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United States

Result: PASS

Report Date: May 11, 2015

Customer Name: Dennis J. Duel & Associates Inc.
Tested To: NSF ISO11143
Description: ISO11143 Model DD2011
Test Type: Efficiency and operation
Test Dates: 05-May-15, 06-May-15
Test Location: NSF International Ann Arbor MI
Job Number: J-00172739
Project Number: 10008136 (PL01)
Project Manager: Sharon Steiner

Executive Summary: The Model DD2011 met the ISO 11143:2008 requirements for amalgam retention efficiency, operation and maintenance, and labeling. Testing was completed according to ISO 11143:2008.

Thank you for having your product tested by NSF International.

Please contact your Project Manager if you have any questions or concerns pertaining to this report.

Tests Performed By: Michael Chamberlain

Report Authorization: _____

Ata Ciechanowski, P.E., Assistant Director – Engineering Laboratory



Test Sample

Manufacturer: Dennis J. Duel & Associates Inc.
Designation: Model DD2011 Amalgam Separator
Type Classification: Type 3 - Filtration
Serial Number: 032415
Maximum Flow Rate: 1 Liter per minute
Maximum Fillable Volume: 0.360 Liters
Total System Volume: 0.360 Liters
System Dimensions: Height – 164 mm
Length – 96 mm
Width – 96 mm

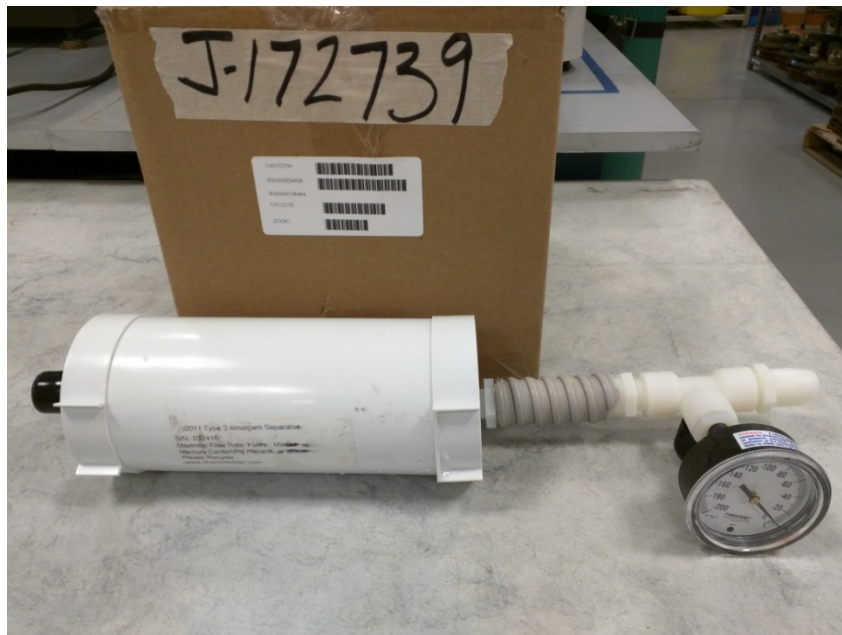


Figure 1 – DD2011 Amalgam Separator



The D2011 Amalgam separator consists of a canister that holds a spun fiber filter. The entire unit is changed out when full. The system also employs a vacuum gauge as a warning and alarm system. The gauge is connected to a tee in the vacuum line upstream of the filter cartridge.

Test Standard

Testing was performed to determine compliance of the supplied sample to ISO 11143:2008 “*Dentistry – Amalgam separators*”. ISO 11143 specifies requirements for amalgam separators, such as amalgam retention efficiency and instructions for use, operation and maintenance.

Amalgam Sample

Amalgam test samples were obtained from “bm becker messtechnik gmbH”. Each sample consisted of 10 g dental amalgam as specified in ISO Standard 11143. The detailed reports on the test samples are included in Appendix A.

Particle Size Distribution:

- 3000 mg, < 100 µm
- 1000 mg, 100µm – 500 µm
- 6000 mg, 500µm – 3150 µm

Amalgam Sample Lot Numbers:

- Charge 100416-10/14

Test Procedure

The test procedure used to determine the efficiency of the separators is defined in ISO 11143 for Type 3 systems. Deviations from the standard test procedure are noted below.

