Test Plan

Phase 4 of Medical Concentrator Assessment Project

Voltage Supply to Oxygen Concentrators

For Use by LabTest Certification

Rev01

2024-02-27

NOTE: This test plan and set of test protocols is to be reviewed and adjusted as required by appropriate LabTest Certification personnel to ensure safety. Appropriate LabTest Certification personnel are to determine the equipment set up that ensures safe operation and accurate results.

The **PURPOSE** of this high-level test plan is to provide LabTest Certification with information that allows them to write detailed Test Procedures and design a test equipment setup that will be safe and accurate.

The below tests are to be performed on O2 concentrator models supplied by DT Global specifically for Voltage Supply Testing.

Sequence of Tests

Surge Voltage testing will be performed on concentrators straight from the shipping box without any modifications. (After Surge Voltage testing these concentrators will be used for Repairability assessment.)

The other three tests will be performed in the environmental chamber after completion of Performance testing. For clarity, the performance tests and the other three voltage tests listed below will be performed on a different copy of the concentrator model.

The order of the tests will be:

1. Low Supply Voltage
2. High Supply Voltage
3. Voltage Withstand

For Discussion

- *I can't think of a reason why we need to perform the Low Supply Voltage, the High Supply Voltage and the Withstand Voltage tests prior to the in-chamber performance tests.*
    - ***o*** *Performing these three tests after performance testing may be more real world because concentrators that experience off spec supply voltages will probably have been operating for some time as opposed to be straight out of the box. Thoughts?*
- *I am less sure about the Surge Voltage Tests. My concern is not sequencing after the Performance tests. My concern is that we should perform the Surge Voltage test before we modify the ON/Off switch wiring? Is this concern valid?*
- *Question:* ***Michael****, In Phase 3, Did we perform surge voltage tests after or before the on/off switch wiring was modified?*

1. Surge Voltage Immunity Test

This test uses a new unmodified concentrator.

At each test point, note any changes to the below parameters after each injection.

- Product flow of 10 lpm as indicated on the concentrator's rotameter.
- Product O2% alarm status.
- Supply current (amps) to O2 concentrator.
- Occurrence of unexpected/strange noises or smells.

1.1. Operate at normal voltage supply (230 VAC/50 Hz) for 15 minutes at 10 lpm to ensure normal operation is acceptable.

1.2. Apply Surge Voltages of 500 VAC

- Line to Neutral - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Line to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Wait 3 mins and check operation of concentrator.
- Line to Neutral – Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Line to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Wait 3 minutes to cool components.
- Turn concentrator off with power switch on front panel, Wait 60 secs, Turn power on, Wait until concentrator has completed startup sequence and is operating stability. Note if the concentrator does not start up in the normal manner.

1.3. Apply Surge Voltage of 1,000 VAC

- Line to Neutral - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Line to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Wait 3 mins and check operation of concentrator.
- Line to Neutral – Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Line to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Wait 3 minutes to cool components.
- Turn concentrator off with power switch on front panel, Wait 60 secs, Turn power on, Wait until concentrator has completed startup sequence and is operating stability. Note if the concentrator does not start up in the normal manner.

1.4. Apply Surge Voltage of 1,500 VAC

- Line to Neutral - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Line to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Wait 3 mins and check operation of concentrator.
- Line to Neutral – Negative peak at 270°, 2 injections. Wait 1 minute between injections.

- Line to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Wait 3 minutes to cool components.
- Turn concentrator off with power switch on front panel, Wait 60 secs, Turn power on, Wait until concentrator has completed startup sequence and is operating stability. Note if the concentrator does not start up in the normal manner.

1.5. Apply Surge Voltage of 2,000 VAC

- Line to Neutral - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Line to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Positive peak at 90°, 2 injections. Wait 1 minute between injections.
- Wait 3 mins and check operation of concentrator.
- Line to Neutral – Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Line to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Neutral to Ground - Negative peak at 270°, 2 injections. Wait 1 minute between injections.
- Wait 3 minutes to cool components.
- Turn concentrator off with power switch on front panel, Wait 60 secs, Turn power on, Wait until concentrator has completed startup sequence and is operating stability. Note if the concentrator does not start up in the normal manner.

1.6. Operate at normal voltage supply (230 VAC/50 Hz) for 15 minutes at 10 lpm to ensure normal operation is acceptable.

NOTE: For concentrators with a ground line but no ground pin in the plug, LTC will install a ground pin. If there is no ground line the tests requiring a Ground Line will not be performed.

2. Low Supply Voltage Test

This test is performed in the environmental chamber after performance testing has been completed.

At each test point, note any changes to the below parameters after each injection.

- Product flow of 10 lpm as indicated on the concentrator's rotameter.
- Product O2% alarm status.
- Supply current (amps) to O2 concentrator.
- Occurrence of unexpected/strange noises or smells.

ATTENTION: Be prepared to stop the test if the device turns itself off, and more importantly if a motor stalls which will cause the current to increase dramatically. Hopefully motors would have included thermal protection. That would be something to ask the manufacturer.

