

19 July 2019

CPAC Equipment, Inc. RH-PRO11 Instrument Test Report

Temperature Testing Conducted on Hu-Friedy Dental Instruments

Parameters:

CPAC Quality Assurance will test Hu-Friedy composite instruments by processing through a total of 250 cycles in the CPAC Equipment Inc., RH-PRO11 High Velocity Hot Air (HVHA) Sterilizers. Document the inventory of instruments received, recording any identifying marks, numbers, colors, and purpose with photographs of each instrument received before initial testing for comparison purposes. Test the instruments in the RH-PRO11 HVHA Sterilizer conducting inspections with photographs to determine instrument integrity, degradation, any discoloration or deformities after various cycle testing increments. Test each instrument pouched for the first ten (10) cycles, noting the unit tested in, the temperature at which the instruments were exposed during each of the 12 minute pouched cycles, noting any deformities with comparison photographs taken at the end of each cycle increment. Upon completion of the initial (10) cycle increment, unwrap the instruments and conduct the remaining increment testing of the Hu-Friedy instruments unwrapped on the 12 minute wrapped cycle. Upon completion of the cycle testing, document each instrument with photographs and notes comparing each from start to completion of testing for evidence of discoloration, deformity, or other abnormal effects of exposure to the high heat temperatures of the RH-PRO11 HVHA Sterilizer. Submit test results to the manufacturer for further review and evaluation of degradation through exposure to the RH-PRO11 HVHA temperatures. Manufacturers to report back to CPAC the results of their evaluations.

Testing:

Tables 1 – 4 below show the instrument inventory (Table 1), the inventory in the two tray configuration for cycle 1-10 testing (Table 2), the single tray configurations for cycle tests 11-250 (Table 3), and the Sterilizer inventory used for cycle testing to include serial number, cycles run, average temperature and time of exposure during the testing (Table 4). Multiple sterilizers were used for the cycle testing as described in Table 4 and listed in the increment testing.

Conducted 250 individual 12-minute test cycles at 375°F. Prior to conducting any tests, photos of the instruments were taken, both unwrapped and wrapped (pouched) for test comparisons before and after each single cycle test (cycles 1-10) and each incremental set of tests. Each individual handpiece was pouched for the first 10 cycles of testing as a precaution from damage (melting) due to the high heat exposure, and divided between two (2) trays. Subsequent testing of the instruments was completed using a single tray configuration of the instruments unwrapped to attain maximum heat exposure. A total of 250 cycles were conducted for exposure of the Hu-Friedy instruments to the high heat temperatures of the CPAC Equipment, Inc., RH-PRO11 High Velocity Hot Air Sterilizers to determine heat tolerance and compatibility of the instruments.

The following incremental test formats were used:

- 1) One (1), ten (10) cycle increment, individual instruments wrapped and separated into two (2) trays varying shelf placement, on the 12-minute wrapped separate cycles with 5 of 10 cycles run in each of two RH-PRO11 units, S/N PR10040 and PR10042 – Cycles 1-10.
 - 2) Two (2), five (5) cycle increments and one (1) Ten (10) cycle increment; 5 of 10 cycles each in the first run, between two RH units, S/N PR10040 and PR10042, with the instruments unwrapped in a single tray and shelf location varied, run on the 12 minute wrapped cycle, the 2nd run of ten (10) consecutive cycles run in RH-PRO11 unit PR10045, run on the 12 minute wrapped cycle – Cycles 11-20 and 21-30.
 - 3) One (1), Twenty (20) cycle increment, run continuous for maximum exposure in RH-PRO11 unit, S/N PR10051 (230V unit), on the 12-minute wrapped cycle – Cycles 31-50.
 - 4) Six (6), Twenty-five (25) cycle increment tests run across multiple days, for maximum heat exposure testing of each increment to simulate a regular working day, using units; S/N PR10044 (Cycles 51-75), S/N PR10043 (Cycles 76-100), S/N 10037 (Cycles 101-125), S/N PR10046 (Cycles 126-150), S/N PR10047 (Cycles 151-175), S/N PR10048 (Cycles 176-200), comparison photographs were taken after each 25 cycle test sets.
 - 5) One (1), Fifty (50) cycle increment test in RH-PRO11 unit, S/N PR10049 (Cycles 201-250), to simulate worse case exposure to the high heat over a long period of time.
- Upon completion of each cycle testing increment, comparison photographs were taken with particular emphasis on the final cycle test set, conducting a visual inspection of the handpieces and noting any physical damage or effects from the HVHA process. The cycle data was compiled into the resulting charts and attached spreadsheet. Tests were run from 18 – 28 June 2019.

