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Your contact:
Isabelle Bourg
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Letter to our Distributor Customers

Besançon, 2019-05-15

Subject: Urgent-Field Safety Notice/Safety Information
Distributor Information – warning addendum to X-Cid2 user guide

Sent by email with return receipt or by registered letter with acknowledgement of receipt or international tracked parcel post

Dear Customer

This letter is to inform you of the addition of an addendum to the user guide for our X-Cid2 washer.

1 – Details in relation to the machine

Micro-Mega Product Ref: 51100003

Description: X-Cid2 230V EUR

Serial Numbers Concerned: the addendum concerns all X-Cid2 currently being used by end users.



2 – Subject and Contents of the Addendum

This addendum supplements the measures in the current X-Cid2 user guide to pre-treat Dental HandPieces before they are put into the X-Cid2.

The first thing to do when sterilising Dental Handpieces is to clean all external surfaces with a disinfecting wipe followed by mechanical brushing, if necessary.

The current X-Cid2 user guide does not mention this. In addition, the manufacturers of Dental Handpieces do not all specifically recommend this step and it is not required by any rules or regulations.

Therefore these pre-treatment steps are being added in an addendum to the X-Cid2 user guide, enclosed with this letter.

3 – Risks for the User or Patient

If the user does not remove any external residues before putting it in the X-Cid2, it is possible that the outside of the Dental HandPieces will not be cleaned correctly and a build up of protein residues will occur. If enough residues build up, this may reduce the efficacy of sterilisation.

However such a build-up of protein residues on the outside only occurs infrequently since such residues are visible to the naked eye. Therefore users will be warned by the fact that the part will not look clean.

4 – Actions for Distributors

You are receiving this letter either because we have sent you an X-Cid2 or you ordered an X-Cidol2 since 01/01/2016 (this item has a 2 year lifetime and the X-Cid2 cannot operate without it).

As one of our distributors you are requested to take the necessary steps to forward this information to all health care professionals and establishments concerned.

1 – Isolating and processing your stock

- Check and quarantine your X-Cid2 stock.
- Process your X-Cid2 machines in stock: see Section 5 “Procedure for processing your X-Cid2”.

2 – Informing your customers

This information concerns:

- All customers to whom you have sold an X-Cid2.
- All customers to whom you have sold an X-Cidol2 over the past two years.

2a – For your customers who are not end users:

- Send them this field safety notice as well as Appendix 2, 3, 4 and 5.
- Ask them to quarantine their stock and add the addendum to bring the machines into compliance.
- Ask them to fill in the distributor questionnaire and return it within one week to the named contact person.
- Ask them to propagate this information throughout the machine’s sales and distribution chain.

2b – For your customers who are end users:

- Send them Appendix 2, 3 and 4.
- Ask them to very carefully read the addendum to the X-Cid2 user guide (Appendix 3).
- Ask them to complete the end-user questionnaire and return it within one week to the named contact person (Appendix 4).

3 - Questionnaire to be completed

The distributor form should be sent back to the named contact person within one week of receipt at the latest (Appendix 5).

5 – Procedure for updating your stock of X-Cid2 machines

This section describes the steps to update your stock of X-Cid2 machines.

1	Open the outer cardboard box containing the X-Cid2.
2	Open the second box.
3	Remove the documentation holder on the side of the box. If necessary, carefully lift the protective film on the machine to access the holder.
4	Put the addendum into the holder as the first document.
5	Put the holder back on the side of the machine. Reposition the outer film on the machine if necessary.
6	Seal the box with brown packing tape.
7	Seal the outer cardboard box with brown packing tape.



6 – Your point of contact

Isabelle Bourg
Customer Quality Engineer
email: Isabelle.bourg@micro-mega.com

MICRO-MEGA
12 Rue du Tunnel
25000 BESANCON

7 – Notification of this safety bulletin

The relevant market authorities have been informed of this Field Safety Notice.

Please accept our apologies for this inconvenience and do not hesitate to contact us if you require any further information.

Yours faithfully,

Isabelle Bourg
Customer Quality Engineer
MICRO-MEGA

Stéphane Claude
Delegated General Manager
MICRO-MEGA

Enc.

