

Third edition
2023-08

Flow control devices for connection to a medical gas supply system

*Dispositifs de contrôle du débit pour raccordement à un système
d'alimentation en gaz médicaux*



Reference number
ISO 15002:2023(E)

© ISO 2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of ISO 15002:2023. Click [here](#) to purchase the full version from the ANSI store.

Contents

	Page
Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 General requirements	3
4.1 Risk management.....	3
4.2 Usability.....	3
4.3 Materials.....	4
4.4 Oxygen compatibility.....	4
4.5 Environmental conditions.....	4
5 Design requirements	5
5.1 General.....	5
5.2 Gas inlets.....	6
5.3 Outlet connectors.....	6
5.4 Mechanical strength.....	6
5.5 Leakage.....	6
5.6 Flow indication.....	7
5.7 Accuracy.....	7
5.8 Stability of indicated flow.....	8
5.9 Continuous increase in flow.....	8
5.10 Security of components.....	8
5.11 Flow controls and flow selectors.....	8
6 Packaging	9
7 Information supplied by the manufacturer	9
7.1 General.....	9
7.2 Marking.....	9
7.3 Instructions for use.....	10
Annex A (informative) Rationale	11
Annex B (informative) Examples of <i>flow control devices</i> and gas supply inlets	13
Annex C (normative) Test methods	15
Annex D (informative) Hazard identification for risk assessment	20
Bibliography	22

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas supply systems*.

This third edition cancels and replaces the second edition (ISO 15002:2008), which has been technically revised. It also incorporates the Amendment ISO 15002:2008/Amd.1:2018.

The main changes are as follows:

- title changed as the requirements for *flow control devices* are the same regardless of the gas supply and they control the flow, they do not measure the flow;
- layout changed from requirements for each type of *flow control device* to the common requirements as they are the same for each *flow control device*;
- test methods have been rationalised and put into a new [Annex C](#);
- hazard identification list added as a new [Annex D](#);
- the maximum flow that can be achieved when the flow control is opened fully has been included as a marking requirement on the device so that the user will know what could be delivered to the patient. A rationale has also been added to cover this marking requirement;
- a new requirement has been added for stability of setting;
- the environmental conditions have been aligned with IEC 60601-1-12, emergency equipment, as *flow control devices* are used in such environments; and
- the requirement for accuracy has been rationalised for clarity.

This is a preview of ISO 15002:2023. [Click here to purchase the full version from the ANSI store.](#)

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html

Introduction

Flow control devices are used to administer a prescribed flow of gas to a patient interface device (e.g. nasal cannula, facemask) from a pressure gas source, such as a medical gas supply system. These devices need to deliver accurate flows under varying conditions of temperature and inlet pressures. Therefore, it is important that the performance characteristics be specified and tested in a defined manner.

[Annex A](#) provides additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this document but will expedite any subsequent revisions.