



INDIANA Clinical and Translational
Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR SENSIT P100 PERSONAL O₂ MONITOR

CHAPTER: 3-Equipment

SOP #: SF-3-03.02

SUPERSEDES SOP #: N/A

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DATE: 26 MAR 2024

QA APPROVAL: [Signature]
Quality Compliance Specialist

DATE: 04 Apr 2024

1. REVISION

1.1. Significant changes incorporated in this version include:

1.1.1. Throughout SOP, eliminated:

1.1.1.1. Specificity that Sensit monitors are utilized only at TK

1.1.1.2. Directives redundant to appendices

1.1.1.3. Directive that fresh air calibration completion is permitted in TK 258, which is not a normal O₂ environment

1.1.1.4. Specificity that non-functional units be removed to "management office". Non-functional equipment is "removed from in-service area" per SOP directives.

1.1.1.5. Directives requiring generating a new Appendix A annually (Appendix A revised accordingly)

1.1.1.6. Directives limiting documentation of bump testing and fresh air calibration

1.1.1.7. Overly-specific equipment specifications that can be obtained from the equipment manual

1.1.1.8. Document review directives redundant to Section 8

1.1.2. Corrected Section 3 principle defining purpose of using personal O₂ monitors.

1.1.3. Added dry ice to Materials List, Section 5

1.1.4. Added Section 6.1.4 directive defining that O₂ monitors are not shut down inside the LN₂ freezer room.

1.1.5. Sections 6.5.1, 6.5.2, & 6.5.3 significantly revised to align with Sensit procedure for calibration of new versus refurbished equipment; permit bump testing against dry ice vapor; direct completion of Level II calibration; and add alternate equipment shipment directives; and remove errant Section 6.5.2.1.1 bump testing directive.

1.1.6. Clarify directives defining span calibration due date in Step 6.5.1.3 and Section 6.5.2.4.2.

1.1.7. Added Sensit Technologies' website in Section 7

1.1.8. Appendix A revised to align with Section 6.5.1 revisions

1.1.9. Appendix B revised to:

- 1.1.9.1. Change name to align with other equipment SOPs (Section 9 revised accordingly)
- 1.1.9.2. Reconfigured to facilitate bump testing with dry ice
- 1.1.9.3. Add unit of measure to acceptance criteria
- 1.1.9.4. "Alarm Triggered in < 20 Seconds" completion and assessment of acceptance criteria consolidated into one column.
- 1.1.9.5. "Additional Bump Tests, As Needed" and "Additional Fresh Air Calibrations, As Needed" sections revised to remove "N/A" options; and consolidate "Other (define in comments section)" to "Other (define)"; and correct inconsistency in "O₂% Acceptable" header in "Additional Fresh Air Calibration, As Needed" section."
- 1.1.10. Appendix C & Appendix D revised to:
 - 1.1.10.1. Consolidate Appendix C and Appendix D Components of the Sensit P100 monitor Appendix/Postings into one Appendix/Posting, Appendix C.
 - 1.1.10.2. Directives streamlined to enhance compliance
 - 1.1.10.3. Define R3 Equipment Out of Service areas
- 1.1.11. Appendix D revised to:
 - 1.1.11.1. Remove CBP directives for fresh air calibration to improve the training process.
 - 1.1.11.2. Align with revisions in the SOP body, defined in this section.

2. PURPOSE

2.1. This Standard Operating Procedure (SOP) defines the procedures for using a Sensit P100 portable personal O₂ monitor unit in the Indiana CTSI Specimen Storage Facility (SSF) to monitor the oxygen level in the Liquid Nitrogen Freezer Rooms. 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 SSF Liquid Nitrogen Freezer Rooms. This procedure satisfies guidance set forth in ISBER.

3. PRINCIPLE

3.1. Personal O₂ monitors are utilized when entering the Liquid Nitrogen Freezer Room for personal safety measures. This is necessary 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) the personal O₂ monitor may be used to provide early detection of low oxygen in the immediate vicinity of personnel 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 O₂ alarms are pre-set to alarm at levels below 19.5% and above 23.5% O₂.

