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Test Report

No. 0006/1

on the separation efficiency of the amalgam sedimentation separator 'amalsed® - green'

- identical with amalgam sedimentation separator SRAB 99D -

Although this report is a translation by the author himself, the German manuscript, including its annexes, is the only valid original document

Client:
medentex GmbH
Piderits Bleiche 11, 33689 Bielefeld/Germany

Order number:
46484

Official Expert:
Prof.Dr.drs.drs. Jerome Rotgans, Ph.D., D.D.S., M.D., M.H.P.E.

Inspecting Authority for Amalgam Separators
at the Scientific Laboratory
of the Chair of Conservative Dentistry
in collaboration with
Labor für Research & Development
Dr. Födisch Umweltmesstechnik AG
Zwenkauer Str. 159 in 04420 Markranstädt/Germany

Test Result:	The amalgam separator has a **typical efficiency of 98.529 %** **at a maximum water flow of 3.0 l/min** as required from the DIN EN ISO 11143:2008 specifications.

TEST REPORT
on the separation efficiency of amalgam separators

in accordance with

☒ **DIN EN ISO 11143:2008**

☐ **Principals of Approval of the Deutsche Institut für Bautechnik (DIBt – German Institute for Structural Engineering) in Berlin/Germany**

1 TEST CONDITIONS

1.1 General requirements

a) DIN VDE 1000 / 3.79
b) General Principles for the Safety-fair Design of Technical Products
c) VB6 103 / 2.83
d) VVV Health Services

These requirements are fulfilled.

1.2 Test object

a) Product description

Type designation: amalgam sedimentation separator 'amalsed®-green', identical with amalgam sedimentation separator SRAB 99D.

Device type no.: not applicable

Serial number of the empty separator: 55743

Serial number of the full separator: 55743

Technical data: cf. Table I

Maximum permitted water flow	3.0 l/min
Total volume	4,358 cm^3
Maximum permitted amalgam mass	1,000 g
Volume of the distribution compartment	1,199 cm^3
Volume of the pre-sedimentation area	1,400 cm^3
Volume of the fine-sedimentation area (net 305.6 cm^3 see below)	930 cm^3
Volume of the exit compartment	829 cm^3
Surface of the net without reduction of the meshes	188.42 cm²
Total surface of the meshes in the net	182.08 cm²
Reducing effect of the net	3.3 %
Free cross section of the net i.e. the remaining cross sectional surface in the separator if the net is integrated in the separator	130 cm²
Surface of the separating plate without holes	188.9 cm²
Total surface of the holes in the separating plate	1.82 cm²
Reducing effect of the separation plate	99.03 %
Free cross section of the separating plate i.e. the remaining cross sectional surface in the separator if the separating plate is integrated in the separator	1,82 cm²
Fluid velocity for 3.0 l/min	0.30 cm/s
Retention time for 3.0 l/min	87,12 s

Table I: Technical data of the amalgam sedimentation separator 'amalsed®-green', identical with amalgam sedimentation separator SRAB 99D.

b) Type classification in accordance with paragraph 4 DIN EN ISO 11143:

Type 1 ☐ Type 2 ☒ Type 3 ☐ Type 4 ☐

c) Description of the device

The separator functions according to the sedimentation principle. It is separated in three compartments (cf. figure 1): The input compartment, the distribution compartment and the exit compartment with a total volume of 4,358 cm^3.