- Effluent Collecting Vessel
 - A large glass flask was used. The standard specifies a single stainless steel vessel with a minimum volume of 45 liters.
- Filters
 - Diameter of filter membranes was 47 mm. The standard specifies 50 mm minimum.
 - Nominal pore size used was 1.2 microns. The standard specifies pore sizes of 12.0, 3.0, and 1.2 microns
 - One filter was used during filtering. When needed due to filter blinding, additional filters were used to process the remaining effluent from each test replicate.



- Separating gauze was not used between filter membranes.
- Filtering was completed by vacuum instead of pressure.

Filters

One filter was used for amalgam retention efficiency tests:

- 1.) 1.2 micron nominal pore size, cellulose nitrate membrane filter, 47 mm diameter

During the empty trials and full trials, system effluent was passed through 1.2 micron filters. After each filter blinded, a new filter was installed to complete the process. As shown in tables 2 and 3, multiple filters were sometimes required for each replicate test.

Number of Tests Performed

Six tests were run on the sample separator provided by the manufacturer: Three tests were run on the separator when empty and three tests were run on the separator when filled to 95% of the maximum fillable volume.

The separator was filled to 95% of the maximum fillable volume with 70% glass beads 1 mm in size and 25% amalgam scrap ground to less than 300 micron. Table 1 shows the filling volumes for each material.

Table 1 – Loading of the Full Amalgam Separator

Model	Specified Maximum Filling Level (mL)	Volume of Scrap Amalgam Used (mL)	Volume of Glass Beads Used (mL)
DD2011	360	90	252

Test Data

The results from the efficiency tests are shown in Tables 2 and 3. The tare weight and final weight includes a stainless steel weighing dish. This helped to keep the residue in place during drying.



Table 2 – Empty Amalgam Separator Test Results

Empty Trial	Filter Size	Initial Filter Weight (g)	Final Filter Weight (g)	Un-separated Amalgam (g)	Weight of Challenge (g)	Efficiency
1	1.2 µm	8.71130	8.71380	0.00250	9.98836	99.975%
Trial 1 Total				0.00250		
2	1.2 µm	9.14357	9.15557	0.01200	9.99580	99.880%
Trial 2 Total				0.01200		
3	1.2 µm	8.92758	8.94114	0.01356	9.99156	99.864%
Trial 3 Total				0.01356		
Average						99.906%

Table 3 – Full Amalgam Separator Test Results

Empty Trial	Filter Size	Initial Filter Weight (g)	Final Filter Weight (g)	Un-separated Amalgam (g)	Weight of Challenge (g)	Efficiency
1	1.2 µm	8.82747	8.88333	0.05586	9.99207	99.093%
1	1.2 µm	8.57587	8.61067	0.03480		
Trial 1 Total				0.09066		
2	1.2 µm	9.14397	9.15827	0.01430	9.99368	99.857%
Trial 2 Total				0.01430		
3	1.2 µm	8.81793	8.82508	0.00715	9.98785	99.928%
Trial 3 Total				0.00715		
Average						99.626%



Efficiency

The minimum efficiency required by ISO 11143 is 95% by mass.

Empty Amalgam Separator: DD2011 Efficiency, $\eta_1 = 99.906\%$

Full Amalgam Separator: DD2011 Efficiency, $\eta_2 = 99.626\%$

The lowest efficiency measured from the full and empty tests (η_1 or η_2) is the amalgam separator efficiency. Therefore, the overall efficiency for the sample is determined to be 99.626%.

Warning System (Type 3 System)

The DD2011 is provided with a vacuum gauge that indicates proper vacuum at the chair. When the vacuum drops to less than the acceptable level, the filter should be changed.

Alarm System for Collecting Container (Type 3 System)

The DD2011 is provided with a vacuum gauge that indicates proper vacuum at the chair. When the vacuum drops to less than the acceptable level, the filter should be changed.

Alarm System for Malfunction

Not applicable to a Type 3 system.