4. SCOPE

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

The M10 BiOS Room (TK 258) is outside the scope of SSF SOPs per IU Genetics Biobank (IUGB), with the exception of wall-mounted O₂ monitors and LN₂ operations.

5. MATERIALS


5.1. Personal O₂ Monitor – Sensit P100


5.2. Sensit P100 O₂ Manual Calibration Kit, which includes:

- 5.2.1. 100% Nitrogen Bottle, sourced from Sensit Technologies (99.9% Nitrogen acceptable) or other approved vendor
- 5.2.2. Regulator
- 5.2.3. Hose Assembly
- 5.2.4. P100 Adaptor
- 5.3. Cleaning Cloth
- 5.4. Dry ice

6. PROCEDURE

6.1. Use of the personal O₂ monitor: Refer to SOP SF-2-2 Liquid Nitrogen System and Liquid Nitrogen Freezer Room Operations for directives defining when personnel are required to wear a personal O₂ monitor.

- 6.1.1. Before entering the Liquid Nitrogen freezer room, retrieve a personal O₂ monitor. Select a unit that is on, if available.
 - 6.1.1.1. Confirm the unit is displaying an O₂ value between 19.5% and 23.5%. A typical value is ~20.9%.
 - 6.1.1.2. Confirm that no error codes are displayed (such as BAT, BAT + LO, I2C, and BAD).
 - 6.1.1.3. Documentation of these actions is not required.
 - 6.1.1.4. If the unit does not meet these criteria:
 - 6.1.1.4.1. Notify SSF Management and remove unit from the in-service area. If issue cannot be resolved, remove unit from service per Section 6.5.3.
 - 6.1.1.4.2. 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 the left On / Off  button.
 - 6.1.2.2. Proceed per Steps 6.1.1.1 – 6.1.1.3
 - 6.1.2.3. If the unit does not meet these criteria, Notify SSF Management and remove unit from the in-service area. If issue cannot be resolved, remove unit from service per Section 6.5.3.
 - 6.1.2.4. If the instrument is started up in an area that is not a normal-oxygen environment, error code “BAD” will illuminate after the automatic zeroing, followed by a reading based on factory zero set points.
 - 6.1.2.4.1. Confirm startup location is a normal oxygen environment (~20.9% per a wall-mounted O₂ monitor) or move to a normal oxygen environment.
 - TK 250 or R3-C158, near the wall-mounted O₂ monitor, are acceptable normal oxygen environment locations.
 - 6.1.2.4.2. Restart equipment per Section 6.1.2.1 up to two additional times in a normal oxygen environment.
 - 6.1.2.4.3. If error recurs near a wall-mounted O₂ monitor indicating normal oxygen environment, notify SSF Management and remove unit from the in-service area. If issue cannot be resolved, notify SSF Management and remove unit from service per Section 6.5.3.
- 6.1.3. Clip personal O₂ monitor onto clothes so as to not obstruct the monitor’s air intake before entering the Liquid Nitrogen freezer room.
- 6.1.4. P100 O₂ monitor batteries are designed to last for two years continuous use, therefore turning off the O₂ monitors is not required.

- 6.1.4.1. Do not shut down the personal O₂ monitor while inside the Liquid Nitrogen freezer room.
- 6.1.4.2. To shut down units:
 - 6.1.4.2.1. Press and hold the On / Off  button for 6 seconds. An audible clicking sound is emitted from the O₂ monitor as it shuts off.
 - 6.1.4.2.2. Observe that the display indicates “OFF”, then becomes blank.
 - 6.1.4.2.3. Return to storage area.
 - 6.1.4.2.4. If the unit fails to perform as described above, notify SSF Management and remove unit from the in-service area. If issue cannot be resolved, remove unit from service per Section 6.5.3.
- 6.1.5. Components of the Sensit P100 Personal O₂ Monitor (Appendix C) are posted with the Sensit P100 O₂ monitors for reference.

