VIRTUAL DISTRIBUTOR PARTNER MEETING

FEB 10, 2022

Internal Use Only

BELMONT® MEDICAL TECHNOLOGIES

WELCOME & AGENDA

AGENDA

- Smiths Level 1 Recall / Safety Notifications / CE Mark Suspension
- Available Marketing Tools / Upcoming Trade Shows / Website Expectations/Contest
- Advantages of Belmont RI-2 to Competitive Rapid Infusers
- Distributor Success Stories / Converting Level 1 to The Belmont RI-2
- Sales Guidance
- Q&A

REVIEW NOTIFICATIONS

REVIEW REGULATORY NOTIFICATIONS

- Timeline of key notifications:
  - Aug 2021: FDA Class 1 Recall for Smiths Level 1 Fast Flow device
  - Aug-Nov 2021: EU Safety Notification & EU distribution hold
  - Feb 2022: Temporary CE Mark suspension

- Business Impacts according to the Field Safety Notice (FSN):
  - A distribution hold is in effect in EU members states:
    - No products can ship from Smiths to distributors and to customers
    - Distributors cannot ship products to customers
  - Hospitals are instructed by Smiths to temporarily discontinue use of all affected products
  - Users are instructed to seek out alternative devices

FDA CLASS I RECALL & LETTER TO HEALTH CARE PROVIDERS

Aug 17, 2021

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URGENT MEDICAL DEVICE RECALL NOTICE

LEVEL 1® Fast Flow and Irrigation Fluid Warming Systems
Potential for Aluminum Ions to Leach into Warmed Fluids

Affected Device Models: Level 1® Fast Flow Fluid Warming System and Level 1® NORMOFLO® Irrigation System

Type of Action: Correction

Date: August 17, 2021

Attention: Nurses, Clinicians, Physicians, Risk Managers, Recall Coordinators

Affected Devices: Level 1® Fluid Warming System disposable products listed below:

Affected Product Model Name	Affected Product Model Number
Level 1® Fluid Warmer	H-1000, H-500
Level 1® Fluid Warming System	H-1025, H-1028, H-1200
Level 1® Normothermic I.V. Fluid Administration Set	D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL, D-70, DI-70
NORMOFLO® Fluid Warmer	H-1100, H-1129
NORMOFLO® Irrigation Warming Set	IR-40, IR-500, IR-600, IRI-600, IRI-600B, IR-700

Reference Page 4 for representative pictures for some of these devices.

Dear Customer,

The purpose of this notice is to advise you that Smiths Medical has initiated a voluntary recall for certain Affected Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System Disposables listed above which contain aluminum heat exchangers, due to the potential for aluminum ion leaching into warmed fluids.

REASON FOR RECALL

Smiths Medical has investigated the potential for aluminum ion leaching in Smiths Medical fluid warming products and is providing users with operating parameters to ensure safe operation of the devices under certain clinical use conditions.

Please note that this is an advisory notification and not a product removal. **No product return is necessary.**

This recall is being performed with the knowledge of the Food and Drug Administration.

Medical Device Recall Notice: Level 1® Fluid Warmer Aluminum Leaching
Smiths Medical Ref # 3012307300-08/10/2021-012-C

Page 1 of 4

7367_02_01AS_V1.1

Sep 15, 2021

Potential Risk of Aluminum Leaching with Use of Certain Fluid Warmer Devices - Letter to Health Care Providers

September 15, 2021

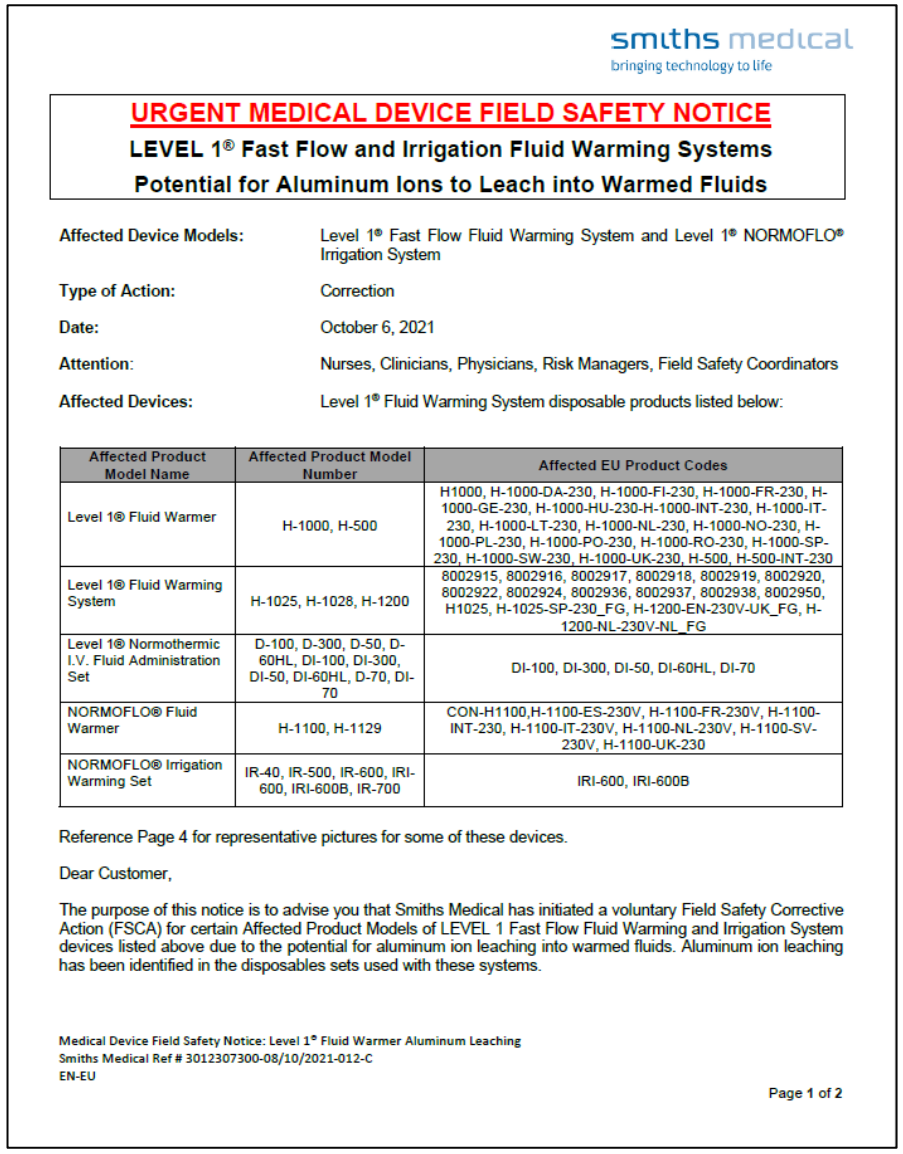
The U.S. Food and Drug Administration (FDA) is reminding health care providers about the use of certain fluid warmers and the potential for aluminum leaching and exposing the patient to high levels of aluminum. Based on information reviewed by the FDA, aluminum leaching may occur when the fluid warmer is designed with an aluminum heating element where the heated aluminum is in direct contact with the fluids or blood products being administered to a patient.

The FDA has identified the devices listed in the table below as having this type of design. Three original equipment manufacturers (Eight Medical International BV, Smisson Cartledge Biomedical and Smith Medical) provided revised instructions for use for these devices, a type of voluntarily recall action, which were initiated on the dates shown. Users who did not purchase devices from these original equipment manufacturers may not be aware of the revised instructions. A fourth original equipment manufacturer (Vyaire Medical) voluntarily removed its product from the market.

Manufacturer Name	Device Information	Recall Notice
Eight Medical International BV	Recirculator 8.0 Disposable Lavage kit (Product Code: 8100) Lot Numbers: 20021361, 20202106, 20018480, 19854186, 20019438, 19854185, 20019438, 19854184, 18687686	Recall Notice (/medical-devices/medical-device-recalls/eight-medical-international-recalls-recirculator-80-disposable-lavage-kits-due-potential-exposure) Initiated June 4, 2021
Smisson-Cartledge Biomedical	ThermaCor 1200 Disposable Sets Disposable Set Models: PTC-1200, DNC-1200, PNC-1200	Recall Notice (/medical-devices/medical-device-recalls/smisson-cartledge-biomedical-llc-recalls-thermacor-1200-disposable-sets-risk-patient-contact) Initiated February 18, 2021

EU SAFETY NOTIFICATION & DISTRIBUTION HOLD AUG THRU NOV 2021

Global Recall, Urgent Safety, Temporary Use Discontinuation & Distribution Hold Notices for the Smiths Level 1® Fast Flow Warmer			
United States	6-Aug-2021	Ireland	6-Oct-2021
Canada	11-Aug-2021	Slovenia	6-Oct-2021
Denmark	19-Aug-2021	Switzerland	6-Oct-2021
Hong Kong	19-Aug-2021	Spain	6-Oct-2021
Germany	2-Sep-2021	Italy	29-Oct-2021
Saudi Arabia	8-Sep-2021	France	3-Nov-2021
Poland	11-Sep-2021	Sweden	4-Nov-2021
Australia	21-Sep-2021	Spain	5-Nov-2021
Japan	22-Sep-2021	Netherlands	11-Nov-2021



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URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

LEVEL 1® Fast Flow and Irrigation Fluid Warming Systems

Potential for Aluminum Ions to Leach into Warmed Fluids

Affected Device Models: Level 1® Fast Flow Fluid Warming System and Level 1® NORMOFLO® Irrigation System

Type of Action: Correction

Date: October 6, 2021

Attention: Nurses, Clinicians, Physicians, Risk Managers, Field Safety Coordinators

Affected Devices: Level 1® Fluid Warming System disposable products listed below:

Affected Product Model Name	Affected Product Model Number	Affected EU Product Codes
Level 1® Fluid Warmer	H-1000, H-500	H1000, H-1000-DA-230, H-1000-FI-230, H-1000-FR-230, H-1000-GE-230, H-1000-HU-230-H-1000-INT-230, H-1000-IT-230, H-1000-LT-230, H-1000-NL-230, H-1000-NO-230, H-1000-PL-230, H-1000-PO-230, H-1000-RO-230, H-1000-SP-230, H-1000-SW-230, H-1000-UK-230, H-500, H-500-INT-230
Level 1® Fluid Warming System	H-1025, H-1028, H-1200	8002915, 8002916, 8002917, 8002918, 8002919, 8002920, 8002922, 8002924, 8002936, 8002937, 8002938, 8002950, H1025, H-1025-SP-230_FG, H-1200-EN-230V-UK_FG, H-1200-NL-230V-NL_FG
Level 1® Normothermic I.V. Fluid Administration Set	D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL, D-70, DI-70	DI-100, DI-300, DI-50, DI-60HL, DI-70
NORMOFLO® Fluid Warmer	H-1100, H-1129	CON-H1100,H-1100-ES-230V, H-1100-FR-230V, H-1100-INT-230, H-1100-IT-230V, H-1100-NL-230V, H-1100-SV-230V, H-1100-UK-230
NORMOFLO® Irrigation Warming Set	IR-40, IR-500, IR-600, IRI-600, IRI-600B, IR-700	IRI-600, IRI-600B

Reference Page 4 for representative pictures for some of these devices.

