
Urgent Field Safety Notice

Commercial name/Model: Portable dental unit / DU893

FSCA-identifier: BfArM-Fallnummer: 10805/17

Type of action: Sending spare parts to distributor

Dec. 2017

Attention:

Dear user,

This letter is intended to provide you with information as following:

Details on affected devices:

Description of the problem:

When using the saliva ejector, the liquid and air is slumped via the tube into the waste water bottle. Due to pressure the air is blown off through three lateral perforations at the top of the waste water bottle. With the blown off air can contain infectious material like viruses and bacteria, can be inhaled by nearby persons, e.g. dentist, nurse, other patient, and can lead to cross infection.

Advise on action to be taken by the distributor:

1. Please pass this Notice to all related responsible personnel in the hospital or clinic who has purchased the DU893 machine from your esteemed company.
2. Please inform them that during using DU893, when the water level of the drain bottle is around half position, please pour out the waste water, then install back the bottle and continue to use.
3. If you receive any feedback on the above questions from your customers, please kindly inform us and we will send you a set of additional drain bottle timely, to cooperate with the existing DU893 for using.
4. Please check appendix for detailed replacement steps.

Transmission of this Field Safety Notice:

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail or Fax.

Contact reference person:

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with us.

Tel: 0086-0512-82627666

Fax: 0086-0512-82603908

Email: sales@dynamicgroup.cn

This Notice has been notified the appropriate Regulatory Agency.
(Closing paragraph)

Signature _____



Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Affected Products : Portable dental unit / DU893
FSCA : BfArM-Fallnummer: 10805/17
Type of FSCA : INITIAL REPORT

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Please fill in this form and return this confirmation by E-mail or Fax immediately.

Fax: 0086-0512-82603908
Email: sales@dynamicgroup.cn

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

