NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

CHARACTERIZATION OF THE CLINICAL PERFORMANCE OF A CHAIRSIDE AMALGAM SEPARATOR IN A MILITARY DENTAL TREATMENT FACILITY

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DECLARATION OF INTEREST

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TABLE OF CONTENTS

ABBREVIATIONS

%	Percent
ADA	American Dental Association
ASTM	American Society of Testing and Materials
BUMED	U. S. Navy Bureau of Medicine and Surgery
ºC	Degrees Celsius
CAS	Chairside amalgam separator
CFR	Code of Federal Regulations
cm	Centimeters
CMC	Criteria maximum concentration
DTF	Dental treatment facility
EPA	Environmental Protection Agency
FDA	U.S. Food and Drug Administration
g	Grams
HVE	High volume evacuation
h	Hours
IAW	In accordance with
ICP-MS	Inductively-coupled plasma mass spectrometry
inHg	Inches mercury
ISO	International Organization of Standardization
L	Liters
mL	Milliliters
µm	Micrometers
mm	Millimeters
NAMRU-SA	Naval Medical Research Unit San Antonio
NIDBR	U.S. Naval Institute for Dental and Biomedical Research
PFA	Perfluoroalkoxy
PHI	Protected health information
PII	Personally identifiable information
POTW	Publically owned treatment works
RCRA	Resource Conservation and Recovery Act

SRE	Solids retention efficiency
UFC	Unified Facilities Criteria
WHO	World Health Organization

EXECUTIVE SUMMARY

Background: Dental amalgam is a safe, low-cost, and durable restorative material. However, amalgam must be removed from dental wastewater to comply with the U.S. Environmental Protection Agency (EPA) ruling, effective 14 July 2017, which mandates the use of dental amalgam separators with ≥95% efficiency in all dental practices that place or remove amalgam.
Objective: The purpose of this study is to evaluate the latest commercially available chairside separator technology (DD2011P, Duel & Associates) as a suitable solution for compliance with the EPA rule.
Methods: DD2011P chairside amalgam separators (CAS), paired with pressure monitoring systems, were clinically evaluated to assess compliance with the EPA rule, to determine the new model's lifecycle, and gather data which could be used to monitor filter performance and predict the end of separator service life. Separators were installed in a military dental treatment facility, on specific chairs selected where dental providers performed a high volume of procedures utilizing amalgam. Data associated with flow resistance, filter efficiency, effluent metal content, number of amalgam procedures, and patients seen were collected.
Results: Data showed the average service-life of the DD2011P to be 67±38 work days. DD2011P separators performed above the 95% retention efficiency specified in the ISO standard, even after pulled from service due to pressure drop. Effluent concentrations of mercury, silver, and copper correlated loosely with the number of amalgam capsules used in the preceding two-week period, and overall, filter efficiency increased with use. Pressure data showed trends of increasing pressure drop in the weeks preceding failure. Total solids were a fraction of the CAS's fillable volume, and consisted of approximately 43% amalgam solids.
Conclusions: We concluded that the DD2011P amalgam separator meets the EPA dental wastewater effluent guideline and performs adequately in a military dental clinical setting. Our clinical evaluation of the DD2011P showed variability in service life due to a variety of clinical factors beyond the amount of amalgam used in practice, however, the average clinical service life was shown to be roughly 3 months. We further determined that there is substantial room for improvement in unit design and size, to produce the best available technology at the least cost/burden to the dentist to maintain compliance with federal and local dental wastewater guidelines. Additionally, the steady increase of pressure drop which preceded separator failure is

potentially useful toward developing an advance warning system to alert dental staff to declining separator performance and the need to replace the unit.

INTRODUCTION

Naval Medical Research Unit San Antonio (NAMRU-SA) is the lead agent for the Navy's Dental Mercury Abatement Program (BUMEDINST 5450.167A, 2011). As such, NAMRU-SA is tasked by the U.S. Navy Bureau of Medicine and Surgery's (BUMED's) Environmental Program Manager (M41) to test and evaluate dental amalgam separator technology, serve as a consultant and subject matter expert to the fleet for any dental mercury abatement issues, and maintain a forward-thinking approach to future mercury abatement and other environmental compliance requirements as directed by federal law and BUMED. In support of these efforts, NAMRU-SA has recently completed a clinical evaluation of the DD2011P (Dennis J. Duel and Associates, Mundelein, Illinois, USA) chairside amalgam separator (CAS) in a military treatment facility, with the specific aim of evaluating this model's performance and ability to meet U.S. Environmental Protection Agency (EPA) dental wastewater regulatory compliance (Olivera, et al., 2018). An additional component of the above study was an investigation into the dental chair high volume evacuator (HVE) suction performance over time with an installed in-line DD2011P. Electronic pressure sensors were placed at the inlet and outlet of the separator and the pressure differential was monitored over time. During the course of these investigations, additional CAS performance characterization data were collected which are otherwise not reported in the literature. They are reported herein. This technical report, in conjunction with our recently published manuscript (Olivera, et al., 2018), represent a comprehensive evaluation of the clinical performance of the DD2011P chairside amalgam separator. Here we present additional data to address further questions and the implications of our findings, as well as propose future directions for this work.

According to EPA, amalgam process wastewater from dental offices is the main source of Mercury (Hg) loading to publically owned treatment works (POTWs) (U.S. Environmental Protection Agency, 2017). Hg discharges from dental offices have been attributed to approximately half of total Hg loading to POTWs in the United States (Vandeven et al., 2005). Hg concentrations in dental wastewater can range from 100-2,000 mg/L (Welland, 1991); (Washington State Department of Ecology, 2018). EPA's most recent estimate is that 5.1 tons of Hg and 5.3 tons of other dental amalgam metals (i.e., silver [Ag], copper [Cu], Tin [Sn], and zinc

[Zn]) are collectively discharged to POTWs annually in the United States (U.S. Environmental Protection Agency, 2017).

In order to reduce the discharge of Hg-containing dental amalgam to POTWs, the EPA published its final rule of the Effluent Limitations Guidelines and Standards for the Dental Category under 40 Code of Federal Regulations (CFR) Part 441, with the effective date of 14 July 2017. Already existing sources (i.e., dental offices operating prior to 14 July 2017) which discharge to POTWs must demonstrate compliance by 14 July 2020 and must submit a one-time compliance report to their respective control authority no later than 12 October 2020. New sources (i.e., dental offices operating for the first time after 14 July 2017) which discharge to POTWs must demonstrate compliance upon opening and submit said compliance report no later than 90 days after the wastewater is first discharged to POTWs. The rule mandates the installation of dental amalgam separators which are certified as meeting ≥95% solids retention efficiency (SRE), in accordance with International Organization of Standardization (ISO) method 11143:2008 (ISO Standard, 2008), on all chairs where dental amalgam is placed or removed more than occasionally. The rule exempts mobile units, as well as practices in which amalgam restoration placement and removal are not typically performed, including the exemption of practices limited to the specialties of oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, and prosthodontics.

With the implementation of these new pretreatment standards prior to effluent release to the POTWs, EPA estimates a reduction in POTW discharge of amalgam-related Hg from 1,003 to 11 lbs per year. The final rule will cost affected dental offices an approximate average of $800 per year. EPA projects the total annual cost of the final rule to be $59-$61 million (U.S. Environmental Protection Agency, 2017). EPA's cost analysis, however, is based mainly on civilian dental practices, which are typically much smaller than many military facilities and use amalgam to a lesser degree. The costs for implementing the rule in military dental treatment facilities (DTFs) may be significantly higher.

In 1991, the U.S. Naval Institute for Dental and Biomedical Research (NIDBR), in collaboration with the American Dental Association (ADA), began evaluating the SRE of commercially available amalgam separators in order to mitigate Hg discharges from Navy DTFs.

NIDBR then founded a mercury management program that developed pretreatment systems for amalgam process wastewater. In 2001, NIDBR began a global effort to install and monitor pretreatment systems in Navy DTFs to ensure compliance with local and international discharge limits. The NIDBR Mercury Abatement Program became the Navy's lead agent for testing and evaluation of pretreatment systems for Hg mitigation in DTF wastewater. One pretreatment device, a filtration-based CAS, was developed by NIDBR in 2008 as a relatively low-cost alternative or addition to centrally located pretreatment systems (Stone et al., 2008). NIDBR's original CAS featured a replaceable polypropylene filter element with a nominal pore size of 0.5 µm which demonstrated 96.8% SRE when tested per ISO 11143:2008 protocols (Stone et al., 2008); (ISO Standard, 2008). Further development of the original NIDBR CAS concept was continued at NAMRU-SA where the Navy Mercury Abatement Program continues to test heavy metals control devices and provide guidance on CAS installation and maintenance to DTF personnel. The most recent version of the NIDBR CAS concept is a pleated filter-upgraded prototype of the commercially available DD2011, herein referred to as the DD2011P, (Dennis J. Duel & Associates); (The Simple One, 2017), see **Figure 1**. The DD2011P model has been certified per the ISO 11143:2008 test method (ISO Standard, 2008) as having 99.6% SRE.

Advancements in filtration technology, including amalgam chair-side traps which capture amalgam scrap and large particles >700 µm, as well as amalgam separators capable of capturing smaller particles, have significantly reduced Hg loading to POTWs. Amalgam wastes are typically composed of metal scrap ranging from <1 µm to 1 mm in diameter. Most amalgam scrap is captured by in-line chair side amalgam traps, which prevent vacuum line blockage by removing the larger tooth fragments and dental material waste particles. The remaining smaller amalgam particles, the majority of which are <100 µm in size, (Drummond et al., 2003) are usually removed from the dental wastewater by an amalgam separator using filtration, sedimentation, centrifugation, or a combination of these methods, before the wastewater is released into POTWs (U.S. Environmental Protection Agency, 2017). The remaining amalgam particulate which is too fine to be removed by standard separation methods is passed on to the POTWs where it is extracted in sewage sludge, which may be discarded in landfills, incinerated, or introduced to agricultural land as fertilizer (U.S. Environmental Protection Agency, 2017).

The goals of this study were to characterize the real-world performance of the DD2011P CAS in a military DTF. We sought to characterize its failure modes and how end of service life failure may be predicted, because as the CASs are used, they eventually clog over time due to the collection of amalgam and dental debris within the filtration material. As progressive clogging occurs, the suction available at the HVE tip decreases due to the increasing pressure drop across the filter. We therefore set out to determine if changes in pressure drop could be used to monitor CAS performance and predict CAS failure due to accumulation. We also used this clinical installation opportunity to test a recently developed quick disconnect fitting which was designed to simplify CAS replacement. Overall, we tested the hypothesis that while the chairside separator is sufficient to meet EPA regulatory guidelines as ISO tested, there are opportunities to identify areas for improvement in design to achieve reduced size and cost, while maintaining or improving efficiency.

MATERIALS AND METHODS

Materials

DD2011P Chairside amalgam separator *(Dennis J. Duel and Associates, Mundelein, IL, USA)*

A-dec 500 dental chairs *(A-dec, Newberg, OR, USA)*

Tytin™ spherical dental amalgam *(Kerr Corporation, Orange, CA, USA)*

American Society of Testing and Materials (ASTM) Ultrapure, Type 1 water *(MilliporeSigma, St. Louis, MO, USA)*

Fisher Chemical TraceMetal™ grade HNO_3 *(Thermo Fisher Scientific, Waltham, MA, USA)*

Flowcheck® vacuum meter *(RAMVAC, Spearfish, SD, USA)*

Thermo Scientific iCAP Q ICP-MS instrument *(Thermo Fisher Scientific, Waltham, MA, USA)*

Fisher Chemical TraceMetal™ Grade HCl *(Thermo Fisher Scientific, Waltham, MA, USA)*

MARS 6 microwave digestion oven *(CEM Corporation, Matthews, NC, USA)*

1 mm diameter, solid borosilicate glass beads *(Sigma-Aldrich, St. Louis, MO, USA)*

HeraTherm laboratory benchtop incubator *(Thermo Fisher Scientific, Waltham, MA, USA)*

Single use pressure sensors (*PendoTECH, Princeton, NJ*)

Microprocessor controller (*Arduino AG, Turin, Italy*)

Methods

ISO 11143:2008 Solids Retention Efficiency Testing of DD2011P Chairside Amalgam Separators

Prior to installation in the DTF (Budge Dental Clinic, Fort Sam Houston DENTAC, JBSA Fort Sam Houston, TX), quality assurance testing per ISO 11143:2008 (ISO-Standard, 2008) was performed on one DD2011P CAS to verify the model could attain the minimum requirement of 95% SRE. Further, SRE results could be compared to those reported by the certified testing laboratory to evaluate internal laboratory performance for quality assurance purposes. CAS units from the same lot as the tested unit were installed in the DTF for evaluation. ISO 11143:2008 (ISO-Standard, 2008) testing was also performed on the DD2011P CAS units at the end of service life (n=4) to ensure the SRE remained above the minimum requirement of 95%. SRE testing of the amalgam separators at the ends of their service lives was performed per ISO 11143:2008, §9.3.2.2 to §9.3.2.8 (ISO-Standard, 2008). The full test condition described in §9.3.2.9 was not performed as no further solids would be added to an amalgam separator beyond the end of its service life, and therefore would not reflect realistic clinical conditions.

Performance Evaluation of DD2011P Chairside Amalgam Separators in a Military Dental Treatment Facility

DD2011P CAS units were evaluated in a military DTF to determine service life expectancy, effluent Hg concentrations, as well as SRE, and mass of accumulated solids. Four general dentistry providers were identified in the DTF who placed the highest number of amalgam restorations, as determined by review of individual provider production numbers in the previous six months. Individual providers operated on one or two chairs exclusively. In total, six chairs were selected for this study: Two providers worked on two chairs each, and two other providers each worked on a single chair only. CAS units were tare weighed, then installed on the six A-dec 500 dental chairs (**Figure 2**). CAS end of service life was defined by meeting one of two criteria: Either the HVE system no longer met the required vacuum of 6-8 inHg (as specified in the Unified Facilities Criteria [UFC]) or the DTF staff reported poor HVE suction.

DD2011P Chairside Amalgam Separator vacuum sensor implementation

Pressure drop across the CASs was determined by measuring the pressure differential between two vacuum pressure sensors (PendoTECH, Princeton, NJ), one installed near the inlet and the other near the outlet of the separator. Sensors were installed inline within the vacuum tubing using 1" bore hose barb sensor-in-tube adapters, also from PendoTECH. An Arduino microcontroller (Arduino AG, Turin, Italy) was programmed to operate the two sensors and record pressure measurements at one-second intervals. Recorded pressure data were collected weekly and the data were stripped of weekends, holidays, and nights to yield data sets for each chair during normal working hours. The pressure differentials for each time-point were calculated by subtracting the outlet pressure from the inlet pressure. Data were smoothed using 1-week and 2-week moving averages, wherein starting from a particular day, the entirety of business-hours pressure differentials from the previous week or previous two weeks were averaged to create a single data point representing that day.