Dear Customer,

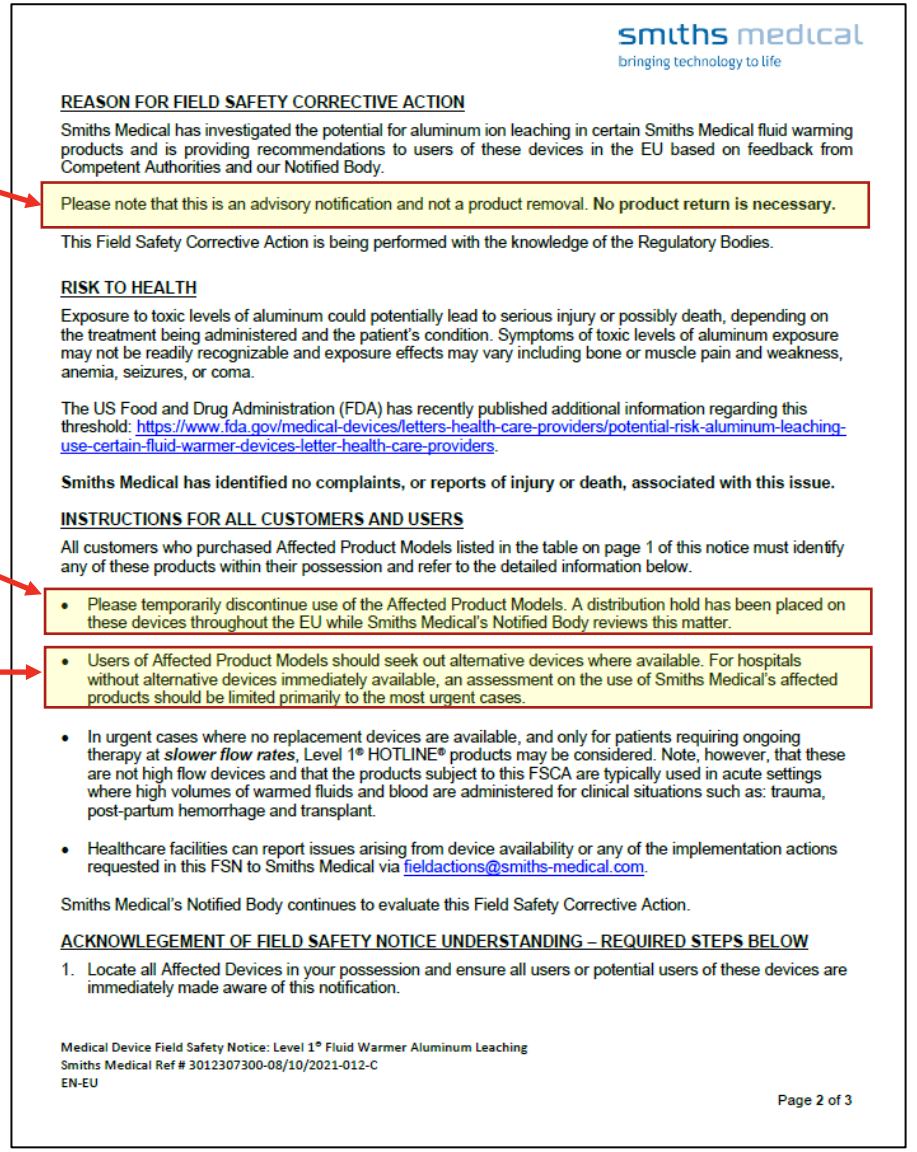
The purpose of this notice is to advise you that Smiths Medical has initiated a voluntary Field Safety Corrective Action (FSCA) for certain Affected Product Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System devices listed above due to the potential for aluminum ion leaching into warmed fluids. Aluminum ion leaching has been identified in the disposables sets used with these systems.

Medical Device Field Safety Notice: Level 1® Fluid Warmer Aluminum Leaching
Smiths Medical Ref # 3012307300-08/10/2021-012-C
EN-EU

Page 1 of 2

EU SAFETY NOTIFICATION & DISTRIBUTION HOLD (PAGE 2)

- *"Please note that this is an advisory notification and not a product removal. No product return is necessary."*
- *"Please temporarily discontinue use of the Affected Product Models. A distribution hold has been placed on these devices throughout the EU while Smiths Medical's Notified Body reviews this matter."*
- *"Users of Affected Product Models should seek out alternative devices where available. For hospitals without alternative devices immediately available, an assessment on the use of Smiths Medical's affected products should be limited primarily to the most urgent cases."*



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REASON FOR FIELD SAFETY CORRECTIVE ACTION

Smiths Medical has investigated the potential for aluminum ion leaching in certain Smiths Medical fluid warming products and is providing recommendations to users of these devices in the EU based on feedback from Competent Authorities and our Notified Body.

Please note that this is an advisory notification and not a product removal. **No product return is necessary.**

This Field Safety Corrective Action is being performed with the knowledge of the Regulatory Bodies.

RISK TO HEALTH

Exposure to toxic levels of aluminum could potentially lead to serious injury or possibly death, depending on the treatment being administered and the patient's condition. Symptoms of toxic levels of aluminum exposure may not be readily recognizable and exposure effects may vary including bone or muscle pain and weakness, anemia, seizures, or coma.

The US Food and Drug Administration (FDA) has recently published additional information regarding this threshold: https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-aluminum-leaching-use-certain-fluid-warmer-devices-letter-health-care-providers.

Smiths Medical has identified no complaints, or reports of injury or death, associated with this issue.

INSTRUCTIONS FOR ALL CUSTOMERS AND USERS

All customers who purchased Affected Product Models listed in the table on page 1 of this notice must identify any of these products within their possession and refer to the detailed information below.

- Please temporarily discontinue use of the Affected Product Models. A distribution hold has been placed on these devices throughout the EU while Smiths Medical's Notified Body reviews this matter.
- Users of Affected Product Models should seek out alternative devices where available. For hospitals without alternative devices immediately available, an assessment on the use of Smiths Medical's affected products should be limited primarily to the most urgent cases.
- In urgent cases where no replacement devices are available, and only for patients requiring ongoing therapy at ***slower flow rates***, Level 1® HOTLINE® products may be considered. Note, however, that these are not high flow devices and that the products subject to this FSCA are typically used in acute settings where high volumes of warmed fluids and blood are administered for clinical situations such as: trauma, post-partum hemorrhage and transplant.
- Healthcare facilities can report issues arising from device availability or any of the implementation actions requested in this FSN to Smiths Medical via fieldactions@smiths-medical.com.

Smiths Medical's Notified Body continues to evaluate this Field Safety Corrective Action.

ACKNOWLEGEMENT OF FIELD SAFETY NOTICE UNDERSTANDING – REQUIRED STEPS BELOW

1. Locate all Affected Devices in your possession and ensure all users or potential users of these devices are immediately made aware of this notification.

Medical Device Field Safety Notice: Level 1® Fluid Warmer Aluminum Leaching
Smiths Medical Ref # 3012307300-08/10/2021-012-C
EN-EU

Page 2 of 3

EU SAFETY NOTIFICATION & DISTRIBUTION HOLD (PAGE 3 & 4)

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2. Complete and return the attached Response Form to smithsmedical7367@stericycle.com to acknowledge your receipt and understanding of this Field Safety Notice within 10 days of receipt.

3. **DISTRIBUTORS:** Please immediately forward a copy of this notification and attachments to any of your customers to whom you've distributed affected product. Request that they complete the Response Form and return it to you. Please indicate your identity as the distributor and the consignees name and address.

Adverse events or quality problems experienced with the use of this product must be reported to Smiths Medical via globalcomplaints@smiths-medical.com.

For questions or difficulties encountered regarding this Field Safety Corrective Action contact fieldactions@smiths-medical.com.

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,

Daniel Khalili
Senior Vice President and Chief Global Regulatory and Quality Officer
Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442 USA

Enclosures:
Attachment 1 – Field Safety Notice Response Form

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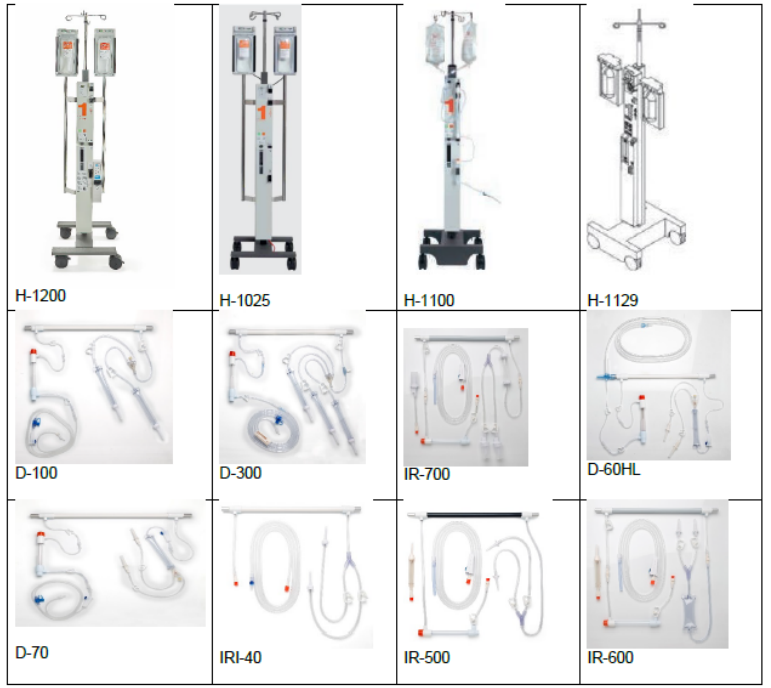
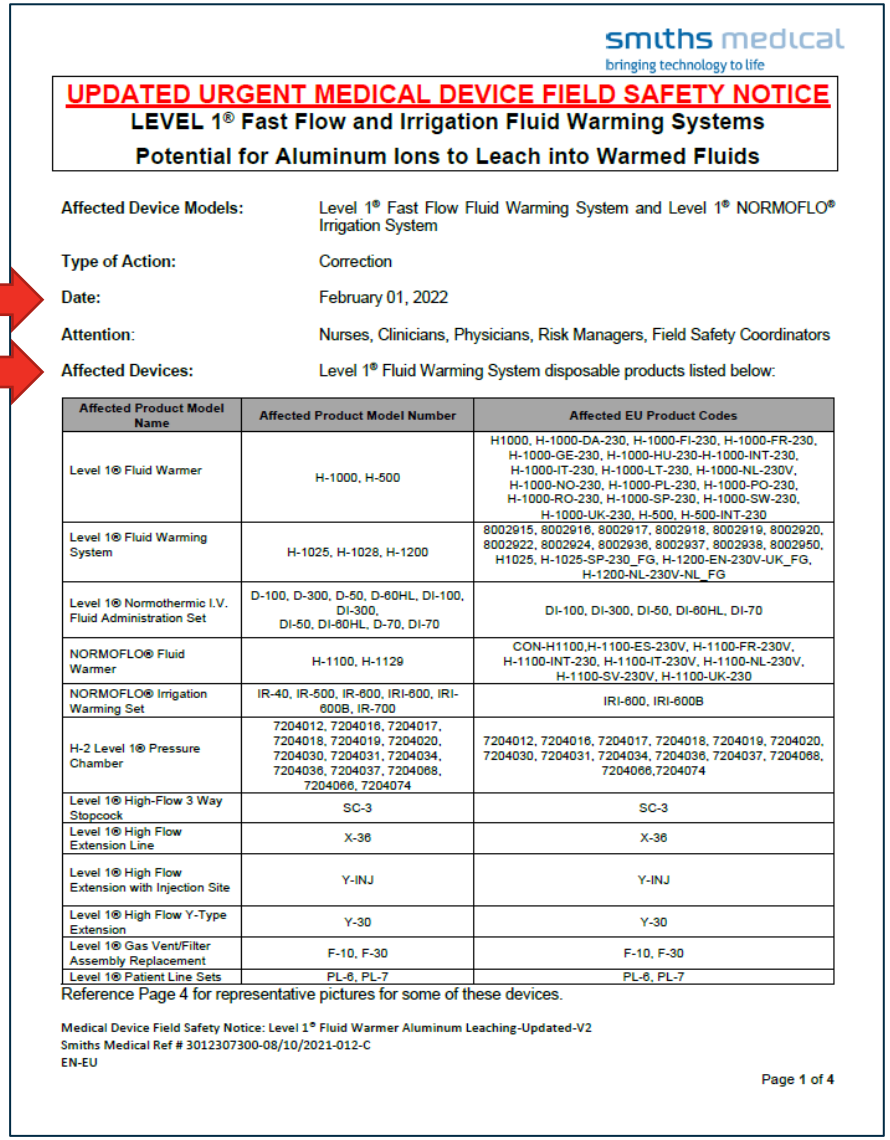