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 O₂ Monitor Alarms and Stationary Alarms.
- 6.2.2. Please note: A personal O₂ 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 LN₂ room.**
 - The monitor has been engulfed by LN₂ vapor (e.g. a monitor suspended from around the neck which accidentally descends into an LN₂ freezer will cause an alarm.)
 - The monitor’s gas sensor has been obstructed.
 - The wearer is exhaling into the gas sensor.
- 6.2.3. Relocating to another area in the room and readjusting the monitor’s position ensures that the monitor is cleared of the temporary issue.
- 6.2.4. If an O₂ monitor is deemed faulty, notify SSF Management and remove unit from the in-service area. If issue cannot be resolved, remove unit from service per Section 6.5.3.

6.3. Cleaning:

- 6.3.1. As needed, wipe surface of the device with a clean damp cloth.
 - Do not use abrasive cleaning agents, which may damage the optical lens.
 - Do not wipe the sensor or sounder which can be damaged by excess moisture.
- 6.3.2. Documentation of cleaning is not required.

6.4. Function Verification:

- 6.4.1. Perform Bump Test as directed per Section 6.5.2.1.2.

6.5. Management and Maintenance:

- 6.5.1. Upon receipt of new equipment and equipment returning after inspection / repair, record the following information on the SSF Sensit Personal O₂ Monitor Manufacturer Maintenance Log (Appendix A):
 - 6.5.1.1. For new equipment, document:
 - 6.5.1.1.1. Manufacturer Serial Number on a new Appendix A.
 - 6.5.1.1.2. Confirm receipt of a separate EU Declaration of Conformity (DoC) for each unit received.
 - 6.5.1.1.3. Record Calibration Date, defined as the “Date of Issue” recorded on the DoC.
 - 6.5.1.1.4. Confirm DoC includes at minimum:

- O₂ monitor serial number
 - Date of issue (calibration)
 - Span-calibration data, which must include:
 - Gas type (e.g. fresh air, O₂)
 - Concentration of calibration gas
 - Lot number of calibration gas
 - Successful Verification Checks, indicated by “PASS” and including at minimum:
 - Power-Up / Test Sequence
 - Alarm Level Category Selection
 - Push Button Function
 - Alarm Function: Visual / Audio / Vibration
- 6.5.1.2. For existing equipment returning from inspection / repair / calibration:
- 6.5.1.2.1. Confirm Manufacturer Serial Number on Appendix A, creating a new Appendix A as needed
- 6.5.1.2.2. Confirm receipt of a separate Certificate of Test and Conformity (CTC) for each unit returned.
- 6.5.1.2.3. Record Calibration Date, defined as the Date “Tested For Compliance” recorded on the CTC.
- 6.5.1.2.4. Confirm CTC includes at minimum:
- O₂ monitor serial number
 - Tested for compliance date (calibration)
 - Span-calibration data must include:
 - Gas type (e.g. fresh air, O₂)
 - Concentration of calibration gas
 - Lot number of calibration gas
 - As Received and As Returned data
 - Successful Final Inspection, indicated by “PASS”
- 6.5.1.3. Span-calibration due date, defined in Section 6.5.2.4
- 6.5.1.4. Perform Bump Test to ensure functionality per Section 6.5.2.1.2.
- 6.5.1.5. Date in Service, defined as the date Bump Test was performed successfully
- 6.5.1.6. File any documents produced by Sensit, including calibration test reports and service reports, in the Facility Manager’s office.
Submit the completed Appendix A to SSF Management for review.

6.5.2. Routine Maintenance

6.5.2.1. Bump Testing

6.5.2.1.1. User performs Bump Test:

- Any time there are concerns about the equipment
- At defined intervals at minimum and per Section 6.5.2.1.2:
 - Weekly,
 - After a unit is dropped or impacted, and
 - As directed following calibration

6.5.2.1.2. Perform Bump Test as follows, documenting results on Appendix B:

- 6.5.2.1.2.1. Turn monitor on, or ensure monitor is on, per Section 6.1.1 or 6.1.2.
- 6.5.2.1.2.2. Obtain dry ice or nitrogen gas cylinder sourced from Sensit Technologies or other approved vendor.

6.5.2.1.2.3. Bump Test Using nitrogen gas cylinder:

6.5.2.1.2.3.1. Record or confirm equipment and cylinder information on Appendix B, page 1.

- If a new Nitrogen gas cylinder or dry ice is utilized, create a new Appendix B as needed.