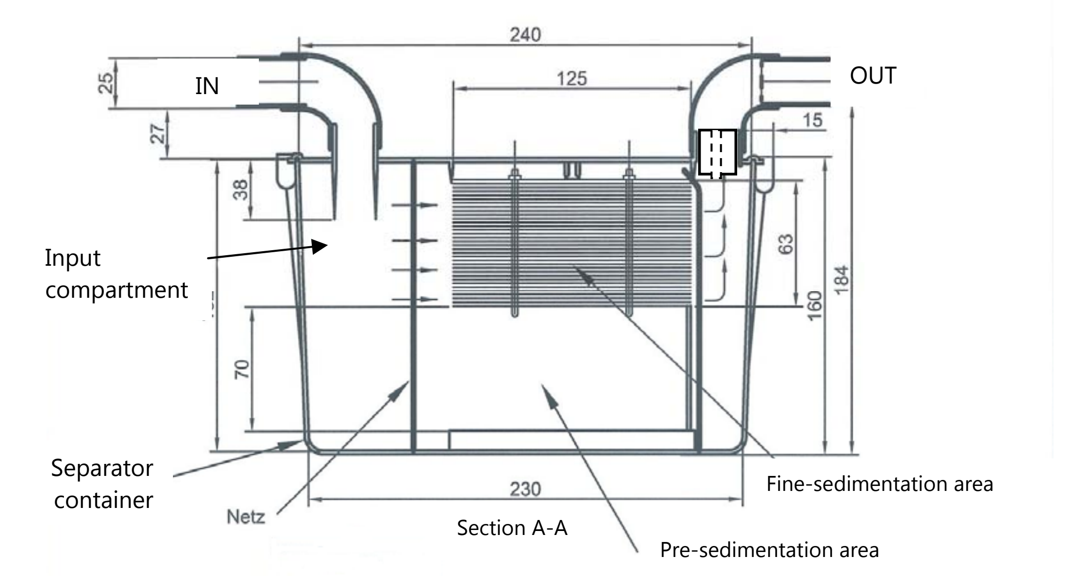

Figure 1: Sectional drawing of the amalgam sedimentation separator ‚amalsed®-green', identical with amalgam sedimentation separator SRAB 99D.

Input and distribution compartment are separated by a wide-mesh metallic net. Already the input compartment functions as sedimentation area because 'amalgam rocks', big particles like tooth splinter, items like cotton rolls etc. are retained by the net.

For all three compartments count that the bottom of separator shows in width running rips, in the distribution compartment with additional crossed rips. These rips increase the separator efficiency in relation to a smooth bottom surface.

The distribution compartment is divided into two sub-compartments. One sub-compartment, in dimension approximately the lower half of the volume of the distribution compartment, is the pre-sedimentation area. This area is - in the direction of the exit-compartment - constructed as blind alley. Because of this construction sewage cannot flow directly into the exit compartment. Most coarse and middle-fine amalgam particles are separated in the pre-sedimentation area.

The other sub-compartment, the fine-sedimentation area, is located above the pre-sedimentation area and serves as a zone where (mostly floating) finest amalgam particles are separated. In this area a cassette with 33 horizontal metal sheets is located. These sheets contribute to an enormous enlargement of the sedimentation surface.

Pre- and fine-sedimentation area are separated from the exit compartment by a sturdy separating plate. This plate has holes in its upper half which is congruent with the cross-sectional dimension of the fine-sedimentation area. Its lower part has no openings, it is the end of the blind alley of the pre-sedimentation area. By this construction, sewage is obstructed to flow directly into the exit-compartment: It is forced to flow there via the fine-sedimentation area.

This forced flow is supported by a lip on the top of the separating plate in backward direction of the exit compartment, and a corresponding silicone seal between the top of the cassette and the cover of the separator. Finally a throttle disc is mounted in the exit pipe.

Because of the relatively few holes in the separating plate sewage flow rate experiences such a reduction that finest particles sediment easily on the sheets of the cassette.

Net, cassette and separating plate are firmly integrated in the separator, the separator is sealed, its inner content not accessible without breaking two seals.

Sewage from the dental unit is introduced to the separator by the inlet, the outlet of the separator is connected with the drainage pipe. Sewage is cleaned by sedimentation. The separator serves at the same time as container for the separated amalgam.

After a standing time of six or 12 months the separator must be replaced (cf. paragraph 3.3).

1.3 Test procedure (simplified description)

In accordance with paragraph 9 DIN EN ISO 11143 the separator will be flushed with clear, filtered water. During water flow test slurry is added to the separator equably. If added completely the separator is flushed at maximum water flow (3.0 l/min) for 10 minutes. As flushing is finished the drain value of the effluent collecting vessel is opened and air pressure of 1.5 x 10^5 Pa (1.5 bar) is applied. As soon as the effluent collecting vessel is empty the membrane filters are dried at 90 °C for 3 hours and weighted after 24h desiccators storage.