Table 1 – Test Instrument Inventory

Item	Instrument Description/Name	ID Markings	Mat/Color
1	Christensen Crown Remover, Straight	CRCH1	Anodized Alum
2	Dental Composite Xts, Large Contact Instrument	TNFCIL	Anodized Alum
3	Dental Composite Xts, Large Contact Instrument	TNFCIL	Anodized Alum
4	CF II Double End Amalgam Carrier w/ Med & Large Syncote Tips	AC5202 M1	Anodized Alum
5	CF II Double End Amalgam Carrier w/ Med & Large Syncote Tips	AC5202	Anodized Alum
6	1.2 MM, Composite Filling Restorative Spatula	TNMASS1	Anodized Alum
7	1.5 MM, Composite Filling Restorative Spatula	TNMASS2	Anodized Alum
8	XTS Composite Dental Spatula	TNCIGFT3 P2	Anodized Alum
9	Straight Streamline Direct Flow, .30K Xts Insert	UI30SFS	Blue
10	Straight Streamline Direct Flow, .30K Xts Insert	UI30SFR	Red
11	#10 universal Streamline, .30K Ultrasonic Insert	UI1030K	Purple

Table 2 – Instrument arrangement for 2 tray testing

Item	TRAY 1	Item	TRAY 2
1	Christensen Crown Remover, BDC21	6	1.2mm Composite Dental Spatula – TNMASS1
2	XTS Contact Instrument, Lrg TNFCIL - 1	7	1.5mm Composite Dental Spatula – TNMASS2
3	XTS Contact Instrument, Lrg TNFCIL - 2	8	Dental Spatula, Xts Composite – TNCIGFT3
4	Dbl End Amalgam Carrier, AC5202-M1/L1	9	.30K Straight Streamline – U130SFS, Blue
5	Dbl End Amalgam Carrier, AC5202	10	.30K Straight Streamline – U130SFR, Red
		11	.10 Universal Streamline – UI1030K, Purple

Table 3 – Single tray alignment of instruments for test cycles 11 – 250

	Cycles 11 - 50						Cycles 51 - 250										
Item	1	2	3	4	5	Item	1	2	3	4	5	6	7	8	9	10	11
Item	6	7	8	9	10	11											

Table 4 – Sterilizer Inventory used for testing

Test Date	Serial #	Cycle #’s	Shelf	Tray Layout	Avg Temp °F	Total Exposure Time	Avg Cycle Time
6/17/19	PR10042	1-5,	2&3,	2 Tray	370.9	21.1M Indiv 3H:31M Group	21.1M
6/18/19		16-20	1&4	2 Tray			
6/17/19	PR10040	6-10,	2&3,	2 Tray	372.6	21.2M Indiv 3H:32M Group	21.15M
6/18/19		11-15	1&4	2 Tray			
6/18/19	PR10045	21-30	3	1 Tray	371.5	3H:32M	21.1M
6/19/19	PR10051	31-50	3	1 Tray	372.1	7H:10M	21.1M
6/20/19	PR10044	51-75	2	1 Tray	374.7	8H:49M	21.1M
6/21/19	PR10043	76-100	3	1 Tray	371.2	8H:50M	21.1M
6/24/19	PR10037	101-125	2	1 Tray	372.0	8H:54M	21.2M
6/25/19	PR10046	126-150	3	1 Tray	376.9	8H:56M	21.1M
6/26/19	PR10047	151-175	3	1 Tray	371.6	8H:53M	21.1M
6/27/19	PR10048	176-200	3	1 Tray	374.4	9H:12M	22.1M +1D *
6/27-28/19	PR10049	201-250	3	1 Tray	373.1	18H:25M	26.1M +5D *