6.5.2.1.2.3.2. Prepare the approved Nitrogen gas cylinder, attaching the regulator as needed, with the P100 calibration adaptor attached to the regulator.



Gas Cylinder



Regulator



P100 Calibration Adaptor

6.5.2.1.2.3.3. Note the time, and apply gas to the sensor area using the P100 calibration adaptor.

6.5.2.1.2.3.4. Proceed per Steps 6.5.2.1.2.5 – 6.5.2.1.2.8.

6.5.2.1.2.4. Bump Testing Using Dry Ice:

6.5.2.1.2.4.1. On Appendix B, page 1, record or confirm equipment serial number. Check box next to Gas Cylinder Data N/A or confirm box already checked.

- If testing method changes to Nitrogen gas cylinder, create a new Appendix B as needed.

6.5.2.1.2.4.2. Note the time, and expose the personal O₂ monitor sensor area to dry ice vapor.

6.5.2.1.2.4.3. DO NOT expose personal O₂ monitor to dry ice temperatures.

6.5.2.1.2.4.4. Proceed per Steps 6.5.2.1.2.5 – 6.5.2.1.2.8.

6.5.2.1.2.5. Monitor for audible and vibrating alarm, which should occur in less than 20 seconds, and document results.

6.5.2.1.2.6. Confirm O₂ monitor returns to normal range (19.5% - 23.5% O₂) and stops alarming following removal from test gas.

- 6.5.2.1.2.7. Document O₂ level reported by the monitor following the Bump Test.
- 6.5.2.1.2.7.1. If the unit does not meet acceptance criteria or stop alarming after Bump Test, repeat Bump Test.
- 6.5.2.1.2.7.2. If Bump Test fails, repeat using alternate test gas (e.g. another Nitrogen gas cylinder, or dry ice.)
- Create a new Appendix B for the alternate test gas as needed.
 - If alternate test gas is unavailable, proceed to Step 6.5.2.1.2.7.3.
- 6.5.2.1.2.7.3. If testing fails, fresh air calibrate per Section 6.5.2.2.3 and repeat Bump Test.
- 6.5.2.1.2.7.4. If bump testing and fresh air testing fail, notify SSF Management and remove unit from the in-service area. If issue cannot be resolved, remove unit from service per Section 6.5.3.
- 6.5.2.1.2.8. Monthly and as needed, initiate a new copy of Appendix B.

6.5.2.2. Fresh Air Calibration

- 6.5.2.2.1. Sensit P100 O₂ monitors autozero to fresh air when powered on and via the procedure defined in Section 6.5.2.2.3.
- 6.5.2.2.2. User performs Fresh Air Calibration:
- Any time there are concerns about the equipment
 - At defined intervals at minimum and per Section 6.5.2.2.3:
 - Weekly,
 - After a unit is dropped or impacted
- 6.5.2.2.3. Perform Fresh Air Calibration as follows, documenting actions on Appendix B, page 2:
- 6.5.2.2.3.1. In a Normal Oxygen Environment:
- ~20.9% per a wall-mounted O₂ monitor
 - TK 250 and R3-C158, next to the wall-mounted O₂ monitor
- 6.5.2.2.3.2. Press the Zero button for 2-3 seconds and release the Zero button.
- 6.5.2.2.3.3. All segments of the display flash.
- 6.5.2.2.3.4. The working display, including the current O₂ level, is displayed.
- 6.5.2.2.3.5. If equipment is showing an atypical O₂ level before or after fresh air calibration (e.g., a reading consistently below 20.5% O₂ or above 21.2% O₂), repeat calibration up to 2 additional times in a normal oxygen environment.
- 6.5.2.2.3.6. If calibration fails, notify SSF Management and remove unit from the in-service area.