Effluent Sample Collection from High Volume Evacuation System/Chairside Amalgam Separator

Effluent samples were collected from clinically-installed DD2011P CAS units (n=9) every two weeks for up to a 12-month period in order to characterize Hg concentrations. Two sequential 1 L volumes of ASTM Ultrapure, Type-1 water were aspirated through the HVE system of each of the six dental chairs and collected in borosilicate glass sample containers which were connected to the outlet of each CAS. Prior to effluent sample collection, sample containers, tubing, and connection fittings were cleaned per EPA standard test method guidelines (U.S. Environmental Protection Agency, 2014; Chapter Three: Inorganic Analytes). From each 1 L flush, three 50 mL aliquots were prepared and preserved with Fisher Chemical TraceMetal™ grade HNO_3 per the EPA standard test methods indicated for aqueous total Hg and aqueous total metals (U.S. Environmental Protection Agency, 2007). In order to ensure compliance with the UFC, vacuum levels through the HVE aspirator were measured with a Flowcheck® vacuum meter immediately

after each effluent sample collection. Effluent sample collections from a CAS unit were terminated after failure, as described above, or 12 months after the installation date, whichever occurred first.

Effluent Sample Preparation, Hg Analysis by Inductively-Coupled Plasma Mass Spectrometry, and Statistical Analysis

CAS effluent samples were prepared for trace metals analysis via inductively-coupled plasma mass spectrometry (ICP-MS), following microwave-assisted acid digestion per EPA Method 3015A (U.S. Environmental Protection Agency, 2007; Method 3015A revision 1). Aliquots were diluted in a digestion matrix comprised of 45 mL of ASTM Ultrapure, Type 1 water, 4 mL of concentrated Fisher Chemical TraceMetal™ Grade HNO_3, and 1 mL of concentrated Fisher Chemical TraceMetal™ Grade HCl. The diluted aliquots were then transferred to 75 mL perfluoroalkoxy (PFA) vessels and digested in a MARS 6 microwave digestion oven. Each digestion batch of analytical samples included quality control samples in accordance with EPA Methods 3015A and 6020B in order to evaluate laboratory performance and analyte recovery bias and precision (U.S. Environmental Protection Agency, 2007); (U.S. Environmental Protection Agency, 2014; Method 6020B revision 2). Digests were analyzed for Hg concentrations on a Thermo Scientific iCAP Q ICP-MS instrument per EPA Method 6020B (U.S. Environmental Protection Agency, 2014; Method 6020B Revision 2). Hg concentration means with standard deviations were calculated from the concentrations of the three aliquots collected from each HVE system flush of each sampling event. Data distribution of the Hg concentration means was assessed for normality using the Shapiro-Wilk test. Statistical differences in the pooled mean Hg concentrations between each HVE system flush were assessed using a Student's *t*-test with the type I error rate (significance level) set at 0.05 ($\alpha = 0.05$).

Mass of Total Solids Accumulated by DD2011P Chairside Amalgam Separators at End of Service Life

DD2011P CAS units were evaluated for mass of total solids captured during each unit's service life (i.e., from the time of installation to the time of failure), using a modified version of Method 2540B by Rice et al. (Rice et al., 2012). The initial tare weight of each CAS was measured prior to deployment in the DTF by drying at 103-105 °C for 1 h, cooling in a desiccator at 23 °C, and then weighing the CAS. This desiccation and weighing cycle was repeated until a consistent weight (<4% difference between the current and previous measurements) was observed. After the separators reached the ends of their service lives, this process was repeated to yield the final weight of each CAS. The total solids accumulated for each CAS were calculated by subtracting the initial tare weight from the final weight.

An unused DD2011P CAS unit was opened by removal of the end cap with a drywall saw, as close to the inlet end as possible. The fillable space between the filter element and the housing was measured by filling this space with 1 mm diameter glass beads. The beads were recovered, and their total volume and weight determined. The volume of the CAS, as determined by this method, was multiplied by the density of amalgam powder (1.694 g/cm^3 for the specific particulate composition described by ISO 11143:2008 (ISO-Standard, 2008), and prepared from Kerr Tytin™ amalgam, to determine the mass of amalgam which could occupy the fillable space of the unit.

Composition of Solids Accumulated by Chairside Amalgam Separators at End of Service Life

Six CAS units were collected from the DTF, each at the conclusion of its respective service life. Following removal, the CAS inlet and outlet ports were capped and CAS were transported to the NAMRU-SA for solids recovery and analysis. The ISO Method 11143:2008 testing apparatus was assembled with the CAS installed in reverse orientation to generate backflush. Each CAS was flushed from outlet to inlet with 1 L deionized water and the effluent containing captured sediment was collected. Effluent samples collected from the six CAS units were combined in a single 6 L container. The PVC housing of the CASs were opened by removal of the end caps with a drywall saw, as close to the inlet ends as possible. Sediment which remained inside the CAS housing and on the filter surface after backflush was removed by scraping and irrigation, and pooled with the

effluent and sediment collected by backflush. Sediment and effluent were homogenized by orbital shaking and then the solids were allowed to sediment at the bottom of the container and the supernatant was transferred to another container. Sediment was dried overnight using a Thermo Scientific Heratherm^{TM} laboratory benchtop incubator. Metals composition was determined by homogenizing sediment to a uniform mixture, then three independent 250 mg aliquots were taken and digested per EPA Method 3051A: microwave assisted acid digestion of sediments, sludges, soils, and oils. Digested samples were then diluted by serial dilution to concentrations of 1/100, 1/10,000, 1/100,000, and 1/1,000,000. ICP – MS was used as described above to determine concentration of Hg, Ag, Cu, and Sn.

Clinical Procedural Data Collection

Daily procedural data from the evaluation time period for each provider were collected at the end of the study. The electronic procedure logs collected from the DTF included only the names of providers and procedures performed. Clinical data reflecting amalgam restorations removed were not collected due to personally-identifiable information (PII)/protected health information (PHI) concerns. Neither PII nor PHI of the individual patients treated were requested, collected, or viewed by the investigators. Procedures (dental fillings) in which amalgam was placed (2017 Current Dental Terminology codes D2140, D2150, D2160, and D2161) were tabulated. These data were used to calculate the average number of amalgam surfaces placed per workday on each chair in the study, beginning with the date the CAS was installed and continuing through the end of its service life. For Providers 1 and 2, this rate was divided by two across each of the two chairs that were used exclusively by these providers. For Providers 3 and 4, each operated on a single chair, and therefore, all procedures were attributable to their single respective chair. Providers performed all amalgam restorations with Valiant Ph.D. which contains 40-45% Hg per capsule (Ivoclar Vivadent 2014).

RESULTS

ISO 11143:2008 Solids Retention Efficiency Testing of DD2011P CAS

To confirm the function of our ISO 11143:2008 test rig and take a preliminary measure of CAS retention efficiency, we performed the method on one separator from the production lot which we would install for the study: It achieved an SRE of 99.18% on the empty test and 97.40% on the full test. At the end of service life, the mean SRE of the CAS units by ISO 11143:2008 (ISO-Standard, 2008) was 99.82 ±0.14% (n=4), with the lowest SRE from the Chair 5 CAS at 99.65% and the highest SRE from the Chair 2 CAS at 99.95% (**Figure 3**). The accredited testing lab that performed ISO-certification tests on the DD2011P reported 99.906% for the empty test condition and 99.626% for the full test condition (National Sanitation Foundation International [NSF], 2015).

DD2011P Clinical Service Life

All clinical data collection, beginning with the initial installation of the six CAS units on 25 August 2016, concluded on 23 August 2017. Five of the six original CAS units reached the ends of their service lives when they failed due to accumulated particulate and the resulting persistent increase in pressure drop or loss of suction noted by the dental staff. The first three CAS units to fail (i.e., Study Chairs 3, 4, and 6) were replaced and continued on study as additional experimental replicates for the estimation of service life expectancy, effluent metals analyses, and pressure sensor data. All three of the replicate CAS units concluded their service lives due to high pressure drop and/or loss of suction as well. The mean service life of the original five and three replacement DD2011P units (n=8) was 131.6 ± 45.1 calendar days, or 67.1 ± 37.6 workdays (**Table 1**). One CAS remained in use for 363 calendar days, never having accumulated sufficient pressure drop for withdrawal nor eliciting complaints of poor suction from the dental staff. However, it was removed from the study after one year of use. This particular unit, Chair 2 – CAS 1, proved to be a statistical outlier by Grubbs' test and was excluded from mean service life calculations.

Amalgam scrap, spent amalgam capsules, and estimated amalgam used during separator service life

Total dental amalgam capsules and total dental amalgam scrap were collected at each chair during the full course of each separator's service life and totals were compiled from the bi-weekly collections from the amalgam capsule and scrap collection bins provided at each chair. Amalgam scrap consisted of non-contact scrap that was not used in the restoration, plus excess contact amalgam scrap trimmed from the restoration and recovered from the dental unit evacuation trap. Amalgam scrap was separated from the capsules, composite material, and other contaminants, then weighed. A loose correlation was seen between dental amalgam capsules used and the service life of the CAS, and in general, separators which were in service a short time show fewer amalgam capsules used and less amalgam scrap collected in that time-frame. On average, 255.0 ± 130.6 capsules were used and an average of 99.25 ± 66.68 g of amalgam scrap were collected during a separator's service life (see **Figure 4**).

Feedback was solicited from the dental staff from each chair regarding procedural details, i.e., number of patients per week per chair, amalgam use, waste line cleaning habits, general observations, etc. Results of this canvas can be seen in **Table 2**. It is worth noting that while all staff reported using the provided collection bin for all of their empty amalgam capsules and amalgam scrap, there is a discrepancy between the amalgam use indicated from the collected capsules (2.55 capsules/chair/day, see **Figure 5**) and the much higher reported amount of amalgam work conveyed in **Table 2**. Further, capsule counts and collected scraps also underreport amalgam work when compared to the reviewed dental procedural logs. **Table 1** summarizes the information collected from the Budge Clinic database (no PII / no PHI) and reveals that the amalgam work reported by this source more closely matches the estimates reported in the staff survey than it does the collected capsules and scrap. We conclude, using the more robust clinical database information, that the average number of actual work days (slightly less than was calculated, due to leave or other factors) which comprised the separators' service lives was 67±38 days, and that the average number of amalgam surfaces placed per day during the separators' lives was 8.4±1.4.

Effluent wastewater grab sample analyses

Bi-weekly dental wastewater samples were collected for trace metals analysis from installed DD2011P CASs in clinical use at Budge Dental Clinic. Dental amalgam constituents of interest (i.e. mercury and silver, both of which are Resource Conservation and Recovery Act [RCRA]-regulated metals, and copper, which is toxic and highly soluble) were measured. Concentrations of each analyte from CAS effluents were determined for each of the six chairs for dates ranging from two weeks after installation (06 September 2016) through the end of the service life of each CAS (the scale of the x-axis varies to accommodate different lengths of service life) (**Figure 6**). Study chairs 3, 4, and 6 each included one original CAS, which were all installed on 25 August 2016, and one replacement CAS, each of which was installed when the original failed. Therefore, study chairs 3, 4, and 6 show sequential data from two CAS units. Effluent metals concentrations data (reference the left y-axis) are overlaid against the number of spent amalgam capsules collected from the corresponding chair during the collection period (blue bars, reference the right y-axis) (**Figure 6**).

Observed metals concentration in the first rinse (**Table 3a**) and second rinse (**Table 3b**) were roughly equivalent, supporting the hypothesis that leaching of metals into solution from filtered dental amalgam particles occurs but contributes a relatively small amount to the concentration of metals in the CAS effluent. Overall, slight decreases from the first rinse to the second rinse were observed (**Table 3c**), and in the case of Hg and especially Cu, these differences were statistically significant**.**

Total solids accumulation during separator service life

The mean total solids accumulated in each DD2011P CAS at their respective end of service life was 195.4 ± 63.4 g (n=6) (**Table 4**). **Figure 7** shows that solids accumulation in CAS unit was mainly due to filtration, as evidenced by the presence of particulate material coating the filter media. Sedimentation within the filter housing only accounted for a small portion of the total accumulated solids, as evidenced by minimal amounts of particulate residing within the space between the filter media and the interior housing wall of the CASs. The total fillable volume of

the CAS was determined to be 500.4 cm^3, and this corresponds to a mass in 1mm glass beads of 634g or 2953g of amalgam powder (of the specific particulate composition described by ISO 11143:2008[ISO Standard, 2008: ISO 11143:2008]). Composition of the material accumulated in the CASs (an average of 254.933 g) during their service lives was determined to be 57% non-amalgam materials (145.422 g), while the remaining 43% was amalgam (109.511 g). Mercury (20.9%) was the major metal of the recovered solids, with silver (11.7%), Tin (6.1%) and Copper (4.3%) comprising the remaining amalgam constituents (**Table 5**).

Suction performance and vacuum differential

During each of the bi-weekly visits to Budge Dental Clinic, the vacuum at the dental chair's HVE tip was measured using a RAMVAC Flowcheck® instrument. Under normal operating conditions during business hours, the centralized vacuum system consistently pulled approximately 8 inHg at the chairs. After initial installation, empty amalgam separators had a negligible pressure drop, and were observed early in their service lives to support approximately 8 inHg at the HVE tips. During the course of the trial, as the amalgam separators accumulated particulate matter, the measured vacuum at the HVE tips decreased and became more erratic. Chair 3 – CAS 1 and Chair 5 – CAS 1 were replaced during the scheduled Budge Clinic visits when the vacuum at the HVE tip deviated outside the acceptable range (see **Figure 8**, 17 November 2016 and 24 February 2017). It was noted that the effluent collection would precede separator failure occasionally, although why this occurred is unknown. Several times, dental staff requested CAS unit replacement immediately following data collection because suction was no longer adequate (see **Figure 8**, Chair 4 - CAS 1 on 16 December 2016, Chair 6 - CAS 1 on 16 December 2016, Chair 1 - CAS 1 on 23 March 2017, Chair 4 – CAS 2 on 21 April 2017, and Chair 6 – CAS 2 on 5 May 2017).

Results of the pressure data analysis have demonstrated patterns that can be utilized in predicting the effective lifespan of the separators. Daily averages and weekly averages were calculated from the working-hours data sets. A moving average strategy was developed whereby from a given day, the preceding week or the preceding two weeks of pressure differentials were

averaged. One-week moving averages (gray lines) and two-week moving averages (black lines) of pressure differentials for each chair, calculated at weekly intervals, are shown in **Figure 9**. Across all CASs, using the two-week moving average method, a persistent differential between inlet pressure and outlet pressure is seen to precede failure, although data recorded on Chairs 1 and 4 show a magnitude of pressure drop of approximately half that of the other installations (**Figure 9**, Chair 1 – CAS 1, Chair 4 – CAS 1, Chair 4 – CAS 2).

DISCUSSION

In order to keep a forward looking approach to future mercury abatement and other environmental compliance requirements as directed by federal law and the U.S. Navy Bureau Of Medicine and Surgery (BUMED), NAMRU-SA has recently completed a clinical evaluation of the DD2011P chairside amalgam separator (CAS) in a military treatment facility. The first specific aim of evaluating this model's performance was to determine its suitability for meeting EPA dental wastewater regulatory mandates in the context of military dental treatment facilities. The second specific aim was to answer a broader set of questions: How long could the DD2011P last under heavy usage/high amalgam placement conditions? How easy is it to install and replace, and how could we improve the implementation and/or performance of the device?