Removal of Filled Collecting Container

The filled collecting container can be removed and sealed so that no spillage occurs during replacement and transfer of the container.

Maximum Fillable Volume

The maximum fillable volume of the collecting container is 360 mL.

DD2011 Volume: 360 mL

Electrical Safety

DD2011 Amalgam Separator does not incorporate any electrical components.



Results Obtained

Efficiency Pass/Fail Criteria:	DD2011, 99.626%	Pass
Warning System:	DD2011 –	Pass
Alarm System for Collecting Container:	DD2011 –	Pass
Removal of Filled Collecting Container:	DD2011 –	Pass
Maximum Fillable Volume:	DD2011 –	Pass



Appendix A Test Sample Particle Size Distribution Reports

Manufacturer Certificate for samples according ISO 11143

Production date: September 14
Charge 100416-10/14

Customer: NSF International
789 N. Dixboro Rd
ann Arbor, MI 48105

Sedigramm chart date: October 23, 2014

Order No: Email dated November 19, 2014, Order No. 109472

Delivery: November 25, 2014

ISO 11143
ISO amalgam sample

Fraction 1: 500 - 3150 µm
Fraction 2: 100 - 500 µm
Fraction 3: < 100 µm

Fraction 1	500 - 3150µm	6g ± 10mg
Fraction 2	100 - 500µm	1g ± 5mg
Fraction 3	<100µm	3g ± 5mg
Total		10g ± 5mg

Probe No	Anteil [g]:			
	Fraction 1	Fraction 2	Fraction 3	Total
25	6,001	0,997	3,001	9,999
26	5,998	1,001	3,001	10,000
27	6,003	0,998	3,000	10,001
28	6,002	0,998	3,000	10,000
29	6,000	0,999	3,002	10,001
30	5,999	0,999	3,002	10,000
31	6,004	0,998	2,999	10,001
32	5,998	1,001	3,001	10,000
33	5,996	1,004	2,999	9,999
34	5,998	1,003	3,000	10,001
35	6,002	1,001	3,000	10,003
36	6,000	1,001	2,999	10,000
37	6,000	1,002	3,001	10,003
38	6,003	0,999	3,000	10,002
39	5,999	1,003	3,001	10,003



Kornverteilung

Kornanalyse:

Sample Density:

Liquid Density:

Sample-Density ISO-Norm:

Umrechnung Partikelgröße auf "Normdichte":

Micromeritics 23.10.2014

$\rho_s = 12,0650 \text{ [kg/m}^3\text{]}$

$\rho_L = 1,1728 \text{ [kg/m}^3\text{]}$

$\rho_{s,N} = 9,5000 \text{ [kg/m}^3\text{]}$

Werte von Low Diameter ↓
Mass Finer Wert interpoliert ↓

$$d_2 = d_1 \cdot \sqrt{\frac{\rho_s - \rho_L}{\rho_{s,N} - \rho_L}}$$

Messwerte		Messwerte berechnet		EBe 08.02.95	ISO-Norm
Partikel-Größe d_1	Feinfraktion Durchgang	norm. Partikel-Größe d_2	Feinfraktion bewertet 100%	Feinfraktion Soll	Feinfraktion Soll
[μm]	[%]	[μm]	[%]	[%]	[%]
300	99,5	343,1			
250	99,4	285,9			
150	99,0	171,6			
100	97,2	114,4	100,0	100,00	100,00
80	96,5	91,5	99,3	98,75	99,15
60	94,3	68,6	97,0	97,50	97,89
50	92,7	57,2	95,4	96,25	96,58
40	90,4	45,7	93,0	93,75	94,87
30	86,2	34,3	88,7	90,00	92,40
20	77,1	22,9	79,3	82,50	84,90
15	68,5	17,2	70,5	75,00	75,70
10	54,1	11,4	55,7	58,75	55,00
8	45,3	9,1	46,6	46,25	43,53
6	34,5	6,9	35,5	31,25	28,50
5	28,2	5,7	29,0	22,50	20,00
4	21,3	4,6	21,9	15,00	12,54
3	13,9	3,4	14,3	8,13	7,14
2	6,5	2,3	6,7	2,50	2,85
1	2,0	1,1	2,1		