- 6.5.2.2.3.7. If issue cannot be resolved, remove unit from service per Section 6.5.3.
- 6.5.2.2.4. Monthly, and as needed, initiate a new copy of Appendix B.
- 6.5.2.3. Low battery:
- 6.5.2.3.1. Sensit P100 sensors and batteries are designed for 2 years of continuous normal use.
- 6.5.2.3.2. Factory-trained personnel perform all internal servicing, including battery replacement.
- Upon obtaining a “BAT” or “BAT + LO” code, remove unit from service and send to Sensit for battery replacement per Section 6.5.3.2.
 - Request sensor evaluation at battery replacement.
- 6.5.2.4. Sensit Span Calibration
- 6.5.2.4.1. Sensit span-calibrates new equipment and re-calibrates equipment following repair, however Sensit does not issue a calibration due date nor document a calibration due date on their Sensit EU DoC and CTC calibration documentation.
- 6.5.2.4.2. SSF assigns a Span Calibration due date, defined as two years from date of issue on DoC or CTC.
- 6.5.2.4.3. Ship equipment to Sensit for span calibration biennially (every two years), at minimum, per the units’ Scan Calibration due date and Section 6.5.3.2.
- 6.5.3. Non-Routine Maintenance
- 6.5.3.1. Non-Routine Maintenance by Sensit
- Error code “I2C” indicates a communication error in the EEPROM. Service is required.
 - Remove unit to be inspected from service, per Section 6.5.3.2.
- 6.5.3.2. For Sensit inspections, repair, and calibration:
- 6.5.3.2.1. Complete a Sensit Authorization for Service form, saved on the SSF Shared drive.
- 6.5.3.2.1.1. Select Calibration Certificate Needed in the Payment Section.
- 6.5.3.2.1.2. In the Product Information comments section, request:
- Inspection, refurbishment, repair as needed
 - Level II Calibration, which provides As Received data, As Returned data, and indication of Final Inspection.
 - Calibration gas concentration and lot number
 - A separate CTC for each unit shipped for inspection / repair /calibration
- 6.5.3.2.2. Alternately, order inspection, repair, or calibration as directed on the Sensit Technologies’ website.
- 6.5.3.2.3. Remove unit to be repaired/inspected from service, documenting on Appendix A the date out of service and reason.
- 6.5.3.2.4. Submit the completed Appendix A to SSF Management for review.
- 6.5.3.2.5. Post signage in storage area indicating that X unit(s) are out of service.

- 6.5.3.2.6. Clean the surface of the unit per Section 6.3.
- 6.5.3.2.7. Ship the equipment and Authorization form to Sensit Technologies.
- 6.5.3.2.8. Upon receipt, intake equipment per Section 6.5.1.

7. REFERENCES

- 7.1 ISBER Best Practices (current version)
- 7.2 International Safety Equipment Association
- 7.3 Sensit P100 Personal O₂ Monitor Operations Manual
- 7.4 Sensit Technologies
 - Customer service: (888) 473-6748
 - 851 Transport Drive, Valparaiso, IN 46383
 - www.gasleaksensors.com
- 7.5 Definition: Bump Testing is a qualitative check in which the sensors are exposed to challenge gas for a time and at a concentration to activate all of the alarms to at least the lower alarm settings. The test confirms that the gas is capable of reaching the sensors, that when they are exposed to gas, the sensors respond, the response time (time to alarm) after gas is applied is within normal limits, and that the alarms are activated and function properly.

8. DOCUMENTATION

- 8.1. Maintenance logs are 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 O₂ monitor are maintained per SF-1-6.
- 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 – Sensit P100 Personal O₂ Monitor Manufacturer Maintenance Log (1 Page)
 - APPENDIX B – Sensit P100 Personal O₂ Monitor Maintenance Log: Bump Test / Fresh Air Calibration (2 Pages)
 - APPENDIX C – Components of the Sensit P100 Personal O₂ Monitor (1 Page)
 - APPENDIX D – Collaborating Biobank Personnel (CBP) Training (4 Pages)

10. COLLABORATING BIOBANK PERSONNEL (CBP) TRAINING DIRECTIVES

- 10.1. CBP comply with Read and Understand training on SF-3-03, SOP for Sensit P100 Personal O₂ Monitor, by reading Collaborating Biobank Personnel (CBP) Training Appendix D of this SOP.
- 10.2. CBP comply with directives defined in Appendix D.