SMITHS LEVEL 1 CE MARK SUSPENSION – PAGE 1

- Date: February 1st, 2022
- Affected Devices: All Level 1 Fast Flow systems and disposables
- Previous notice mentioned Smiths Medical has 6 months to resolve the issues.
- As of 2.17, the following countries have posted:
  - Czech Republic
  - Denmark
  - UK
  - Italy
  - Switzerland
  - The Netherlands
  - Australia

Notification links can be found on the belmontmedtech.com/alufree page



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UPDATED URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

LEVEL 1® Fast Flow and Irrigation Fluid Warming Systems

Potential for Aluminum Ions to Leach into Warmed Fluids

Affected Device Models: Level 1® Fast Flow Fluid Warming System and Level 1® NORMOFLO® Irrigation System

Type of Action: Correction

Date: February 01, 2022

Attention: Nurses, Clinicians, Physicians, Risk Managers, Field Safety Coordinators

Affected Devices: Level 1® Fluid Warming System disposable products listed below:

Affected Product Model Name	Affected Product Model Number	Affected EU Product Codes
Level 1® Fluid Warmer	H-1000, H-500	H1000, H-1000-DA-230, H-1000-FI-230, H-1000-FR-230, H-1000-GE-230, H-1000-HU-230-H-1000-INT-230, H-1000-IT-230, H-1000-LT-230, H-1000-NL-230V, H-1000-NO-230, H-1000-PL-230, H-1000-PO-230, H-1000-RO-230, H-1000-SP-230, H-1000-SW-230, H-1000-UK-230, H-500, H-500-INT-230
Level 1® Fluid Warming System	H-1025, H-1028, H-1200	8002915, 8002916, 8002917, 8002918, 8002919, 8002920, 8002922, 8002924, 8002936, 8002937, 8002938, 8002950, H1025, H-1025-SP-230_FG, H-1200-EN-230V-UK_FG, H-1200-NL-230V-NL_FG
Level 1® Normothermic I.V. Fluid Administration Set	D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL, D-70, DI-70	DI-100, DI-300, DI-50, DI-60HL, DI-70
NORMOFLO® Fluid Warmer	H-1100, H-1129	CON-H1100,H-1100-ES-230V, H-1100-FR-230V, H-1100-INT-230, H-1100-IT-230V, H-1100-NL-230V, H-1100-SV-230V, H-1100-UK-230
NORMOFLO® Irrigation Warming Set	IR-40, IR-500, IR-600, IRI-600, IRI-600B, IR-700	IRI-600, IRI-600B
H-2 Level 1® Pressure Chamber	7204012, 7204016, 7204017, 7204018, 7204019, 7204020, 7204030, 7204031, 7204034, 7204036, 7204037, 7204068, 7204066, 7204074	7204012, 7204016, 7204017, 7204018, 7204019, 7204020, 7204030, 7204031, 7204034, 7204036, 7204037, 7204068, 7204066,7204074
Level 1® High-Flow 3 Way Stopcock	SC-3	SC-3
Level 1® High Flow Extension Line	X-36	X-36
Level 1® High Flow Extension with Injection Site	Y-INJ	Y-INJ
Level 1® High Flow Y-Type Extension	Y-30	Y-30
Level 1® Gas Vent/Filter Assembly Replacement	F-10, F-30	F-10, F-30
Level 1® Patient Line Sets	PL-6, PL-7	PL-6, PL-7

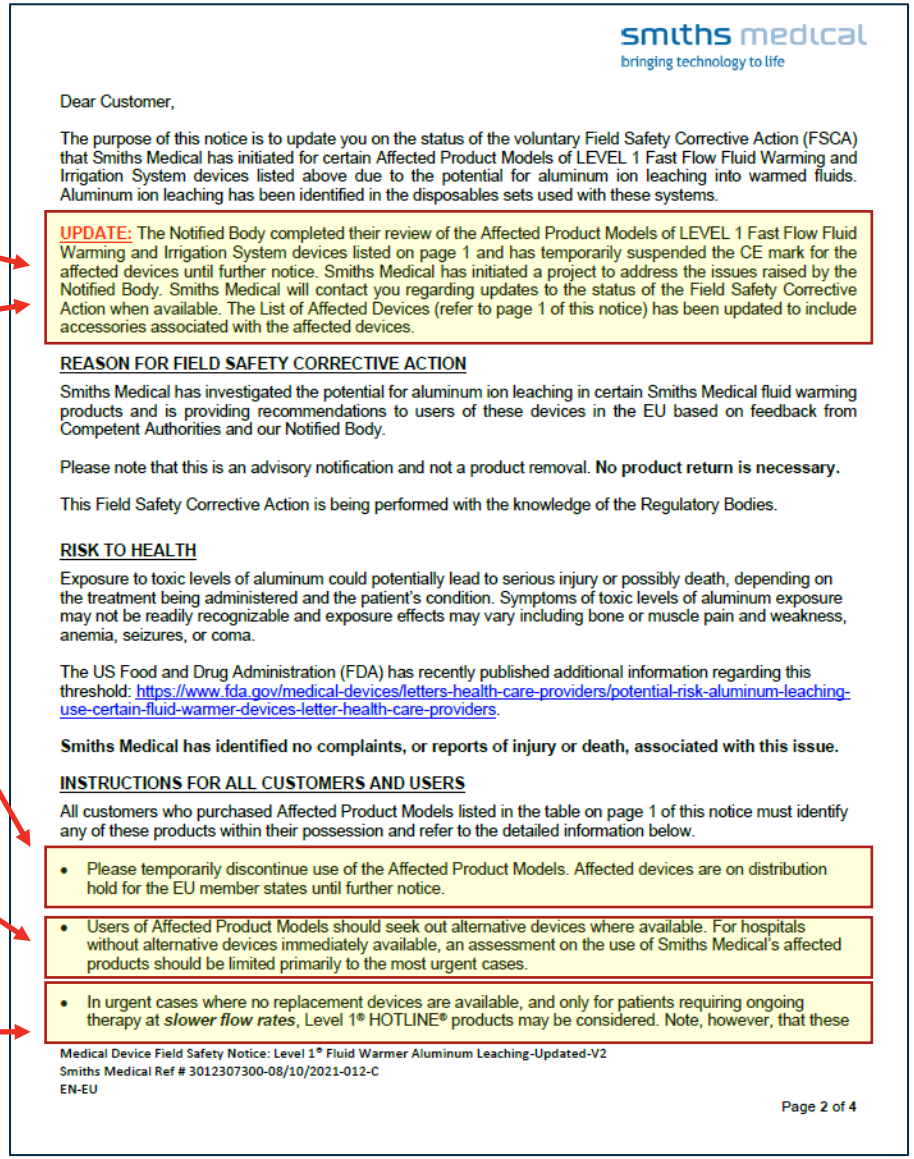
Reference Page 4 for representative pictures for some of these devices.

Medical Device Field Safety Notice: Level 1® Fluid Warmer Aluminum Leaching-Updated-V2
Smiths Medical Ref # 3012307300-08/10/2021-012-C
EN-EU

Page 1 of 4

SMITHS LEVEL 1 CE MARK SUSPENSION – PAGE 2

- *"The Notified Body completed their review of the Affected Product Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System devices listed on page 1 and has temporarily suspended the CE mark for the affected devices until further notice."*
- *"Smiths Medical has initiated a project to address the issues raised by the Notified Body."*
- *"Please temporarily discontinue use of the Affected Product Models. Affected devices are on distribution hold for the EU member states until further notice."*
- *"Users of Affected Product Models should seek out alternative devices where available. For hospitals without alternative devices immediately available, an assessment on the use of Smiths Medical's affected products should be limited primarily to the most urgent cases."*
- *"In urgent cases where no replacement devices are available, and only for patients requiring ongoing therapy at **slower flow rates**, Level 1® HOTLINE® products may be considered…"*



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Dear Customer,

The purpose of this notice is to update you on the status of the voluntary Field Safety Corrective Action (FSCA) that Smiths Medical has initiated for certain Affected Product Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System devices listed above due to the potential for aluminum ion leaching into warmed fluids. Aluminum ion leaching has been identified in the disposables sets used with these systems.

UPDATE: The Notified Body completed their review of the Affected Product Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System devices listed on page 1 and has temporarily suspended the CE mark for the affected devices until further notice. Smiths Medical has initiated a project to address the issues raised by the Notified Body. Smiths Medical will contact you regarding updates to the status of the Field Safety Corrective Action when available. The List of Affected Devices (refer to page 1 of this notice) has been updated to include accessories associated with the affected devices.