1.4 Test period: 01/2011

1.5 Test performed at:

Laboratory for Research & Development
Dr. Födisch Umweltmesstechnik AG
Zwenkauer Str. 159 in 04420 Markranstädt/Germany

1.6 Amalgam samples

1.6.1 Particle size distribution used

a) Standard samples in accordance with paragraphs 8.1 to 8.4 DIN EN ISO 11143 ☒

b) Standard samples in accordance with paragraph 4.4.4 of the DIBt Principles for Approval ☐

1.6.2 Manufacturer:

bm becker messtechnik gmbh
Kölner Str. 6, 65760 Eschborn/Germany

1.6.3 Amalgam sample series (cf. table II and figure 2).

Sample number	1 (17*)	2 (18*)	3 (20*)	4 (23**)	5 (24**)	6 (25**)
Date of manufacture	April 2008			November 2010		
Lot number	100416-02/08			100416-11/10		

Table II: Characteristics of the used amalgam samples.
*) in accordance with the Analysis Certificate dated 22 July 2008 (cf. Annex).
**) in accordance with the Analysis Certificate dated 22 December 2001 (cf. Annex).

Figure 2: Proof of the six used amalgam standard samples.

1.7 Membrane filters

1.7.1 Typ of membrane filters:

Cellulose nitrate (Sartorius); d = 50 mm

1.7.2 Membrane filter column:

separating gauzes with nominal pore size of 50 µm
membrane filter with a nominal pore size of 2,7 µm
separating gauzes
membrane filter with a nominal pore size of 1,2 µm
separating gauzes (drain side)
supporting mesh

1.8 CONFIGURATION OF THE TESTING FACILITY

including test object in accordance with DIN ISO EN 11143, paragraph 7 (cf. figure 3).

Figure 3: Configuration of the test facility.

2 SEPARATION EFFICIANCY

2.1 Characteristic values for water flow rate

a) Maximum water flow rate: Q_{max} = 3.0 l/min

b) Minimum water flow rate: not applicable

2.2 Characteristic values for maximum fill level

a) Fill level: not applicable

b) Fill volume: Simulation with 300 g quartz flour F300 + 57,6 g river sand (cf. paragraph 4.2.3)

c) Net weight: Simulation with quartz-mix (cf. above)

2.3 Leak test

In- and outlet of the separator are clearly defined. Before, during and after the test no leakage or spillage occurred.

2.4 Efficiency

Calculation of the value of efficiency according to equation [1].

$$\eta = \frac{100 * [m_1 - (m_3 - m_2)]}{m_1}$$ equation [1],

where

m_1 = mass, in grams, of the amalgam sample.
m_2 = mass, in grams of both filters before the efficiency test.
m_3 = mass, in grams of both filters after the efficiency test.

2.4.1 Efficiency of the empty amalgam separator

a) with *maximum* water flow

Run 1) 98.295 % with sample no. 1 (17)

Run 2) 98.546 % with sample no. 2 (18)

Run 3) 98.747 % with sample no. 3 (20)

Mean value η_{m1} = 98.529 %

cf. table III for details.

Measurement	Mass of amalgam sample	Mass amalgam pre-test	Mass amalgam post-test	**Efficiency**
Run 1	m_1 = 9.975 g	m_2 = 1.070 g	m_3 = 1.240 g	η_1 = 98.295 %
Run 2	m_1 = 9.975 g	m_2 = 1.080 g	m_3 = 1.225 g	η_2 = 98.546 %
Run 3	m_1 = 9.980 g	m_2 = 1.050 g	m_3 = 1.175 g	η_3 = 98.747 %

Table III: Masses of amalgam measured during run 1 through 3 with empty separator.

b) with *minimum* water flow: not applicable

2.4.2 Efficiency of the full amalgam separator

a) with *maximum* water flow

Run 1) 99.299 % with sample no. 4 (23)

Run 2) 99.990 % with sample no. 5 (24)

Run 3) 99.989 % with sample no. 6 (25)

Mean value η_{m2} = 99.969 %

cf. table IV and paragraph 4.2.3 for details.