Sensit P100 Personal O₂ Monitor Manufacturer Maintenance Log			
Unit Serial Number		Page	of

New Equipment / Returned Equipment Log						
Calibration Date	DoC / CTC Service Documents Filed <i>(Y or N)</i>	Span Calibration Due Date	Bump Test Completed <i>(Y or N)</i>	Date in Service	Initials / Date	Management Reviewed <i>(Initials / Date)</i>

Date out of Service	Reason for Maintenance Request	Initials / Date	Management Reviewed <i>(Initials / Date)</i>

Comments

Month / Year:					
Sensit P100 Personal O₂ Monitor Maintenance Log: Bump Test					
O ₂ Monitor Serial Number:		Gas Cylinder Data N/A <input type="checkbox"/>			
<u>Gas Cylinder Data</u>		Cylinder #:		Initials / Date:	
Lot #:			Expiration Date:		
Weekly	Alarm Triggered in < 20 Seconds Y or N (<i>Acceptable Value = Y</i>)	Monitor Stops Alarming After Test Y or N (<i>Acceptable Value = Y</i>)	Sensit Monitor O ₂ % After Test (<i>record value, % O₂</i>)	Sensit Monitor O ₂ % Acceptable Y or N (<i>Acceptable Value = 19.5% - 23.5%</i>)	Completed (<i>Initials / Date</i>)
Week 1					
Week 2					
Week 3					
Week 4					
Week 5 <input type="checkbox"/> N/A					
Additional Bump Tests, As Needed	Alarm Triggered in < 20 Seconds Y or N (<i>Acceptable Value = Y</i>)	Monitor Stops Alarming After Test Y or N (<i>Acceptable Value = Y</i>)	Sensit Monitor O ₂ % After Test (<i>record value, % O₂</i>)	Sensit Monitor O ₂ % Acceptable Y or N (<i>Acceptable Value = 19.5% - 23.5%</i>)	Completed (<i>Initials / Date</i>)
<input type="checkbox"/> Following Calibration <input type="checkbox"/> Dropped / Impacted <input type="checkbox"/> Other (define)					
<input type="checkbox"/> Following Calibration <input type="checkbox"/> Dropped / Impacted <input type="checkbox"/> Other (define)					
Comments					
Reviewed By / Date:					

Sensit P100 Personal O₂ Monitor Maintenance Log: Fresh Air Calibration				
O ₂ Monitor Serial Number:		Month / Year:		
Weekly	Calibration Completed Y or N (Acceptable Value = Y)	Sensit Monitor O ₂ % (<i>record value, % O₂</i>)	Sensit Monitor O ₂ % Acceptable Y or N (<i>Acceptable Value = 19.5% - 23.5%</i>)	Completed (<i>Initials / Date</i>)
Week 1				
Week 2				
Week 3				
Week 4				
Week 5 <input type="checkbox"/> N/A				
Additional Fresh Air Calibration, As Needed	Calibration Completed Y or N (Acceptable Value = Y)	Sensit Monitor O ₂ % (<i>record value, % O₂</i>)	Sensit Monitor O ₂ % Acceptable Y or N (<i>Acceptable Value = 19.5% - 23.5%</i>)	Completed (<i>Initials / Date</i>)
<input type="checkbox"/> Dropped / Impacted <input type="checkbox"/> Other (define)				
<input type="checkbox"/> Dropped / Impacted <input type="checkbox"/> Other (define)				
<input type="checkbox"/> Dropped / Impacted <input type="checkbox"/> Other (define)				
Comments				
Reviewed By / Date:				