REASON FOR FIELD SAFETY CORRECTIVE ACTION

Smiths Medical has investigated the potential for aluminum ion leaching in certain Smiths Medical fluid warming products and is providing recommendations to users of these devices in the EU based on feedback from Competent Authorities and our Notified Body.

Please note that this is an advisory notification and not a product removal. **No product return is necessary.**

This Field Safety Corrective Action is being performed with the knowledge of the Regulatory Bodies.

RISK TO HEALTH

Exposure to toxic levels of aluminum could potentially lead to serious injury or possibly death, depending on the treatment being administered and the patient's condition. Symptoms of toxic levels of aluminum exposure may not be readily recognizable and exposure effects may vary including bone or muscle pain and weakness, anemia, seizures, or coma.

The US Food and Drug Administration (FDA) has recently published additional information regarding this threshold: https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-aluminum-leaching-use-certain-fluid-warmer-devices-letter-health-care-providers.

Smiths Medical has identified no complaints, or reports of injury or death, associated with this issue.

INSTRUCTIONS FOR ALL CUSTOMERS AND USERS

All customers who purchased Affected Product Models listed in the table on page 1 of this notice must identify any of these products within their possession and refer to the detailed information below.

- Please temporarily discontinue use of the Affected Product Models. Affected devices are on distribution hold for the EU member states until further notice.
- Users of Affected Product Models should seek out alternative devices where available. For hospitals without alternative devices immediately available, an assessment on the use of Smiths Medical's affected products should be limited primarily to the most urgent cases.
- In urgent cases where no replacement devices are available, and only for patients requiring ongoing therapy at ***slower flow rates***, Level 1® HOTLINE® products may be considered. Note, however, that these

Medical Device Field Safety Notice: Level 1® Fluid Warmer Aluminum Leaching-Updated-V2
Smiths Medical Ref # 3012307300-08/10/2021-012-C
EN-EU

Page 2 of 4

SMITHS LEVEL 1 CE MARK SUSPENSION – PAGE 3 & 4

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are not high flow devices and that the products subject to this FSCA are typically used in acute settings where high volumes of warmed fluids and blood are administered for clinical situations such as: trauma, post-partum hemorrhage and transplant.

- Healthcare facilities can report issues arising from device availability or any of the implementation actions requested in this FSN to Smiths Medical via fieldactions@smiths-medical.com.

ACKNOWLEGEMENT OF FIELD SAFETY NOTICE UNDERSTANDING – REQUIRED STEPS BELOW

1. Locate all Affected Devices in your possession and ensure all users or potential users of these devices are immediately made aware of this notification.
2. Complete and return the attached Response Form for the Updated Notice to OUS-Smiths@Sedgwick.com to acknowledge your receipt and understanding of this Updated Field Safety Notice within 10 days of receipt.
3. **DISTRIBUTORS:** Please immediately forward a copy of this notification and attachments to any of your customers to whom you've distributed affected product. Request that they complete the Response Form and return it to you. Please indicate your identity as the distributor and the consignees name and address.

Adverse events or quality problems experienced with the use of this product must be reported to Smiths Medical via globalcomplaints@smiths-medical.com.

For questions or difficulties encountered regarding this Field Safety Corrective Action contact fieldactions@smiths-medical.com.

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,

Johana Schrader MSc, et MSc
Authorized Representative

Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442 USA

Enclosures:
Attachment 1 – Field Safety Notice Response Form

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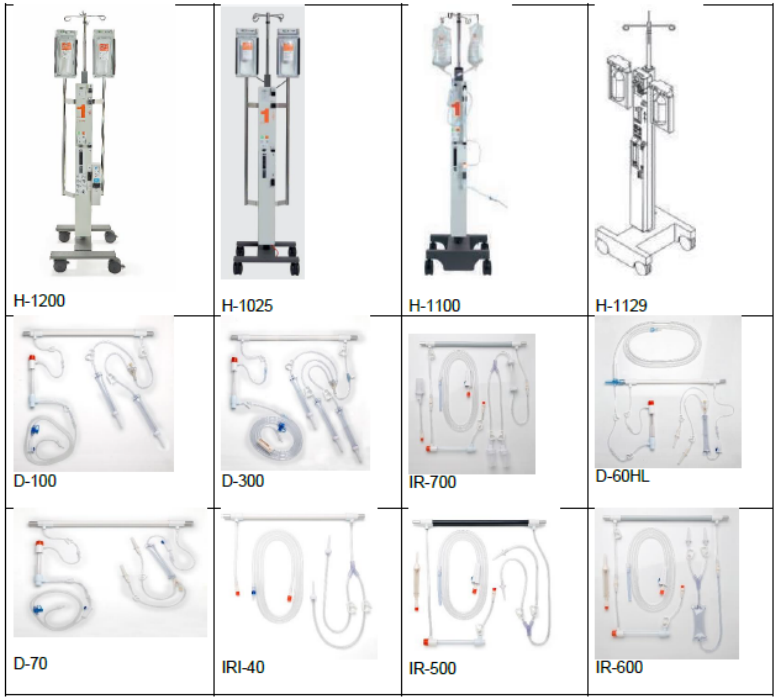


Medical Device Field Safety Notice: Level 1® Fluid Warmer Aluminum Leaching-Updated-V2
Smiths Medical Ref # 3012307300-08/10/2021-012-C
EN-EU

CURRENT SITUATION SUMMARY

- Can Smiths Medical ship products to its distributors or to customers?
  - No, based on the information in the Field Sales Notice (FSN), there is no further distribution of the affected products at this time.

- Can Smiths distributors ship products to customers?
  - No, based on the information in the Field Sales Notice (FSN), there is no further distribution of the affected products at this time.

- Can customers use their existing inventory of Level 1 disposables?
  - Based on this information in the FSN, end users are asked to discontinue the use the affected products until further notice. If alternative devices are not available, only for urgent case, the FSN suggests it could be used. At this point, it becomes a hospital-based decision.

REVIEW MARKETING TOOLS AVAILABLE

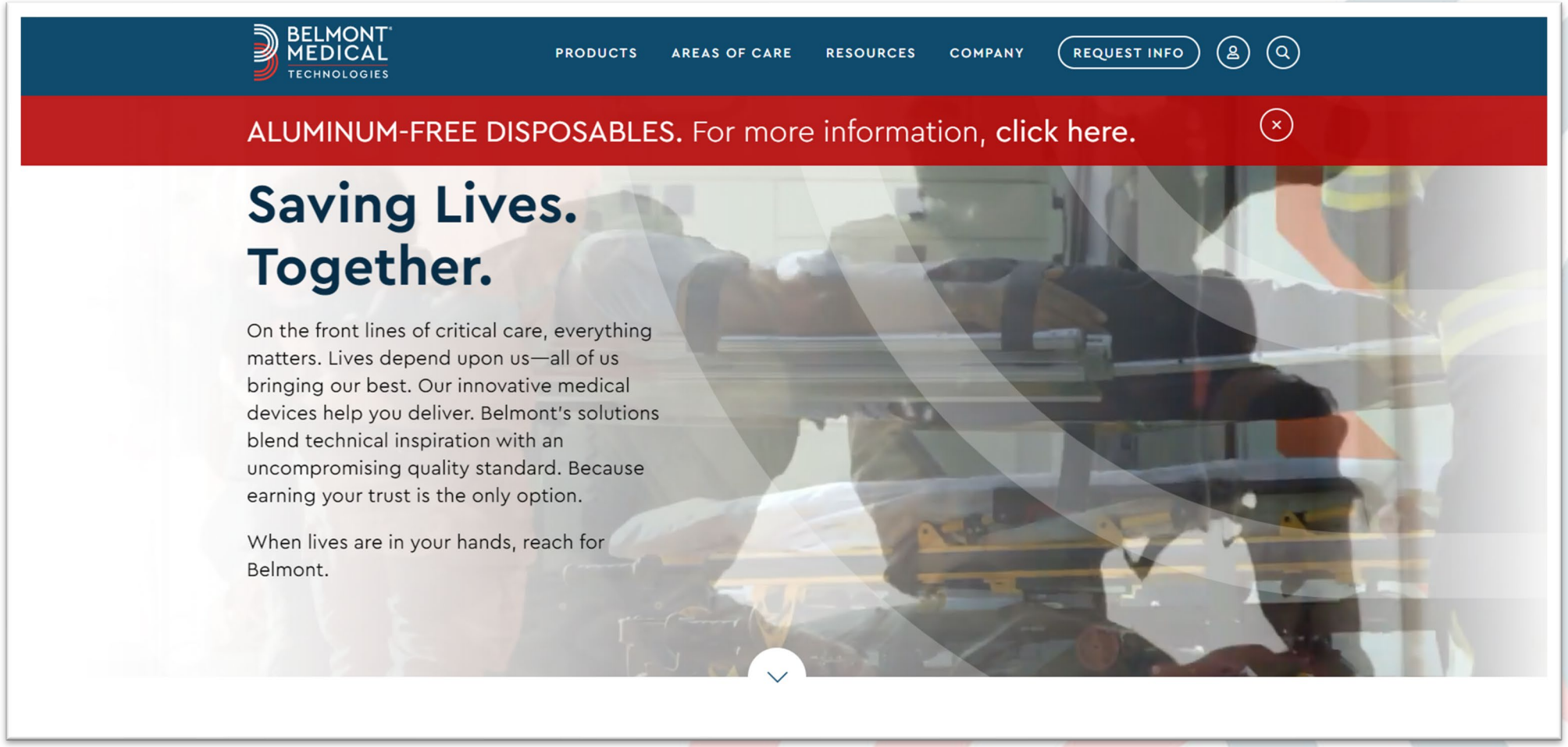
701-00474 Rev B

MARKETING TOOLS AVAILABLE

- Website banner
- Aluminum-free landing page
- RI-2 brochures translated in 7 languages
- Social media posts
- Alu-Free Postcard Mailers
- Competitive comparisons vs Smiths, Fluido, Ranger and Gamida
- Tradeshow tools
- Distribution Partner Portal
- Messaging Expectations, digital marketing & contest

WEBSITE BANNER

Aluminum-Free Disposables. For more information, click here



WEBSITE ALU FREE LANDING PAGE

www.BelmontMedTech.com/AluFree

- Primary Message
- Call out action: Schedule a demo
- Alu leaching evidence for Smiths Level 1 Fast Flow
- Worldwide Regulatory Notifications
- Q&A including parylene coated content
- Key features & benefits of the Belmont Rapid Infuser RI-2
- Articles reference

RI-2 BROCHURES AVAILABLE IN 7 LANGUAGES

English, Chinese, French, German, Italian, Japanese, Spanish

RI-2 BROCHURES AVAILABLE IN 7 LANGUAGES

"All Disposables are 100% ALUMINUM-FREE" Messaging across the brochure

THE BELMONT® RAPID INFUSER RI-2

Rapid, reliable, bubble-free, and 100% aluminum-free delivery of life-saving warmed blood and fluid at the touch of a button.