- Cycles 176-200 were run using a repeat cycle capability with a 1 minute delay between cycles.
Cycles 201-250 were run using the repeat capability with a 5 minute delay between cycles.

The photos below depict the instrument layout for the 2 tray and single tray configurations for cycle testing. Cycles 1 – 10 used the 2 tray configuration to allow the pouches to lie flat without overlap and as a precaution to capture damaged component material due to intolerance to the high heat. Cycles 11-250 used two different single tray configurations. Trays were initially rotated between different shelves inside the units (4 shelf capability) and ultimately between shelf 2 and 3. During single tray testing, the

tray was rotated after each increment, alternating the instrument location (front or back) inside the chamber.

Instrument Tray Alignment-Pre-Testing, cycles 1-10, run in units PR10040 and PR10042



Tray 1



Tray 2

Instruments Post-Cycle photo of trays 1 & 2, after cycle 10



Tray 1



Tray 2

Cycles 11-50 Pre and Post-test photos, Single tray configuration

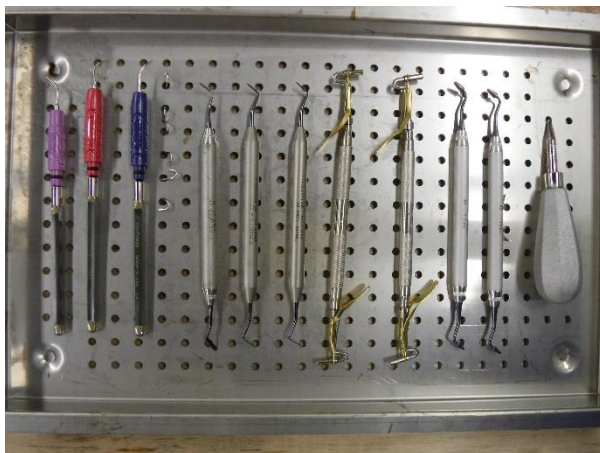


Pre-Cycle 11



Post-Cycle 50

Cycles 51-250 Pre and Post-test photos, Single tray configuration



Pre-Cycle 51



Post-Cycle 250

Individual Instrument Observations:

Instrument #1: Christensen Crown Remover, Straig, CRCH1, UDI +D67123631412, Serial BDC21. Instrument was packaged in a tube and appears to be manufactured with a stainless-steel head fused to an anodized aluminum handle. Package instructions read, “For intended use only by dental professionals. Inspect, clean and sterilize before each use. Do not heat above 350°F/177°C. For resin, do not use dry heat or rapid heat sterilization. Use recommended chemicals only. Do not disinfect with phenols.” There was no damage, discoloration, or deformity noted in this instrument as received, nor any observed at the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F. It is the opinion of the CPAC Quality Assurance team that this instrument is capable of withstanding temperatures to 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instrument #1 as received (left) and after 250 dry heat cycles (right).



Instrument #1 as received



Instrument #1 after 250 dry heat cycles

Instrument #2 & 3: TNFCIL XTS Contact Instrument Large, CAD44, UDI +D6717470091A, C3915/V1. Instruments were packaged and appear to be manufactured with anodized aluminum bodies and stainless steel collars holding the composite tips in place. The instrument bodies are stamped with TNFCIL, Made in USA, CE V4, HU_FRIEDY trademark stamped opposite. Package instructions read, “For intended use only by dental professionals. Inspect, clean and sterilize (autoclave or dry heat). Do not heat above 350°F/177°C. For resin, do not use dry heat sterilization, do not expose to phenols or iodophors.” There was no damage, discoloration, or deformity noted on the instruments or the tips as received, nor any observed at the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F. It is the opinion of the CPAC Quality Assurance team that these instruments are capable of withstanding temperatures to 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instruments #2 & 3 as received and after 250 dry heat cycles.



