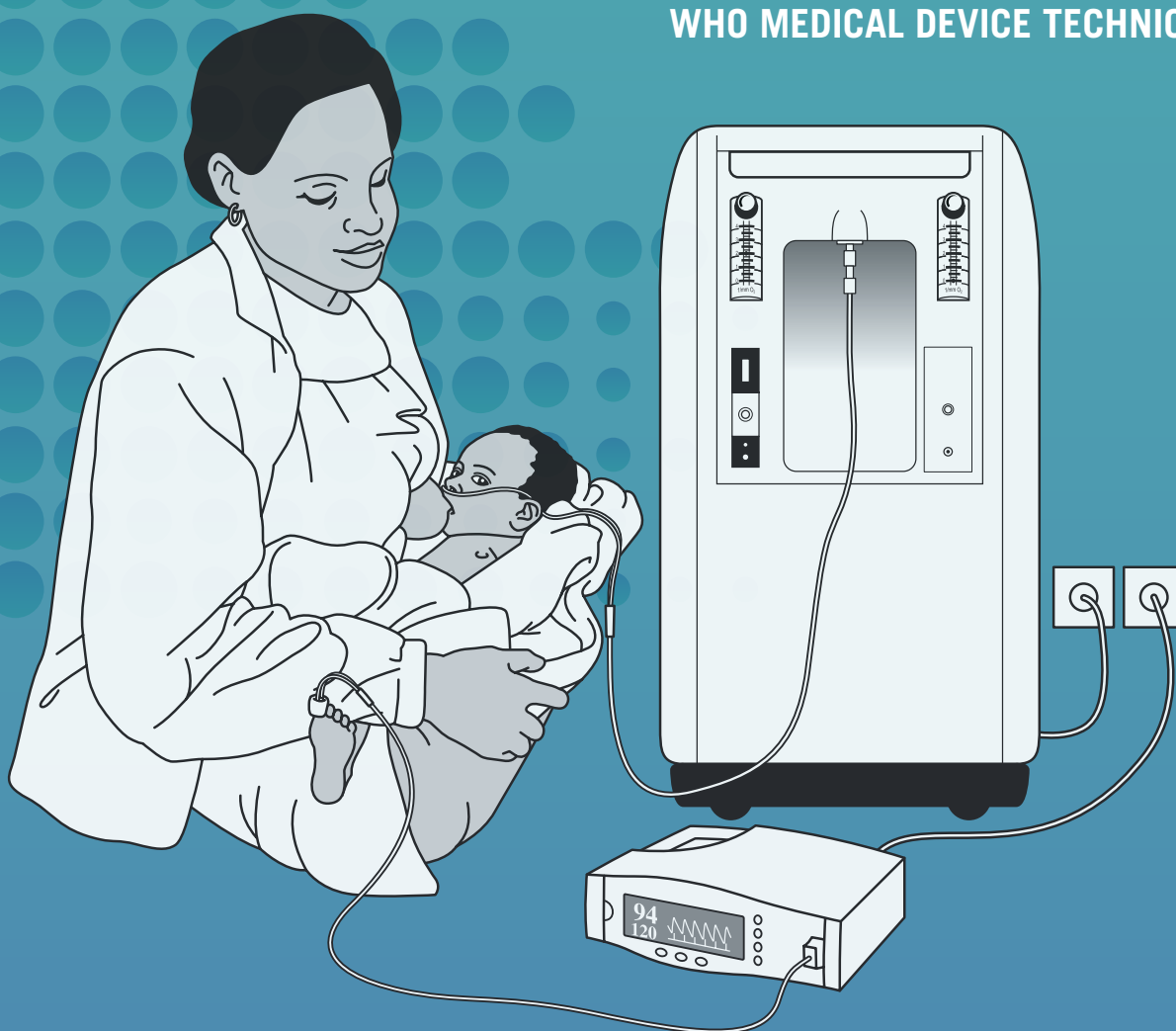


TECHNICAL SPECIFICATIONS FOR OXYGEN CONCENTRATORS

WHO MEDICAL DEVICE TECHNICAL SERIES



Technical specifications for oxygen concentrators

WHO Library Cataloguing-in-Publication Data

Technical specifications for oxygen concentrators.

(WHO Medical Device Technical Series)

1.Oxygen Inhalation Therapy – instrumentation. 2.Durable Medical Equipment – standards. 3.Equipment and Supplies. I.World Health Organization.

ISBN 978 92 4 150988 6

(NLM classification: WX 147)

© World Health Organization 2015

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Illustrations by: David Woodroffe [Illustrator], Patrick McKern [PATH]

Design & layout: L'IV Com Sàrl, Villars-sous-Yens, Switzerland.