The EPA's "Effluent Limitations Guidelines and Standards for the Dental Category," published 14 June, 2017, lays out best practices, requires documentation and self-reporting of compliance, and mandates the use of an ISO-certified separator (>95% efficient) on chairs where amalgam is placed or removed. Military DTFs are subject to the new rule, although having been environmentally conscious, the Navy mandated the use of amalgam separators in its DTFs many years prior to the EPA rule being drafted. Because Navy DTFs differ significantly in size, volume, and architecture from civilian dental clinics, special consideration is warranted with regard to amalgam waste. We set out to assess the suitability of the chairside separator to meet these requirements. At the time of testing, the efficiency specification that would be in the EPA rule was unknown, however, the current median performance for amalgam separators on the commercial market is 99% SRE (U.S. Environmental Protection Agency, 2016). We therefore evaluated an upgraded version of the commercially available, already widely used by the Navy, DD2011 amalgam separator, which incorporates a pleated filter element (herein referred to as the DD2011P). Because the DD2011P is ISO certified as 99.6% efficient, it satisfies the SRE requirement of the EPA rule. To measure the performance of this device and determine its suitability for use in military DTFs, we installed nine DD2011P units in a military DTF, along with a pressure monitoring system on each unit to record suction performance, and with quick-disconnect fittings which were developed in-house to improve the speed and ease of separator installation and replacement.

We especially selected four dental care providers which, at the time assessed, were shown by the clinical database to perform amalgam restorations with the highest frequency. Under these conditions, the separators showed a mean service life of 67 workdays, or approximately 3-5 months. The standard deviation (±37.6) was high for this average, representing a wide range of service life durations. This is not surprising as there are a number of factors which contribute to the separator's expenditure, amalgam use being only part of the picture. We determined from a pooled random sample of six spent separators, that only 43% of the accumulated solids were amalgam. While we did not specifically determine the origin of the other 57%, we can safely surmise it is comprised of tooth structure, dental composite, abrasive particles, and other particulate dental and oral materials. This is not meant to be a robust determination, applicable to all dentists in all facilities, but it does illustrate the point that a filtration-based separator captures more than just amalgam. The ratio of amalgam to other captured material will vary with amalgam placement/removal technique, as well as the size and frequency of these procedures.

Examining **Figure 4**, it can be seen that on average, 255 amalgam capsules (each being a 600 mg, two-spill aliquot) were used in a separator's service life, producing 153 g of amalgam (600 mg x 255 capsules = 153 g). Since, on average, 99 g of amalgam scrap were generated during a separators' service life (see **Figure 4**) only 54 g (153 g – 99 g = 54 g), on average, would remain to be distributed between dental restorations placed and the separator. Since, on average, 195 g of solids were found in spent separators (see **Table 4**), the contribution of amalgam in new restorations toward total solids accumulated in the separator must therefore be no more than 28% (54 g / 195 g = 0.277), and likely much less, assuming that the majority of non-scrap amalgam is incorporated into the dental restorations placed. When we compare this assessment to the workload characterization provided by the DTF clinical staff (**Table 2**) and the amalgam placement data collected from the clinic database (**Table 1**), it can be seen that amalgam placements were actually much more frequent than could be accounted for by counting spent capsules. This observation perhaps accounts for part of the discrepancy between our capsule-count-based estimate of separator deposit composition (28%) and our observed value (43%), most likely because some capsules were disposed of outside of the specified collection bin, and thus were not available to us for counting. It is possible that amalgam scrap measurements are similarly undervalued. Also, it is worth considering that the difference between our estimated 28% ceiling and the observed 43% must be also partially due to the removal of existing amalgam placements,

the waste of which also winds up in the HVE system. This latter observation is most certainly relevant, given that clinical staff reported that on average, 28% of amalgam restorations are to replace existing, failed amalgam (**Table 2**).

With the observation that amalgam deposits comprise less than half of the accumulated solids in the amalgam separator, we sought to determine the contribution of these minority amalgam solids to separator service life. Comparing the duration of separator service life with the clinical data regarding the number of amalgam restorations performed during the service life (**Table 1**), it is clear that the length of service life correlated proportionately with counts of amalgam restorations. If the amount of amalgam placed were a major factor in separator expenditure, this relationship would be inverted, i.e., the more amalgam used, the shorter the service life. Since we observed the opposite, we can conclude that other factors and non-amalgam procedures, which contribute the majority of particulate load, are better determinants of separator service life. Based on this, we suggest that chairs where amalgam restorations or removals are performed be used exclusively for that purpose. This will serve to minimize the contamination of facility plumbing with amalgam sludge, extend separator life, and also limit the amalgam control measures to a subset of chairs, rather than installing and maintaining separators on all chairs.

All CAS units installed at the DTF consistently failed or reached one year in service with relatively little solid material collected in the fillable space (see **Figure 7**). At the end of their service lives, the six DD2011P CAS units were dried and assayed for total solids accumulated within each separator. For the six CAS units sampled from those expended on the study, total solids in the fillable space were a mean of 195.4 ± 63.4 g (see **Table 4)**. We calculated the weight of the fillable volume to be approximately 2,953 g if composed entirely of amalgam particulate, and to be 634 g if composed entirely of lighter, non-metallic materials such as abrasive, tooth, or dental composite. Based on our observation that 43% of the accumulated solids were amalgam (see **Table 5**), the approximate weight of the contents of the fillable space (43% X 2,953g + 57% X 634 g) is 1,631 g. Therefore, the actual deposits accumulated (195.4 g) are less than 12% of the estimated capacity, supporting the assertion that development of a smaller CAS should be pursued, and is likely possible without impacting service life. However, separator size impacts both the cross-sectional flow area and filter surface area, partially determining performance, and therefore care must be taken in balancing size with efficiency and performance. In turn, if a smaller CAS

unit were developed, it could lead to lower initial costs, lower disposal fees, improved ergonomics, less intrusive installation, and greater convenience.

Greater convenience and ease of use can be achieved in other ways as well. For our test installations, we used the recently developed quick disconnect fitting, which replaces the hose-barb to tubing, friction-fit installation with a male coupling that adapts the separator to connect directly with the A-dec chairs' native quick-disconnect female fittings (**Figures 1** and **2**). We visited the clinic every other week to collect effluent samples, vacuum data, and check the suction on our test chairs. During the year-long course of our investigation, we did not observe any leakage or deterioration of the fittings we installed, and only in two instances did the fittings break: One was due to frequent articulation of the dental chair to accommodate a left-handed dentist which caused repetitive acute flexural strain on the connection, and the other was a stress crack that began in the threads after months of being repeatedly disconnected and reconnected. Under normal use, the lifespan of these fittings could be several years (as they can be removed from spent separators and re-used if desired), and overall, the benefits of their use greatly outweighed the minimal cost: Separator removal and reinstallation was shortened from an approximate 20 minutes to an approximate 3 minutes, required only a Philips-head screw driver, and hoses did not need to be pried or cut from the barbs for disassembly. Cutting the hose just next to the hose barb is faster than prying the hose off the barb, and is a common shortcut employed when changing the separators, however, each time this is done it shortens the hose incrementally, increasing the likelihood of kinks and eventually necessitating hose replacement. Use of the quick disconnects results in separator replacements that are faster and easier than the shortcut and also lack the drawbacks. At the time of this writing, bulk pricing for the quick-disconnect fittings runs about $5 for a pair. Based on our positive experience, we have recommended these fittings and have distributed them on request at both the Budge Dental Clinic and Navy DTFs around the country. Feedback has been overwhelmingly positive.

As mentioned above, military DTFs differ from conventional, civilian dental clinics in a number of important ways: They tend to be much larger than civilian clinics, often with dozens of chairs in a single facility, versus several chairs in a civilian clinic. Also, due to mission demands and the logistics of coordinating dental procedures with the schedules of highly mobile service members, amalgam is used as a restorative material more frequently in military DTFs than in the

private sector. These two factors warrant special consideration regarding amalgam waste handling, and are the main reasons why the Navy mandates chairside amalgam separator use (U.S. Navy Bureau of Medicine and Surgery, 2015). Placing the amalgam separator close to the chair where amalgam work is performed (as directed by the UFC) minimizes contamination by removing the vast majority of amalgam waste before it enters the facility's plumbing. This extends the life of the vacuum system by reducing amalgam deposition in the facility's vacuum system plumbing, reducing the likelihood of system failure due to clogging, and also reducing the amount of static amalgam in contact with the effluent, hence reducing leaching of metals into the effluent stream.

In order to assess the consistency of the separator across its service life (i.e. does its performance change in use?), we sought to characterize the separator's performance regarding effluent metals concentrations. On a bi-weekly schedule, we collected two effluent samples, one after the other, from each of the chairs installed at the DTF. The intent was two-fold: firstly, to determine overall metals concentrations in the effluent flow, and secondly, to determine if the first collection would have higher trace metal concentrations than the second collection, which would indicate that the metals trapped in the amalgam separator had leached into solution (the amalgam sludge captured in the separator is damp to wet) since the last rinse. Any dissolved metals would be eluted in the first collection, and therefore lacking in the second. We observed this to be a significant difference in the majority of chairs, with Cu being the most mobile, followed by Hg (**see Table 3a**). Curiously, statistically significant differences between the first and second collections were observed when outliers were excluded from the analysis: These outliers happen to be the most obvious differences between the first and second collections which are visible in **Figure 6 (**Chair 1 on 09 February 2017; Chair 4 on 08 September 2016; Chair 4 on 12 January 2017; and Chair 6 on 08 September 2016), but their contribution to the standard deviation is great enough to compromise statistical significance.

While our grab sample approach does not permit calculation of the dissolved amalgam present in all effluent leaving the DTF, our measurements loosely correlate with the amalgam capsule counts for the preceding week in as much as during weeks when amalgam placement was high, the effluent concentrations were usually greater. Cases where mercury concentration in the first rinse is notably higher than the second rinse were especially so within the first two weeks of

a new CAS being installed (see **Figure 6**, Chair 3, Chair 4, and Chair 6). It is not yet known why this is the case, but it may be that a new CAS becomes more efficient after the first two weeks in service, and at first, smaller particles work through the filter during this break-in period. This effect appears to be minimal, however, and is not representative of the majority of the service life of the CAS. It is, however, consistent with our observation that filter efficiency increases slightly from brand new (99.6%) to expended (99.82%).

Our sampling method does not discriminate between fine particulate and dissolved metals, but even measuring solids and dissolved combined, our measurements never captured Hg concentrations greater than 20 ppm (0.002%) in the effluent samples, and overall, effluent concentrations were much lower than the occasional spikes (See **Figure 6**). Resolution of activity-dependent spikes in dissolved amalgam metals was less than two weeks, suggesting that newly created particulate can release a finite amount of either very fine particles or dissolved metals, and then effluent concentrations of metals again normalize to lower levels. This evidence is consistent with other reports showing the majority of amalgam in wastewater is in the solid phase (99.6%, see Stone, 2004), and therefore mostly captured by filtration.

Evidence of leaching can be found, however, in the ratio of metals which constitute amalgam, and how those ratios shift from the original proportions to different ratios in the separator deposits and effluent metals. For instance, the ratio of Hg compared to Ag and Cu found in spent separator deposits versus the published formulation of the Valiant Ph.D. amalgam, which is the sole formulation used at the Budge DTF, shows that the relative proportions of the metals correlate roughly (see **Figure 10**), although Cu and Ag appear to be under-represented slightly in the separator deposits. It is worth noting however, that the metals' ratios in effluent are skewed from the original, as-packaged ratio and from the ratio of metals in the separator deposits: In particular, note the difference in Cu to Hg ratio for the Effluent (first rinse) vs. the Effluent (second rinse) groups. The concentration difference between the first and second effluent collections was statistically significant, and the Cu to Hg ratios reflect the differences as well, with the first rinse being greater than the second.

This observation is meaningful on two levels: Firstly, the concentration difference between the first and second effluent collections indicates that leaching of copper occurs. Also note that the Separator Deposits group shows a Cu to Hg ratio which is less than the Manufacturer's

Published Values, while the Effluent group Cu to Hg ratios all are greater than the Manufacturer's Published Values. This observation additionally supports the conclusion that copper is leaching into the effluent, in as much as it shows high Cu values in the effluent that match low Cu values in the retained solids. Secondly, the observed changes in Cu to Hg ratio are important as they indicate that Hg and Cu are not leaving the separator in proportional amounts, hence further supporting the assertion that leaching from the solids trapped in the separator occurs, and that Cu is leached to the greatest degree. The change across Ag to Hg ratios also suggests that Hg is leached to a greater degree than Ag, however, we did not see a statistically significant difference to support this hypothesis. This begs the question whether, after extended periods, Cu may leach from the amalgam trapped within the CAS enough to appreciably change its composition and properties. It is possible that after enough Cu is leached from the amalgam, mercury mobility may be further increased. While the EPA notes that the majority of amalgam in effluent is solid particles, for which common amalgam separator technology (filtration, sedimentation, centrifugation) is appropriate, some municipalities have far more stringent restrictions on effluent metals concentrations. The eventual implementation of water polishing via ion exchange resins or other means appropriate to the dissolved fraction may be required to meet ever-tightening regulations on allowable Hg, Ag (both RCRA-regulated metals), and Cu (which is toxic and highly soluble) in wastewater.

As was described in the Results, we noted that on several occasions, dental staff requested CAS unit replacement immediately following effluent collections (see **Figure 8**, Chair 4 - CAS 1 on 16 December 2016, Chair 6 - CAS 1 on 16 December 2016, Chair 1 - CAS 1 on 23 March 2017, Chair 4 – CAS 2 on 21 April 2017, and Chair 6 – CAS 2 on 5 May 2017). While we do not have a definitive answer for why this occurred, we believe that turbulence generated from the fluid bolus applied to the separator to collect our effluent samples redistributed particulate matter across the filter surface, which likely occluded any remaining functional filtration zones.

The vacuum data which we collected were promising, in as much as analysis by the two-week moving average method showed clear upward trends in pressure differential which preceded failure. Appropriate pressure differential thresholds should be evaluated for the purpose of warning the operator (medical device technician or dental caregiver) of impending or immediate and present separator failure. Implementation of a warning system could improve patient care by

allowing the technicians to know in advance that a separator needs replacing soon, and hence to replace it at their earliest convenience rather than suffer the inconvenience of a separator replacement mid-care. There are several caveats to this approach which observed in the course of this study, however.

Firstly, the installation of the vacuum sensing hardware is a modest technical challenge, both in additional plumbing of components, plus the addition of wires and electronics to the system. If these parts were directly incorporated into the separator design, convenience and ease of installation could be achieved, however the cost of these units would be greater and the enhanced separator would then need to be re-evaluated, additionally proven compliant with IEC 61010-1 due to the incorporation of electronics, and re-certified. Perhaps a better solution is an add-on system that is distinct from the separator and offers the early warning capability without requiring re-certification of the separator by an ISO testing authority.