Instruments #2 & 3 as Received



Instruments #2 & 3 as Received

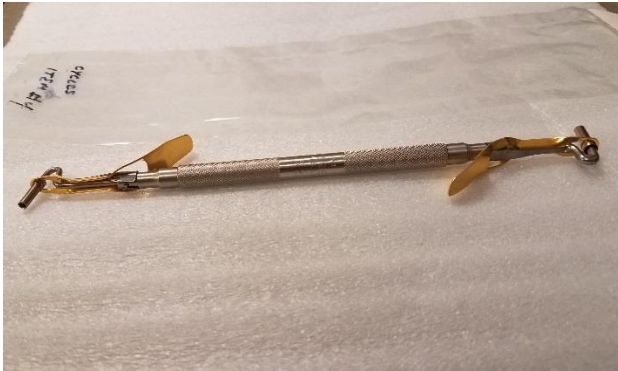


Instrument #2 after 250 test cycles



Instrument #3 after 250 test cycles

Instrument #4: AC 5202 M1, CFII Double End Amalgam Carrier w/ Medium & Large Syncote Coating Tips. Instrument did not come packaged and contained no package instructions or warnings with regard to sterilization or temperature restrictions. Instrument description obtained from Google search on AC5202. Instrument appears to be composed of stainless steel with a cross-cut pattern on the shaft for gripping and includes tension loaded clips (clips are gold in color). The letters M1 HU-FRIEDY –USA- AC 5202 stamped in the center of the handle, L1 stamped in the collar of the large amalgam tip. There was no damage, discoloration, or deformity noted in this instrument or the tips as received, nor any observed at the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F. It is the opinion of the CPAC Quality Assurance team that this instrument is capable of withstanding temperatures in excess of 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instrument #4 as received (left) and after 250 dry heat cycles (right).



Instrument #4 Received



Instrument #4 after 250 test cycles

Instrument #5: AC 5202, CFII Double End Amalgam Carrier w/ Medium & Large Syncote Coating Tips. Instrument did not come packaged and contained no package instructions or warnings with regard to sterilization or temperature restrictions. Instrument description obtained from Google search on AC5202. Instrument appears to be composed of stainless steel with a cross-cut pattern on the shaft for gripping and includes tension loaded clips (clips are gold in color). The letters 0312 CE HU-FRIEDY –USA- AC 5202 stamped in the center of the handle, no other markings. There was no damage, discoloration, or deformity noted in this instrument or the tips as received, nor any observed at the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F. It is the opinion of the CPAC Quality Assurance team that this instrument is capable of withstanding temperatures in excess of 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instrument #5 as received (left) and after 250 dry heat cycles (right).



