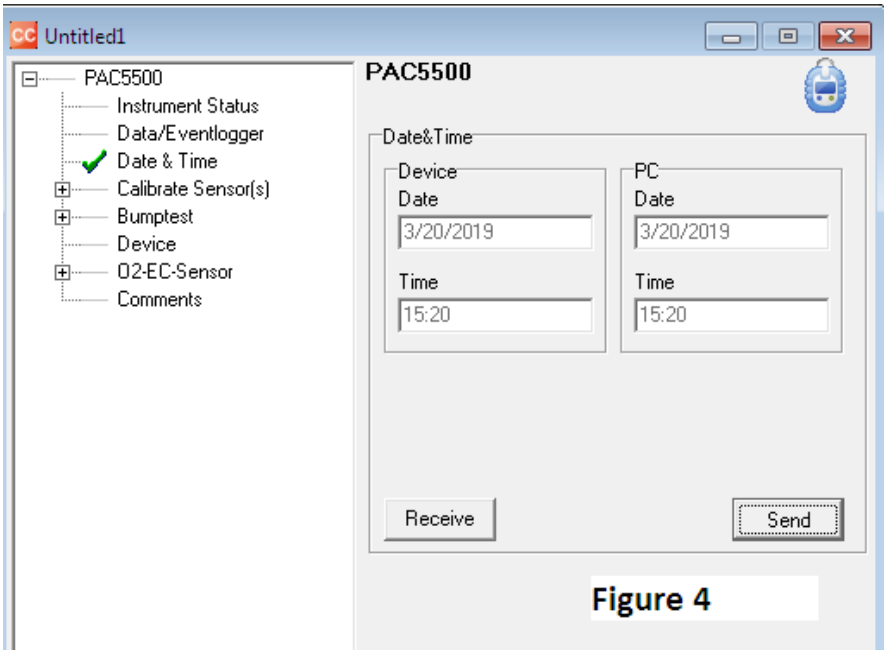


Figure 5. Reset eventlogger

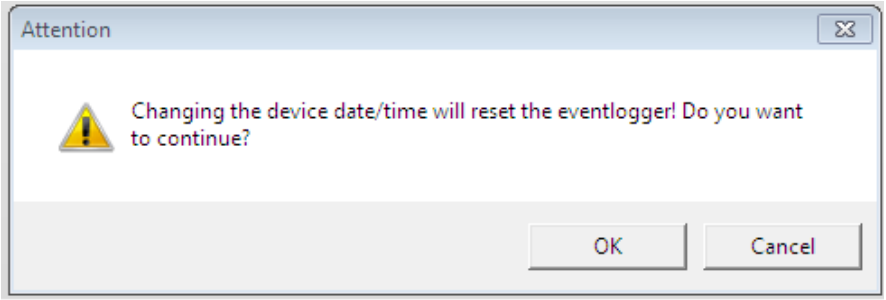


Figure 5

Figures referenced in 6.1.3.4: Communication module and CC-Vision software

Figure 6. Align optics