SAVING LIVES. TOGETHER.

MILITARY

OPERATING ROOM

LABOR & DELIVERY AND PEDIATRICS

EMERGENCY & CRITICAL CARE

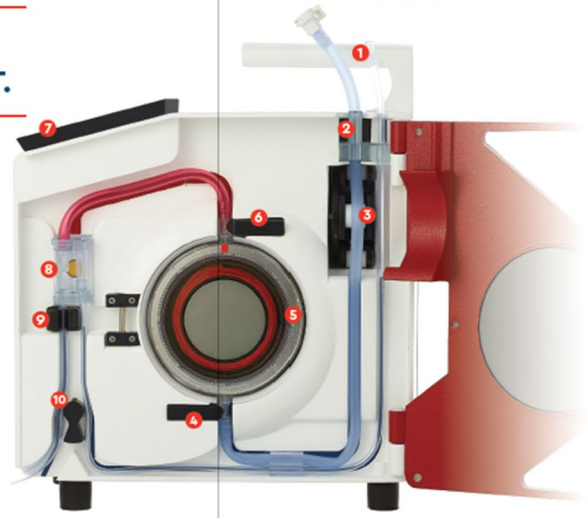
"THE BELMONT" BRINGS CONFIDENCE

Used in the most extreme situations for more than 20 years, The Belmont® Rapid Infuser has earned the trust of clinicians worldwide as the **only rapid infuser offering 100% aluminum-free fluid delivery** with high-flow performance* and comprehensive safety features designed to reduce transfusion complications. Experience peace of mind, knowing you're prepared for the worst but equipped with the best.

BUBBLE-FREE. RELIABLE. FAST.

THE BELMONT® RAPID INFUSER RI-2

1 Vent/Recirculation Line
2 Input Air Detector
3 High Speed Peristaltic Pump
4 Input Temperature Probe
5 Heat Exchanger
6 Output Temperature Probe
7 Touchscreen Display
8 Pressure Sensor/Debubbler
9 Output Air Detector
10 Infuse/Recirculation Valve



100% ALUMINUM-FREE DISPOSABLES
Medical grade stainless steel heat exchanger eliminates risk of aluminum exposure.

AUTOMATIC AIR DETECTION & REMOVAL
Two ultrasonic air detectors and patient safety valve safeguard against air emboli.

AUTOMATIC PRIMING
Fully prime in under 1 minute and easily re-prime without patient disconnection.

HIGH SPEED PERISTALTIC PUMP
Precise control of fluid delivery with flow rates ranging from 2.5 to 1000 ml/min*.

ELECTROMAGNETIC INDUCTIVE HEATING
Dry, inductive heating technology and two infrared temperature sensors provide consistent normothermic fluid within seconds.

ADVANCED PRESSURE REGULATION
Automatic pressure monitoring and flow rate adjustment when pressure exceeds 300 mmHg.

INTUITIVE TOUCH-SCREEN DISPLAY
High contrast display provides easy to follow on-screen instructions, clear descriptions of alarms and alerts, and quick access to device operations.

REAL-TIME DISPLAY OF:

- Set Rate
- Actual Rate
- Total Volume Infused
- Line Pr

ORDERING INFORMATION

RAPID INFUSER RI-2, 1000 ml/min
Infusion rate: 2.5-1000 ml/min
- US: Part #903-00037 (120V)
- International: Part #903-00037A (230V)

RAPID INFUSER RI-2, 750 ml/min
Infusion rate: 2.5-750 ml/min
- US: Part #903-00039 (120V)
- International: Part #903-00039A (230V)
- NSN: 6515-01-661-8500 (120V)

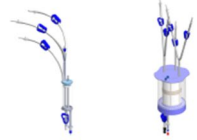
3-SPIKE DISPOSABLE SET
Part #903-00006 (12 sets/case)
Part #903-00106 (6 sets/case)

3.0 LITER RESERVOIR (LVR)
Part #903-00018

4X4 LVR & HEAT EXCHANGER SET
Part #903-00032

PATIENT LINE EXTENSION
Part #903-00022

DUAL PATIENT LINE
Part #903-00004



STANDARD
120 ml Reservoir (3-Spike)

OPTIONAL
3.0 Liter Reservoir (5-Spike)

ALL DISPOSABLES ARE 100% ALUMINUM-FREE

HARDWARE SPECIFICATIONS

DIMENSIONS
13.5 in. x 7.5 in. x 12 in.
342.9 mm. x 190.5 mm. x 304.8 mm.

WEIGHT
28 lb.
12.7 kg.

PORTABILITY
Quick-on IV pole mount/handle at top of unit

POWER
115 volt or 220/240 volt AC input

BATTERY
Internal, rechargeable for transport
Operates all functions without heating

FLUID PUMP
Roller type peristaltic pump
Flow rate 2.5-1000 ml/min

HEATER
Maximum applied power, 1440 watts

APPLIED PART TYPE
Type CF

DEFIBRILLATION-PROOF

SENSORS
2 air detectors, pressure transducer, 2 temperature probes (infrared sensing), pump infusion rate sensor, open door detector, and valve activation sensors

CONTROL COMPUTER
Built-in, controls all functions
Redundant hardware override protection in case of computer failure

DISPLAY
LCD type with waterproof touch pad
- External Dimensions
  5.85 in. x 4.12 in.
  148.1 mm. x 104.7 mm.
- Active Area
  4.53 in. x 3.40 in.
  115.1 mm. x 86.3 mm.

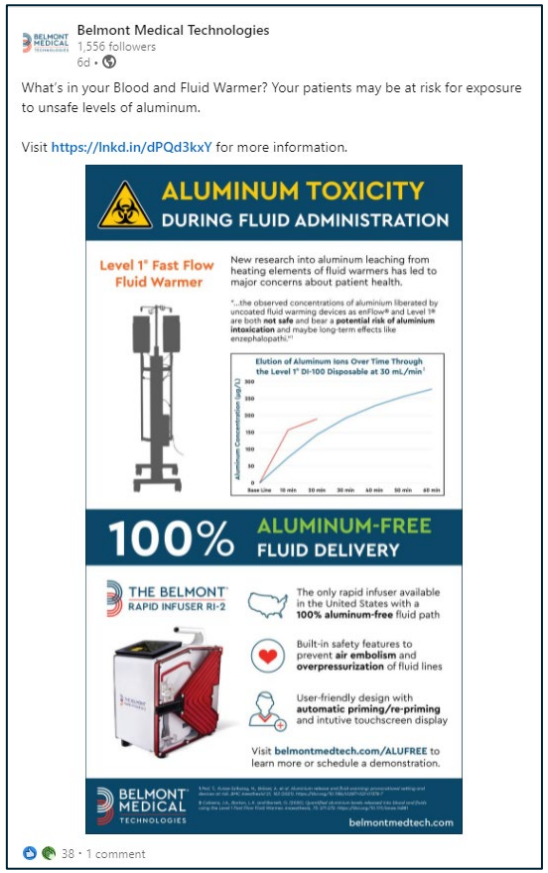
For more information about the products we offer, contact us at sales@belmontmedtech.com.

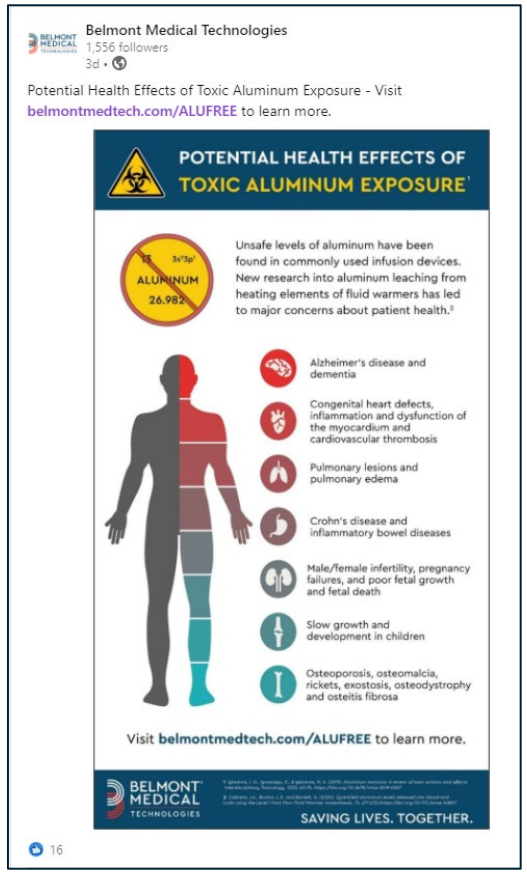
PATIENT WARMING | PATIENT COOLING | FLUID MANAGEMENT

BELMONT® MEDICAL TECHNOLOGIES

780 BOSTON ROAD
BILLERICA, MA 01821, USA
USA: 866.663.0212
WORLDWIDE: +1 978.663.0212
FAX: 978.663.0214
WWW.BELMONTMEDTECH.COM

SOCIAL MEDIA POSTS CAMPAIGN





ALUMINUM FREE CAMPAIGN: WHAT'S IN YOUR FLUID WARMER?

ONE PAGER: BELMONT VS. LEVEL 1

DO YOU KNOW WHAT'S IN YOUR FLUID WARMER?

THE FDA HAS POSTED 3 CLASS I RECALLS IN 2021 DUE TO THE POTENTIAL RISK OF ALUMINUM LEACHING INTO INFUSATES

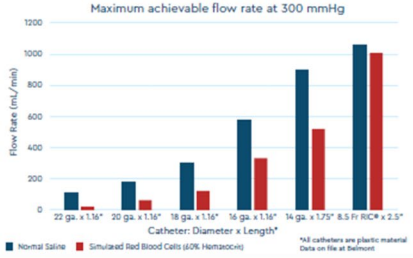
- Level 1® Fast Flow Fluid Warmer and NORMOFLO® Irrigation Warming System (August 2021)
- Recirculator 8.0 (June 2021)
- ThermaCor® 1200 (March 2021)

THE FDA PUBLISHED A SPECIAL LETTER TO HEALTH CARE PROVIDERS WARNING ABOUT THE "POTENTIAL RISK OF ALUMINUM LEACHING WITH USE OF CERTAIN FLUID WARMER DEVICES" ON SEPTEMBER 15, 2021

- Health issues may go undetected, or be attributed to other comorbidities
- Aluminum leaching may cause bone pain, muscle pain, muscle weakness, blood and metabolic derangements (such as increased levels of calcium or interference with iron absorption leading to anemia), and neurological effects (such as altered consciousness, seizures, and coma)
- Avoid using the identified fluid warmers when treating at-risk populations: patients with poor renal function, neonates, infants, pregnant mothers, and elderly patients
- Use alternative therapies to maintain patient temperature, such as an alternative fluid warmer

CATHETER SIZE LIMITATIONS

Maximum achievable flow rate at 300 mmHg



WHY WORRY WHEN YOU DONT HAVE TO?

