ISO 23402-1:2020 (E)

Dentistry — Portable dental equipment for use in non#permanent healthcare environment — Part 1: General requirements

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 Classification

4.1 General
4.2 For electrically operated devices
4.3 According to intended use environment
4.4 According to supply sources
4.5 According to transport conditions

5 Requirements

5.1 General
5.2 Transport requirements
5.2.1 General
5.2.2 Grips or other handling devices
5.2.3 Maximum mass
5.2.4 Maximum dimensions
5.2.5 Environmental exposure
5.2.6 Impact
5.2.7 Drop
5.2.8 Vibration
5.2.9 Particulate and liquid ingress during transport
5.2.10 Flammability
5.3 Assembly and disassembly requirements
5.4 Utility requirements
5.5 Operational requirements
5.5.1 Ambient operating conditions
5.5.2 Usability
5.5.3 Applied parts not intended to supply heat to a patient
5.5.4 Cleaning and disinfection of external surfaces
5.5.5 Noise

6 Sampling

7 Measurement and test methods

7.1 Visual inspection of the device
7.2 Visual inspection of the documentation

8 Manufacturer's instructions

8.1 General
8.2 Instructions for use
8.3 Technical description

9 Marking

9.1 Marking on the equipment
9.2 Marking of packaging

10 Packaging

Annex A (informative) Applicable testing methodology from IEC 60601-1:2005/Amd 1:2012

Page count: 10