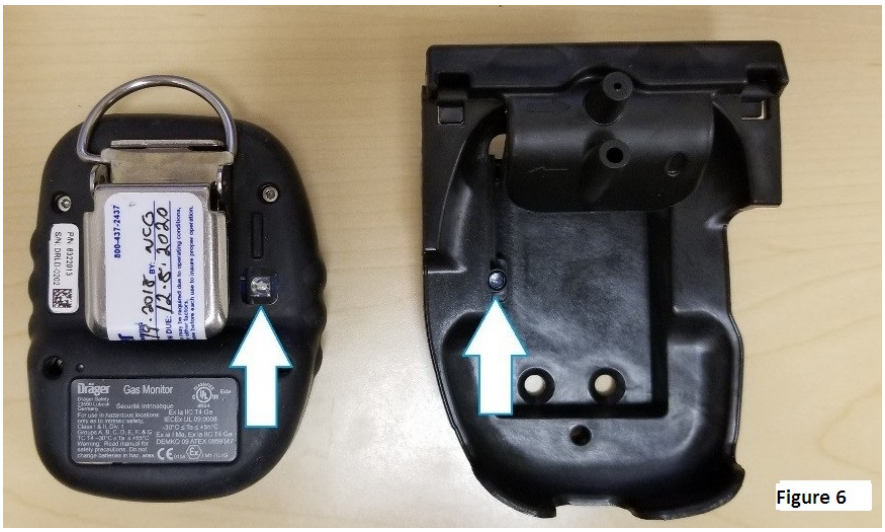


Figure 6

Figure 7. Back of module with monitor inserted

Figure 8. Front of module with monitor inserted

Figure 9. Receive data menu

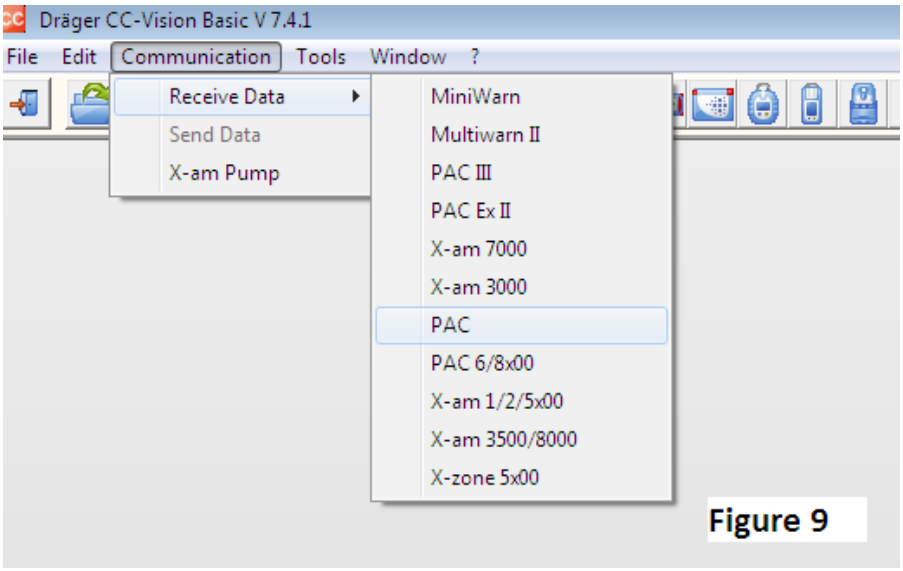


Figure 10. Receive data icon (PAC)