The Belmont® Rapid Infuser maintains a high standard of safety so you can fully focus on providing the best care to your patients without the added concern of aluminum toxicity.

- 100% aluminum-free disposables to eliminate the risk of aluminum exposure
- Displays actual flow rate to equip users with accurate, real-time information to optimally manage therapy
- Automatic air detection and removal to reduce the risk of air embolism
- In-line pressure regulation to protect patient vasculature and maintain intravenous access

For more information or to schedule a demonstration email ALUFREE@belmontmedtech.com or visit belmontmedtech.com/ALUFREE

BELMONT MEDICAL TECHNOLOGIES
Saving Lives. Together.

780 BOSTON ROAD
BILLERICA, MA 01821
866.663.0212
BELMONTMEDTECH.COM

TECHNICAL SERVICE
USA 855.397.4547
WORLDWIDE +1 978.663.0212

NOT ALL RAPID INFUSERS ARE CREATED EQUAL

The Belmont® Rapid Infuser RI-2 is the **ONLY** rapid infuser to offer **100% aluminum-free** fluid delivery along with high-flow performance* and comprehensive safety features designed to reduce transfusion related complications.

THE BELMONT® RAPID INFUSER RI-2

Smiths Medical Level 1® Fast Flow

		THE BELMONT® RAPID INFUSER RI-2	Smiths Medical Level 1® Fast Flow
FUNCTIONALITY	**Dry, electromagnetic induction heating**	✓	✗
	Warms fluid to normothermic temperatures	✓	✓
	Flow rates up to 1000 mL/min*	✓	✓
	Precise control of all flow rates ranging from 2.5 up to 1000 mL/min using a high-speed peristaltic pump	✓	✗
	Near instantaneous fluid warming to 37°C within seconds from powering on	✓	✗
	Automatic priming in under 1 minute and easy repriming without patient disconnection	✓	✗
	Option to provide a bolus of fluid at specific volumes and flow rates	✓	✗
PATIENT SAFETY	**Automatic air detection and removal**	✓	✗
	Automatically regulates flow rate to maintain a safe line pressure under 300 mmHg	✓	✗
	Battery backup in the event of accidental power loss or patient transport between departments	✓	✗
DISP-OSABLES	**100% Aluminum-free disposable and optional consumables**	✓	✗
	Single, color-coded disposable compatible with all flow rates	✓	✗
DISPLAYS AND CONTROLS	**Displays actual flow rate**	✓	✗
	Simple, easy-to-use touchscreen display and controls	✓	✗
	Displays infusate output temperature	✓	✗
	Provides on-screen instructions for alarm conditions	✓	✗
	Operated by single user	✓	✗

For more information or to schedule a demonstration email ALUFREE@belmontmedtech.com or visit belmontmedtech.com/ALUFREE

701-00447 Rev. B

RI-2 1-PAGER COMPETITIVE ADVANTAGES VS FLUIDO & RANGER

NOT ALL RAPID INFUSERS ARE CREATED EQUAL

For more information or to schedule a demonstration email **ALUFREE@belmontmedtech.com** or visit **belmontmedtech.com/ALUFREE**

THE BELMONT® RAPID INFUSER RI-2

Fluido® AirGuard System[1]

		THE BELMONT® RAPID INFUSER RI-2	Fluido® AirGuard System[1]
FUNCTIONALITY	Dry, electromagnetic induction heating[1]	✓	✗
	Warms fluid to normothermic temperatures[1]	✓	✓
	Flow rates up to 1000 mL/min[1]	✓	✓
	Precise control of all flow rates ranging from 2.5 up to 1000 mL/min using a high-speed peristaltic pump[1]	✓	✗
	Near instantaneous fluid warming to 37°C within seconds from powering on[2]	✓	✗
	Automatic priming in under 1 minute and easy repriming without patient disconnection[1]	✓	✗
	Option to provide a bolus of fluid at specific volumes and flow rates[1]	✓	✗
PATIENT SAFETY	Automatic air detection and removal[1]	✓	✗
	Automatically regulates flow rate to maintain a safe line pressure under 300 mmHg[1]	✓	✗
	Infuse during battery operation in the event of accidental power loss or interdepartmental transport[1]	✓	✗
DISP-OSABLES	100% Aluminum-free disposable and optional consumables[1]	✓	Unknown
	Single, color-coded disposable compatible with all flow rates[1]	✓	✗
DISPLAYS AND CONTROLS	Displays actual flow rate[1]	✓	✓
	Simple, easy-to-use touchscreen display and controls[1]	✓	✗
	Displays infusate output temperature [1]	✓	✓
	Provides on-screen instructions for alarm conditions[1]	✓	✗
	Operated by single user[1]	✓	✗

1. The 37°Company Fluido® AirGuard System User Manual INT/R757-EN/0-09/15
2. The 37°Company Fluido® Blood and Fluid Warming Brochure INT/R032-EN/7-01/21

701-00473 Rev. A

NOT ALL RAPID INFUSERS ARE CREATED EQUAL

The Belmont® Rapid Infuser RI-2 is the **ONLY** rapid infuser to offer **100% aluminum-free** fluid delivery along with high-flow performance* and comprehensive safety features designed to reduce transfusion related complications.

THE BELMONT® RAPID INFUSER RI-2

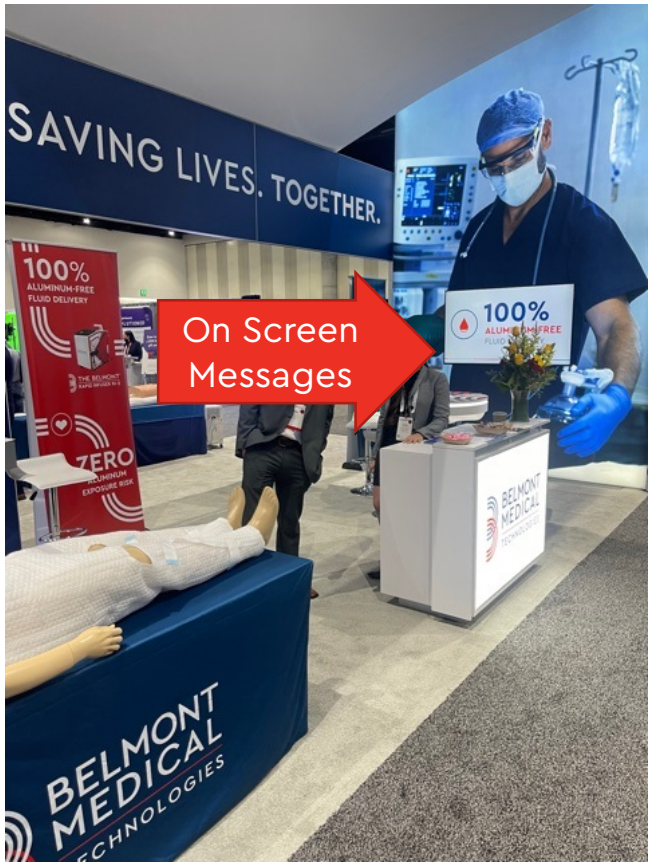
3M™ Ranger™ (Model 245)

		THE BELMONT® RAPID INFUSER RI-2	3M™ Ranger™ (Model 245)
FUNCTIONALITY	Dry, electromagnetic induction heating	✓	✗
	Warms fluid to normothermic temperatures	✓	✓
	Flow rates up to 1000 mL/min*	✓	✗
	Precise control of all flow rates ranging from 2.5 up to 1000 mL/min using a high-speed peristaltic pump	✓	✗
	Near instantaneous fluid warming to 37°C within seconds from powering on	✓	✗
	Automatic priming in under 1 minute and easy repriming without patient disconnection	✓	✗
	Option to provide a bolus of fluid at specific volumes and flow rates	✓	✗
PATIENT SAFETY	Automatic air detection and removal	✓	✗
	Automatically regulates flow rate to maintain a safe line pressure under 300 mmHg	✓	✗
	Battery backup in the event of accidental power loss or patient transport between departments	✓	✗
DISP-OSABLES	100% Aluminum-free disposable and optional consumables	✓	✓
	Single, color-coded disposable compatible with all flow rates	✓	✗
DISPLAYS AND CONTROLS	Displays actual flow rate	✓	✗
	Simple, easy-to-use touchscreen display and controls	✓	✗
	Displays infusate output temperature	✓	✗
	Provides on-screen instructions for alarm conditions	✓	✗
	Operated by single user	✓	✓

Source: 3M™ Ranger™ Operator's Manual 202457B

TRADESHOW – KEY BELMONT MESSAGES

Saving Lives. Together || 100% Aluminum-Free



BELMONT WILL BE AT ESA 2022 WITH EXPANDED PRESENCE!

- Milan June 4-6, 2022
- Expanded booth presence with 12 m²

MILAN
04 ▸ 06
JUNE

MARKETING ASSETS ACCESS VIA PORTAL

- To access the Belmont Partner Portal, click on the icon at the top right of the main navigation bar on the Belmont website www.belmontmedtech.com

- Your login credentials (email address) and password were shared with your selected access contact last year. If they need their password reset or you have questions on which contact has access, please email marketing@belmontmedtech.com

- You will need set up **2-Factor Authentication** and verify a phone number via text message after the first login. This is required to secure the portal/logins.

