ISO 4823:2021-02 (E)

Dentistry - Elastomeric impression and bite registration materials

Contents

Page

Foreword ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Classification **2**

5 Requirements **3**
5.1 Packaging requirements 3
5.2 Labelling requirements 3
5.2.1 Outer packages (containing one or more primary containers) 3
5.2.2 Primary containers within outer packaging 3
5.3 Requirements for information in the manufacturer's instructions 4
5.3.1 General 4
5.3.2 Identifying information 4
5.3.3 Specific instructions for use 4
5.4 Requirements for characteristics and properties 5
5.4.1 Component colours (hand-spatulated or hand-kneaded mixes) 5
5.4.2 Mixing time (hand-spatulated or hand-kneaded mixes) 5
5.4.3 Consistency 5
5.4.4 Working time 5
5.4.5 Detail reproduction 5
5.4.6 Linear dimensional change 5
5.4.7 Compatibility with gypsum 5
5.4.8 Elastic recovery 5
5.4.9 Strain in compression 5
5.4.10 Minimum time in the oral cavity for bite registration materials 6
5.4.11 Compression set of bite registration materials 6
5.4.12 Hardness of bite registration materials 6

6 Pre-test planning approaches **6**
6.1 Sampling 6
6.2 Pre-test product examinations 7
6.2.1 Examinations for compliance with labelling requirements 7
6.2.2 Examinations for effectiveness of the packaging 7
6.2.3 Examinations for compliance with requirements for instructions for use 7
6.3 Essential pre-test preparatory practices 7
6.3.1 Laboratory conditions 7
6.3.2 Apparatus function verification steps 8
6.3.3 Volume of materials to be mixed for each specimen 8
6.3.4 Standardized approaches to proportioning, mixing, and handling of hand mixed materials to be tested 8
6.3.5 Timing for the specimen preparation and test procedures 8
6.3.6 Simulated oral time/temperature treatment of specimens formed in completely closed mould assemblies 8
6.4 Pass/fail determinations 8
6.5 Expression of test results 8

7 Test methods — Specific **8**
7.1 Mixing time 8
7.1.1 Apparatus 8

7.1.2 Specimen preparation and test procedure (five specimens) 9
7.1.3 Pass/fail determination and expression of results 9
7.2 Consistency 9
7.2.1 Apparatus and materials 9
7.2.2 Advance preparation steps 9
7.2.3 Specimen preparation and test procedure (5 specimens) 10
7.2.4 Pass/fail determination and expression of results 10
7.3 Working-time 10
7.3.1 Apparatus 10
7.3.2 Working time test 11
7.4 Detail reproduction 12
7.4.1 Apparatus and materials 12
7.4.2 Specimen preparation 12
7.4.3 Test procedure 13
7.4.4 Pass/fail determination and expression of results 13
7.5 Linear dimensional change 13
7.5.1 Apparatus and materials 13
7.5.2 Test block line-length measurement procedure 14
7.5.3 Specimen preparation 14
7.5.4 Test specimen measurement 14
7.6 Compatibility with gypsum 15
7.6.1 Apparatus and materials 15
7.6.2 Specimen preparation 16
7.6.3 Test procedure 16
7.6.4 Pass/fail determination and expression of results 16
7.7 Elastic recovery 17
7.7.1 Apparatus and materials 17
7.7.2 Specimen preparation 17
7.7.3 Test procedure 18
7.7.4 Calculation of results 18
7.7.5 Pass/fail determination and expression of results 18
7.8 Strain in compression 18
7.8.1 Apparatus 18
7.8.2 Specimen preparation 19
7.8.3 Test procedure 19
7.8.4 Calculation of results 19
7.8.5 Pass/fail determination and expression of results 19
7.9 Minimum time in the oral cavity and compression set for bite registration materials 19
7.9.1 Apparatus 19
7.9.2 Specimen preparation 19
7.9.3 Test procedure 19
7.9.4 Evaluation 20
7.9.5 Pass/fail determination and expression of results 20
7.10 Hardness of bite registration materials 20
7.10.1 Apparatus 20
7.10.2 Specimen preparation 20
7.10.3 Test procedure 20
7.10.4 Evaluation 21
7.10.5 Pass/fail determination and expression of results 21
Annex A (normative) **Figures** **22**
Annex B (normative) **Standardized hand mixing methods** **30**
Bibliography **33**