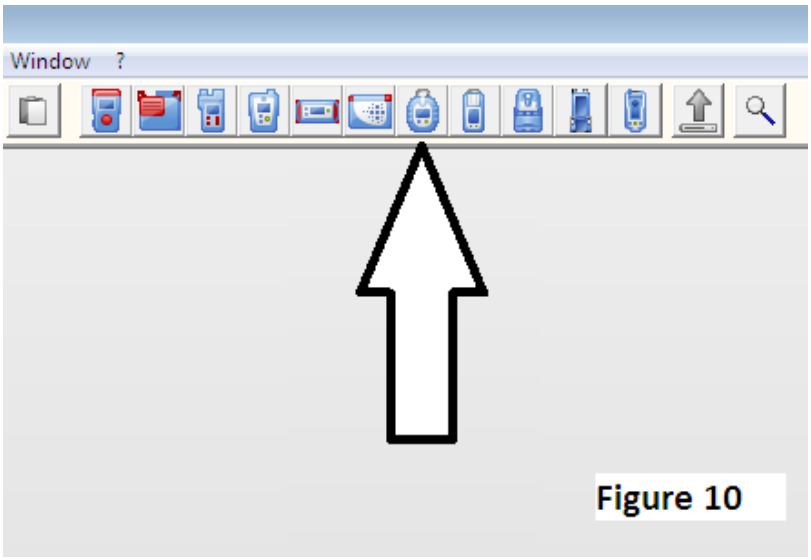


Figure 11. Instrument status

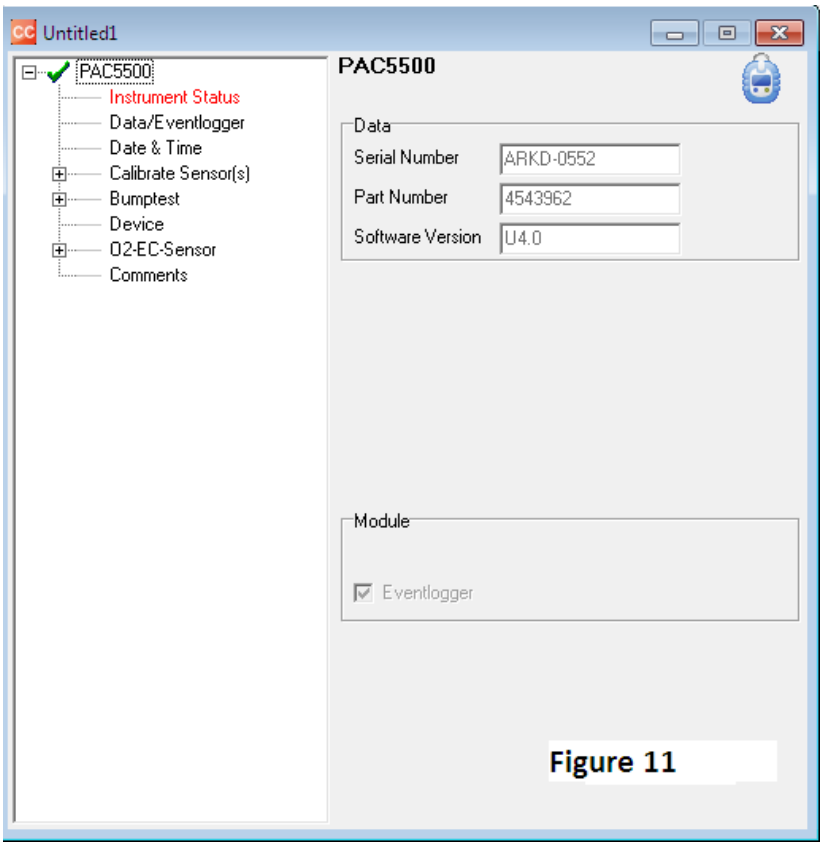


Figure 12. Faults and Warnings

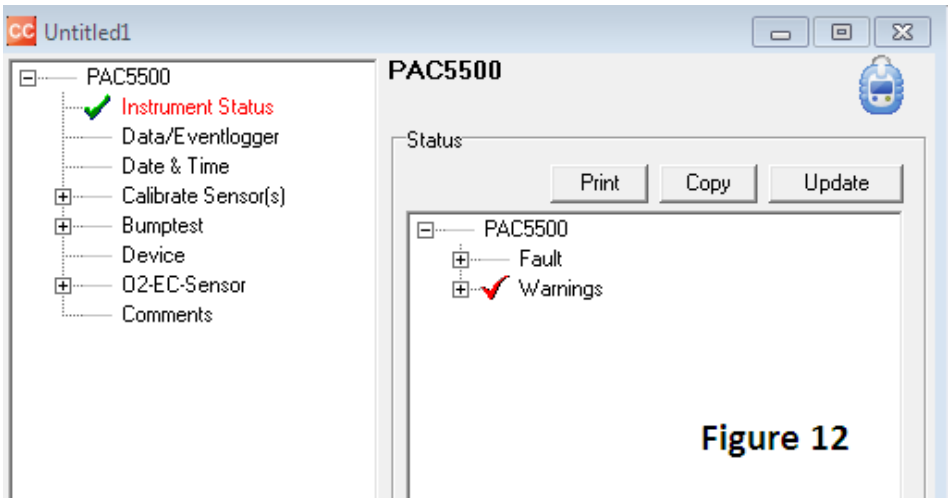