Appendix 1: Customer deliveries.

Appendix 2: Letter to end users.

Appendix 3: Addendum to X-Cid2 user guide.

Appendix 4: End-user questionnaire.

Appendix 5: Distributor questionnaire.

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Letter to Hospitals, Health Care Professionals and Health Care Centres

Besançon, 2019-05-15

Subject: Urgent-Field Safety Notice/Safety Information
Information to Hospitals, Health Care Professionals and Health Care Centres
Safety Addendum to X-Cid2 User Guide

Sent by email with return receipt or by registered letter with acknowledgement of receipt or international tracked parcel post

Dear Customer

This letter is to inform you of the addition of an addendum to the user guide for our X-Cid2 washer.

1 – Details in relation to the machine

Micro-Mega Product Ref: 51100003

Description: X-Cid2 230V EUR

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2 – Subject and Contents of the Addendum

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3 – Risks for the User or Patient

If the user does not remove any external residues before putting it in the X-Cid2, it is possible that the outside of the Dental HandPieces will not be cleaned correctly and a build up of protein residues will occur. If enough residues build up, this may reduce the efficacy of sterilisation.

However such a build-up of protein residues on the outside only occurs infrequently since such residues are visible to the naked eye. Therefore users will be warned by the fact that the part will not look clean.

4 – Actions for End Users

As a user of the machine you are requested to take the following measures.

1 – Read and Understand the Addendum

- Read the addendum to the X-Cid2 user guide completely and very carefully (Appendix 3).
- Inform and train all persons in your establishment who are concerned by these measures.

2 - Questionnaire to be filled in

The end user form should be sent back within one week of receipt at the latest to the named contact person (Appendix 4).

5 – Your point of contact

Isabelle Bourg
Customer Quality Engineer
email: Isabelle.bourg@micro-mega.com

MICRO-MEGA
12 Rue du Tunnel
25000 BESANCON

7 – Notification of this safety bulletin

The relevant market authorities have been informed of this safety bulletin.

Please accept our apologies for this inconvenience and do not hesitate to contact us if you require any further information.

Yours faithfully,

Isabelle Bourg
Customer Quality Engineer
MICRO-MEGA

Stéphane Claude
Delegated General Manager
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Appendix 3: Addendum to X-Cid2 user guide.

Appendix 4: End-user questionnaire.

Appendix 3: Addendum to X-Cid2 User Guide

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Pre-treatment of dynamic dental instrument holder

As part of the use of an X-Cid2 instrument

Addendum to notice ref. 60300544

X-Cid*2 was designed to clean and lubricate the dynamic dental instrument holder (PID) between patients. Pre-treatment steps and recommendations are still required for effective external cleaning. The subject of this addendum is to describe these steps and recommendations. The steps described below must be performed before placing the PIDs in the X-Cid2



Warning: Always use a bactericidal, virucidal and fungicidal cleansing product or pre-moistened wipes suitable for the disinfection of medical instruments and recommended by the PID manufacturer. Never use wipes or other chlorine-based products or hydrochloric acid-based liquids. Never use protein fixing wipes or other products (e.g. products containing aldehydes)



Warning: Follow the product recommended dilutions, contact time and precautions of use.



Warning: Wear suitable personal protective equipment (gloves, safety glasses, mask, apron)



Warning: Some PIDs require specific handling. Please see the manufacturer's recommendations.



Always proceed to re-treat immediately after using the PID. Debris must never be allowed to dry on the instrument.

See Instruction DGS/R13 No. 2011-449 dated 1st December 2011 on updated recommendations aiming at reducing the risks of unconventional transmissible agent transmission during invasive procedures, Section 4.1.1

Materials required

- ▶ Pre-moistened wipes or lint-free cloth saturated with X-Cidol 2 or other bactericidal, virucidal and fungicidal cleansing product (hereinafter called disinfectant wipe)



Warning: Always use a bactericidal, virucidal and fungicidal cleansing product or pre-moistened wipes suitable for the disinfection of medical instruments and recommended by the PID manufacturer. Never use wipes or other chlorine-based products or hydrochloric acid-based liquids. Never use protein fixing wipes or other products (e.g. products containing aldehydes)



Warning: Follow the product recommended dilutions, contact time and precautions of use.

