

W&H Dentalwerk



W&H Dentalwerk, PO Box 1, 5111 Bürmoos, Austria

To our Partners

Ihr Zeichen:
Ihre Nachricht:
Unser Zeichen: ALE
Bearbeiter:
t +43 6274 6236
wh.com

Sept. 10th, 2014

URGENT FIELD SAFETY NOTICE

Software-Update

concerning

Piezomed SA-320

Dear Partner,

In the course of internally performed quality tests, we determined that within our Piezo Surgery Units

Type "Piezomed SA-320"
serial numbers 00901 up to 01455

the minimally supplied amount of coolant liquid (at a power setting of 100%) does not conform with the value fixed in the technical specifications.

Proper application, in accordance with the supplied instructions, will not result in any risk for the patient. Nevertheless, we cannot exclude that at certain working steps respectively in certain modes of operation the used working instrument (tip) could get overheated.

For reducing all risks of hazard, we have decided to arrange via our service partners a software-update for all possibly affected devices and in this way to increase the flow rate of the coolant pump.

We kindly ask you, as our distribution partner, to forward this information immediately to your customers and the affected users and to arrange the preparations necessary for the update of the devices on your stock as well as those being in use already. The said software-update can be done either by a service technician at the customer's site or at an authorized W&H-repair shop.

W&H Dentalwerk



Please be so kind to inform your customers and end users whether you could arrange the update at their site or if the device should be sent directly to one of the authorized W&H-service stations.

Until the update will be performed the concerned devices can be used furthermore under consideration of the following safety instructions:

- Ensure there is sufficient coolant directly at the treatment site.
- Keep the handpiece moving at all times when operating the Piezomed instrument.
- Do not exert too much pressure on the Piezomed instrument. This can cause the Piezomed instrument to heat up or break, resulting in injury to the patient.
- Do not make any levering motions with the Piezomed instrument.
- Never let the Piezomed instrument run freely without coolant.

The process of software-update can start - upon completion of all necessary preparations – latest in calendar week 39.

Already now, we want to express our apologies for all inconveniences related to this measurement!

Please maintain awareness on this notice and resulting action for an appropriate period (till the measure will be completed) to ensure effectiveness of the corrective action.

Confirmation about any performed updates and the serial numbers of the concerned devices may be addressed per E-mail to: [REDACTED]@wh.com

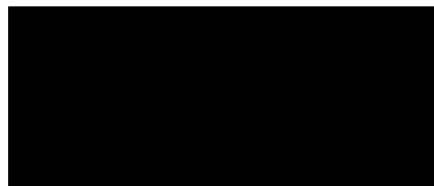
The authorities, competent and concerned by this Field Safety Notice in your country, have been notified.

In case of any question regarding this Field Safety Notice, please contact:

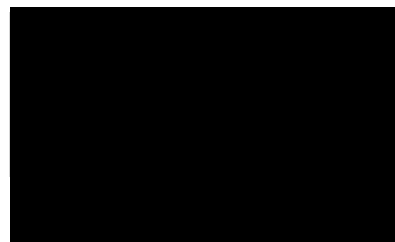
+43 / 6274 / 6236 - [REDACTED]
+43 / 6274 / 6236 - [REDACTED]

With the best regards,

W&H Dentalwerk Bürmoos GmbH
A-5111 Bürmoos



Vice President



Product Management