Technical copy-editing: AvisAnne Julien

Contents

Acknowledgements	3
Abbreviations	5
Executive summary	6
1. Introduction	7
1.1 The role of oxygen concentrators	7
1.2 Hypoxaemia and the need for oxygen therapy	8
1.3 Background and scope of technical specifications	9
1.4 Purpose of the document	9
1.5 Intended audience for this document	10
2. Technical specifications for oxygen concentrators	11
2.1 Description	11
2.2 Technical specifications	13
2.2.1 Oxygen concentration	14
2.2.2 Flow control	14
2.2.3 Indicators and alarms	15
2.2.4 Outlets	15
2.2.5 Enclosure	16
2.2.6 Power	16
2.2.7 Documentation and compliance	17
2.3 Context-dependent considerations	17
2.3.1 Maximum flow output	17
2.3.2 Oxygen concentration output at higher altitudes	18
2.3.3 Humidification	18
2.3.4 Blended oxygen gas	18
3. Guidance regarding oxygen concentrator consumables, accessories and other related equipment	19
3.1 Importance of pulse oximetry	19
3.2 Patient delivery accessories	20
3.3 Patient delivery consumables	20
3.4 Accessories to divide flow to multiple patients	22
3.5 Supporting equipment during power failure	23
3.5.1 Oxygen cylinders	23
3.5.2 Power supplies and conditioning	23
3.6 Optional equipment for other applications of oxygen concentrators	25
3.6.1 Anaesthesia	25
3.6.2 Bubble CPAP	26
3.6.3 Nebulizers	26

4. Guidance for handling oxygen concentrators	27
4.1 Potential hazards	27
4.2 Installation	28
4.3 Training	29
4.4 Handling and use	29
4.5 Cleaning and decontamination	30
4.6 Maintenance	31
5. Procurement guidance for oxygen concentrators	34
5.1 Needs assessment	34
5.1.1 Define programme context	34
5.1.2 Forecast programme requirements	35
5.1.3 Customize the specifications	35
5.2 Programme planning	35
5.3 Procurement planning	36
5.4 Assessment of procurement options and procurement method	36
5.5 Manufacturers and warranties	37
5.6 Safety standards and regulatory approvals	38
5.7 Documentation	40
5.8 Manufacturer user and maintenance manuals	40
5.9 Consumables and spare parts	41
6. Areas for future research	43
Annex 1 Oxygen concentrator technical specifications	45
Annex 2 Examples of manufacturers of oxygen concentrators	49
Annex 3 Sample calculation of back-up energy requirement for an oxygen concentrator	52
Annex 4 Glossary	53
Annex 5 Research on access to oxygen therapy in low-resource settings (LRS) for the treatment of childhood pneumonia	54
References	57

Acknowledgements

Due to the concern over the lack of oxygen supplies in low- and middle-income countries, especially in regards to the treatment of childhood pneumonia, the development of this document was initiated. This document was prepared in line with other similar WHO medical device publications.

Grace Wu (PATH consultant) drafted the technical specifications document under the supervision and guidance of Adriana Velazquez Berumen of the World Health Organization (WHO) Department of Essential Medicines and Health Products, with additional input from Meena Cherian (WHO Department of Service Delivery and Safety), Shamim Qazi (WHO Department of Maternal, Newborn, Child and Adolescent Health [MCA]) and Wilson Were (WHO MCA). Additional preparation and draft-editing were provided by: Jaclyn Delarosa (PATH), Gene Saxon (PATH), Alec Wollen (PATH), Fay Venegas (PATH), John Ballenot (PATH), Glenn Austin (PATH), Stephen Himley (PATH consultant), Amy Ginsburg (PATH) and Darin Zehrung (PATH).

This document builds primarily on the outcomes of a meeting of subject-matter experts in oxygen concentrators, organized by PATH and the Bill & Melinda Gates Foundation in Seattle on 13–14 August 2014. The goal of this expert advisory group meeting was to build consensus on approaches to improve oxygen concentrators to treat paediatric patients with hypoxaemia or severe respiratory distress in low-resource settings (LRS). The meeting identified several key issues related to technical specifications for oxygen concentrator equipment, including procurement, performance and maintenance.

A result of this meeting was a first draft of oxygen concentrator technical specifications aimed to guide the development, purchase, utilization and maintenance of oxygen concentrators for use in low-resource settings. Members of the group included: Mike Eisenstein (PATH), Keith Klugman (Bill & Melinda Gates Foundation), David Mukanga (Bill & Melinda Gates Foundation) and Muhammad Zaman (Boston University). In addition, WHO expresses its appreciation to members of this expert advisory group meeting that also provided feedback throughout the development of this document: Glenn Austin (PATH), Jim Black (University of Melbourne), Jaclyn Delarosa (PATH), Trevor Duke (University of Melbourne), Penny Enarson (International Union Against Tuberculosis and Lung Disease), Mike English (Kenya Medical Research Institute – Wellcome Trust Research Programme), Amy Ginsburg (PATH), Stephen Howie (Medical Research Council), Rasa Izadnegahdar (Bill & Melinda Gates Foundation), Robert Jacobson (Consultant), David Peel (Ashdown Consultants), Shamim Qazi (WHO MCA), Gene Saxon (PATH), Alec Wollen (PATH) and Grace Wu (PATH consultant).

WHO extends its gratitude to the following external reviewers for their expertise and important feedback: Mohammad Ameen (National Health Systems Resource Centre [NHSRC], India), Anjeneya (NHSRC, India), Prabhat Arora (NHSRC, India), Anthony Ciccarello (Philips Healthcare), Robert Dickinson (University of Cape Town and Northwestern University), Robert DiBlasi (Seattle Children's Hospital and Research Institute), Jim Gilkison (Sanrai International), Hamish Graham (University of Melbourne), Godfrey Katabaro (Tanga Regional Referral Hospital), Jitendar Kumar (NHSRC, India), Ludo Scheerlinck (United Nations Children's Fund [UNICEF]) and Ofer Yanay (University of Washington and Seattle Children's Hospital).

We thank PATH for initiating content development and to the Bill & Melinda Gates Foundation for financially supporting this publication.

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_27326

