
**Needle-based injection systems for
medical use — Requirements and test
methods —**

**Part 5:
Automated functions**

*Systèmes d'injection à aiguille pour usage médical — Exigences et
méthodes d'essai —*

Partie 5: Fonctions automatisées





COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

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

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	4
4.1 General requirements	4
4.2 Medicinal product preparation	5
4.3 Needle preparation	6
4.4 Needle hiding	6
4.5 Priming	6
4.6 Dose setting	6
4.7 Needle insertion	6
4.8 Injection depth control	6
4.9 Dose delivery	7
4.10 Recording of device functions	7
4.11 Needle retraction	7
4.11.1 Completion of dose delivery	7
4.11.2 Needle retraction distance	7
4.11.3 Communication of completion	7
4.12 Disabling the NIS-AUTO	7
4.13 Needle shielding	8
4.13.1 General	8
4.13.2 Needle shielding before injection	8
4.13.3 Needle shielding after injection	8
4.14 Needle removal from the NIS-AUTO	8
5 Test methods	8
5.1 General	8
5.2 Test conditions	9
5.3 Actuation	9
5.4 Medicinal product preparation	9
5.5 Needle inspection	9
5.6 Needle hiding	9
5.7 Priming	10
5.8 Needle extension	10
5.9 Injection time	10
5.10 Dose accuracy	11
5.11 Retracted position	11
5.12 Disabling the NIS-AUTO	11
5.13 Needle shielding	11
5.13.1 Needle shielding before and after injection	11
5.13.2 Needle shielding after free fall	11
6 Information supplied with the NIS-AUTO	11
Annex A (informative) Rationale for requirements	12
Annex B (informative) Example of a test method for dose accuracy at intended injection depth	14
Annex C (informative) Needle extension and intended injection depth	16
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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 11608-5:2012), which has been technically revised.

The main changes are as follows:

- this document has been clarified to explain that an automated function is one which does not require user interaction after the action which initiates the function, including designating injection depth control as automated when the user does not have control over the depth to which the needle is inserted, even where needle insertion is performed manually.

A list of all parts in the ISO 11608 series can be found on the ISO website.

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.