- We recommend you watch the overview video covering how to access and navigate the portal – **Introduction to the Belmont Partner Portal:** https://youtu.be/4RFQLVJuGu8

BELMONT'S EXPECTATIONS FOR ALU MESSAGE ON DISTRIBUTOR PARTNER WEBSITES:

The Belmont® Rapid Infuser RI-2 Product Page - Mandatory Requirements:

- The Belmont Rapid Infuser RI-2 should be listed on the partner website
- Proper trademark usage and naming of the product
- At least one new product photo
- Mention of all Belmont disposables being 100% aluminum-free (make sure to add hyphen between "aluminum" and "free")
- Brief description of the product
- List of the following product features/benefits:
  - **Automatic air detection and removal –** Helps to protect patients from air emboli
  - **High-speed peristaltic pump with flow rates ranging from 2.5 to 1000 mL/min –** Enables precise control of fluid delivery
  - **Dry, electromagnetic induction heating –** Near instantaneous fluid warming without the potential infection risk posed by water-bath style warmers

BELMONT'S EXPECTATIONS FOR ALU MESSAGE ON DISTRIBUTOR PARTNER WEBSITES:

The Belmont® Rapid Infuser RI-2 Product Page

Strongly Recommended

- Link to Belmont's website and aluminum-free landing page (www.belmontmedtech.com/alufree)

Optional Additions (Recommended):

- List of the following product features/benefits:
  - **Automatic Priming and Repriming –** Fully primes in under 1 minute and easily reprimes without patient disconnection
  - **Advanced Pressure Regulation –** Automatic pressure regulation and flow rate adjustment when pressure exceed 300 mmHg
  - **Intuitive Touchscreen Display –** Provides easy-to-follow on-screen instructions, clear descriptions of alarms and alerts, and quick access to device operations
  - **Real-time Display of Set Rate, Actual Rate, Total Volume Infused, Line Pressure, and Output Fluid Temperature**

Further reference to Belmont's brand standards can be found on the portal (Belmont Brand Standards Guide)

BELMONT'S EXPECTATIONS FOR ALU MESSAGE ON DISTRIBUTOR PARTNER WEBSITES CONT'D:

BRAND STANDARDS

1. Registered (®) symbol should always be displayed as Superscript (when possible).
2. There should be no space between the word (noun) and the Registered (®) symbol.
3. The full name of the device should be used with the correct punctuation/capitalization

Improper Usage Examples:

The Belmont® Rapid Infuser RI-2 | The Belmont ® Rapid Infuser RI-2 | Rapid Infuser RI-2

the Belmont® Rapid Infuser RI-2 | The Belmont® Rapid Infuser RI2 | rapid infuser ri-2

Correct Usage Examples:

The Belmont® Rapid Infuser RI-2

1. The default Belmont logo should always contain a registration symbol.

Correct Usage Example:

BELMONT® MEDICAL TECHNOLOGIES

Improper Usage Example:

BELMONT MEDICAL TECHNOLOGIES

NEW PRODUCT PHOTOGRAPHY

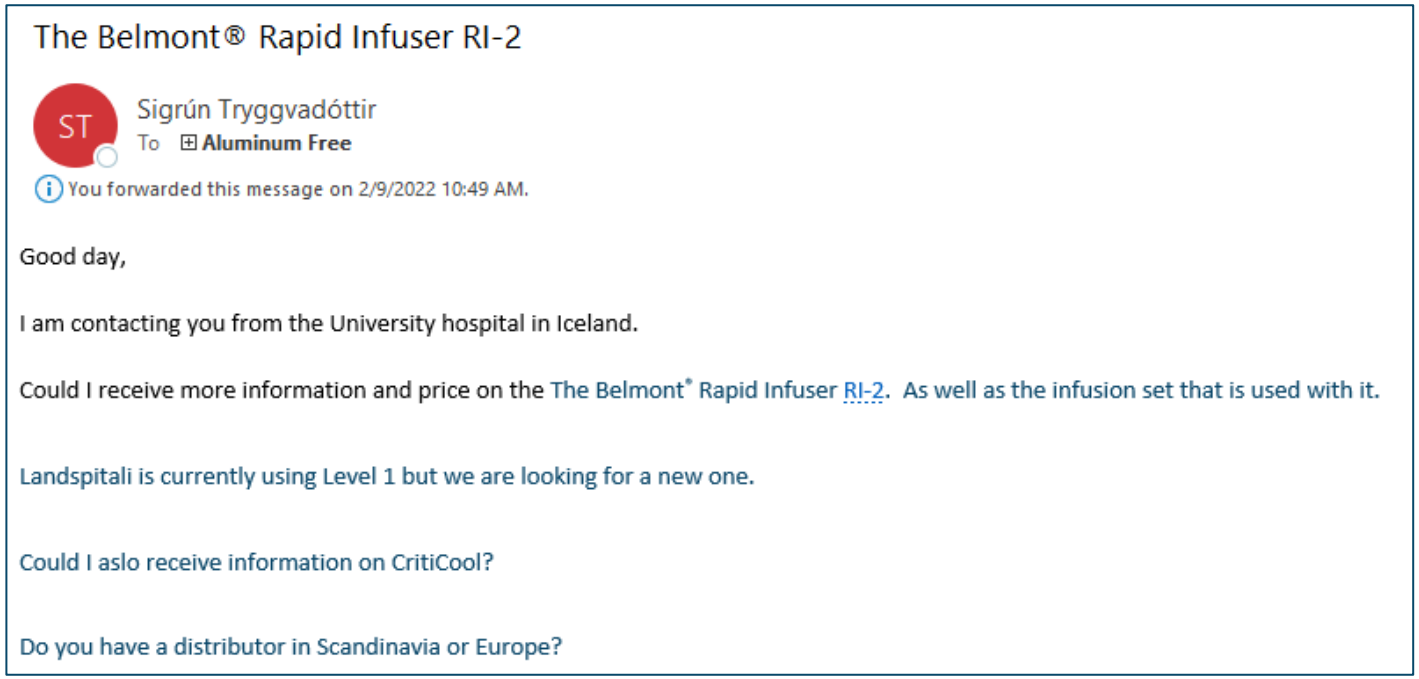
Preferred Choice

2nd

3rd

IMPORTANCE OF IMPROVING YOUR ONLINE PRESENCE

- Search engines rely on various factors to determine when and where your website will show up in a search query
- Developing content that covers a wider range of search queries leads to increased website visibility + web traffic = more sales opportunities
- Take for example a sales inquiry for an EU partner we received from our Aluminum-Free Landing Page to replace their Level 1 unit
- If you're interested in seeking additional training on the Partner Portal, SEO, or website related activities please contact marketing@belmontmedtech.com



The Belmont® Rapid Infuser RI-2

ST

Sigrún Tryggvadóttir

To ⊞ **Aluminum Free**

You forwarded this message on 2/9/2022 10:49 AM.

Good day,

I am contacting you from the University hospital in Iceland.

Could I receive more information and price on the The Belmont® Rapid Infuser RI-2. As well as the infusion set that is used with it.

Landspitali is currently using Level 1 but we are looking for a new one.

Could I aslo receive information on CritiCool?

Do you have a distributor in Scandinavia or Europe?

INTRODUCING WEBSITE MARKETING CONTEST

- What?
  - Add The Belmont® Rapid Infuser RI-2 Product content
  - See Mandatory Requirements from previous slide

- Award:
  - First 3 distributors to update their website with ALU-Free messaging will be awarded a free exhibitor badge to attend ESA
  - First 10 distributors will receive a special gift!

COMPETITIVE REVIEW

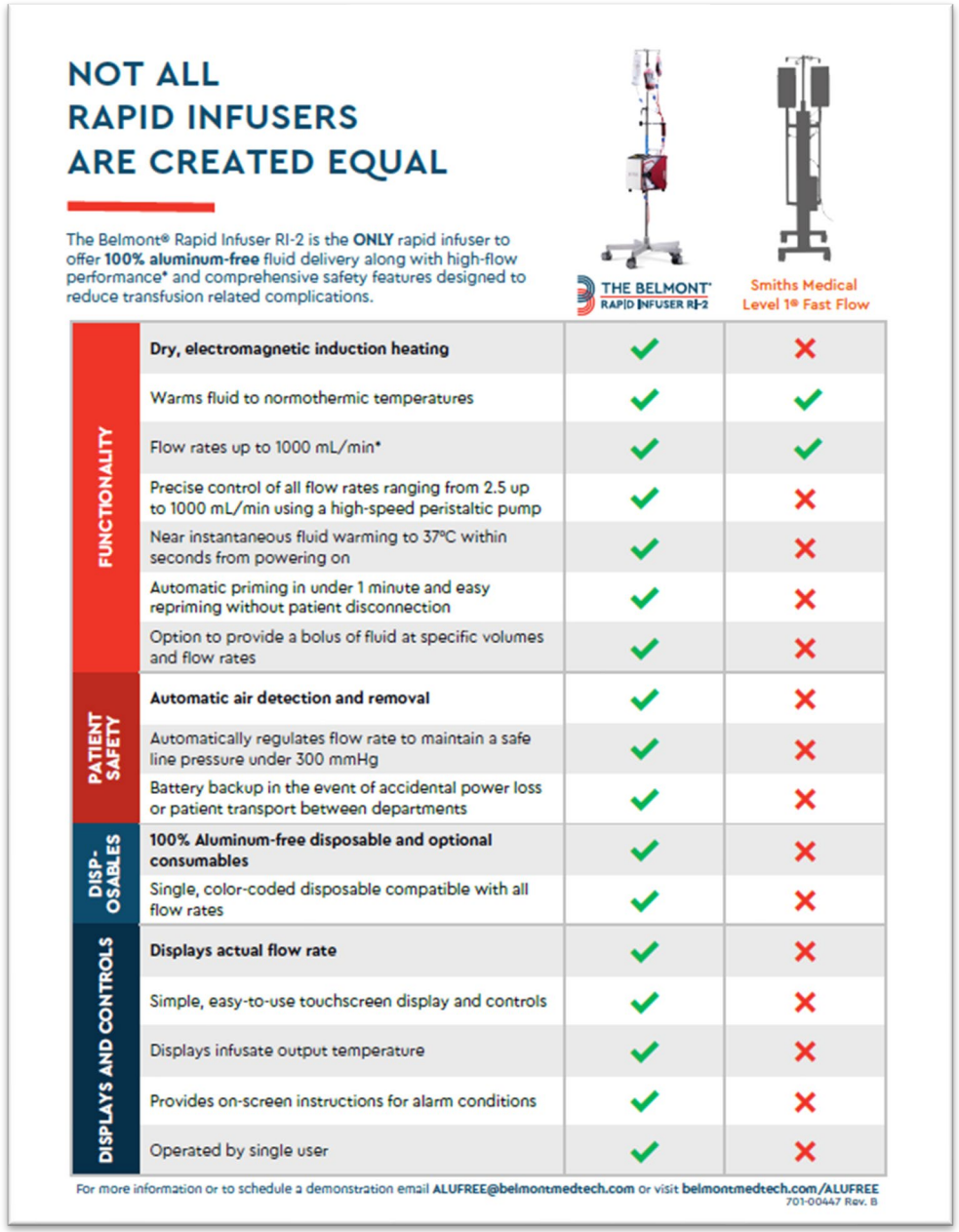
THE BELMONT IS CLEARLY A BETTER INFUSER THAN LEVEL 1!

