**MPBE COVID-19 Rapid Technology Assessment Bulletin**

# AERTI AE Series Medical Oxygen Concentrator (AE-8-W)

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## About MPBE COVID-19 Rapid Technology Assessment Bulletins

As the COVID-19 emergency evolves, an increasingly wide range of technology is being offered for supply to hospitals and other healthcare providers. This technology extends beyond the standard and familiar medical technologies deployed in clinical settings. These 'new' technologies may be completely new innovations targeted at COVID-19, devices previously regarded as niche that are finding a role in COVID-19 applications, medical devices or models that have not been routinely used in Ireland, or consumer devices that have been adopted for COVID-19 applications. It is important that healthcare providers can quickly assess the suitability of these technologies for application in their environment.

The Dept. of Medical Physics and Bioengineering at St. James's Hospital, Dublin Ireland, has been providing a rapid COVID-19 technology assessment service to the hospital in order to quickly evaluate

specific technologies and innovations being considered for use in the hospital. Summaries of the evaluations are provided in short Bulletins highlighting the main findings. The Bulletins are intended to assist clinical and other staff assess suitability of the technology, and to highlight any important operational or other issues. These reviews are not presented as exhaustive assessments.

**Disclaimer:** Bulletins are provided outside St. James's Hospital to assist the wider health service and do not in any way amount to a recommendation of any specific provider, technology, machinery, software or otherwise. Furthermore, the Bulletins are providing a review of usage and are not suggestive as to suitability, transferability or advice. Assessments are considered with regard to the specific physical and clinical environment in St. James's Hospital and not all findings may be transferable. Assessments in these Bulletins focus on technical aspects; clinical efficacy, cost, legal and infection control issues are generally not in the scope of the technical reviews. As such, St James's Hospital accepts no liability whatsoever in relation to the issue and/or usage of any of the product(s) being reviewed in any particular Bulletin.

## 1. Device: *AERTI AE-W-8 Medical Oxygen Concentrator*

The device assessed is an **AERTI Medical Oxygen Concentrator** by *Shenyang Aerti Tech Co. Ltd.* - **Model:** *AERTI AE-W-8*.

## 2. Classification

The device is a CE marked medical device (Class IIa) providing 8 L/min oxygen supply (93%±3%) with a low oxygen concentration (<82%) alarm. All concentrators of this design must meet International Standards Organization (ISO) requirements (based on ISO 80601-2-69:2014, which supersedes EN ISO 8359:2009/A1:2012).

## 3. General Performance & Key Findings

MPBE assessed a sample of 2 (out of 50) Oxygen Concentrators, in terms of flowrate, oxygen concentration, and electrical safety. One of the two devices reviewed was faulty (faulty rotameter). Each device would need to be assessed for flowrate accuracy, $O_2$ concentration and low $O_2$ concentration alarm, and electrical safety at a minimum before being deployed.

**Accuracy**:
In general the device was found to be within specification for oxygen concentration (93±3°C) during lab tests, although the flowrate was outside of manufacturer's tolerance at settings below 5L/min. Clinical input may be needed on the impact of inaccuracies at flow rates below 5L/min if this inaccuracy is common across multiple devices. These inaccuracies at flow rates below 5L/min would need to be

considered by clinical teams, if this inaccuracy is consistent across multiple devices.

**Devices/Systems Controls:**
*Flowmeter:* The Flowmeter on the device does not stop the user adjusting flowrates above the stated maximum flow of 8L/min – which is outside the specification requirements of the ISO 80601-2-69:2014 standard – i.e. it shouldn't allow a rate higher than 8L/min. The implications of this are that the oxygen concentration level ($FiO_2$) will start to fall at a flowrate over 8L/min and will drop below the device output tolerance of 90%-96% $O_2$ concentration, and continue to drop below the 82% low concentration alarm on the device. If these devices are being deployed, training should reinforce that users don't set a value over 8L/min so as to avoid this undesirable drop in concentration. This shortcoming and its associated potential risks should be considered when deciding to use these devices.

*Low $O_2$ Concentration alarm:* on a the device tested, the low $O_2$ purity alarm was activated between 81%-87% concentration – this is outside of the tolerance set by the manufacturer (82%±3%). If consistent across multiple devices, this could result in alarms sounding before the 82% low purity threshold is reached as the $O_2$ concentration level is dropping from the 90%-96% range.

**Caveat:** at the time of publication, only two devices were tested – with one device having a faulty rotameter which couldn't be assessed for flowrate.

## 4. Other Technical & User Considerations

- **Electrical Safety:** Device is labelled as an electrical safety Class II B device. The two devices tested passed associated electrical safety tests. The devices have no battery backup.

- There is no obvious self-checking of the 'overheating alarm' or 'low oxygen concentration alarm'.

- **Rotameter/Flowmeter was faulty in one of the two devices** which didn't allow for any change in flow in that device – suggestive of mechanical damage. We recommend that a mechanical check of all devices purchased be carried out before deciding to deploy.

- **Maintenance**: A check for low $0_2$ output with a gas analyser should be performed annually if being deployed: checks every 12 months/5000 hours minimum as per WHO guidelines [1].

- The manufacturer recommends changing of **filters** after specific time limits (every 1,500 hours for the 'High Efficiency Filter') which would need to be assessed by Infection Prevention and Control.

- As per WHO [1] guidelines, "**documentation of conformance with the ISO standard** for oxygen concentrators and necessary regulatory approval(s) should always be requested from the manufacturer..". These **should be sought from the supplier to SJH**.

- **Further reviews** of these devices should be sought including Infection Prevention and Control. In particular, review would be needed of the humidifier bottle and inner tubing, nasal cannula, high efficiency filter and replacements, inlet filter and replacements, casing, storage, etc.

- **Clinical Facilitators/Training:**
    - If the units are being deployed, clinical training by facilitators should be made aware of the unreliability of the device over 8L/min and not to use a setting above this level since the $O_2$ concentration will drop below the tolerance level.
    - Facilitators would also need to be aware that the flow rates under 4 L/min are higher than the stated tolerance.

## 5. References

[1] World Health Organisation (2015) -Technical Specifications for Oxygen Concentrators. *WHO Medical Device Technical Series, ISBN 978 92 4 150988 6.*

**APPENDIX 1:**

| **Document Log** | | | |
|---|---|---|---|
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