Runs	Mass of amalgam sample	Mass amalgam pre-test	Mass amalgam post-test *with quartz*	*Efficiency with quartz contamination*
Run 1	m_1 = 9,999 g	m_2 = 1,1151 g	m = 1,1651 g	*η_1 = 99,500 %*
Run 2	m_1 = 9,999 g	m_2 = 1,1243 g	m = 1,1721 g	*η_2 = 99,522 %*
Run 3	m_1 = 10,001 g	m_2 = 1,1205 g	m = 1,1659 g	*η_3 = 99,546 %*

Runs	Mass of flushed amalgam and quartz	Mass of flushed quartz interpolated*	Mass of flushed amalgam (m_3 - m_2)	**Efficiency**
Run 1	m = 0.065 g	m = 0.058 g	m = 0.007 g	η_1 = 99.929 %
Run 2	m = 0.020 g	m = 0.019 g	m = 0.001 g	η_2 = 99.990 %
Run 3	m = 0.010 g	m = 0.009 g	m = 0.001 g	η_3 = 99.989 %

Tabelle IV: Masses of amalgam measured during run 1 through 3 with full separator.
*) cf. Section 4.2.3 Table V.

b) with *minimum* water flow: not applicable

2.4.3 Typical efficiency

Lowest efficiency concluded from the mean values η_{m1} and η_{m2}: **η_{min}= 98.529 %**

2.5 Test of the warning and alarm systems in accordance with DIN EN ISO 11143

- Par. 9.7: Test of warning systems for removable collecting containers

  passed ☐ **failed** ☐ **not applicable** ☒

- Par. 9.8: Test of alarm systems for removable collecting containers

  passed ☐ **failed** ☐ **not applicable** ☒

- Par. 9.9: Test of the alarm systems in response to a malfunction of the amalgam separator

  passed ☐ **failed** ☐ **not applicable** ☒

2.6 Test result

2.6.1 The amalgam separator has the procedure to test its efficiency in accordance with paragraph 9 DIN EN ISO 11143 with amalgam samples in accordance with paragraph 8 DIN EN ISO 11143 with a separation efficiency in accordance with paragraph 5.1 of **at least 95 %**

passed ☒ **failed** ☐ **not applicable** ☐

2.6.2 The amalgam separator has the procedure to test its efficiency in accordance with paragraph 3.3.2 DIBt Principles of Approval and in accordance with paragraph 9 DIN EN ISO 11143 with amalgam samples in accordance with paragraph 8 DIN EN ISO 11143 with a separation efficiency of **at least 98 %**

passed ☒ **failed** ☐ **not applicable** ☐

2.6.3 The amalgam separator has the procedure to test its efficiency in accordance with paragraph 9 DIN EN ISO 11143 with amalgam samples in accordance with paragraph 8 DIN EN ISO 11143 with a separation efficiency in accordance with - for example - paragraph 374-4 a1: Requirements for the Management of Elemental Mercury and Dental Amalgam Waste at Dental Facilities, Environmental Conservation Law Section 27-0926 of New York State of **at least 99 %**

passed ☐ **failed** ☒ **not applicable** ☐

2.6.4 The amalgam separator has the procedure to test its efficiency in accordance with paragraph 3.3.3 DIBt Principles of Approval and in accordance with paragraph 9 DIN EN ISO 11143 with amalgam samples in accordance with paragraph 4.4.4 DIBt Principles of Approval with a separation efficiency of **at least 95 %**

passed ☐ **failed** ☐ **not applicable** ☒

3 OTHER REMARKS REGARDING THE TEST

3.1 In the standard not to specified methods

3.1.1 Membrane filter column

As membrane filter with a nominal pore size of 3 µm meshes in the needed diameter (d ≥ 50 mm) are not any longer available the membrane filter column as described in paragraph 7.1.8 DIN EN ISO 11143 was composed with two membrane filters with as nominal pore size of respectively 2,7 and 1,2 µm. The membrane filter with nominal pore size of 12 µm was not installed.

3.1.2 Simulating full testing

The design of the separator is based on a maximum permissible total mass of 1.000 g separated amalgam. A particular characteristic of the separator is the cassette with 33 sedimentation sheets in the fine-sedimentation area in which in between it is neither possible nor possible to evenly distribute the prescribed glass beads between the sedimentation sheets. For this reason quartz powder was chosen as an alternative.