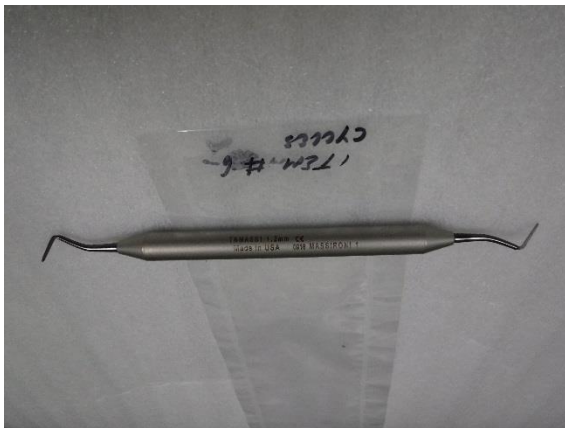
Instrument #5 Received



Instrument #5 after 250 test cycles

Instrument #6: 1.2 MM, Composite Filling Restorative Spatula, TNMASS1, CE 0918. Instrument did not come packaged and contained no package instructions or warnings with regard to sterilization or temperature restrictions. Instrument description obtained from Google search on TNMASS and MASSIRONI, 1.2mm. Search results indicated instrument was either a Gingival Retraction Cord Packing instrument or a Restorative Spatula as no clear description was provided and the instrument resembled Instrument #8. Instrument appears to be composed of brushed stainless steel with flat composite tips similar to those of the spatula, Instrument #8. The lettering TNMASS1 1.2mm Made in USA CE 0918 MASSIRONI 1 is stamped on one side of the handle shaft, HU_FRIEDY trademark

stamped opposite, no other markings. There was no damage, discoloration, or deformity noted in this instrument or the tips as received, nor any observed at the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F. It is the opinion of the CPAC Quality Assurance team that this instrument is capable of withstanding temperatures in excess of 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instrument #6 as received (left) and after 250 dry heat cycles (right).



Instrument #6 Received



Instrument #6 after 250 test cycles

Instrument #7: 1.5 MM, Composite Filling Restorative Spatula, TNMASS2, CE 0918.

Instrument did not come packaged and contained no package instructions or warnings with regard to sterilization or temperature restrictions. Instrument description obtained from Google search on TNMASS and MASSIRONI, 1.5mm. Search results indicated instrument was either a Gingival Retraction Cord Packing instrument or a Restorative Spatula as no clear description was provided and the instrument resembled Instrument #8. Instrument appears to be composed of brushed stainless steel with flat composite tips similar to those of the spatula, Instrument #8. The lettering TNMASS2 1.5mm Made in USA CE 0918 MASSIRONI 2 is stamped on one side of the handle shaft, HU_FRIEDY trademark stamped opposite, no other markings. There was no damage, discoloration, or deformity noted in this instrument or the tips as received, nor any observed at the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F. It is the opinion of the CPAC Quality Assurance team that this instrument is capable of withstanding temperatures in excess of 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instrument #7 as received (left) and after 250 dry heat cycles (right).



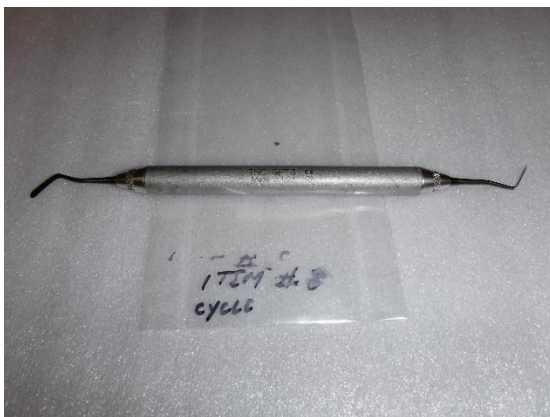
Instrument #7 Received



Instrument #7 after 250 test cycles

Instrument #8: XTS Composite Dental Spatula, TNCIGFT3, CE P2.

Instrument did not come packaged and contained no package instructions or warnings with regard to sterilization or temperature restrictions. Instrument description obtained from Google search on part TNCIGFT3. Search results indicated instrument is an XTS Composite Dental Spatula. Instrument appears to be composed of anodized aluminum with stainless steel collars on either end holding flat composite tips. The lettering TNCIGFT3 Made in USA CE P2 is stamped on one side of the handle shaft, HU_FRIEDY trademark stamped opposite, no other markings. There was no damage, discoloration, or deformity noted in this instrument or the tips as received. At the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F the instrument showed indications of a foreign matter stained or baked to the ends of the anodized shaft. As the instrument was unpackaged when received, it is unknown what the material is or how it came to be on the instrument. The pouch material did not stick to the instrument and no other cleaning or material was applied prior to testing. Based on the testing though, it is the opinion of the CPAC Quality Assurance team that this instrument is capable of withstanding temperatures in excess of 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instrument #8 as received (left) and after 250 dry heat cycles (right).



