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Quality Report

on the condition and function of handpieces and turbines from leading instrument manufacturers after more than one year of use and regular reprocessing in Careclave (4-in-1 Solution by MELAG Medizintechnik)

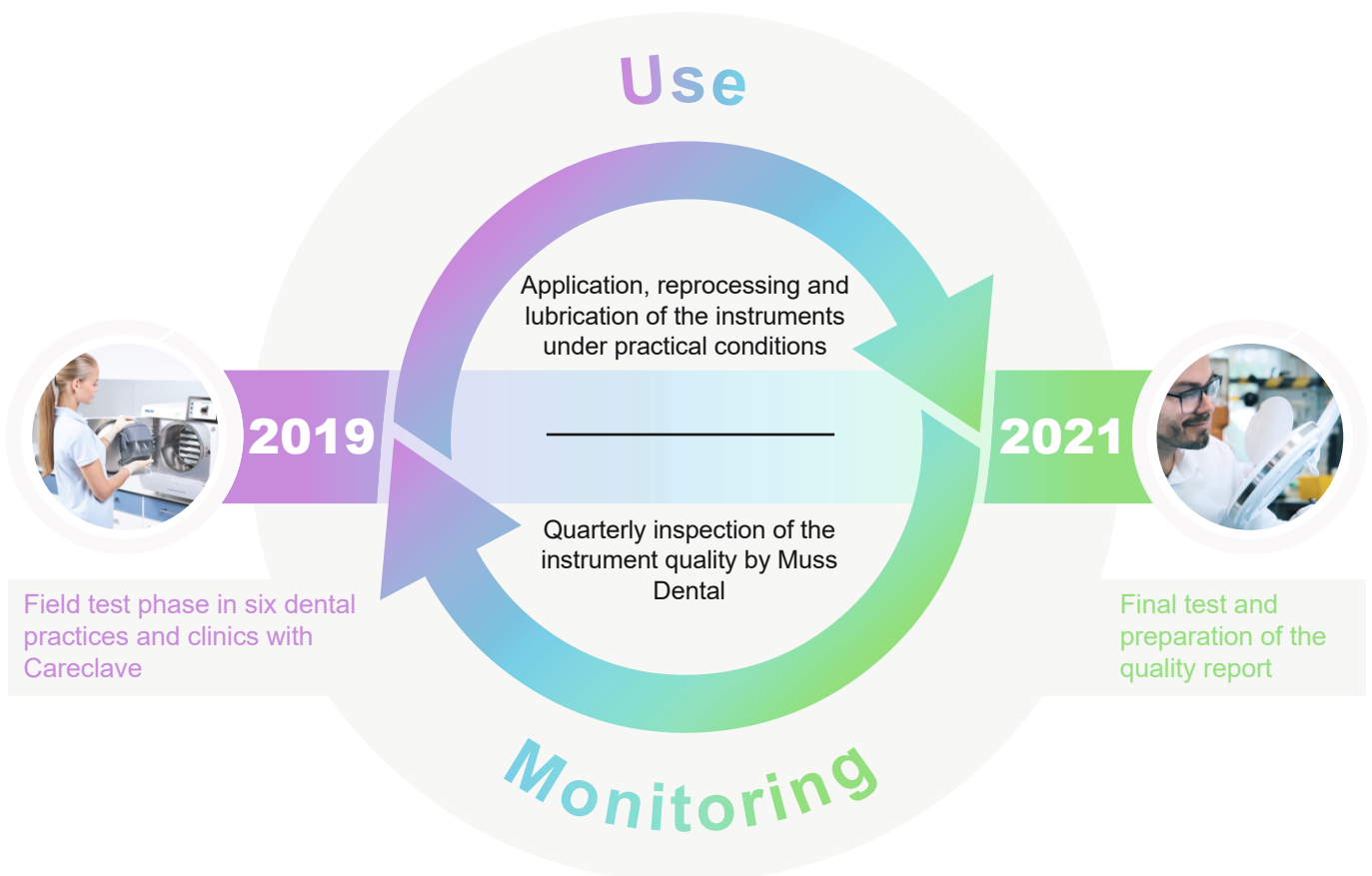


Description

Muss Dental GmbH was commissioned to test dental handpieces and turbines (hereinafter referred to as instruments) for function and wear as part of a test phase lasting more than one year.

The test series extended from November 2019 to February 2021. At the beginning of this test series, brand-new instruments were used in six different dental practices and clinics for the daily treatment of patients. The instruments were checked by us at regular intervals and completely opened at the end of the test series.