Secondly, it can be seen that pressure drop was recorded as negative during some recording periods on some of the installations (**Figure 9**, Chair 1 – CAS 1, Chair 2 – CAS 1, Chair 4 – CAS 2, Chair 5 – CAS 1), which may suggest sensor drift. Therefore, initial calibration and regular follow-on calibrations are necessary for the system to work correctly. For comparison purposes going forward, pressure data will be normalized so that the lowest recorded differential is zero, thus allowing us to use the full data set for benchmarking the performance algorithm. It is possible in future versions of this test rig to use a self-calibration routine in the software to sense periods of inactivity (no pressure fluctuations), when the suction pump is off (pressure differential is small or zero), during non-business hours, and use this time to reset zero values.

Scale, on the other hand, would need to be calibrated by other means. A difference in scale can be observed in Chair 4 (**Figure 9**), where the separator failed due to inadequate suction, while the recorded vacuum data showed only half the pressure drop at failure as was observed on other chairs. It may be that this was due to small air leaks between the sensors on chairs 1 and 4, however, the Vac-Check procedure we performed indicated sufficient suction at the HVE tip, which would have been inconsistent with HVE system leaks. More likely, this scaling issue was due to sensor drift, skewing the accuracy of the readings, and thus causing a reduction in the read pressure differential. Since the same observation is true for both Chair 4 data sets (Chair 4 – CAS 1 and Chair 4 – CAS 2), additional weight is added to this supposition. More weight for this

supposition can be gained by considering that in the course of the separators' service lives, the tubing and fittings (potential leak sources) were manipulated many times, yet this caused no variance in the differential.

At any rate, these technical challenges regarding the electronic vacuum sensor system highlight the need for proper, routine calibration in any system that is used to monitor the separator's function. Since the retention of amalgam in a separator is now a mandatory practice, the importance of calibration is even greater. It is then worth considering whether this could substitute for the standard practice of checking the HVE suction monthly with the Flowcheck® meter to avoid it being a redundant task, although likely not, since the Unified Facilities Criteria define compliant HVE operation by readings taken at the HVE tip. Perhaps too, it is worth consideration whether the addition of an early warning system is worth the added cost and complexity when separator failure is easy to diagnose and the replacement of a failed separator now requires only a screwdriver and a couple of minutes. Alternatively, it is reasonable to consider that a disposable mechanical sensor, built into the separator, could accomplish this task at a lower price-point and without the complications of an electrical system.

MILITARY SIGNIFICANCE

Naval Medical Research Unit San Antonio is tasked by BUMED to assure environmental compliance with respect to BUMED, U.S. Navy, DoD, and federal rules and regulations. NAMRU-SA supports readiness by assuring compliance with said rules and regulations, keeping our Sailors, Marines and monetary resources focused on the mission, avoiding unnecessary delay and expense due to the loss of manpower and reallocation of resources to address an unmitigated environmental hazard that could have been prevented. This work also contributes to a forward thinking approach to risk mitigation and compliance assurance, as rules and regulations change and tighten over time. Additionally, good environmental stewardship by the U.S. Navy demonstrates our commitment to leading from the front in affairs that affect not only our service men and women, but our entire nation and the world as a whole.

Nationally, the EPA launched 82 FR 27154 (40 CFR 441), effective 14JUL17, with the goal to reduce mercury discharges from dental offices into POTWs. Utilizing amalgam separators and best management practices, the goal of this ruling is to reduce the discharge of mercury by 5.1 tons, and other metals by 5.3 tons (U.S. Environmental Protection Agency 2017). This focus on mercury reduction is reinforced internationally by the Minamata Convention on Mercury, which the United States signed on November 6, 2013. The Minamata Convention intends to reduce the use and release of mercury into the environment, under paragraph 3 of Article 4, where signing countries are required to phase down the use of dental amalgam and promote alternatives for dental restorations.

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Figure 1. The DD2011P chairside amalgam separator with installation parts: (**A**) The DD2011P is packaged with three sets of hose barbs to accommodate different tubing sizes and vinyl caps are furnished to close off the connections when the separator is removed for disposal. (**B**) Quick-disconnect fittings developed by NAMRU-SA and fielded to Navy dental facilities for testing and improved convenience of installation. (**C**) Mounting brackets which anchor the separator to the back of A-dec 500-series chairs.

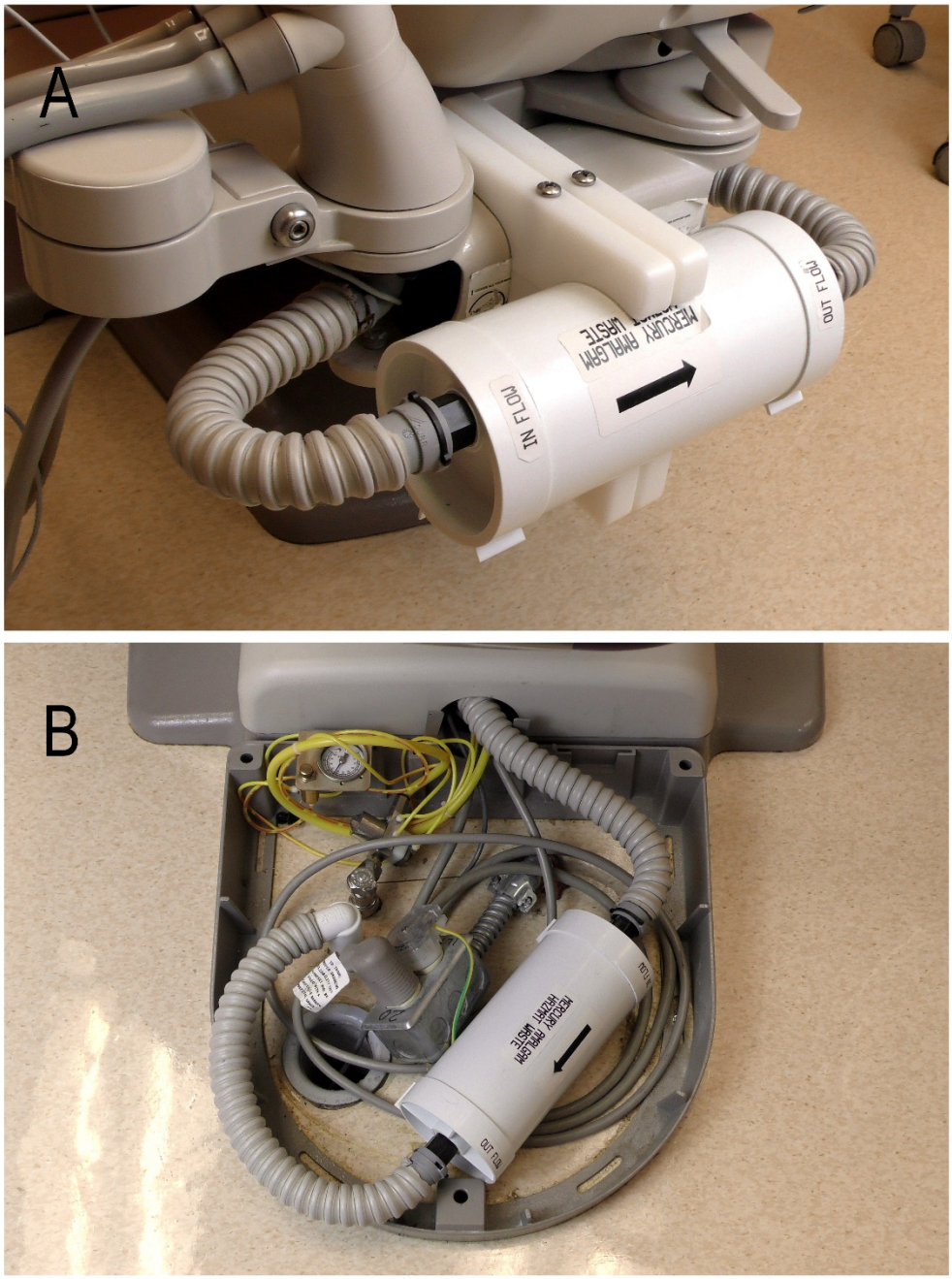


Figure 2. A typical installation of the DD2011P chairside amalgam separator (white cylinder) on the rear support link of an A-Dec 500-Series dental chair (**A**). This particular installation makes use of the optional mounting brackets (white clamps with screws). An alternative installation is shown (**B**) in which the separator is contained within the floor box under the chair. Both installations illustrate the use of the quick-disconnect fittings (black).

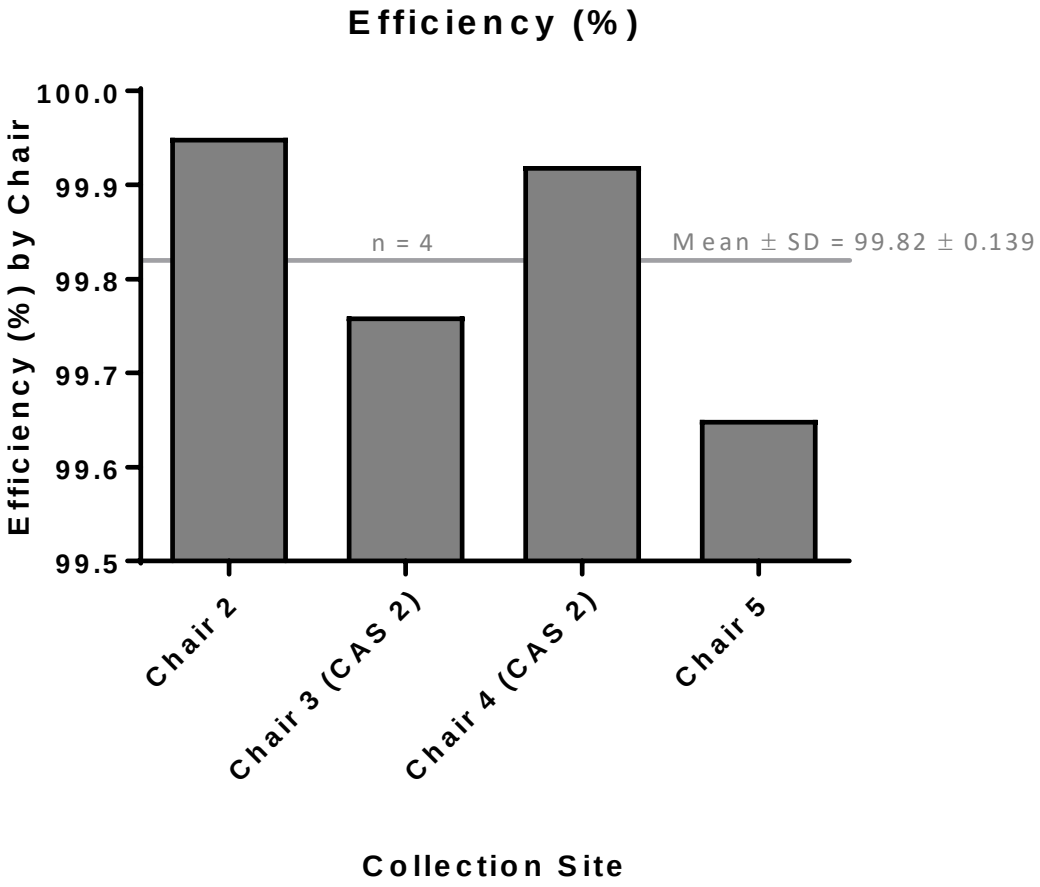


Figure 3. Four DD2011P CAS units were recovered from Budge Clinic after their service lives were expended, dried and weighed for total solids analysis, and then re-wetted and subjected to a modified efficiency test based on the ISO 11143:2008 method. A defined mixture of dental amalgam particulate was suspended in filtered water, passed through the spent CAS units, and the mass of dental amalgam exiting the separators weighed to calculate the efficiency. The mean efficiency of four CAS units is represented by the gray line, indicating mean ± standard deviation.

Service Life in Workdays, Total Amalgam Surfaces Placed, and Amalgam Surfaces Placed Per Day During the Service Life of Each Amalgam Separator.				
Provider No.	**Chair (CAS) No.**	**Service Life (Workdays)**	**Total Amalgam Surfaces Placed**	**Amalgam Surfaces Placed/Day**
Provider 1	Chair 1 (1)	93	528	5.7
	Chair 2 (1)	157	1200	7.6
Provider 2	Chair 3 (1)	42	400	9.5
	Chair 3 (2)	38	336	8.8
	Chair 4 (1)	57	544	9.5
	Chair 4 (2)	64	474	7.4
Provider 3	Chair 5 (1)	42	311	7.4
Provider 4	Chair 6 (1)	51	510	10.0
	Chair 6 (2)	60	549	9.2
		67.1 ± 37.6	**539 ± 263**	**8.4 ± 1.4**

Table 1. Selected clinical data were collected for the dates during which each CAS unit was in service. The number of workdays (days on which procedures were recorded) and number of amalgam surfaces placed (2017 Current Dental Terminology codes D2140, D2150, D2160, and D2161) were determined for each chair. The average number of amalgam surfaces placed per day was calculated as Total Amalgam Surfaces Placed/Service Life (Workdays). The means ± standard deviation are indicated (n=9) for Service Life (Workdays), Total Amalgam Surfaces Placed, and Amalgam Surfaces Placed/Day.

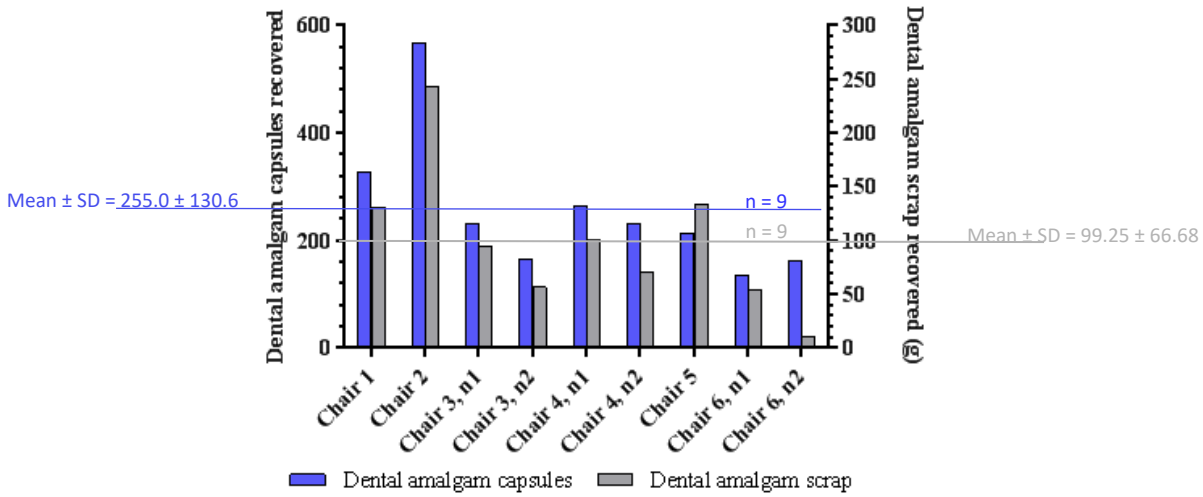


Figure 4. Dental amalgam capsules and scrap were recovered at each dental chair for the duration of each separator's service life. The total numbers of capsules collected during the service lives are displayed in blue, and correspond to the left Y-axis. The total weights in grams (g) of amalgam scrap collected during the service lives are displayed in gray, and correspond to the right Y-axis. The means for nine experimental replicates are represented by the horizontal lines with means ± standard deviations.