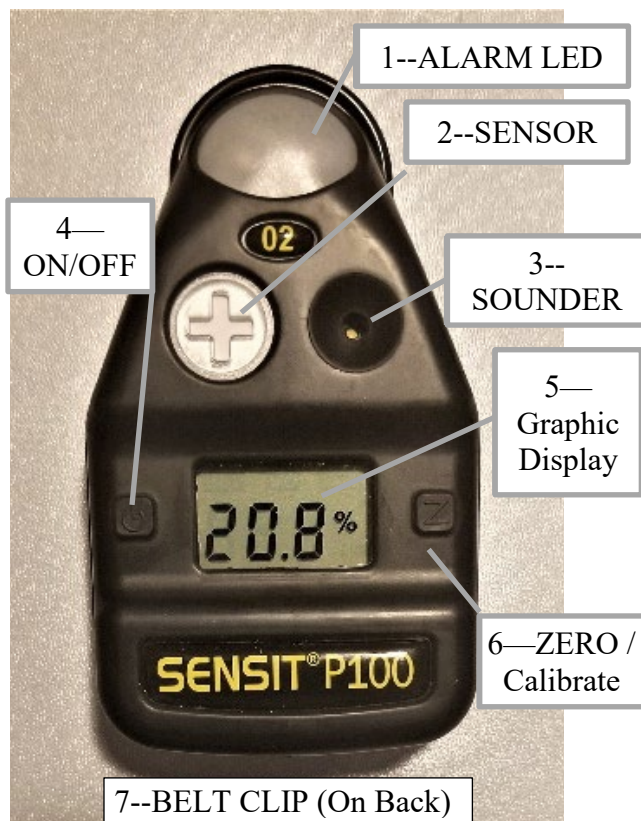
Components of the Sensit P100 Personal O₂ Monitor

Before use:

- Note: Oxygen level in the O₂ monitor's vicinity is displayed at all times when the monitor is in use.
- Confirm the monitor is displaying an O₂ value between 19.5% and 23.5%.
- Confirm that NO error codes are displayed.
- If the above conditions are not met:
 - Place the affected monitor in the "Equipment Out of Service Area":
 - *Indicated by an Equipment Out of Service sign*
 - R3 C158A - On the SSF bench in the R3-C158A lab, which is adjacent to the LN₂ freezer room, R3-C156
 - R3 C158B - In the SSF's technician office (R3-C158B)
 - TK 250 – On the northern bench in TK 250, near the sink
 - Select a different monitor for use
 - Notify SSF Management at ictsissf@iupui.edu

During use:

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



1. ALARM LED

- Flashes when the monitor alarms
- Provides visual alarm in dark or poorly lit conditions

2. SENSOR - Measures amount of oxygen available through the gas opening

3. SOUNDER - Audible Alarm horn sounds when monitor alarms

**** VIBRATING ALARM** - Vibrates when monitor alarms, along with LED and Audible Alarms

4. On / Off Button - Turns monitor On and Off

5. GRAPHIC DISPLAY

- O₂ level displayed at all times while in use
- At start-up, the Unit:
 - Displays programming data
 - Alarm Sounds, Illuminates, and Vibrates
 - Low (LO) / high (HI) alarm levels display
 - Zeroes to fresh air

6. Zero / Calibrate Button - Used by SSF to initiate calibration

7. Belt Clip - Attach instrument to the outermost garment as close to your head/face as practical.

Collaborating Biobank Personnel (CBP) Training

Standard Operating Procedure (SOP) SF-3-03 for **Sensit P100 Personal O₂ Monitor** defines the Indiana CTSI Specimen Storage Facility (SSF) procedures for using a Sensit P100 portable personal O₂ monitor unit suitable to monitor oxygen level in the Liquid Nitrogen (LN₂) Freezer Rooms.


Personal O₂ monitors are utilized in the LN₂ Freezer Room for personal safety measures:

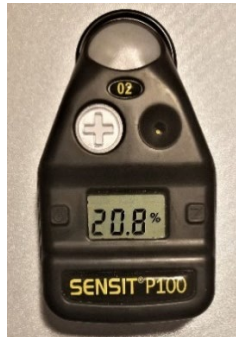
1. **Because oxygen in the atmosphere may be displaced by nitrogen, thus creating an environment that is dangerously low in oxygen**
2. To provide early detection of low oxygen in the immediate vicinity of personnel
3. Because stationary, wall-mounted oxygen monitors are NOT in the immediate vicinity of the employee and thus may not detect a pocket within the room that has a dangerously low oxygen level

Personal O₂ monitor units are pre-set to alarm at levels below 19.5% and above 23.5% O₂.

