CORE DIAGNOSTICS

Abbott Laboratories
1915 Hurd Drive
Irving TX, 75038 USA

Single Registration Number (SRN):
US-MF-000017777

Urgent Field Safety Notice

Immediate Action Required

Date Issued October 5, 2026

Product

Product Description	List Number (LN)	Serial Number (SN)	UDI
ARCHITECT *i*2000SR Processing Module*	03M74	See Attachment A	

*Only ARCHITECT *i*2000SR with an Induction Heater (IH) Control Module are impacted.

Explanation

Through customer complaint investigations, an issue has been identified with the 5 Amp (5A) diode used in the Induction Heater (IH) Control Module on the ARCHITECT *i*2000SR IH Kit. The diode may be exposed to current exceeding its specified rating, potentially resulting in component failure. Failure could cause localized electrical arcing, circuit board damage, and smoke generation.

The IH Control Module housing is classified as a fire enclosure in accordance with International Electrotechnical Commission (IEC) 61010-1 and is designed to contain thermal events. Protective features include flame-retardant circuit board material and a metal fire-rated enclosure, which help prevent propagation beyond the module. In all failures, the observed damage remained contained within the IH Control Module, and no injuries or property damage have been reported.

Impact to User Safety

There is potential for operator injury and property damage due to smoke, burn, hot surfaces, etc. caused by the excess current on the diode.

As of the issuance of this letter, there have been zero occurrences of property damage and no reported occurrences of operator injury for this issue.

Necessary Actions to be Taken by Customer

Your local Abbott service representative will contact you to schedule an update to your IH Control Module.

Until your IH Control module is replaced, follow the instructions below:

- If you observe smoke or electrical arcing coming from your instrument, follow the Emergency shutdown procedure found in Section 5 of the ARCHITECT System Operations Manual and call your local service representative.
- Laboratory users should not access the internal components of the IH Control Module.

Complete and return the Customer Reply Form.

If you have forwarded the product listed above to other laboratories, please inform them of this product correction and provide them with a copy of this letter.

Please retain this letter for your laboratory records.

Contact Information	If you or any of the health care providers you serve have questions regarding this information, please contact your local area Customer Service. If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

Attachment A

ARCHITECT *i*2000SR Processing Module
List Number (LN) 03M74-01- Serial Numbers (SN) and UDI

SN	UDI
ISR02892	(01)00380740023386(21)ISR02892
ISR03518	(01)00380740023386(21)ISR03518
ISR03807S	(01)00380740023386(21)ISR03807S
ISR62315	(01)00380740023386(21)ISR62315
ISR62891	(01)00380740023386(21)ISR62891
ISR62895	(01)00380740023386(21)ISR62895
ISR62899	(01)00380740023386(21)ISR62899
ISR62901	(01)00380740023386(21)ISR62901
ISR62902	(01)00380740023386(21)ISR62902
ISR63006	(01)00380740023386(21)ISR63006
ISR63008	(01)00380740023386(21)ISR63008
ISR63010	(01)00380740023386(21)ISR63010
ISR63012	(01)00380740023386(21)ISR63012
ISR63013	(01)00380740023386(21)ISR63013
ISR63102	(01)00380740023386(21)ISR63102
ISR63104	(01)00380740023386(21)ISR63104
ISR63105	(01)00380740023386(21)ISR63105
ISR63106	(01)00380740023386(21)ISR63106
ISR63107	(01)00380740023386(21)ISR63107
ISR63110	(01)00380740023386(21)ISR63110
ISR63119	(01)00380740023386(21)ISR63119
ISR63128	(01)00380740023386(21)ISR63128
ISR63132	(01)00380740023386(21)ISR63132
ISR63135	(01)00380740023386(21)ISR63135
ISR63136	(01)00380740023386(21)ISR63136
ISR63137	(01)00380740023386(21)ISR63137
ISR63138	(01)00380740023386(21)ISR63138
ISR63141	(01)00380740023386(21)ISR63141
ISR63142	(01)00380740023386(21)ISR63142
ISR63179	(01)00380740023386(21)ISR63179
ISR63182	(01)00380740023386(21)ISR63182
ISR63183	(01)00380740023386(21)ISR63183
ISR63186	(01)00380740023386(21)ISR63186
ISR63188	(01)00380740023386(21)ISR63188
ISR63196	(01)00380740023386(21)ISR63196
ISR63197	(01)00380740023386(21)ISR63197
ISR63199	(01)00380740023386(21)ISR63199
ISR63292	(01)00380740023386(21)ISR63292
ISR63293	(01)00380740023386(21)ISR63293