Workload Characterization Provided by Clinical Staff Survey				
Chair Number	**Reported Use (estimated average number of Patients/week)**	**Reported Frequency of Amalgam Work (estimated percentage of work which is amalgam placement or removal)**	**Reported Percentage of Amalgam Work Which is to Replace Failed Amalgam**	**Reported Amalgam : Composite use ratio**
Chair 1	30	75%	25%	3:1
Chair 2	20	75%	25%	9:1
Chair 3	25	80%	30%	3:1
Chair 4	25	80%	50%	7:3 (2.33:1)
Chair 5	30	95%	10%	19:1
Chair 6	40	50%	30%	1:1
	28.3 patients/week (average estimate).	**75.83%** of work is amalgam-based (average estimate).	**28.3%** of amalgam work is to replace failed amalgam (average estimate).	**6.2** amalgam placements are done for every composite placement (average estimate).

Table 2. Study closeout questionnaire for Budge Dental Clinic staff. Questionnaires were distributed among the dentist/dental technician teams which worked at the chairs of interest during the data collection period. Staff were asked to provide estimates of patients per week, frequency of amalgam work, how often amalgam work is done to replace failed amalgam, and the relative use of amalgam compared to composite. Results are the averages of six chair-specific sets of answers.

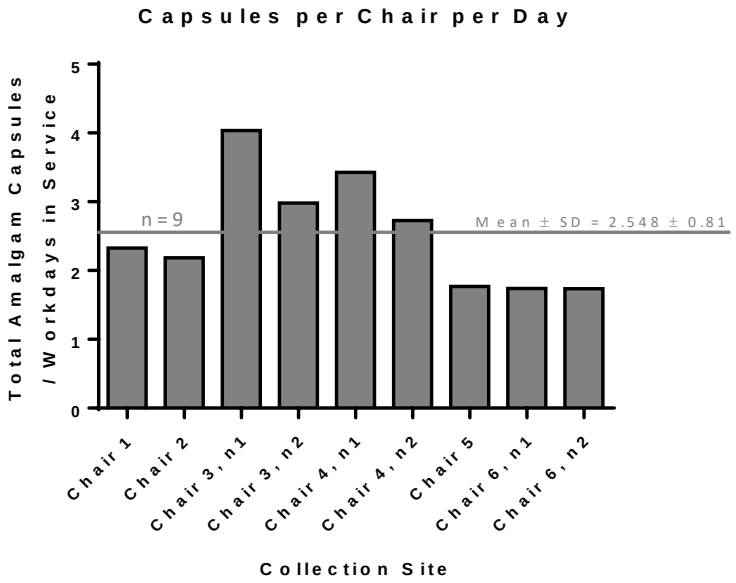
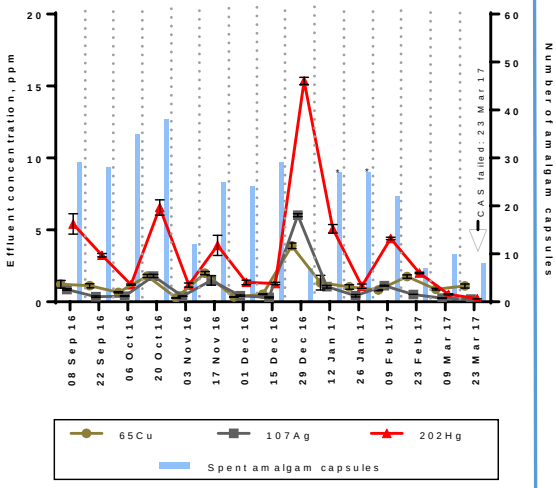
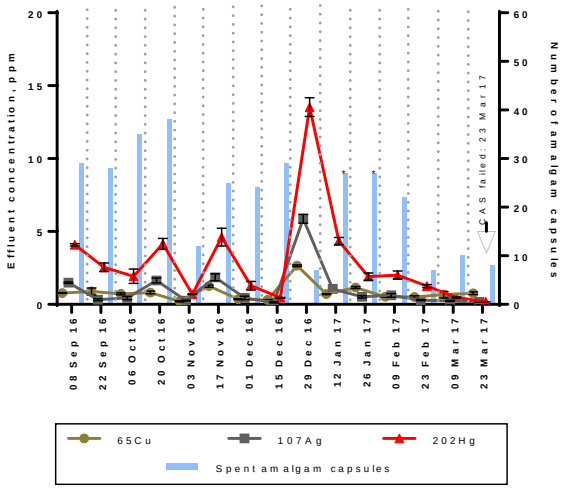


Figure 5. The total amalgam capsule count for each separator's service life (reported in **Figure 4**) was divided by that separator's total service life in working days (reported in **Table 1**) to calculate the average number of amalgam capsules used per day at each chair. The mean for nine experimental replicates is represented by the horizontal line with mean ± standard deviation.

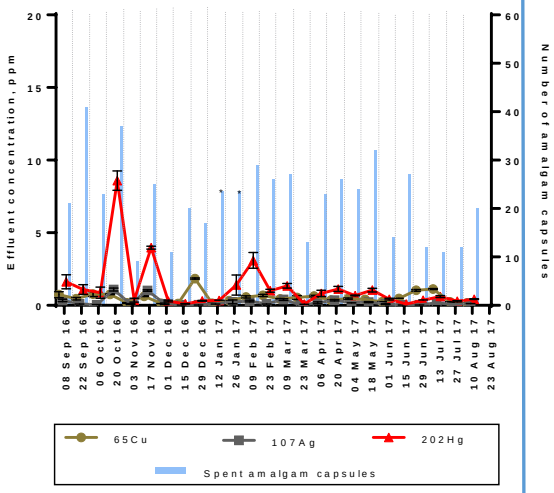
Chair 1, Rinse 1



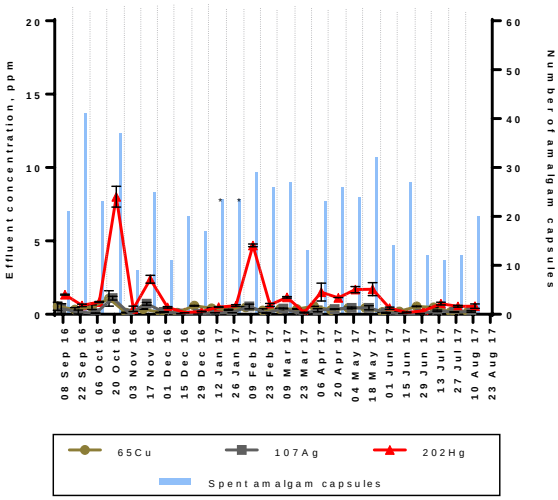
Chair 1, Rinse 2



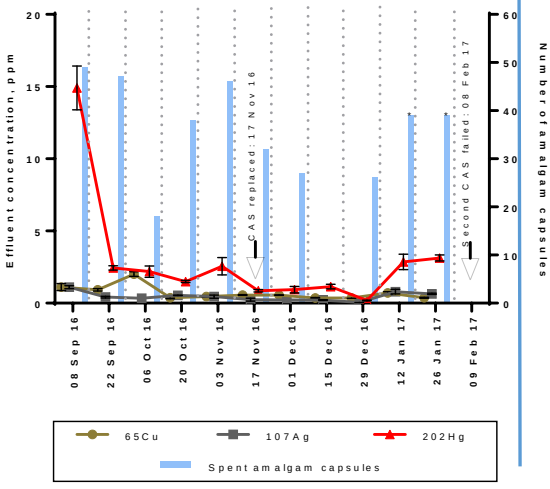
Chair 2, Rinse 1



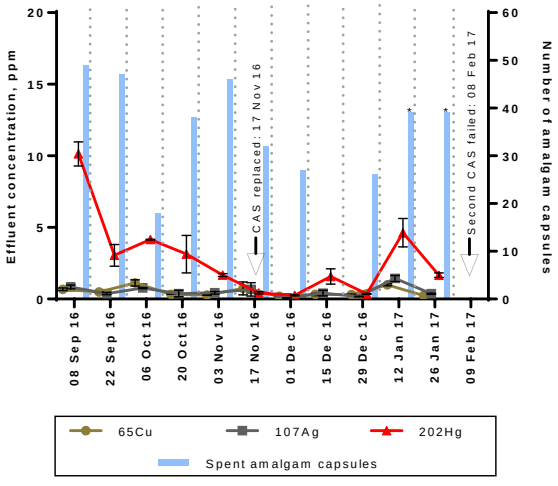
Chair 2, Rinse 2



Chair 3, Rinse 1



Chair 3, Rinse 2



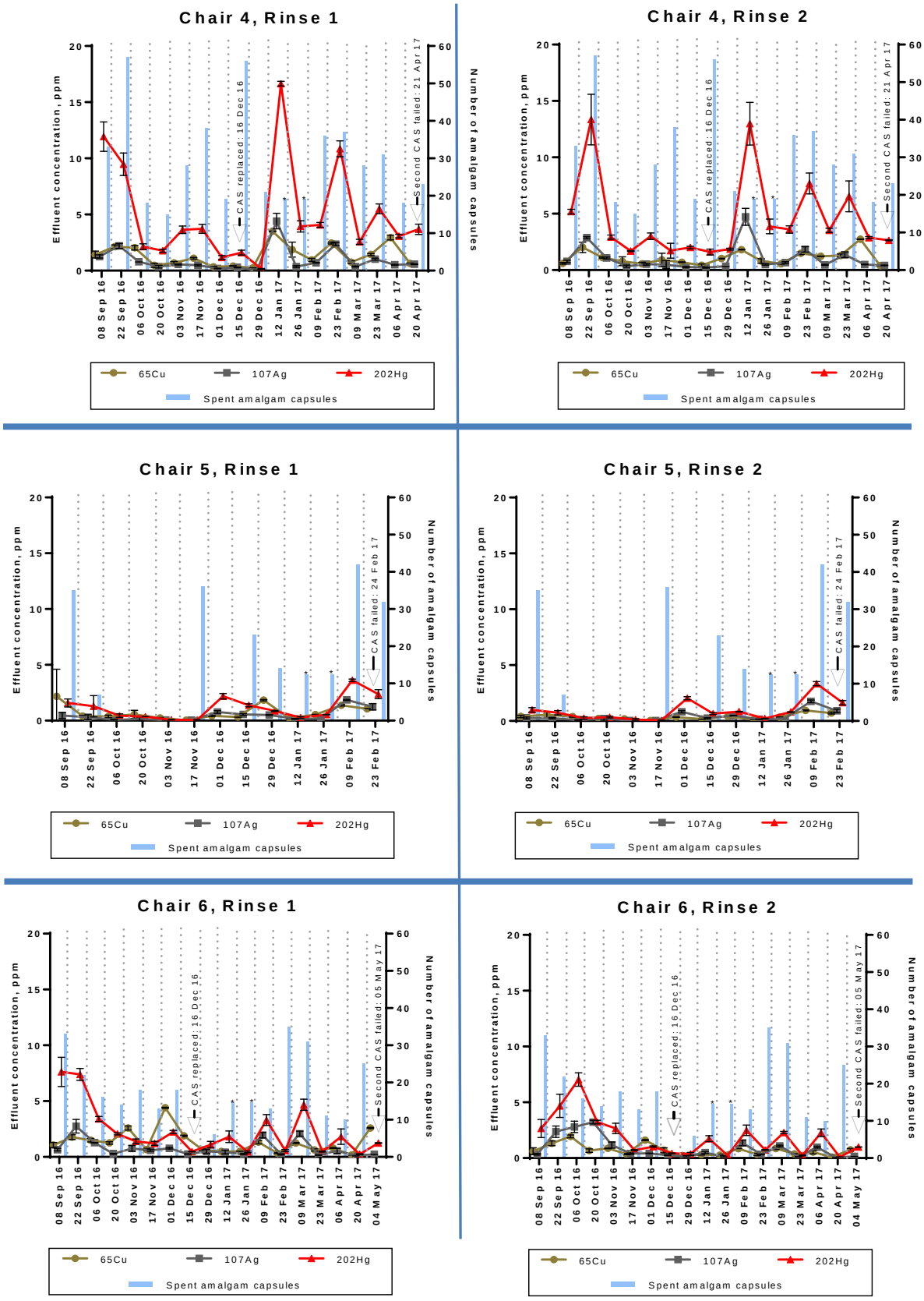


Figure 6. Samples of effluent were collected from installed amalgam separators and analyzed for mercury, silver, and copper. Concentrations (ppm) of each metal are shown (reference the left Y-axis), juxtaposed against the number of spent amalgam capsules collected from the corresponding chair during the corresponding period (blue bars, reference the right Y-axis).

Table 3a. Mean (SD) concentration of ^{65}Cu, ^{107}Ag, and ^{202}Hg in FIRST RINSE CAS effluent collection- outliers removed from calculations

Chair no.	^{65}Cu, mg/L	^{107}Ag, mg/L	^{202}Hg, mg/L
1	1.06 ± 0.53	0.68 ± 0.50	2.67 ± 2.06
2	0.49 ± 0.28	0.18 ± 0.21	0.91 ± 0.93
3	0.58 ± 0.26	0.46 ± 0.30	1.78 ± 0.99
4	1.38 ± 0.97	0.75 ± 0.67	4.33 ± 3.47
5	0.53 ± 0.38	0.37 ± 0.36	1.16 ± 1.06
6	1.14 ± 0.73	0.65 ± 0.59	2.30 ± 2.23

Table 3b. Mean (SD) concentration of ^{65}Cu, ^{107}Ag, and ^{202}Hg in SECOND RINSE CAS effluent collection- outliers removed from calculations

Chair no.	^{65}Cu, mg/L	^{107}Ag, mg/L	^{202}Hg, mg/L
1	0.69 ± 0.30	0.68 ± 0.58	2.14 ± 1.57
2	0.34 ± 0.15	0.22 ± 0.19	0.95 ± 0.99
3	0.53 ± 0.33	0.60 ± 0.39	2.09 ± 1.58
4	0.94 ± 0.41	0.81 ± 0.77	3.88 ± 2.67
5	0.37 ± 0.25	0.31 ± 0.28	0.73 ± 0.61
6	0.70 ± 0.50	0.88 ± 0.98	1.58 ± 1.30

Table 3c. Paired t-tests and percent change between mean concentrations of ^{65}Cu, ^{107}Ag, and ^{202}Hg in Rinse 1 (R1) and Rinse 2 (R2) for Chairs 1-6.