Therefore, based on the particle size distribution of the ‘German Standard Quartz Sample‘ (cf. Annex 2 of the Zulassungsgrundsätze für Amalgamabscheider - edition January 2010. Berlin: Deutsches Institut für Bautechnik, DIBt Mitteilungen 2010;41:(3):121-127) a mix of 300 g quartz flour F300, [composed of 50% quartz flour-SMF MILLISIL W3 (d_{50} = 90 µm) and 50% quartz sand Frechen F34 (d_{50} = 210 µm)] and 57.6 g river sand was chosen as substitute. The 357,6 g quartz flour/river sand-mix corresponds with the volume of 1,000 g amalgam.

For practical reasons the first three runs have been performed with an empty separator, followed by the second three runs with a new but quartz-mix loaded ‘full’ separator.

3.2 Details of events that influence the test result

3.2.1 Ultrasonic treatment

During preparation of the test slurry in accordance with paragraph 8.5 DIN EN ISO 11143 (ultrasonic treatment) air bubbles have been observed on the fluid surface in which finest amalgam particles were captured avoiding them to stir: The application of one drop of dish wash soap (GUT&GÜNSTIG der KOFUR Handelsges.mbH/Hamburg: www.drinfo.eu) solved the problem.

3.2.2 Preparation of test slurry

During earlier procedures to determine the efficiency of a separator a ‘build up of slime’ became apparent whilst producing the test slurry in accordance with DIN EN ISO 11143, paragraph 8.5 (addition of sodium pyrophosphate). As this phenomenon resulted in an unreasonable prolongation of the rinsing procedure (in accordance with paragraph 9.3.2.7 DIN EN ISO 11143) for more than 5 hours the test was halted. Based on this experience, the test slurry was produced without adding sodium pyrophosphate.

3.2.3 Corrections of efficiency by application of quartz

It became apparent whilst testing the full separator that a large part of the filtered material on the membrane filter with nominal pore size 2.7 µm contained quartz. The reason for this observation can be traced back to the method used to fill the 'full separator' with quartz, and in particular to the low density of quartz which was also rinsed out without providing samples.

The flushed and filtered amalgam mass for each run follows from the mass differences of the collectively flushed amalgam-quartz-mix. To determine the mass of flushed quartz, measurements of 'empty runs' (i.e. without application of an amalgam sample) of 10 minutes each were taken under the same, continuous conditions of 3.0 l/min, one on the evening and one on the morning before the start of the test, two in-between and one after the (three) runs with an amalgam sample.

As a result a graph could be drawn through the five measurement points of flushed quartz allowing to calculate the proportion of amalgam in run 3, 5 and 7 by interpolation (cf. Figure 4).

