

[insert your company letterhead]

Urgent Field Safety Notice

Product Correction

Ultramat S

Date: October 2025

Dear Doctor,

SDI Limited ('SDI') is conducting a product correction of the capsule triturator/mixer Ultramat S ('Unit'). This potentially affected product may have been supplied to your organisation.

Issue description

If a user rapidly unplugs the Unit from the mains socket and immediately touches the Unit's plug pins, there is potential for the user to experience a small electrical discharge, similar to everyday static.

The potentially affected Units have serial numbers 144445 and above. Please note that this does not affect the Ultramat 2 unit.

Customer actions

There is no danger to the user.

The situation can be completely nullified by switching the Unit off at the rear switch before removing the plug from the mains socket.

Alternatively, you can send your Unit to SDI to have a corrective modification installed. To enquire about a unit modification, email germany@sdi.com.au by 31st December 2025, noting the serial number of your Unit.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected Units have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all Unit-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback

Faithfully,

[company representative name]

[company representative title]

Product information

Commercial product name	Ultramat S
Primary clinical purpose of device	Use by dental professional to mix encapsulated products such as amalgam and glass ionomer capsules.
Unique Device Identifier (UDI-DI)*	9336472005542
Device Model/Catalogue/part number(s)*	5546058

Additional details

Background of issue	This risk was first detected after a reported observation in the DE
Probability of problem arising	0.09% probability, based on customer data, leading to a 'probable' classification.
Issue description	Small electrical discharge, similar to everyday static, which is not life threatening.
Further information	There is no danger to the user. The situation can be completely nullified by switching the Unit off at the rear switch before removing the plug from the mains socket. Alternatively, you can send your Unit to SDI to have a corrective modification installed. To enquire about a unit modification, email uk@sdi.com.au noting the serial number of your Unit.
Local SDI representative	Local representative: Mrs Beate Hohe Mobile: +49 (0) 172 71 56973
Action date	Users should contact germany@sdi.com.au by 31st December 2025 if they are seeking a corrective modification.

Urgent Field Safety Notice

Product Correction

Ultramat S ('Unit /Product')

October 2025

Dear [Dealer]

SDI Limited ('SDI'), is actioning a field safety notice ('FSN') for the above Product.

This potentially affected Product may have been supplied to your organisation for purchase by your customers. We ask you to review and make the below available to affected customers.

Issue description

If a user rapidly unplugs the Unit from the mains socket and immediately touches the Unit's plug pins, there is potential for the user to experience a small electrical discharge, similar to everyday static.

The potentially affected Units have serial numbers 144445 and above. Please note that this does not affect the Ultramat 2 unit.

Customer actions

There is no danger to the user.

The situation can be completely nullified by switching the Unit off at the rear switch before removing the plug from the mains socket.

Alternatively, users can return the unit to SDI to have a corrective modification installed. To enquire about a Unit modification, users should email germany@sdi.com.au by 31st December 2026.

Required dealer actions

1. Please circulate the accompanying communication '*Urgent Field Safety Notice: Ultramat S*' to your customers who have or are likely to have purchased the Unit from you, by 15 October 2025.



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SDI LIMITED ACN 008 075 581 | ABN 27 008 075 581

HEAD OFFICE 3-15 BRUNSDON STREET, BAYSWATER. PO BOX 314, VICTORIA, 3153 AUSTRALIA.

TOLL FREE 1800 337 003 | TELEPHONE +61 3 8727 7111

FAX +61 3 8727 7222 | info@sdi.com.au | www.sdi.com.au

2. Please complete the dealer reply form noted on pages two and three, returning them to SDI by 30 October 2025. Return by emailing uk@sdi.com.au or using the details on section 5.

Field Safety Notice Customer Reply Form Dealer Reply Form (UK)

Please complete and return to SDI by 15 October 2025, even if you have no affected Units

1. Field Safety Notice (FSN) information	
FSN Reference number	TBA
FSN Date	October 2025
Product/ Device name	Ultramat S
Product Code(s)	5546058
Batch/Serial Number (s)	Serial number 144445 and above

2. Your Details	
Account name	
Account number	
Organisation address	
Department/Unit	
Shipping address if different to above	
Contact name	
Title or function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation		
Please check boxes where appropriate		
3a	☐	I confirm receipt of the Field Safety Notice and that I read and understood its content
3b	☐	I performed all required dealer actions requested by the FSN (page 1)
3c	☐	The information and required actions have been brought to the attention of all relevant users and executed.
3d	☐	I have stocks of the product that need actioning by SDI <i>Note: If selected, complete details in section 4</i>
3e	☐	I do not have any stock of this product
3f	☐	I have a query please contact me. (e.g. need clarification).
Dealer details		
Print Name:		
Signature:		
Date:		



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4. Existing unit supply to be actioned

If the previous 3d box has been checked, enter the serial numbers of each unit on hand:

5. Return acknowledgement to sender

Please complete this form and return to SDI via the details below

Email	germany@sdi.com.au
Customer Helpline	00800 0225 5734
Postal Address	SDI Germany GmbH Hansestrasse 85 51149, Cologne Germany
Deadline for returning the customer reply form*	30 October 2025

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN, even if you have no affected inventory.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Sincerely,

Lyn Chau

Senior Quality & Regulatory Affairs Manager (Management Representative)

SDI Limited