	^{65}Cu				^{107}Ag				^{202}Hg			
Chair no.	***p*-value**	**n**	**% change in means from R1 to R2**	**R1 to R2**	***p*-value**	**n**	**% change in means from R1 to R2**	**R1 to R2**	***p*-value**	**n**	**% change in means from R1 to R2**	**R1 to R2**
1	0.004**	14	42	decrease	0.918	14	1	decrease	0.070	14	22	decrease
2	0.002**	24	35	decrease	0.156	24	17	increase	0.770	24	4	increase
3	0.154	10	11	decrease	0.750	10	27	increase	0.429	10	16	increase
4	0.052	16	38	decrease	0.504	16	8	increase	0.410	16	11	decrease
5	0.012*	12	35	decrease	0.171	12	17	decrease	0.037*	12	46	decrease
6	0.003**	18	48	decrease	0.519	18	30	increase	0.090	18	37	decrease

**95% confidence interval, **99% confidence interval, ***99.9% confidence interval.*

Table 3. First Rinses (3a) and Second Rinses (3b) of effluent collection were compared. Values represent all effluent metal concentrations determined for each effluent collection during each separators' service life. Where the data collection for a particular chair included two separators, data from the two separators were pooled. Because service life varied, the number of collections therefore varied, so n is unique to each chair. Outliers were determined by Grubbs' test and were removed from the analysis. The p-value of each comparison, the percent change between the first and second rinses, and the direction of change are noted for each chair (3c).

DD2011P Total Solids Captured During Service Life				
Provider No.	**Chair Number**	**Tare Weight (g)**	**Final weight (g)**	**Total Solids (g)**
Provider 1	Chair 1	409.55	563.65	154.1
	Chair 2	409.33	661.55	252.22
Provider 2	Chair 3	402.74	604.04	201.3
	Chair 4	419.41	664.41	245
Provider 3	Chair 5	407.42	638.57	231.15
Provider 4	Chair 6	420.44	509.02	88.58
				195.4 ± 63.4

Table 4. Five separators under study reached capacity and were replaced, while the sixth separator (Chair 2) was replaced at one year in service. Total Solids are the difference between the tare weight and the final weight. Total solids for each separator are listed, with the mean ± standard deviation shown at the bottom. For Total Solids, n=6.

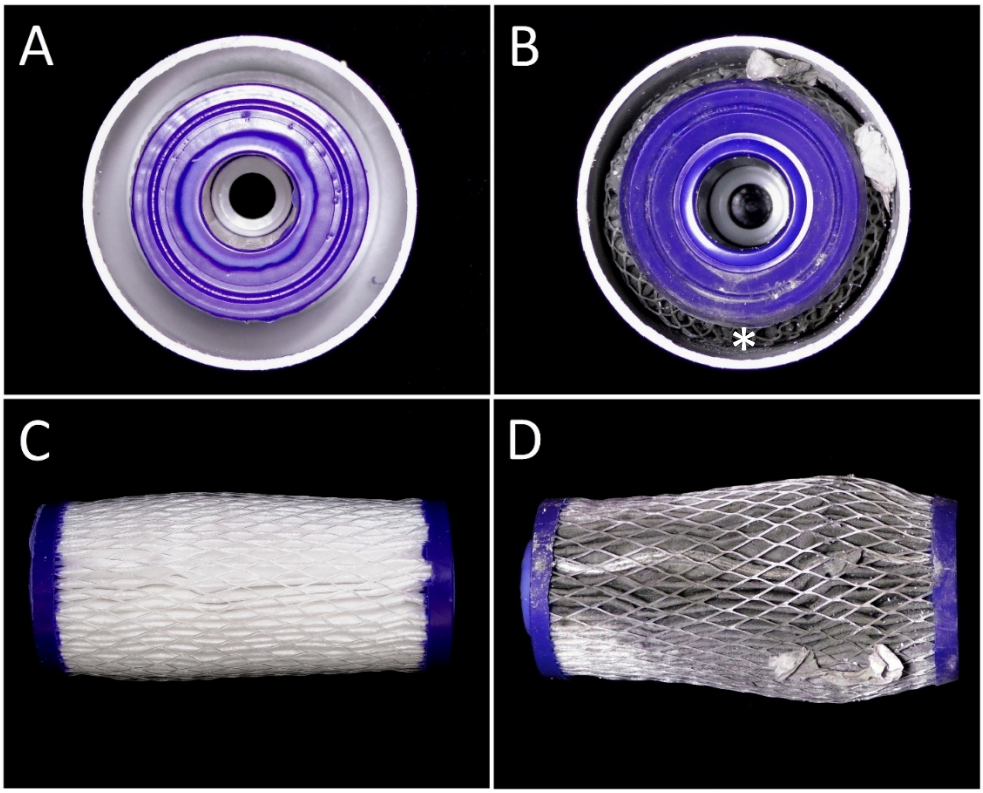


Figure 7. Representative cross-sectional and interior views of a DD2011P CAS before installation and at the end of its service life. Panel **(A)**: Cross-sectional view of a DD2011P CAS before installation. Panel **(B)**: Cross sectional view of the CAS at the end of service life. Note the minimal amount of accumulated sediment (white asterick) within the interior space between the filter element and the plastic filter housing. Panel **(C)** shows the interior filter medium removed from a new DD2011P CAS unit. Panel **(D)** shows the same filter medium removed from a CAS at the end of its service life.

Amalgam Separator Solids Composition (solids of 6 separators pooled)						
Solids Component	**Cu**	**Ag**	**Sn**	**Hg**	**Other Non-amalgam Material**	**Total**
Mean Mass/Sample (n=3)	10.993 ± 0.498 mg	29.728 ± 2.705 mg	15.616 ± 0.815 mg	53.174 ± 1.647 mg	145.422 mg	254.933 ± 3.201 mg
Mean % of Sample (n=3)	4.3%	11.7%	6.1%	20.9%	57.0%	100.0%
	43.0% of solids					

Table 5. Composition of accumulated material was assessed from pooled material collected from six expended amalgam separators. Mass sample means per element are shown ± standard deviation. Percent composition per element was calculated from the mean total sample weight, which is also shown ± standard deviation. Standard deviation for Other Non-amalgam Material is not shown, as these values were not measured directly, but calculated from the subtraction of the calculated amalgam content from the known solids. Amalgam is comprised of copper (Cu), silver (Ag), tin (Sn), and mercury (Hg), and these four elements made up 43.0% of the accumulated material.

