

DIN EN ISO 21563:2022-02 (E)

Dentistry - Hydrocolloid impression materials (ISO 21563:2021)

Contents		Page
European foreword		4
Foreword		5
1	Scope	6
2	Normative references	6
3	Terms and definitions	6
4	Classification of agar hydrocolloid impression materials	8
5	Requirements — Characteristics and properties	9
6	Pre-test planning approaches	10
6.1	General	10
6.2	Sampling	10
6.3	Pre-test product examinations	10
6.3.1	General	10
6.3.2	Examinations for compliance with labelling requirements	10
6.3.3	Examinations for effectiveness of the packaging	10
6.3.4	Examinations for compliance with requirements for instructions for use	11
6.4	Essential pre-test preparatory practices	11
6.4.1	Laboratory conditions	11
6.4.2	Apparatus function verification steps	11
6.4.3	Test material handling and use	11
6.4.4	Simulated oral time/temperature treatment of specimens formed in completely closed moulds	12
6.4.5	Order of conducting tests	12
6.4.6	Test schedules timing	12
6.4.7	Pass/fail determinations	12
6.4.8	Expression of test results	13
7	Test methods	13
7.1	General	13
7.2	Working time test (alginate materials only)	13
7.2.1	Apparatus and materials (the array of devices or materials used or available for an undertaking)	13
7.2.2	Specimen preparation	13
7.2.3	Test procedure	14
7.2.4	Pass/fail determinations/and expression of results	14
7.3	Initial setting time test (alginate impression materials only)	14
7.3.1	Apparatus	14
7.3.2	Specimen preparation	14
7.3.3	Test procedure	14
7.3.4	Pass/fail determinations and expression of results	15
7.4	Detail reproduction test before and after specimen disinfection	15
7.4.1	Apparatus and materials	15
7.4.2	Examination and conditioning of equipment and accessories	15
7.4.3	Specimen preparation	15
7.4.4	Test procedure steps	17
7.4.5	Pass/fail determination and expression of results	17
7.5	Compatibility with gypsum test	17
7.5.1	Apparatus and materials	17
7.5.2	Specimen preparation	18
7.5.3	Test procedure	19
7.5.4	Pass/fail determination and expression of results	19

7.6	Elastic recovery test.....	19
7.6.1	Apparatus and materials.....	19
7.6.2	Specimen preparation.....	19
7.6.3	Test procedure.....	20
7.6.4	Calculation of results.....	21
7.6.5	Pass/fail determinations and expression of results.....	21
7.7	Strain-in-compression test.....	21
7.7.1	Apparatus and materials.....	21
7.7.2	Specimen preparation.....	21
7.7.3	Test procedure.....	21
7.7.4	Calculation of results.....	22
7.7.5	Pass/fail determinations and expression of results.....	22
7.8	Tear strength test.....	22
7.8.1	Apparatus and materials.....	22
7.8.2	Specimen preparation.....	23
7.8.3	Test procedure.....	24
7.8.4	Calculation of results.....	24
7.8.5	Pass/fail determinations and expression of results.....	24
7.9	Linear dimensional change test (Type 3A agar materials with companion alginate only).....	25
7.9.1	Apparatus and materials.....	25
7.9.2	Specimen preparation.....	25
7.9.3	Test procedure.....	26
7.9.4	Calculation of results.....	26
7.9.5	Pass and fail determinations and expression of results.....	26
7.10	Tensile bond strength test (Type 3A agar/companion alginate material specimen only).....	26
7.10.1	Apparatus.....	26
7.10.2	Specimen preparation.....	27
7.10.3	Specimen preparation steps.....	27
7.10.4	Test procedure steps.....	28
7.10.5	Calculation of results.....	28
7.10.6	Pass/fail determination and expression of results.....	28
8	Requirements — Labelling and instructions for use.....	28
8.1	Labelling.....	28
8.2	Requirements — Instructions for use.....	29
8.2.1	General.....	29
8.2.2	For all hydrocolloid impression materials covered by this document — Agar and alginate.....	29
8.2.3	Additional instructions for agar hydrocolloid impression materials only.....	30
8.2.4	Additional instructions for alginate hydrocolloid materials only.....	30
	Annex A (informative) Figures illustrating instruments and accessories used in tests.....	32
	Annex B (informative) Tear test specimen preparation steps for an optional gripping method.....	46
	Bibliography.....	51