SN	UDI
ISR63294	(01)00380740023386(21)ISR63294
ISR63296	(01)00380740023386(21)ISR63296
ISR63297	(01)00380740023386(21)ISR63297
ISR63300	(01)00380740023386(21)ISR63300
ISR63331	(01)00380740023386(21)ISR63331
ISR63335	(01)00380740023386(21)ISR63335
ISR63336	(01)00380740023386(21)ISR63336
ISR63337	(01)00380740023386(21)ISR63337
ISR63338	(01)00380740023386(21)ISR63338
ISR63342	(01)00380740023386(21)ISR63342
ISR63344	(01)00380740023386(21)ISR63344
ISR63346	(01)00380740023386(21)ISR63346
ISR63348	(01)00380740023386(21)ISR63348
ISR63349	(01)00380740023386(21)ISR63349
ISR63350	(01)00380740023386(21)ISR63350
ISR63351	(01)00380740023386(21)ISR63351
ISR63370	(01)00380740023386(21)ISR63370
ISR63371	(01)00380740023386(21)ISR63371
ISR63374	(01)00380740023386(21)ISR63374
ISR63387	(01)00380740023386(21)ISR63387
ISR63392	(01)00380740023386(21)ISR63392
ISR63395	(01)00380740023386(21)ISR63395
ISR63409	(01)00380740023386(21)ISR63409
ISR63413	(01)00380740023386(21)ISR63413
ISR63415	(01)00380740023386(21)ISR63415
ISR63416	(01)00380740023386(21)ISR63416
ISR63456	(01)00380740023386(21)ISR63456
ISR63458	(01)00380740023386(21)ISR63458
ISR63461	(01)00380740023386(21)ISR63461
ISR63462	(01)00380740023386(21)ISR63462
ISR63463	(01)00380740023386(21)ISR63463
ISR63468	(01)00380740023386(21)ISR63468
ISR63469	(01)00380740023386(21)ISR63469
ISR63470	(01)00380740023386(21)ISR63470
ISR63475	(01)00380740023386(21)ISR63475
ISR63477	(01)00380740023386(21)ISR63477
ISR63479	(01)00380740023386(21)ISR63479
ISR63484	(01)00380740023386(21)ISR63484
ISR63491	(01)00380740023386(21)ISR63491

Attachment A

SN	UDI
ISR63505	(01)00380740023386(21)ISR63505
ISR64590	(01)00380740023386(21)ISR64590
ISR64772	(01)00380740023386(21)ISR64772

