

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

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 Customer.PC@sdi.com.au by 31st December 2025.

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 30 October 2025.





1. Field Safety Notice (FSN) information

FSN Reference number

Product/ Device name

Batch/Serial Number (s)

Product Code(s)

FSN Date

Signature:

Date:

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 <u>Customer.PC@sdi.com.au</u> or using the details on section 5.

Field Safety Notice Customer Reply Form Dealer Reply Form (EU) Please complete and return to SDI by 30 October 2025, even if you have no affected Units

October 2025

Serial number 144445 and above

Ultramat S

5546058

TBA

·-				
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)	I performed all required dealer actions requested by the FSN (page 1)			
	The information and required actions have been brought to the attention of all relevant			
users and executed.	users and executed.			
3d	I have stocks of the product that need actioning by SDI			
	Note: If selected, complete details in section 4			
3e ☐ I do not have any stock of this product	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:				





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

4.	Existing	unit	supply	to t	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	<u>Customer.PC@sdi.com.au</u>			
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





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

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, to enquire about a unit modification, please go to https://www.sdi.com.au/au/fsn/ and lodge a request by 31 December 2025, noting the serial number of your Unit.





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

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,

Lyn Chau

Senior Quality & Regulatory Affairs Manager (Management Representative)

SDI Limited





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

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, to enquire about a unit modification, please go
	to https://www.sdi.com.au/au/fsn/ and lodge a request by 31
	December 2025, noting the serial number of your Unit.
	Local representative: Jan Benes Mobile: +42 (0) 323 607 487
Local SDI representative	





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

Action date

Users should enquire about a unit modification to https://www.sdi.com.au/au/fsn/ by 31 December 2025.