The IU Genetics Biobank (IUGB) M10 BiOS Room at TK 258 is outside the scope of SSF SOPs. IUGB has their own procedures for safely accessing TK 258.

If alarm is triggered due to oxygen decrease in the LN₂ Room, immediately vacate the room.

1. SOP SF-2-2, Liquid Nitrogen System And Liquid Nitrogen Freezer Room Operations, defines when personnel are required to wear a personal O₂ monitor.
2. **Before entering the Liquid Nitrogen Freezer Room, retrieve a personal O₂ monitor.**
 - 2.1. The unit must be on.
 - If no powered-on units are available, select a unit and **Turn the Unit On** by pressing the left On / Off  button, AND proceeding only when:
 - *The unit is displaying an O₂ value between 19.5% and 23.5%.*
(A typical value is ~20.9%.)
 - NO Error Codes are displayed on the monitor (such as BAT, BAT + LO, I2C, and BAD).
 - 2.2. The monitor should look like this picture, with an O₂ value between 19.5% and 23.5% & NO error codes



2.3. If the unit does not meet these criteria:

- 2.3.1. Place the affected monitor in the “Equipment Out of Service Area” until issue can be resolved.

- 2.3.2. Equipment out of service areas are *Indicated by an Equipment Out of Service sign* and located at:
- R3 C158A - On the SSF bench in the R3-C158A lab, which is adjacent to the LN₂ freezer room, R3-C156
 - R3 C158B - In the SSF's technician office (R3-C158B)
 - TK 250 – On the northern bench in TK 250, near the sink

2.3.3. Select a different unit for use by repeating Steps 2.1 – 2.3.

2.3.4. Notify SSF at ictsissf@iupui.edu.

2.3.5. **DO NOT USE** an O₂ monitor found in the *Equipment Out of Service Area*

2.4. Before entering the LN₂ Freezer Room, clip personal O₂ monitor onto clothes:

- So as to not obstruct the monitor's air intake
- As close to your head/face as possible

2.5. After exiting the LN₂ Freezer Room, return personal O₂ monitor to storage area.

2.6. Do not turn off the personal O₂ monitor.

3. Alarms

3.1. Follow directives in SOP SF-2-2: LN₂ System And LN₂ Freezer Room Operations for response to Personal O₂ Monitor Alarms and Stationary O₂ Monitor Alarms.

- The personal O₂ monitor will AUTOMATICALLY exit alarm condition and stop audible alarming once O₂ levels surrounding the personal O₂ monitor have returned to 19.5% or above.

3.2. A personal O₂ monitor alarms for the following reasons:

- The monitor has been engulfed by LN₂ vapor
 - E.g. A monitor suspended from around the neck descends into an LN₂ freezer.
- The monitor's gas sensor has been obstructed
 - E.g. Wearer places O₂ monitor in lab coat pocket.
- The wearer is exhaling into the gas sensor.

3.3. Relocate to another area in the room (away from a visible nitrogen source), and readjust the monitor's position per Section 2.4 to ensure (1) optimal accuracy and functionality of the personal O₂ monitor and (2) personal safety.

3.4. If personal O₂ monitor is deemed faulty, place the affected monitor in the "Equipment Out of Service Area" (per Section 2.3) until the issue can be investigated and resolved.

3.5. Notify SSF at ictsissf@iupui.edu.

3.6. **DO NOT USE** a personal O₂ monitor found in the *Equipment Out of Service Area*.

4. O₂ Monitor Functionality Concerns and Issues

- If a personal O₂ monitor is dropped or impacted **OR** you have concerns about a personal O₂ Monitor's Functionality:
 - Place the affected monitor in the "Equipment Out of Service Area" (per Section 2.3), and
 - Notify SSF at ictsissf@iupui.edu that the monitor requires evaluation.

5. Additional Appendix Requiring Review:

- Appendix C: Components of the Sensit P100 Personal O₂ Monitor (1 Page) defines components of the Sensit P100 Personal O₂ Monitors.
 - Appendix C is posted at the LN₂ Freezer Room entrance