The following figure provides an overview of the test series procedure:



Test samples

During the test series, handpieces and turbines of the following manufacturers and types were examined:



- ✓ T1 Line C200L SN: 309587
- ✓ T1 Line C200L SN: 309586
- ✓ T1 Line C200L SN: 309591
- ✓ T2 Line A40L SN: 223535
- ✓ T2 Line A200L SN: 321324
- ✓ T2 Control S SN: 707180



- ✓ EXPERTmatic E15L SN: 2019-1034905
- ✓ EXPERTmatic E20L SN: 2019-1128780
- ✓ EXPERTmatic E15L SN: 2020-1036904
- ✓ EXPERTmatic E15L SN: 2020-1036905
- ✓ MASTERmatic M25L SN: 2020-1049270
- ✓ MASTERmatic M25L SN: 2020-1049271



- ✓ WG-99A SN: 006933
- ✓ WG-99A SN: 006934
- ✓ TG-98L SN: 058641



- ✓ S-Max M15L SN: ABK80200
- ✓ S-Max M15L SN: ABK90182
- ✓ S-Max M15L SN: ABK90184

Procedure of the tests

Before the first use in the dental practices and clinics, the instruments were subjected to an initial test.

The following values were checked and compared with the manufacturer's specifications:

- ✓ Visual condition
- ✓ Leak test (10 - 15 sec.)
- ✓ Spray air flow rate
- ✓ Spray mist
- ✓ Chuck system/holding force of the chuck system
- ✓ Running noise
- ✓ Heating up
- ✓ Light guide (if available)
- ✓ Seat on the coupling (only for turbines)

In addition, the following values were measured in each case:

- ✓ Flow rate of the spray water (ml / min)
- ✓ Current consumption of the drive motor with unloaded handpiece
- ✓ Speed of the turbine in no-load operation

At three-month intervals, the instruments were sent in again and tested. The interim and final results were each compared with the values initially determined.

Measuring instruments and test equipment

The following measuring instruments and test equipment were used:

Manufacturer	Item number	Description
Muss Dental GmbH	MU 9406	Test unit PMU4
Sirona	6337518	Engine BL ISO C
Sirona	1894588	Quick coupling R
W&H	10403400	Clutch RQ-34
W&H	B2012000	Speed measuring device
W&H	C0063000	Holding force tester D=1,6 mm
W&H	C0029600	Test mandrel Ø2,35 mm
W&H	B2006000	Test mandrel Ø1,6 mm
KaVo	0.411.8731	Test manometer
KaVo	0.410.1933	Spray test drill
KaVo	0.411.4601 (3327793)	Holding force tester



Test unit PMU4

The unit is equipped with pressure gauges and flow meters for water, air and motive cooling air.

Result of the audits

No damage or discolouration to the surfaces:

- ✓ None of the instruments were found to have damage to the housing parts that was not caused by daily use in the field (light scratches). Also, no instrument was found to have metal discolouration, which can be attributed to repeated reprocessing in Careclave.

No leaks due to perfect O-rings and seals:

- ✓ None of the instruments showed leaks. The O-rings and seals of the instruments were in perfect condition and were not damaged by the cleaning, disinfection and sterilization processes in Careclave.

No spray image changes or unusual blockages:

- ✓ During the inspection of the spray air and water channels, no unusual clogging or spray image changes were observed. Slight clogging of individual nozzles was observed on some instruments, but this may be from normal operation on the unit.

Chuck systems all clean and well oiled:

- ✓ No failures were found during the inspection of the chuck systems that could not be attributed to the operation of the instruments. Chuck system impairments were only found in two Sirona FG chuck systems where the holding force no longer met the manufacturer's specifications. However, they were all clean and well oiled.

**No unusual running noises or heating:**

- ✓ The current consumption of the motor remained almost constant for all instruments. There were no unusual fluctuations that would allow conclusions to be drawn about blocking components. No unusual running noises or heating of the handpieces were detected.

**No discolouration of the light guides or blindness due to sterilization:**

- ✓ The light guides of all instruments showed no discolouration of the plastic or blindness due to the cleaning, disinfection and sterilization processes in Careclave.

**No leaks and no scratches in the coupling receptacle of the turbines:**

- ✓ When the fit on the couplings was checked, no scratches were found in the coupling receptacle of any turbine. Also none of the turbines showed leaks on the coupling.

**No unusual speed fluctuations:**

- ✓ No unusual speed fluctuations were observed during operation.

Dismantling and final inspection of the instruments after more than a year of testing

Optimum cleaning results:

During the final inspection with disassembly of the individual instruments, it was found that all components were almost equivalent to new parts in terms of cleanliness. Even critical areas, where experience shows that treatment residues adhere, showed only barely visible soiling.

No wear residues or traces of corrosion:

All components had a light film of oil, which can be easily seen in the pictures. There were no traces of corrosion on the gears or the bearing shells in any of the instruments. Wear residues from tooth flanks or other gear residues were not found in the instruments.

No metal abrasion and no noticeable hardening of the seals:

Although the tooth flanks show signs of use, no metal abrasion was found in the instruments. Reprocessing in Careclave did not cause any noticeable hardening on the seals. O-rings and seals were still elastic and functional. The plastic parts also showed no deformation or discolouration.

Impressive result

All tested handpieces and turbines are in very good condition. They are very clean and maintained with a sufficient oil film. None of the usual care defects from everyday practice can be found on or in the instruments.

Even dirt in hard-to-reach places, such as in the pressure lids for drill release or between the housing parts, has been optimally removed.