Figure 13. Warning tree expansion

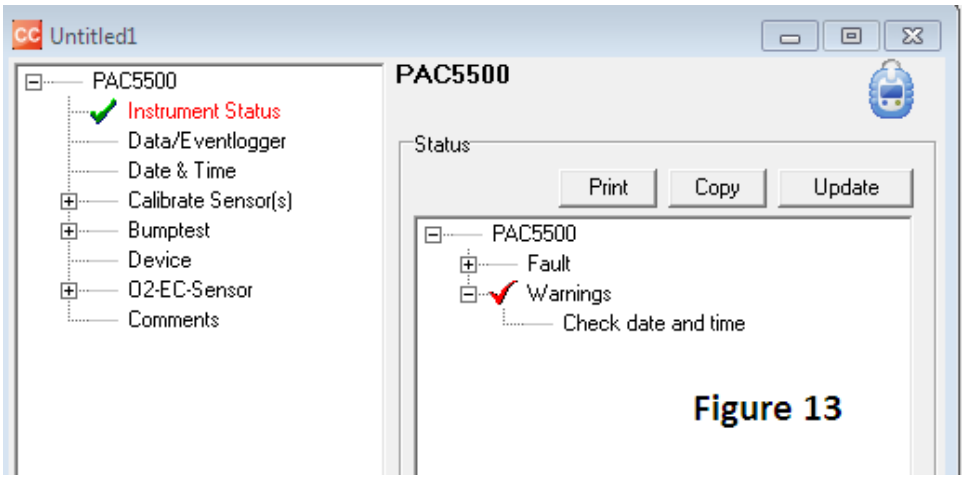


Figure 14. Warning resolved

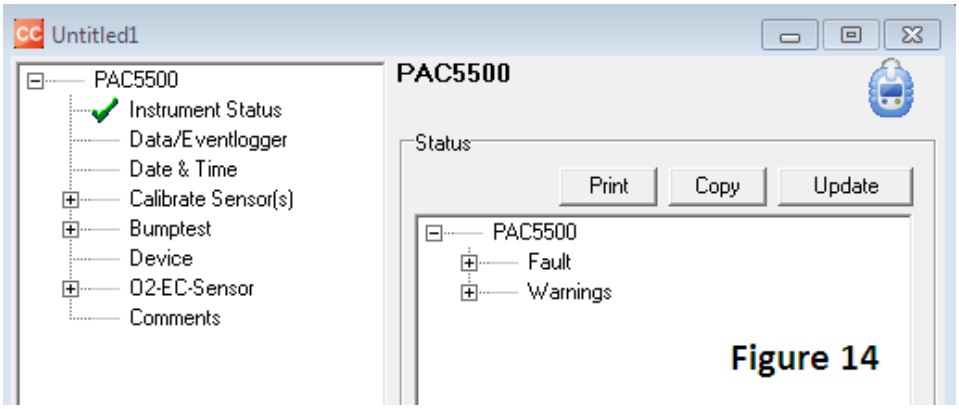
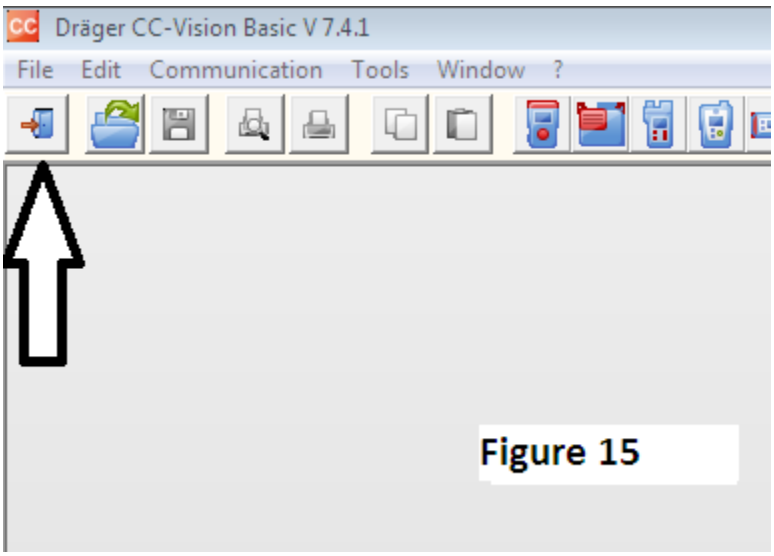