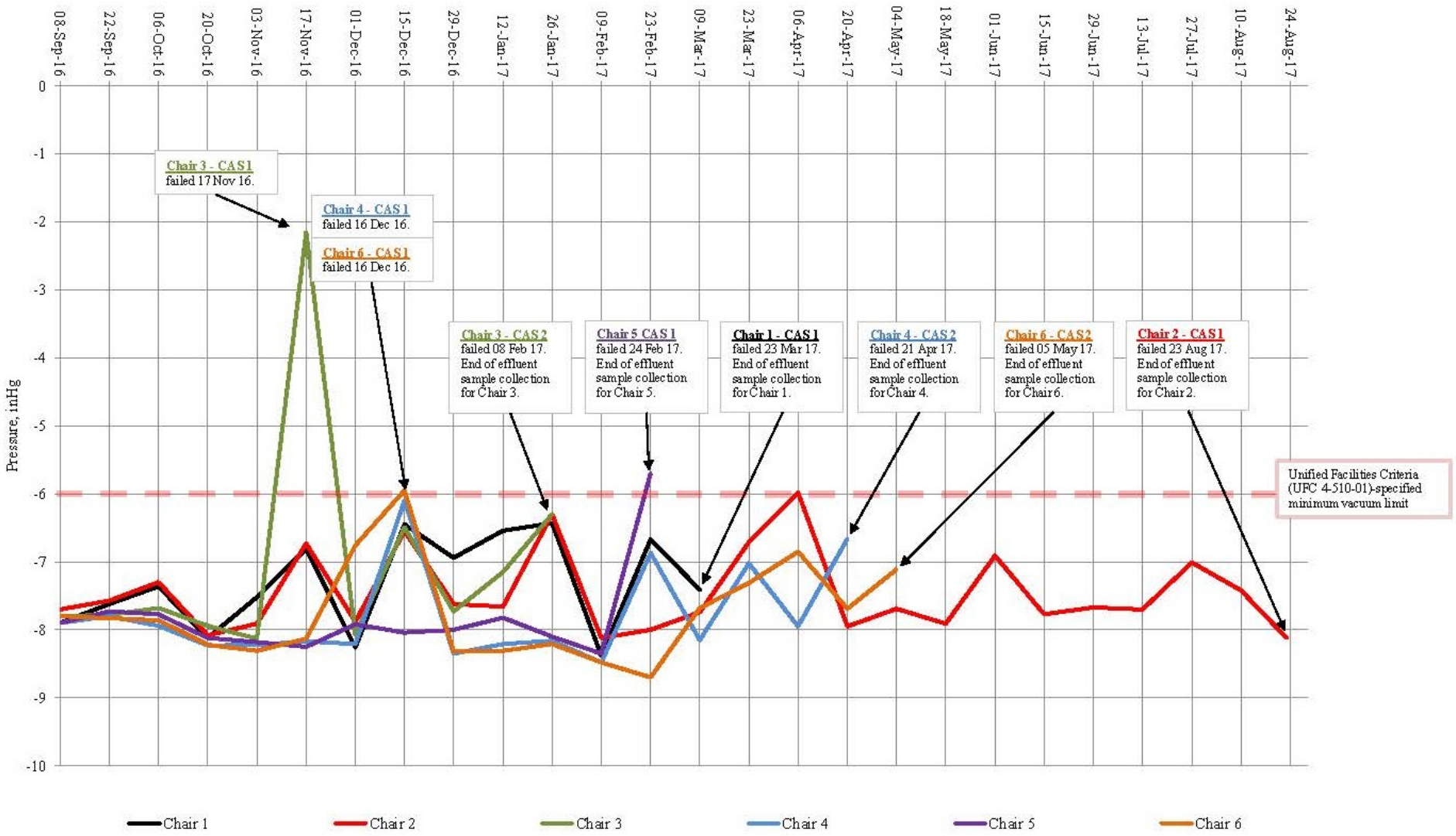
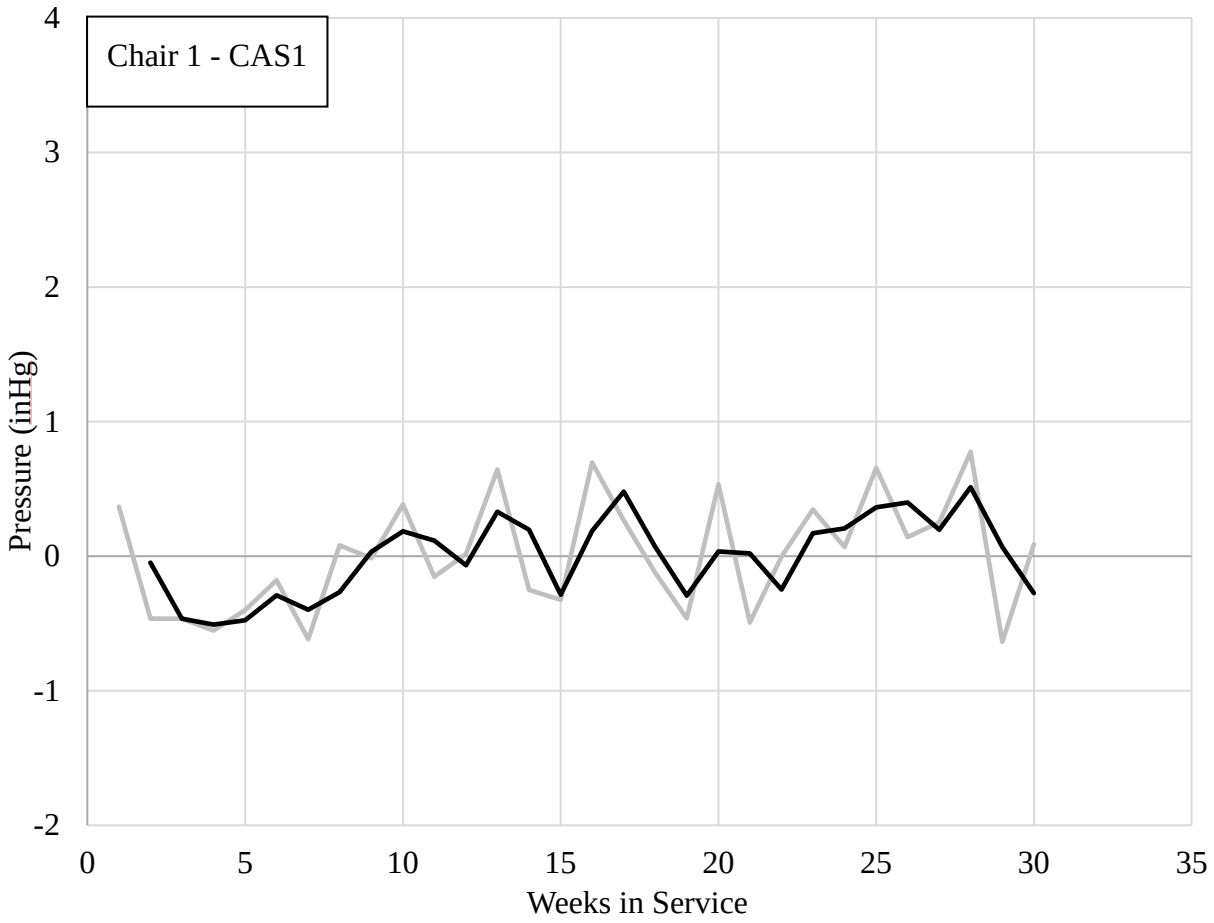
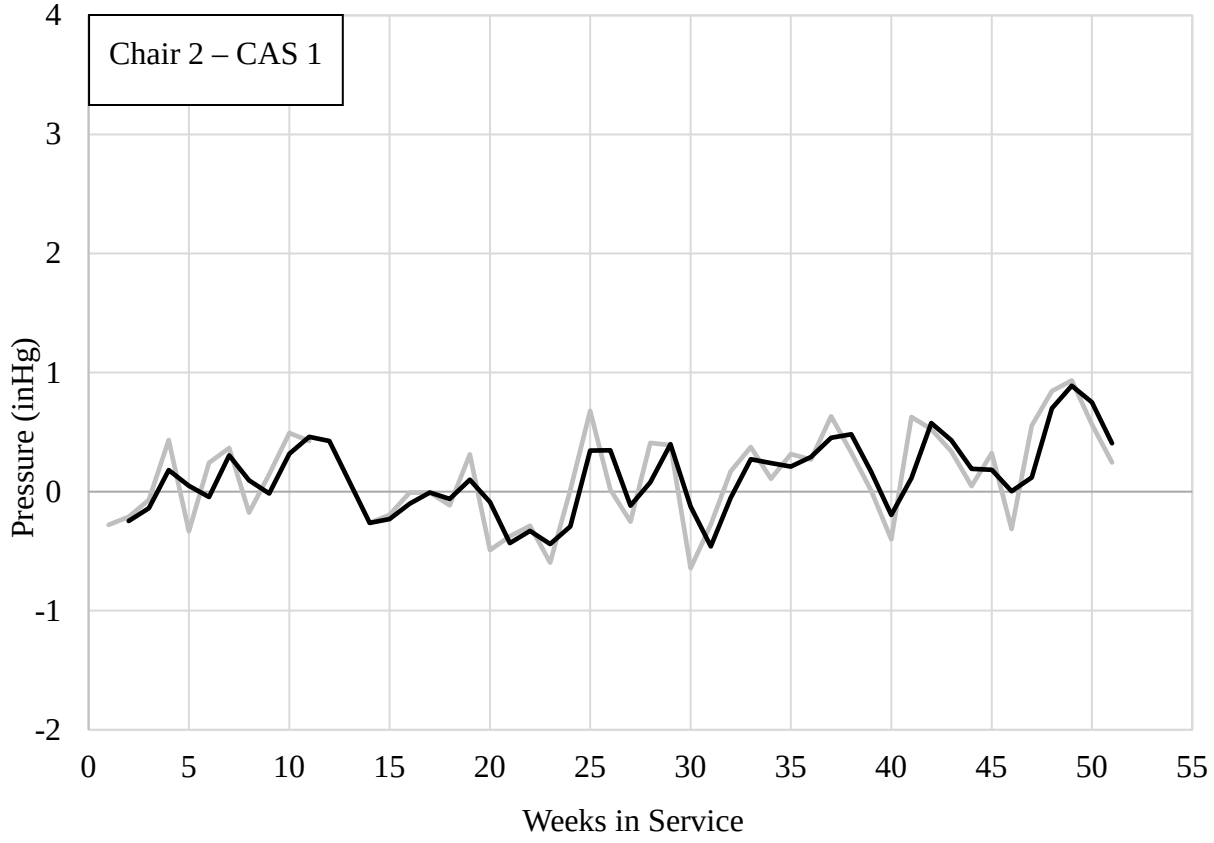
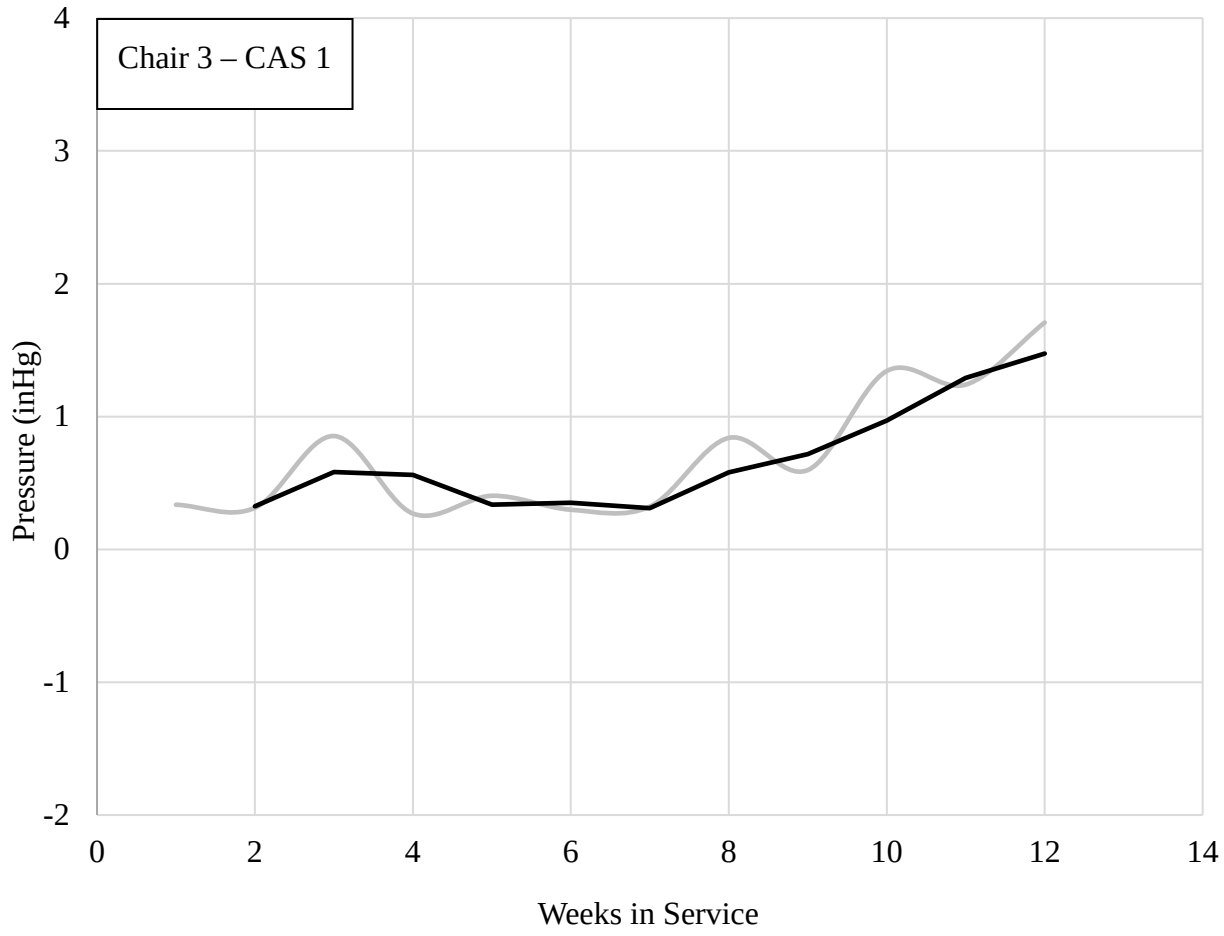
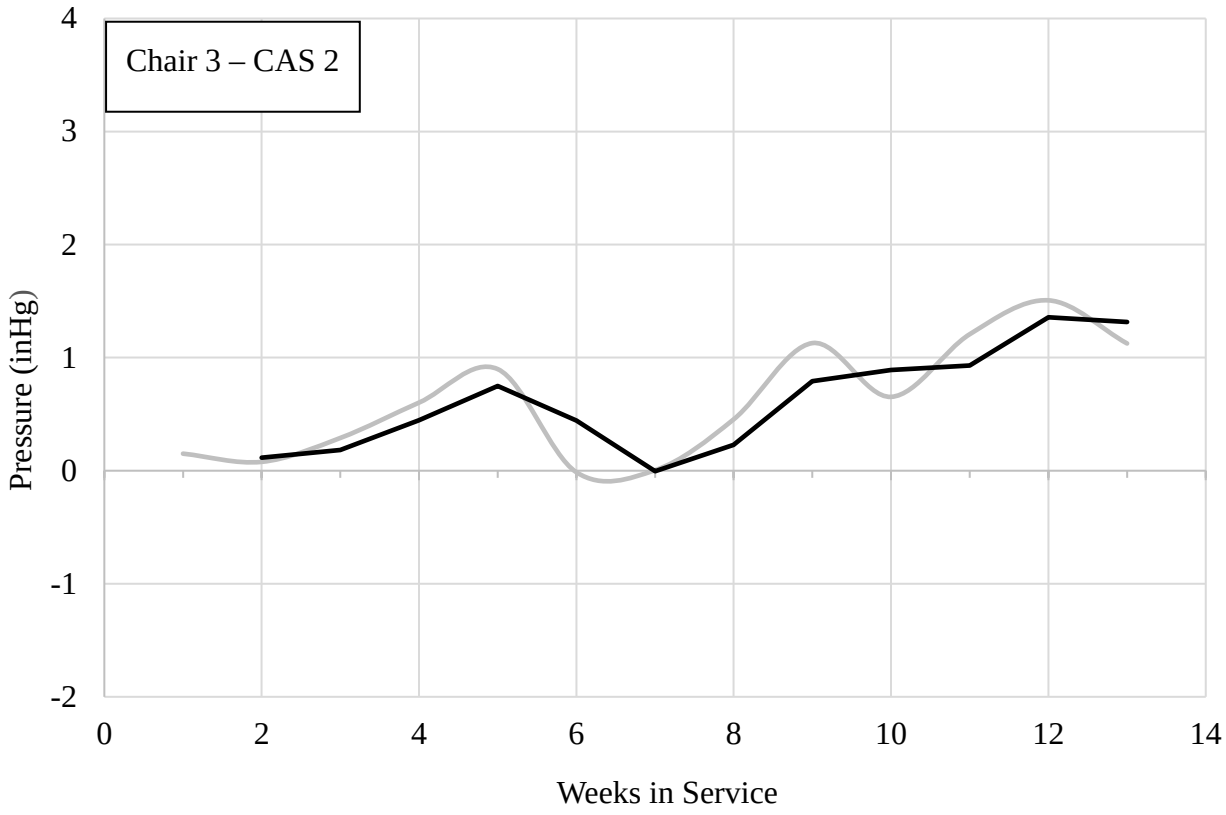


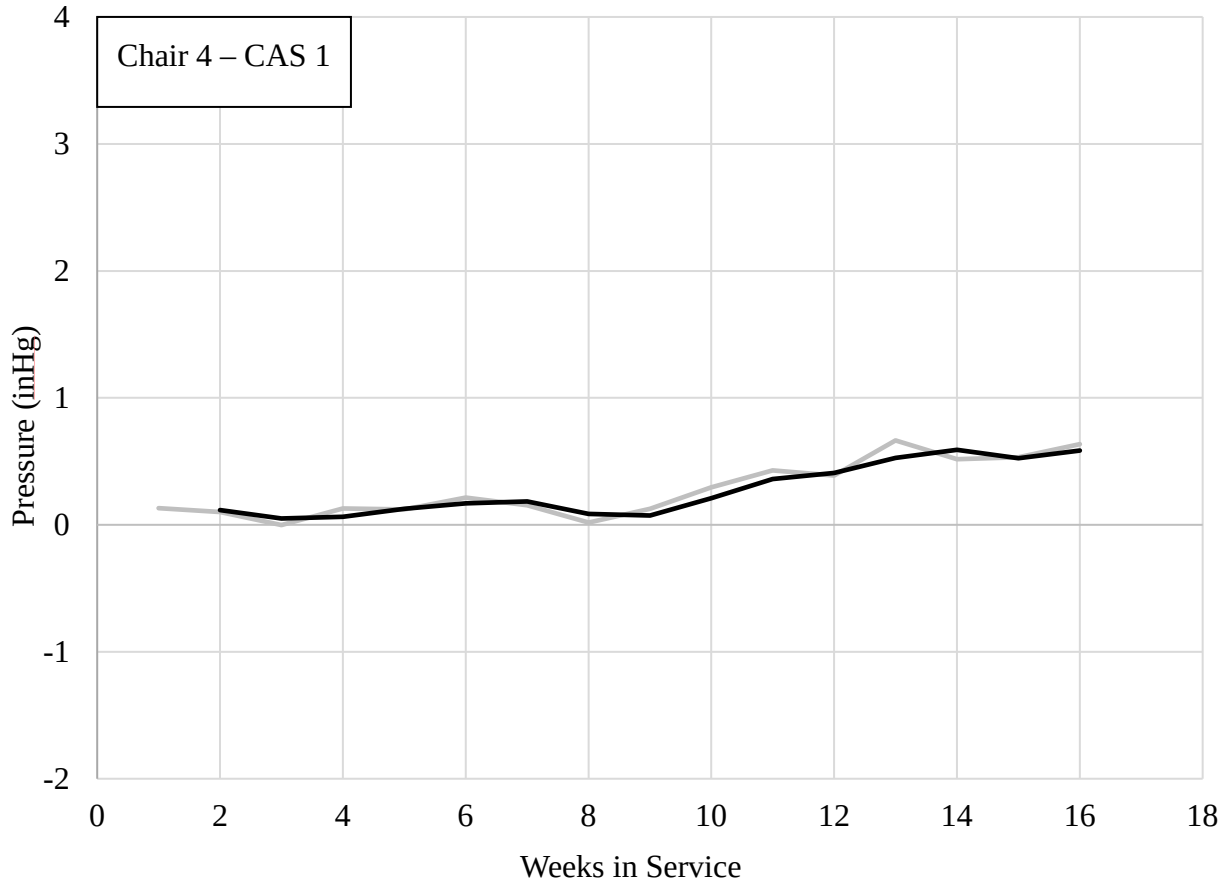
Figure 8. Timeline of amalgam separators' pressure data during their service lives, as recorded during bi-weekly site visits to Budge Dental Clinic. The dates of clinic visits are displayed on the X-axis (top), while pressure readings in inHg, are displayed on the Y-axis. Actual dates of separators' removals from the study are noted in boxes. Criteria for removal of separators from the study were readings above -6 inHg during our bi-weekly site visits, or complaints from Budge Clinic staff of persistent clogging or poor suction.

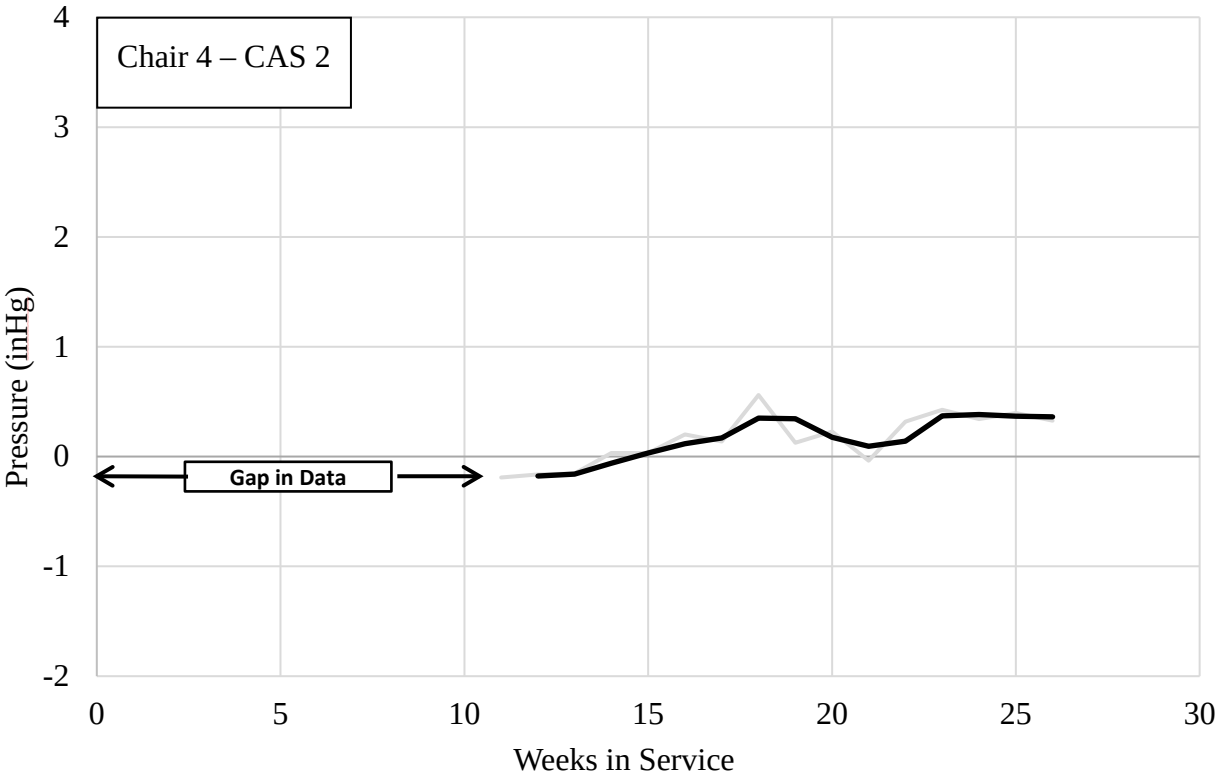

Chair 1 - CAS1
Pressure (inHg)
4
3
2
1
0
-1
-2
0
5
10
15
20
25
30
35
Weeks in Service