SN	UDI
ISR64814	(01)00380740023386(21)ISR64814
ISR62893	(01)00380740023386(21)ISR62893

ARCHITECT *i*2000SR Processing Module – LN 03M74-02- SN and UDI

SN	UDI
ISR05363	(01)00380740006235(21)ISR05363
ISR52673	(01)00380740006235(21)ISR52673
ISR52907	(01)00380740006235(21)ISR52907
ISR53685	(01)00380740006235(21)ISR53685
ISR53721	(01)00380740006235(21)ISR53721
ISR54282	(01)00380740006235(21)ISR54282
ISR54345	(01)00380740006235(21)ISR54345
ISR55288	(01)00380740006235(21)ISR55288
ISR55387	(01)00380740006235(21)ISR55387
ISR55621	(01)00380740006235(21)ISR55621
ISR55801	(01)00380740006235(21)ISR55801
ISR60204	(01)00380740006235(21)ISR60204
ISR60555	(01)00380740006235(21)ISR60555
ISR60621	(01)00380740006235(21)ISR60621
ISR61104	(01)00380740006235(21)ISR61104
ISR61202	(01)00380740006235(21)ISR61202
ISR61518	(01)00380740006235(21)ISR61518
ISR62033	(01)00380740006235(21)ISR62033
ISR62136	(01)00380740006235(21)ISR62136
ISR62209	(01)00380740006235(21)ISR62209
ISR62418	(01)00380740006235(21)ISR62418
ISR62467	(01)00380740006235(21)ISR62467
ISR63314	(01)00380740006235(21)ISR63314
ISR63871	(01)00380740006235(21)ISR63871
ISR64041	(01)00380740006235(21)ISR64041
ISR64673	(01)00380740006235(21)ISR64673
ISR64844	(01)00380740006235(21)ISR64844

ARCHITECT *i*2000SR Processing Module – LN 03M74-56- SN and UDI

SN	UDI
ISR60866	(01)00380740116996(21)ISR60866

Attachment A

ARCHITECT *i*2000SR Processing Module – LN 03M74-65- SN and UDI

SN	UDI
ISR04033	(01)00380740112585(21)ISR04033

ARCHITECT i2000SR Processing Module – LN 03M74-97- SN and UDI

SN	UDI
ISR06470	(01)00380740006273(21)ISR06470
ISR06585	(01)00380740006273(21)ISR06585
ISR07269	(01)00380740006273(21)ISR07269
ISR53232	(01)00380740006273(21)ISR53232
ISR54494	(01)00380740006273(21)ISR54494
ISR54668	(01)00380740006273(21)ISR54668

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Customer Reply

Immediate Action Required

<table>
<tr><td colspan="4">Core Diagnostics Product Correction letter dated October 5, 2026 – FA05OCT2026</td></tr>
<tr><td>Product</td><td colspan="3">
<table>
<tr><td>Product Description</td><td>List Number</td><td>Serial Number</td><td>UDI</td></tr>
<tr><td>ARCHITECT i2000SR Processing Module*</td><td>03M74</td><td colspan="2">See Attachment A</td></tr>
</table>
*Only ARCHITECT i2000SR with an Induction Heater (IH) Control Module are impacted.
</td></tr>
<tr><td>Instructions</td><td colspan="3">Please provide a copy of the accompanying Product Correction letter to the laboratory manager, supervisor or health professional responsible for the impacted product.
Please complete all sections and return this Customer Reply Form to the Abbott contact prior to <u>19OCT2026</u>. Even if you no longer have the instrument(s)/reagent(s), this form is required for the reconciliation of our records.</td></tr>
<tr><td>Abbott contact</td><td colspan="3">E-mail: PMS@abbott.com (insert local e-mail address here)
Fax: 1-800-777-0051 (insert local number here)</td></tr>
<tr><td>Acknowledgement</td><td colspan="3">By completing and signing this document I confirm that the Product Correction Letter was understood and that the necessary actions for the customer were completed. If not, please choose one of the options below.
☐ No, I would like to be contacted by an Abbott Representative.
☐ Not Applicable, Please Explain (e.g. no longer have the instrument):
_____</td></tr>
<tr><td>Customer number</td><td></td><td>Serial Number(s)</td><td></td></tr>
<tr><td>Facility Name(s)</td><td colspan="3"></td></tr>
<tr><td>Address</td><td colspan="3"></td></tr>
<tr><td>City</td><td></td><td>State</td><td></td></tr>
<tr><td>Phone Number</td><td></td><td>E-mail</td><td></td></tr>
<tr><td>Name (print)</td><td></td><td>Title/Position</td><td></td></tr>
<tr><td>Signature</td><td></td><td>Date</td><td></td></tr>
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