Instrument #8 Received



Instrument #8 after 250 test cycles

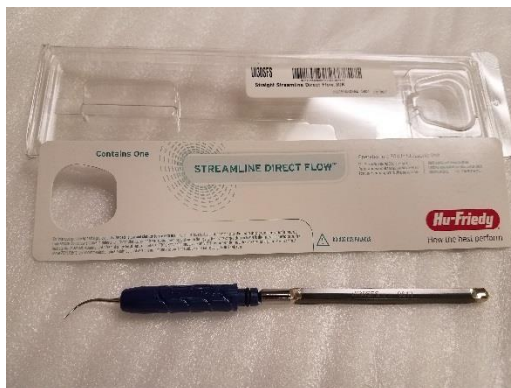
Ultrasonic Inserts, Instruments #9, #10, and #11

The inserts consist of 15-17 flexible metal fins braised on one end, braised/bonded to a stainless-steel collar and shaft on the other end that extends up through the composite grip and connected to the ultrasonic tip (replaceable component) which is attached to the head within the grip. A fluoroelastomer rubber O-ring is attached above the stainless collar on the grip which acts as a seal when seating the insert into a handpiece. Reviewing “Instructions for Use” (IFU’s) on ultrasonic inserts, metal fins or “stack leaves” elongate and contract when an electromagnetic current is applied via the handpiece, thus providing vibration to the tip. Water is used as a coolant for heat generated during these elongation/contraction cycles. These leaves must remain straight and nested with minimal/no gaps to provide optimal vibration to the tip. The shaft of these instruments is flexible and was noted prior to testing that though slightly bent when received, they were easily straightened

Package instructions for each insert read, “For intended use only by dental professionals. Inspect, clean and sterilize before each use. Inserts that have bent, altered, or worn tips or other compromising conditions should be removed from service. Do not use chemical disinfectants prior to sterilization or leave residual cleaning solutions on the inserts. Dry inserts completely prior to sterilization and sterilize using steam. Dry heat sterilizers are not recommended. Use recommended chemicals only. Instruments #9 and #10 also include: Steam sterilize for at least 4 minutes at 270°F/132°C or 30 minutes at 250°F/121°C. Recommend 30-minute dry time after sterilization cycle. Do not heat above 275°F/135°C. Instrument #11 included the following: Steam sterilize for at least 5 minutes at 273°F/134°C or 20 minutes at 250°F/121°C. Do not heat above 275°F/135°C.

There was no damage, discoloration, or deformity noted in the instruments or the tips as received. At the completion of 250 test cycles of exposure to temperatures ranging from 368°F to 378°F over 8-18-hour increments, the metal fins of the insert shafts exhibited no appreciable change in the gapping. It is the opinion of the CPAC Quality Assurance team that this instrument is capable of withstanding temperatures in excess of 400°F and the dry heat sterilization process used in the RH-PRO HVHA series Sterilizers. Instrument descriptions and photos follow:

Instrument #9: U130SFS Straight Streamline Direct Flow, 30K Ultrasonic Insert, XTS Insert (Blue). Instrument was packaged and labeled U130SFS Straight Streamline Direct Flow, 30K, bar code (01)10889950075736(10)0617, 100001840464, CHB21. The letters U130SFS 0617 (Part and Lot numbers), and * Hu-Friedy MADE IN USA CE 0120 stamped on opposite sides of the metal fins of the insert. Instrument #9 as received and after 250 dry heat cycles below.



