
Zobozdravstvo - Prenosna dentalna oprema za zdravstveno oskrbo - 1. del:
Splošne zahteve (ISO/DIS 23402-1:2020)

Dentistry - Portable dental equipment for use in non-permanent healthcare environment
- Part 1: General requirements (ISO/DIS 23402-1:2020)

Zahnheilkunde - Bewegliche dentale Ausrüstung zur Anwendung in nicht-permanenten
Gesundheitseinrichtungen - Teil 1: Allgemeine Anforderungen (ISO/DIS 23402-1:2020)

Médecine bucco-dentaire - Matériel dentaire portatif utilisable dans des environnements
de soins de santé non permanents - Partie 1: Exigences générales (ISO/DIS 23402-
1:2020)

Ta slovenski standard je istoveten z: prEN ISO 23402-1

<https://standards.iteh.ai/catalog/standards/sist/1b12ecab-1a4a-49d9-95aa-0f2409390467/sist-en-iso-23402-1-2020>

ICS:

11.060.20 Zobotehnična oprema Dental equipment

oSIST prEN ISO 23402-1:2020

en

DRAFT INTERNATIONAL STANDARD

ISO/DIS 23402-1

ISO/TC 106/SC 6

Secretariat: DIN

Voting begins on:
2020-01-16Voting terminates on:
2020-04-09

Dentistry — Portable dental equipment for use in non-permanent healthcare environment —

Part 1: General requirements

ICS: 11.060.20

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

SIST EN ISO 23402-1:2020<https://standards.iteh.ai/catalog/standards/sist/1b12ecab-1a4a-49d9-95aa-0f2409390467/sist-en-iso-23402-1-2020>

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING



Reference number
ISO/DIS 23402-1:2020(E)

© ISO 2020

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

SIST EN ISO 23402-1:2020

<https://standards.iteh.ai/catalog/standards/sist/1b12ecab-1a4a-49d9-95aa-0f2409390467/sist-en-iso-23402-1-2020>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

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
Fax: +41 22 749 09 47
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 Classification	2
4.1 General	2
4.2 For electrically operated devices	2
4.3 According to intended use environment	3
4.4 According to supply sources	3
4.5 According to transport conditions	3
4.6 According to human portability	3
5 Requirements	4
5.1 General	4
5.2 Transport requirements	4
5.2.1 General	4
5.2.2 Maximum mass	4
5.2.3 Maximum dimensions	4
5.2.4 Environmental exposure	4
5.2.5 Impact	4
5.2.6 Drop	4
5.2.7 Vibration	4
5.2.8 Particulate and liquid ingress during transport	5
5.2.9 Flammability	5
5.3 Assembly and disassembly requirements	5
5.4 Utility requirements	5
5.5 Operational requirements	5
5.5.1 Ambient operating conditions	5
5.5.2 Usability	5
5.5.3 Applied parts not intended to supply heat to a patient	6
5.5.4 Cleaning and disinfection	6
5.5.5 Noise	6
6 Sampling	6
7 Measurement and test methods	6
7.1 Tests for transport requirements	6
7.2 Environmental exposure	6
8 Manufacturer's instructions	7
8.1 General	7
8.2 Instructions for use	7
8.3 Technical description	7
9 Marking	7
9.1 Marking on the equipment	7
9.2 Marking of packaging	8
10 Packaging	8
Annex A (informative) Applicable testing methodology from IEC 60601-1:2005	9

ISO/DIS 23402-1:2020(E)

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 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

ISO 23402-1 consists of the following parts, under the general title *Dentistry — Portable dental equipment for use in non-permanent healthcare environments*: 2-1:2020

— *Part 1: General requirements*

The following parts are planned or in preparation:

— *Part 2: Portable dental units*

— *Part 3: Portable suction equipment*

— *Part 4: Portable patient chair*

A list of all parts in the ISO 23402 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.