- ▶ Protection equipment: gloves, glasses, mask, apron



Warning: Wear suitable personal protective equipment (gloves, safety glasses, mask, apron) as recommended by the manufacturer of the product used.

- ▶ Running water
- ▶ Soft brush

Appendix 4: End-user questionnaire

Dear Sir / Madam,

You have been contacted following release of a safety bulletin by Micro-Mega relating to **an addendum to the X-Cid2 User Guide**.

We would be grateful if you would please fill in the details below.

Information Requested		Customer Answer
Product Name		X-Cid2 230V EUR
Micro-Mega Product Code		51100003
Serial Nos.		All X-Cid2 currently being used by end users.
Nature of the Information		Addition of an addendum to the X-Cid2 user guide
Address of End-User Establishment	Name of Establishment	
	Your point of contact	
	Address	
	Telephone	
	email	
1. Information to be given to my personnel		
I confirm that I have received, read and understood the Field Safety Notice		Yes <input type="checkbox"/> No <input type="checkbox"/>
List of Serial Nos. used in my establishment		
I certify that I have:		-Informed all persons concerned by this Field Safety Notice within my establishment Yes <input type="checkbox"/> No <input type="checkbox"/> -Trained all persons concerned by this Field Safety Notice within my establishment Yes <input type="checkbox"/> No <input type="checkbox"/>
Do you want to inform us of anything else?		

Date:

Completed by:

Signature:

Return this questionnaire by email within one week of receipt to: Isabelle.bourg@micro-mega.com

It is important that your organisation implements the measures detailed in the Field Safety Notice and confirms that you have received this Field Safety Notice.

A response from your organisation is required so that we can monitor progress with these corrective actions.

Appendix 5: Distributor Questionnaire

Dear Sir / Madam,

You have been contacted following release of a safety bulletin by Micro-Mega relating to **an addendum to the X-Cid2 User Guide**.

We would be grateful if you would please fill in the details below.

Information Requested		Customer Answer
Product Name		X-Cid2 230V EUR
Micro-Mega Product Code		51100003
Serial Nos.		All X-Cid2 currently being used by end users.
Nature of the Information		Addition of an addendum to the X-Cid2 user guide
Distributor Details	Distributor Name	MM to fill in beforehand
	Your point of contact	
	Address	MM to fill in beforehand
	Telephone	MM to fill in beforehand
	email	MM to fill in beforehand
1. Inspection of your stock		
Not relevant		
Number in stock		
List of serial numbers		
I certify that I have quarantined and brought the machines listed above into compliance.		Yes <input type="checkbox"/> No <input type="checkbox"/>
Date brought into compliance		
2. Informing your customers		
Not relevant		
Quantity sent to all your customers		
Serial numbers sent to your customers		
I confirm that I have received, read and understood the Field Safety Notice		Yes <input type="checkbox"/> No <input type="checkbox"/>
For customers who are not end users , I certify that I have:		<p>-Sent a copy of this letter and Appendix 2, 3, 4 and 5 to my customers. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>-Asked them to pass this information along through the sales and distribution chain for the machine. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>-Requested that they quarantine their stock and add the addendum to make the machines compliant. Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>-Requested that they fill in the distributor questionnaire and send it back. Yes <input type="checkbox"/> No <input type="checkbox"/></p>

Please go to next page

For customers who are end users , I certify that I have:	--Sent a copy of this letter and Appendix 2, 3 and 4 to my customers. Yes <input type="checkbox"/> No <input type="checkbox"/> -Asked them to read and understand the addendum and train the relevant personnel. Yes <input type="checkbox"/> No <input type="checkbox"/> -Requested that they fill in the end-user questionnaire and send it back. Yes <input type="checkbox"/> No <input type="checkbox"/>
Do you want to inform us of anything else?	

Date:

Completed by:

Signature:

Return this questionnaire by email within one week of receipt to:

Isabelle.bourg@micro-mega.com

It is important that your organisation implements the measures detailed in the Field Safety Notice and confirms that you have received this Field Safety Notice.

A response from your organisation is required so that we can monitor progress with these corrective actions.