Test Points:

2.1. Operate at normal voltage supply (230 VAC/50 Hz) for 15 minutes at 10 lpm to ensure normal operation is acceptable.
2.2. Reduce voltage to 220 VAC. Operate for 10 min.
2.3. Reduce voltage to 210 VAC. Operate for 10 min.
2.4. Reduce voltage to 200 VAC. Operate for 10 min.
2.5. Reduce voltage to 190 VAC. Operate for 10 min.
2.6. Reduce voltage to 180 VAC. Operate for 10 min.
2.7. Reduce voltage to 170 VAC. Operate for 10 min.
2.8. Reduce voltage to 160 VAC. Operate for 10 min.
2.9. Reduce voltage to 150 VAC. Operate for 10 min.
2.10. Increase voltage to 230 VAC. Operate for 10 min.

Proceed to High Supply Voltage Test

3. High Supply Voltage Test

This test is performed in the environmental chamber after Low Supply Voltage testing has been completed.

At each test point, note any changes to the below parameters after each injection.

- Product flow of 10 lpm as indicated on the concentrator's rotameter.
- Product O2% alarm status.
- Supply current (amps) to O2 concentrator.
- Occurrence of unexpected/strange noises or smells.

Test Points:

3.1. Operate at normal voltage supply (230 VAC/50 Hz) for 15 minutes at 10 lpm to ensure normal operation.
3.2. Increase voltage to 240 VAC. Operate for 10 min.
3.3. Increase voltage to 250 VAC. Operate for 10 min.
3.4. Increase voltage to 260 VAC. Operate for 10 min.
3.5. Increase voltage to 260 VAC. Operate for 10 min.
3.6. Increase voltage to 270 VAC. Operate for 10 min.
3.7. Increase voltage to 280 VAC. Operate for 10 min.
3.8. Increase voltage to 290 VAC. Operate for 10 min.
3.9. Increase voltage to 300 VAC. Operate for 10 min.
3.10. Reduce voltage to 230 VAC. Operate for 10 min.

For all concentrators that shutdown without obvious destructive event:

- Turn off, Immediately turn On. If it doesn't restart wait 10 minutes and try again. If it doesn't restart, try again as convenient until the next day when fully cool. Note observations.
- Check fuses and/or manual circuit breaker of any concentrator that does not restart.

Proceed to High Voltage Withstand Test.

4. High Voltage Withstand Test

This test is performed in the environmental chamber after High Supply Voltage testing has been completed. One concentrator is tested at a time.

At each test point, note any changes to the below parameters after each injection.

- Product flow of 10 lpm as indicated on the concentrator's rotameter.
- Product O2% alarm status.
- Supply current (amps) to O2 concentrator.
- Occurrence of unexpected/strange noises or smells.

4.1. Operate at normal voltage supply (230 VAC/50 Hz) for 15 minutes at 10 lpm to ensure normal operation.
4.2. Increase the voltage to 300 VAC. Hold for 10 minutes
4.3. Increase the voltage to 350 VAC. Hold for 10 minutes
4.4. Increase the voltage to 400 VAC. Hold for 10 minutes
4.5. Increase the voltage to 450 VAC. Hold for 10 minutes
4.6. Increase the voltage to 500 VAC. Hold for 10 minutes
4.7. Operate at normal voltage supply (230 VAC/50 Hz) for 15 minutes at 10 lpm to ensure normal operation.

For all concentrators that shutdown without obvious destructive event:

- Turn off, Immediately turn On. If it doesn't restart wait 10 minutes and try again. If it doesn't restart, try again as convenient until the next day when fully cool. Note observations.
- Check fuses and/or manual circuit breaker of any concentrator that does not restart.

Discussion Points:

1-The reason we included voltages up to 500 VAC in the Withstand Voltage testing was because of WHO/PQS/E007/VS01-VP.6 (Single-phase voltage protection for AC and DC powered refrigerators and freezers).

- *VS01-VP.6's Test 4: Electrical Withstand Test (Section 5.4.6) asks for 500 V to be maintained for 120 minutes.*
- *This standard is meant for "single-phase voltage stabilizers". It is NOT focused on the final product in use (e.g. an oxygen concentrator).*
- *We decided to test 50 V increments from 300 VAC up to and including 500 V for 10 min each (as opposed to the standard's 120 min) because:*
    - *WHO/PQS/E007/VS01-VP.6 tests at 500 V.*
    - *We believed such a test would give an indication of robustness above what is "required" in commercially available medical O2 concentrators.*
    - *The New Horizons' Voltage survey measured supply voltages as high as 507 V (but very rarely above 500 V, 8.1% of locations experienced voltages above 415 V).*

- *Someone (can't remember who) told us that there are people pushing to increase the standard for withstand voltage from 315 V to 500 V due to what various voltage surveys have measured.*

2- Nidek had this to say about the voltage withstand test: ISO standards require the device to operate at +10% / -15% of rated voltage. This device is rated at 220 volts and operates from 187 volts to 242volts. It has voltage surge protectors to handle transient voltages in excess of 500volts for milliseconds. It has a resettable circuit breaker on the front of the machine. We are not aware of any place in the world that has continuous voltage of 500 volts. (Brad B of ECRI: Not really a complaint as much as them saying "This seems excessive.")

Nidek may be correct in their statement about ISO standards, but we are trying to determine which commercial units are most robust to some of the real-world voltages observed.

3- Also on this topic, Rod Hinman (is one of the authors of the ISO standard) told us we may want to always approach the high voltages from 0V. (0 V 500 V as opposed to 450 V 500V) because a protection relay will stay off the whole time while in the latter case high voltage is applied to components briefly. We chose to step up and not start each voltage level from 0V so the test would take less time. We don't believe this will cause the results to be any less useful in assessing robustness in the real-world use.

END