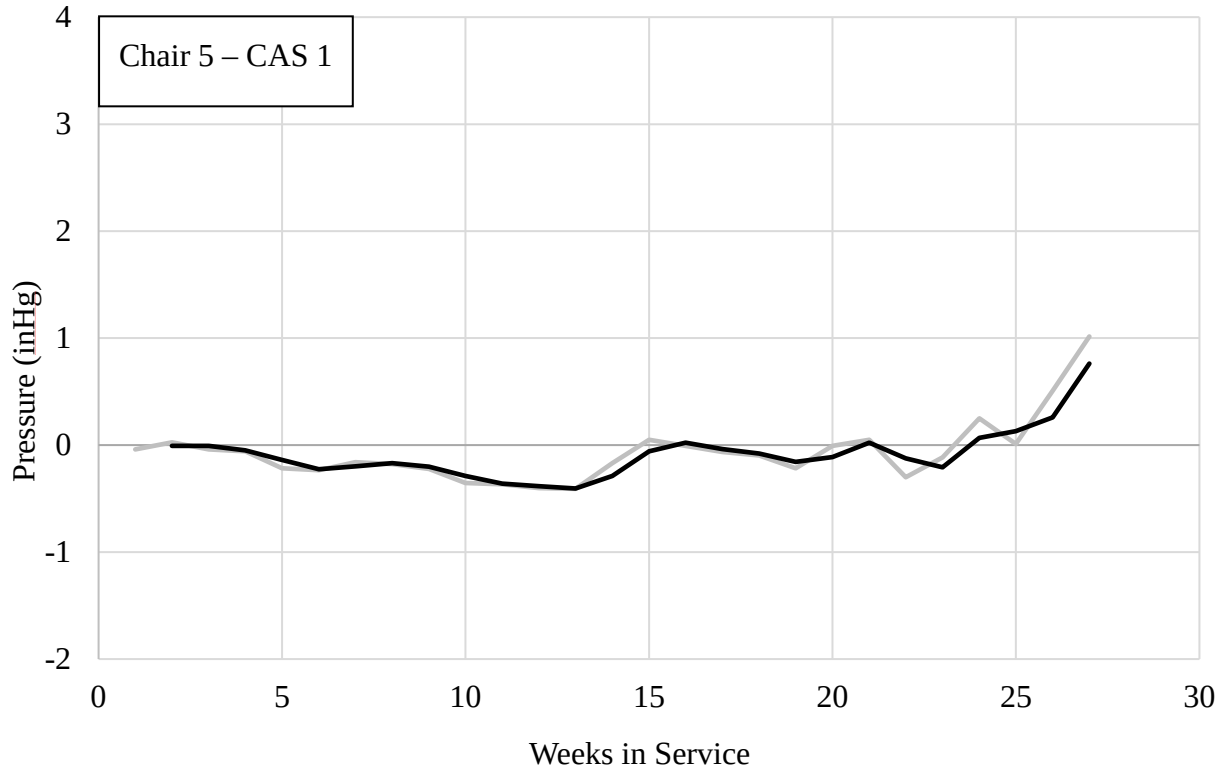

Chair 2 – CAS 1
Pressure (inHg)
4
3
2
1
0
-1
-2
0
5
10
15
20
25
30
35
40
45
50
55
Weeks in Service

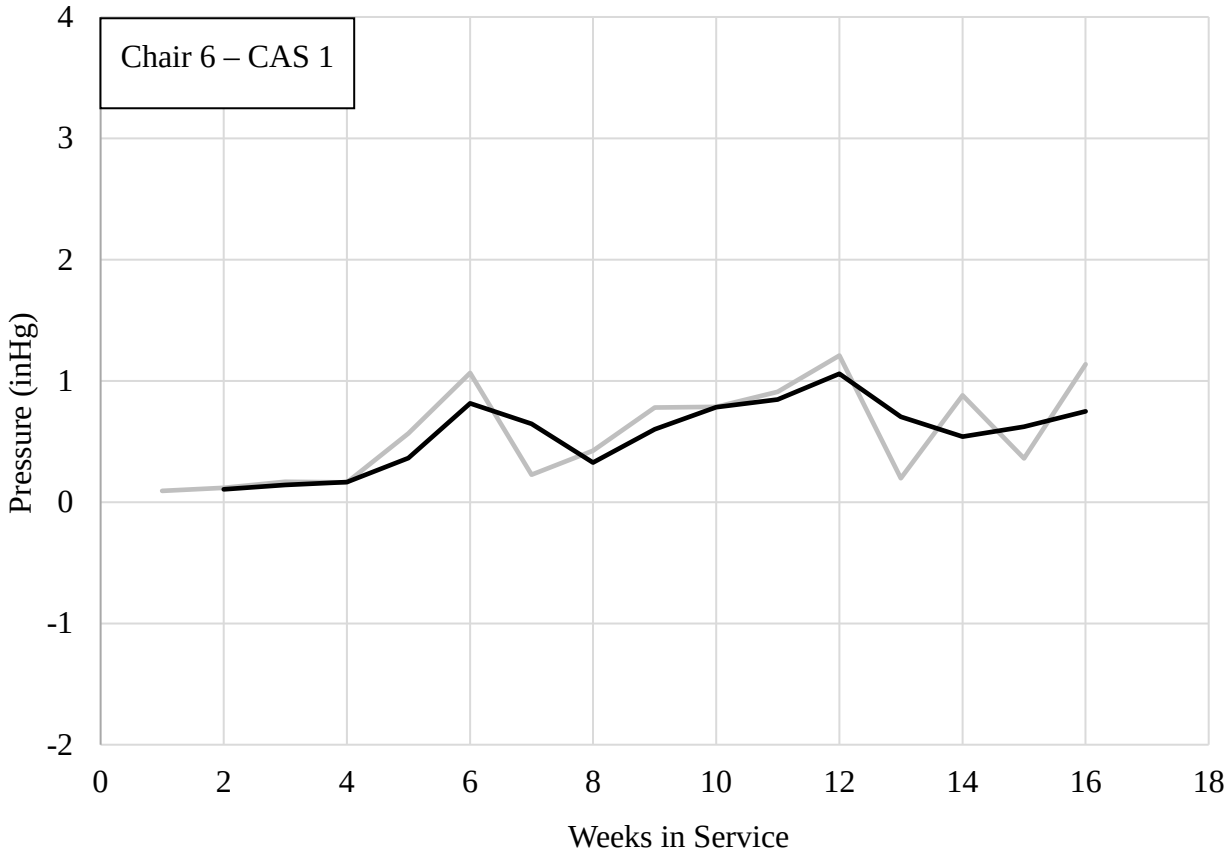

Chair 3 – CAS 1
Pressure (inHg)
4
3
2
1
0
-1
-2
0
2
4
6
8
10
12
14
Weeks in Service


Chair 3 – CAS 2
Pressure (inHg)
4
3
2
1
0
-1
-2
0
2
4
6
8
10
12
14
Weeks in Service


Chair 4 – CAS 1
Pressure (inHg)
4
3
2
1
0
-1
-2
0
2
4
6
8
10
12
14
16
18
Weeks in Service


Chair 4 – CAS 2
Pressure (inHg)
4
3
2
1
0
-1
-2
Gap in Data
0
5
10
15
20
25
30
Weeks in Service


Chair 5 – CAS 1
Pressure (inHg)
4
3
2
1
0
-1
-2
0
5
10
15
20
25
30
Weeks in Service


Chair 6 – CAS 1
Pressure (inHg)
4
3
2
1
0
-1
-2
0
2
4
6
8
10
12
14
16
18
Weeks in Service

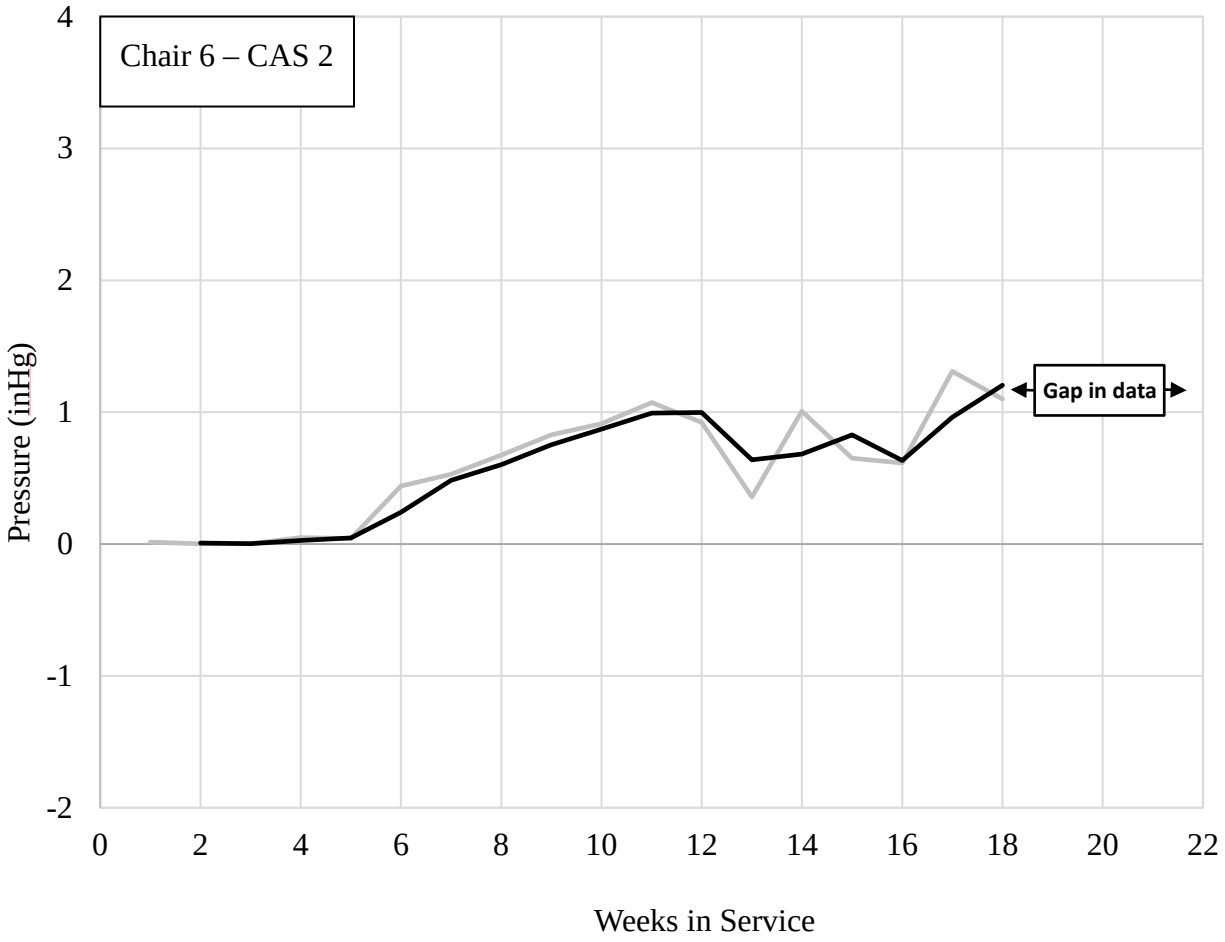


Figure 9. Timelines of pressure sensor differential during amalgam separators' service lives. Moving averages were calculated from data collected during working hours. For each chair, the averages of the preceding week's data, analyzed at weekly intervals, are displayed as gray lines. Similarly, the averages of the preceding two weeks' data for each chair, analyzed at weekly intervals, are displayed as black lines. A loose sensor wire caused data drop-out for Chair 4, CAS 2 (4.2) in the 1-10 week period. Chair 6, CAS 2 (6.2) data were corrupted for the last four weeks of the recording. The other seven pressure data timelines run the complete service life from installation to replacement.

	Valiant Ph.D. Manufacturer's Published Values		Separator Deposits Average of 6 pooled samples		Effluent (all) All effluent samples, Rinse 1 and Rinse 2 n=198		Effluent (first rinse) All effluent measurements, Rinse 1 n=99		Effluent (second rinse) All effluent measurements, Rinse 2 n=99	
	% composition	Ratio to Hg	% composition	Ratio to Hg	Mean concentration (ppm)	Ratio to Hg	Mean concentration (ppm)	Ratio to Hg	Mean concentration (ppm)	Ratio to Hg
Hg	~42.5	1.00	48.6	1.00	2.535	1.00	2.706	1.00	2.364	1.00
Ag	30	0.71	27.2	0.56	0.677	0.27	0.658	0.24	0.696	0.29
Cu	10	0.24	10	0.21	0.806	0.32	0.973	0.36	0.639	0.27

***

p = 0.0007

Figure 10. Amalgam constituent metals Hg, Ag, and Cu are listed as they were determined from published values (Valiant Ph.D.), analysis of deposits from spent amalgam separators (Separator Deposits, see **Table 5**), and the metals measured in clinical effluent (Effluent [all, first rinse, second rinse], see **Table 3).** Ratio to Hg was calculated by dividing each metal % composition by the % composition of Hg. A statistically significant difference in Cu concentration between the first and second rinses was confirmed by Student's t-test, looking at all collection dates, across all chairs.

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14. ABSTRACT

Results showed the average service-life of the DD2011P to be 67±38 work days. DD2011P separators performed above the 95% retention efficiency specified in the ISO standard, even after pulled from service due to pressure drop. Effluent concentrations of mercury, silver, and copper correlated loosely with the number of amalgam capsules used in the preceding two-week period, and overall, filter efficiency increased with use. We conclude that the DD2011P amalgam separator meets the EPA dental wastewater effluent guideline and performs adequately in a military dental clinical setting. Our clinical evaluation of the DD2011P showed variability in service life due to a variety of clinical factors beyond the amount of amalgam used in practice, however, the average clinical service life was shown to be roughly 3 months. We further determined that there is substantial room for improvement in unit design and size, to produce the best available technology at the least cost/burden to the dentist to maintain compliance with federal and local dental wastewater guidelines. Additionally, the steady increase of pressure drop which preceded separator failure is potentially useful toward developing an advance warning system to alert dental staff to declining separator performance and the need to replace the unit.

15. SUBJECT TERMS
Dental amalgam, environmental protection agency, mercury, compliance, amalgam separator

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