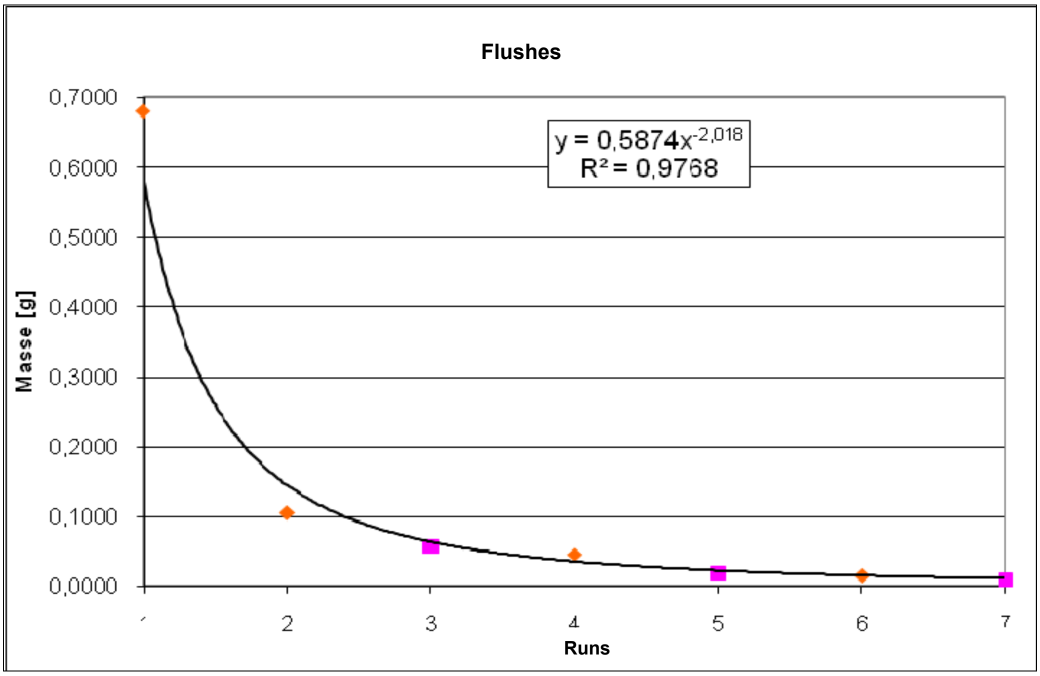

Figure 4: Flushed quartz mix and amalgam with water flow 3,0 l/min.
Runs 3, 5 and 7 are with amalgam samples.
Runs 1, 2, 4 and 6 are ‚empty runs' with flushed quartz only.
Orange diamonds = Masses of flushed quartz.
Purple squares = Masse of flushed quartz interpolated.

Figure 4 shows the masses of the respective flushed amalgam/quartz- and quartz-mixes. The function $y = 0{,}2768x^{-2{,}5016}$ showed ‚best fit‘ for the measured quartz masses in run 1, 2, 4, 6 und 8. During the first run relatively much quartz was flushed. In course of the successive runs the value approaches zero gram.

Table V demonstrates how by measurement of flushed quartz in run 1, 2, 4, 6 and 8 the proportion of flushed amalgam in run 3, 5 und 7 is calculated by interpolation (cf. grey marked cells). The (real) values for flushed amalgam in column ‘Flushed amalgam corrected for quartz‘ are the result of the difference of the values in column ‘Flushed amalgam including quartz’ and column ‘Flushed quartz interpolated’.

Run	Flushed quartz interpolated	Flushed amalgam including quartz	Flushed amalgam corrected for quartz
maximum water flow Q_{max} = 3,0 l/min			
1	0.680 g		
2	0.105 g		
3	0.058 g	0.625 g	0.567 g
4	0.050 g		
5	0.019 g	0.170 g	0.151 g
6	0.015 g		
7	0.009 g	0.150 g	0.141 g

Table V: Results of flushed quartz to calculate flushed amalgam.

3.3 Structural requirements

It was not considered necessary to determine the filling degree by a filling state indicator; the separator will be securely sealed and replaced once the defined service life has elapsed. Yearly/half-yearly replacement is a fundamental principal. A spare separator is automatically made available after a maximum of 6 or 12 months in dependency of the number of employed fte dentists in accordance with the data in Table VI.

Number of employed fte dentists	Maximum standing time of separator
1	12 months
2	12 months
3	6 months
4	6 months

Tabelle VI: Maximum standing time in dependency of the number of dentists/separator.

If more than four fte dentist are connected to one separator the water flow must be determined newly. If this flow exceeds the allowed maximum water flow of the separator of 3.0 l/min a sufficiently large buffer vessel must be installed in responsibility of the manufacturer

of the ‘amalsed®-green’ separator. As far as other installation and purpose conditions arise the maximum standing time has to be recalculated in responsibility of the applicant newly.
A recycling cycle for the separator of maximum 10 times is allowed. Non-water soluble prophylaxis powder from sandblast equipment is not allowed to use in combination with the amalgam separator because of its obstruction and obstruction of the suction system.
Recycling of the filled amalgam separator is allowed exclusively by Sweden Recycling Ltd. c.q. medentex GmbH or authorized companies to guarantee the correct function of the system.

4 CONCLUSION

The separator fulfils – with consideration to the circumstances stated in the paragraphs 3.1 trough 3.3 of this test report – the requirements resulting from the specifications contained in DIN EN ISO 11143 and, for example, § 374-4 Abs. a1 der Requirements for the Management of Elemental Mercury and Dental Amalgam Waste at Dental Facilities der Environmental Conservation Law Section 27-0926 der New York State for a maximum allowed water flow of 3.0 l/min.

Aachen, 7 January 2011

Prof.Dr.drs.drs. Jerome Rotgans

Annex : Certificate of Analysis ‘ISO Standard sample’