Instrument #9 Received



Instrument #9 after 250 test cycles



Instrument #9 Grip and Shaft Pre-Testing



Instrument #9 Grip and Shaft Post-Testing

Instrument #10: U130SFR Straight Streamline Direct Flow, 30K Ultrasonic Insert, XTS Insert (Red). Instrument was packaged and labeled U130SFR Straight Streamline Direct Flow, 30K, bar code (01)10889950075729(10)0617, 100001845087, CHB22. The letters U130SFR 0617 (Part and Lot numbers), and * Hu-Friedy MADE IN USA CE 0120 stamped on opposite sides of the metal fins of the insert. Instrument #10 as received and after 250 dry heat cycles below.



Instrument #10 Received



Instrument #10 after 250 test cycles

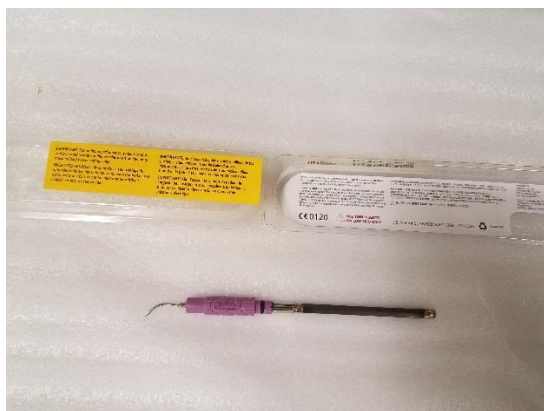


Instrument #10 Grip and Shaft Pre-Testing



Instrument #10 Grip and Shaft Post-Testing

Instrument #11: UI1030K, #10 Universal Streamline, 30KHz Ultrasonic Insert (Purple). Instrument was packaged and labeled UI1030K, #10 Universal Streamline, 30KHz, UDI bar code +D6714399241E, 100000959215, FRS22 0512. The letters UI1030K 0512 (Part and Lot numbers), and * Hu-Friedy MADE IN USA CE 0120 stamped on opposite sides of the metal fins of the insert. Instrument #11 as received and after 250 dry heat cycles below.



Instrument #11 Received



Instrument #11 after 250 test cycles



Instrument #11 Grip and Shaft Pre-Testing



Instrument #11 Grip and Shaft Post-Testing

Summary:

A total of eleven (11) dental instruments composed of various composite materials and anodized aluminum from Hu-Friedy were subjected to two hundred fifty (250), 12-minute test cycles at 370+°F temperatures during the period from 17 to 28 June 2019. During the testing intervals, the instruments were subjected to these temperatures in increments on average of 22 minutes during the first ten (10) single cycles, 3.5 hours for the five (5) and ten (10) cycle increments, 7.2 to 9.2 hours for the twenty-five (25) cycle increments, and 18.4 hours during the fifty (50) test cycle. The purpose of the testing was two-fold; to test sterilizers units coming off the RH-PRO11 Production line, and to test the material, composition, effects, viability, strength, and capability of the Hu-Friedy anodized aluminum and composite instrument make-up when exposed to the CPAC Equipment, Inc., RH-PRO11 High Velocity Hot Air Sterilizer environment for sterilization. Cycle testing was conducted by Paul Smith, CPAC Quality Assurance Manager and Thomas Atkinson, CPAC Production and RH-PRO11 Assembler.

Six (6) of the eleven (11) instruments were packaged and contained instructions “Not to heat above 350°F/177°C or 275°F/135°C, and not to use dry heat sterilization”, as indicated under the Insert Description on page 11 of this report. These were instruments #'s 1 (crown remover), 2 & 3 (XTS Contact Instruments), 9, 10, and 11 (ultrasonic inserts). The crown remover and XTS Large Contact instruments were all metal construction; anodized aluminum, brushed and polished stainless steel, the exception being the composite tips on instruments 2 & 3. The ultrasonic inserts had a soft metal shaft constructed of a series of metal fins brazed together on either end with what appears to be a synthetic polymer grip

material and silicone O-ring at the base of the grip. The remaining five (5) instruments #'s 4-8, were not packaged, were composed of all metal or metal composite materials, and contained no sterilization limit restrictions.