Figure 15. Exit CC-Vision



Collaborating Biobank Personnel (CBP) Training

Standard Operating Procedure (SOP) SF-3-15 for **Dräger Pac 5500 Personal O_2 Monitor**, defines the Indiana CTSI Specimen Storage Facility (SSF) procedures for using a Dräger Pac 5500 portable unit suitable to monitor oxygen level in the R3-C156 Liquid Nitrogen Freezer Room.

Personal O_2 monitors are utilized when entering the Liquid Nitrogen Freezer Room for personal safety measures, **because oxygen in the atmosphere may be displaced by nitrogen, thus creating an environment that is dangerously low in oxygen.**

The use of personal monitors along with the permanently installed devices serves two purposes:

(1) there is a high propensity for false alarms with low oxygen monitors and, if determined that the stationary models are in false alarm by appropriate safety personnel, the personal O_2 monitor may be used to manage that condition and still assure that personnel are not in an unsafe environment AND

(2) the stationary alarms are not in the immediate vicinity of the employee and, thus may not detect a pocket within the room that has a dangerously low oxygen level.

The personal O_2 alarms are pre-set to alarm at levels below 19.5% and above 23.5% O_2.

During Use, if the alarm is triggered due to a decrease of oxygen in the Liquid Nitrogen Room, immediately vacate the room.

1.1. SOP SF-2-2, LIQUID NITROGEN SYSTEM AND LIQUID NITROGEN FREEZER ROOM OPERATIONS, **defines when personnel are required to wear a personal O_2 monitor.**

1.2. **Before entering the R3-C156 Liquid Nitrogen room, retrieve a Dräger Pac 5500 personal O_2 monitor.**

1.2.1. The unit must be on. If no powered-on units are available, select a unit and **turn the unit on** per Section 1.1.1.2.

1.2.2. **Turn the Unit On by** pressing and holding the green OK button as the display counts down 3, 2, and 1. Proceed only when the following are confirmed:

A summary of these items is included in page 3 of this Appendix and posted with the personal O_2 monitors at the facility entrance.

1.2.2.1. The LED, Audible Alarm and the Vibrating Alarm activates in respective sequence.

1.2.2.2. The Audible and Vibrating Alarm levels display.

1.2.2.3. A countdown of approximately 1 minute has been completed and the notification icon [!] is no longer lit. (The O_2 sensor needs approximately 1 minute warm up time for every activation.)

1.2.2.3.1. The low battery icon is not flashing.

1.2.2.3.2. The % Vol of O_2 displays and is greater than 19.5% and less than 23.5%.

1.2.2.3.3. If the unit does not meet these criteria, notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.

1.2.3. ***Confirm the unit is displaying an O_2 value between 19.5% and 23.5%.*** Normal room air averages ~20.9% oxygen.

1.2.4. **Confirm the notification icon [!] is not displayed.**

1.2.5. **Confirm the low battery icon is not flashing.**

1.2.6. The monitor should look like this picture, with *an O_2 value between 19.5% and 23.5%.*

1.2.7. Clip personal O_2 monitor onto clothes so as to not obstruct the monitor's air intake before entering the C156 Liquid Nitrogen Room.