As a result of the heating, cooling, and extreme temperature exposure testing conducted over the course of twelve days, CPAC did not observe any external damage, distinct discoloration, deformities or other anomalies to the instruments resulting from exposure to the sterilization temperatures of the RH-PRO11 HVHA Sterilizers. Instrument #8 (dental spatula) contained some foreign residual material on either end of the handle that became stained or baked on to the handle as a result of the testing. As the instrument was not packaged, CPAC has no knowledge of prior use or location of the instrument and may have contained the residue which went detected during the pre-test observation. The instruments were not cleaned or rinsed with any chemicals or materials prior to testing, and the pouches showed no indications of pouch material transfer to the instruments during the initial ten cycles. Other than contact with the tray, the instruments had no other material contact during the remaining test cycles. At the conclusion of the testing, the ultrasonic inserts exhibited some additional, minor separation of the metal fins in the shafts, but don't believe this would be a detriment to the operability of the instrument: Metal fins seem to be manufactured for flexibility to allow water to pass through them.

Further testing of the ultrasonic inserts (#'s 9 – 11) by the manufacturer should be conducted to ensure internal operability of these instruments as CPAC does not retain the equipment to functionally operate them. It is however, the opinion of the CPAC QA team that these instruments will perform as prescribed under functional operability testing.

It should be noted that CPAC Equipment, Inc. has conducted additional independent testing of pouched instruments to document instrument temperatures during the various sterilization cycles under typical exposure times seen in dental/medical office settings. In virtually all cases, the temperature of pouched instruments does not reach or exceed 340°F during the longest of the dry heat sterilization cycles. In this case the RH-PRO11's longest cycle period is 22 minutes to include an 8-10-minute warm-up and 12-minute sterilization countdown.

Overall, eleven (11) instruments provided by Hu-Friedy for testing are composed of various metals to include anodized aluminum, surgical, polished, brushed stainless steel and brass in the handles, tension releases, shafts, and collars. The tips and grips are composed of synthetic or composite material, and a hi-temp grade silicone O-ring in the case of the ultrasonic inserts. Each instrument was subjected to temperatures up to and including 378°F/192°C for extended periods of time, worse case during this testing, 18 hours, 25 minutes continuous. The instruments were observed and photographed prior to and after each test sequence, and sterilized wrapped (pouched) and unwrapped for test purposes. The latter testing increments were designed for maximum exposure of time and temperature to determine instrument integrity, degradation, any discoloration, deformities or other abnormal effects of exposure to the high heat temperatures of the RH-PRO11 HVHA Sterilizers. This report, test data and photographs have been forwarded to Hu-Friedy.

Based on the testing of these instruments and their material composition, the Quality Assurance Team at CPAC Equipment, Inc. has determined that these instruments are fully capable of withstanding the high temperatures and cycle time exposure rates of the RH-PRO11 HVHA Sterilizers. These instruments



and material composition would also meet the sterilization exposure requirements of the COX RapidHeat Model 6000 Sterilizers that utilize the same sterilization cycle time criteria. The CPAC Equipment, Inc. Quality Assurance Team recommends the use of dry heat sterilization for these instruments and updating the RH-PRO-11 and COX RapidHeat IFU's, to add these instruments and composite materials to their compatibility list of instruments and materials capable of sterilization in these two products. Although the manufacturer may wish to conduct further hi-temp testing of their material, CPAC also recommends the instrument manufacturer's update their IFU's to include the capability to use dry heat sterilization, and the increased temperature capability rating. CPAC Equipment, Inc. looks forward to additional testing and verification of this and other manufacturer's instruments for the application of dry heat sterilization and use of the RH-PRO11 High Velocity Hot Air Sterilizers manufactured at CPAC Equipment, Inc.

Report generated and submitted by Paul Smith, CPAC Quality Assurance Manager