1.2.8. After exiting the Liquid Nitrogen Freezer Room, remove from clothing and return to storage area.

1.2.9. *DO NOT turn off personal O_2 monitors during the workday*, however if needed after hours, shut down instructions are as follows:

1.2.9.1. Press and hold the green OK button and the blue + button simultaneously.

1.2.9.2. Observe for the following:

1.2.9.2.1. The display counts down 3, 2, and 1.

1.2.9.2.2. The LED and Audible Alarm activate momentarily.

1.2.9.2.3. The display becomes blank.

1.2.10. If the unit fails to perform as described above, notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.

1.3. **Alarms**

1.3.1. Follow Personal O_2 Monitor Alarms and Stationary Alarms Response directives in SOP SF-2-2: Liquid Nitrogen System and Liquid Nitrogen Freezer Room Operations.

1.3.2. Please note: A personal O_2 monitor will sometimes alarm for the reasons listed below. **If these reasons listed below are not applicable or if the wearer is unable to immediately determine applicability, vacate the LN_2 room.**

1.3.2.1. The monitor has been engulfed by LN_2 vapor (e.g. a monitor suspended from around the neck which accidently descends into an LN_2 freezer will cause an alarm)

1.3.2.2. The monitor's gas opening has been obstructed, likely by placing the monitor in a pocket.

1.3.2.3. The wearer is exhaling into the gas opening.

1.3.3. Relocating to another area in the room and readjusting the monitor's position on the wearer's person will ensure that the monitor is cleared of the temporary issue.

1.3.4. If an O_2 monitor is deemed faulty, notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.

1.4. Components of the Dräger Pac 5500 Personal O_2 Monitor for Collaborating Biobank Personnel (1 Page) are displayed on page 4 of this Appendix and posted with the Dräger Pac 5500 O_2 monitors for

Collaborating Biobank Personnel (CBP) reference at the R3-C156 Liquid Nitrogen Freezer Room entrance.

1.5. If you have concerns about an O_2 Monitor's Functionality, notify SSF Management and bring the affected monitor to SSF Management Office, R3-C153, until the issue can be investigated and resolved.

Components of the Dräger Pac 5500 Personal O_2 Monitor for Collaborating Biobank Personnel

Before use:

- Confirm the monitor is displaying an O_2 value between 19.5% and 23.5%.
  - Normal room air averages 20.9% oxygen.
- Confirm the notification icon [!] is not displayed.
- Confirm the low battery icon is not flashing.
- If the above conditions are not met:
  - Bring the affected monitor to SSF Management Office, R3-C153, and
  - Select a different monitor for use.

During use:

- If the alarm is triggered due to a decrease of oxygen in the Liquid Nitrogen Room, immediately vacate the room.

1.0 LED

1.1 Illuminates when the monitor is in alarm

1.2 Visual alarm in dark or poorly lit conditions.

2.0 Audible Alarm

2.1 Horn responds when the monitor is in alarm.

3.0 Vibrating Alarm

3.1 Vibrates when the monitor is in alarm along with LED and Audible Alarms.

4.0 OK Button

4.1 Turns monitor On/Off.

4.2 Used to acknowledge alarms

5.0 + Button

5.1 Used to turn monitor off in conjunction with the OK button. *Monitor is NOT to be turned off during the workday.*

6.0 % Vol of O_2 Display Levels

6.1 During the activation sequence / warm-up period:

6.1.1 Alarm levels and the calibration interval are displayed

6.1.2 Countdown (in seconds) flashes

6.1.3 Notification icon [!] is displayed.

6.1.4 "-0-" is displayed for approximately 5 seconds.

6.2 After the activation sequence / warm-up period:

6.2.1 Oxygen level is displayed at all times when the monitor is in use.

6.2.2 The % Vol of O_2 is displayed and is greater than 19.5% and less than 23.5%.

6.2.3 The monitor is ready for use.

7.0 Gas Opening

7.1 The amount of oxygen available is measured through the gas opening