Top RI-2 Features and Benefits

1. 100% aluminum-free disposable – eliminates risk of aluminum exposure from the infusion device
2. Dry, electromagnetic induction heating – reduces the risk of infection and requires no warm-up time, leading to faster initiation of infusion
3. Automatic air detection and removal – reduces the risk of air embolism, and never need to disconnect from the patient to re-prime

Level 1 Features and Weaknesses

1. Aluminum heat exchanger – leaches aluminum into the infusate
2. Water bath heating method – outdated technology; increases risk of infection due risk of water contamination and requires 8–12 minute warm-up time
3. Optional air detector – requires disconnecting from the patient to re-prime the system if air is detected



THE BELMONT OFFERS SUPERIOR PERFORMANCE VS FLUIDO® AIRGUARD

Superior Belmont features compared to the Fluido® AirGuard

1. Automatic air detection and removal – reduces the risk of air embolism, and there is no need to disconnect from the patient to re-prime
2. Dry, electromagnetic induction heating with peristaltic pump control – near instantaneous heating with precise control of all flow rates from 2.5ml/min-1000ml/min
3. Single, color-coded, 100% aluminum-free, disposable for all flow rates – No risk of aluminum exposure and only required to stock one disposable for all flow rates

Fluido AirGuard Features and Weaknesses

1. Automatic air detection – requires manual removal when air is detected and there is the potential need to disconnect from the patient to re-prime
2. Dry, infrared heating method with pressure bag infusion – no precise flow rate control, limits type and size of fluid containers, and requires fluid bags to be "burped"
3. Different disposables for different flow rates* – requires the need to stock multiple disposables for different use cases, only one disposable can provide the highest flow rate

**We cannot identify documentation to confirm whether the Fluido AirGuard System has aluminum in its fluid heat exchanger. Note that the 37 Company does not comment on this topic on their website, even if they confirmed coated alu is present in their Fluido Compact line.*

NOT ALL RAPID INFUSERS ARE CREATED EQUAL

For more information or to schedule a demonstration email **ALUFREE@belmontmedtech.com** or visit **belmontmedtech.com/ALUFREE**

THE BELMONT RAPID INFUSER RI-2

Fluido® AirGuard System[1]

		THE BELMONT RAPID INFUSER RI-2	Fluido® AirGuard System[1]
FUNCTIONALITY	Dry, electromagnetic induction heating[1]	✓	✗
	Warms fluid to normothermic temperatures[1]	✓	✓
	Flow rates up to 1000 mL/min[1]	✓	✓
	Precise control of all flow rates ranging from 2.5 up to 1000 mL/min using a high-speed peristaltic pump[1]	✓	✗
	Near instantaneous fluid warming to 37°C within seconds from powering on[2]	✓	✗
	Automatic priming in under 1 minute and easy repriming without patient disconnection[1]	✓	✗
	Option to provide a bolus of fluid at specific volumes and flow rates[1]	✓	✗
PATIENT SAFETY	Automatic air detection and removal[1]	✓	✗
	Automatically regulates flow rate to maintain a safe line pressure under 300 mmHg[1]	✓	✗
	Infuse during battery operation in the event of accidental power loss or interdepartmental transport[1]	✓	✗
DISP-OSABLES	100% Aluminum-free disposable and optional consumables[1]	✓	Unknown
	Single, color-coded disposable compatible with all flow rates[1]	✓	✗
DISPLAYS AND CONTROLS	Displays actual flow rate[1]	✓	✓
	Simple, easy-to-use touchscreen display and controls[1]	✓	✗
	Displays infusate output temperature [1]	✓	✓
	Provides on-screen instructions for alarm conditions[1]	✓	✗
	Operated by single user[1]	✓	✗

1. The 37°Company Fluido® AirGuard System User Manual INT/R757-EN/0-09/15
2. The 37°Company Fluido® Blood and Fluid Warming Brochure INT/P032-EN/7-01/21

701-00473 Rev. A

HOW TSC/FLUIDO IS ADDRESSING THE LEVEL 1 RECALL

The Surgical Company PTM

Beeldschermweg 6F | 3821 AH Amersfoort The Ne

ABOUT US | PATIENT TEMPERATURE MANAGEMENT | PRODUCT OVERVIEW | BUSINESS PARTNERS

home / virtual37 / news / recall_level1

Recall of Smiths Medical NORMOFLO

29-09-2021

Fluido® is the safe, non-toxic alternative!

Smiths Medical sent out a Field Safety Notice (worldwide), which has resulted in a recall of the Smiths Medical (NORMOFLO) High Flow and Irrigation Fluid Warmers and Warming Sets in the US, Canada and Saudi Arabia.

The FDA has identified this as a Class I recall, the most serious type of recall. The use of these devices may cause serious injuries or death. Other countries will likely follow.

As you are aware various studies were done on the leaching of aluminium into blood and fluids. The results showed various blood and fluid warmers leaching aluminium into the fluid path of the warmers.

The Fluido® Compact, Fluido® AirGuard and Fluido® Irrigation systems do not leach detectable/toxic levels of aluminium or any other inorganic leachables! Fluido® cassettes are coated with parylene to avoid direct contact between the aluminium plates in the cassettes and blood products or IV fluids.

Designed to provide increased safety and ease of use, the Fluido® system helps your patient to remain normothermic without the need to worry about having patients exposed to toxic aluminium levels or other inorganic material. This is substantiated with independent laboratory tests following the ISO 10993 standard series.

Click here for more information and clinical evidence.

Strong features and unique selling points

Fluido® AirGuard System and Fluido® Irrigation have strong features and unique selling points compared to other blood and fluid warmers.

Fluido® AirGuard System

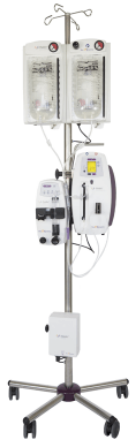
- No detectable aluminium leaching: safe to use
- Infrared technology: fast warming, temperature at the end of the line
- Dry technology: no contamination risk
- Temperature adjustment 30-39°C: flexibility
- 3 different sets: suitable set for all flows 20-750 ml/min

Download brochure Fluido® AirGuard System

Fluido® Irrigation

- No detectable aluminium leaching: safe to use
- Infrared technology: fast and unlimited warming, temperature at the scope
- Dry technology: no contamination risk
- Temperature adjustment 30-39°C: flexibility depe surgical procedure
- URO set, patient lines and spike sets: complete ra patients
- Special adapters: connection to a pump

Download brochure Fluido® Irrigation



› 10-01-2022 | Will we see you at Arab Health?

- https://ptm.tsc-group.com/news/recall_level1

THE RANGER™ IS NOT A RAPID INFUSER

Superior Belmont features compared to the 3M™ Ranger™

1. Dry, electromagnetic induction heating with peristaltic pump control – near instantaneous heating with precise control of all flow rates from 2.5ml/min-1000ml/min
2. Automatic air detection and removal – reduces the risk of air embolism, and there is no need to disconnect from the patient to re-prime
3. Single, color-coded, 100% aluminum-free, disposable for all flow rates – No risk of aluminum exposure and only required to stock one disposable for all flow rates

3M™ Ranger™ Features and Weaknesses

1. Pressure bag infusion and hot plate heating – maximum flow rate of 500ml/min, and there is no method to precisely control the flow rate
2. Bubble trap only – No automatic air detection, requires multiple people to administer and monitor infusion to ensure air does not enter the patient line, need to disconnect from the patient to re-prime
3. Different disposables for different flow rates* – requires the need to stock multiple disposables for different use cases, only one disposable can provide the 500ml/min flow rate

NOT ALL RAPID INFUSERS ARE CREATED EQUAL

The Belmont® Rapid Infuser RI-2 is the **ONLY** rapid infuser to offer **100% aluminum-free** fluid delivery along with high-flow performance* and comprehensive safety features designed to reduce transfusion related complications.

THE BELMONT RAPID INFUSER RI-2

3M™ Ranger™ (Model 245)

		THE BELMONT RAPID INFUSER RI-2	3M™ Ranger™ (Model 245)
FUNCTIONALITY	**Dry, electromagnetic induction heating**	✓	✗
	Warms fluid to normothermic temperatures	✓	✓
	Flow rates up to 1000 mL/min*	✓	✗
	Precise control of all flow rates ranging from 2.5 up to 1000 mL/min using a high-speed peristaltic pump	✓	✗
	Near instantaneous fluid warming to 37°C within seconds from powering on	✓	✗
	Automatic priming in under 1 minute and easy repriming without patient disconnection	✓	✗
	Option to provide a bolus of fluid at specific volumes and flow rates	✓	✗
PATIENT SAFETY	**Automatic air detection and removal**	✓	✗
	Automatically regulates flow rate to maintain a safe line pressure under 300 mmHg	✓	✗
	Battery backup in the event of accidental power loss or patient transport between departments	✓	✗
DISP-OSABLES	**100% Aluminum-free disposable and optional consumables**	✓	✓
	Single, color-coded disposable compatible with all flow rates	✓	✗
DISPLAYS AND CONTROLS	**Displays actual flow rate**	✓	✗
	Simple, easy-to-use touchscreen display and controls	✓	✗
	Displays infusate output temperature	✓	✗
	Provides on-screen instructions for alarm conditions	✓	✗
	Operated by single user	✓	✓

Source: 3M™ Ranger™ Operator's Manual 202457B

THE BELMONT IS AN UPGRADE IN FUNCTIONALITY COMPARED TO GAMIDA FLOW-THERM

Superior Belmont features compared to the Gamida Flow-Therm

1. Automatic air detection and removal – reduces the risk of air embolism, and there is no need to disconnect from the patient to re-prime
2. Dry, electromagnetic induction heating– near instantaneous heating with precise control of all flow rates from 2.5ml/min-1000ml/min
3. Pressure control – automatically regulates the flow rate to accommodate various catheter sizes, without causing high pressure alerts

Flow-Therm Features and Weaknesses

1. Two separate devices – need to have both devices for all features, can infuse cold fluids with just the flow pump
2. Automatic air detection – requires manual removal when air is detected and there is the potential need to disconnect from the patient to re-prime
3. Over pressure alarm – Only alerts at high pressures, does not automatically regulate the flow rate for small catheters

SUCCESS STORIES

SUCCESS STORIES ACROSS THE GLOBE

- US – multiple health systems converting from Level 1 to Belmont
- UK – ~30 Level 1's replaced since the Aug 2021 recall notification
- Ireland – first mover advantage following October notification resulting in 100% conversion or 17 units sale (population of 5.5M)
- Iceland – website lead as a result of CE Mark suspension
- Germany – Daniel Kemmerling – Head of Global Marketing, Barkey GmbH
  - Level 1 market situation in Germany
  - Customer reaction to Level 1 aluminum risk, distribution hold and CE mark suspension
  - Points resonating with customers:
    1. Safety - automated air detection & repriming
    2. Flexibility - Pressure Control
    3. Ease of Use - data on screen, eg. volume infused
- Australia – Derek Foltin – Division Manager - Surgical, Getz Healthcare Australia
  - On 2.11.22, TGA issued a quarantine notice; Level 1 currently not available in Australia
  - As a result, customers are looking to replace Level 1 with Belmont
  - Low flow devices are looking to capture some of the market void
  - Getz proactively informing customers as window of opportunity may be finite

SALES GUIDANCE

701-00474 Rev B

COMMERCIAL DIRECTION

- Ensure that all your Level 1 customers know / Don't assume customers are aware of the situation:
  - Risks of Aluminum Toxicity.
  - Level 1 is on EU distribution hold and has had its CE mark temporarily suspended.
  - According to the FSN, hospitals are instructed to discontinue use of the Level 1.
  - Belmont's disposables are 100% Aluminum-Free, not the case for enFlow, ThermaCor, Recirculator (Eight Medical) or Level 1.

- Actions:
  - Inform the Hospital Safety Officer and/or the Hospital Risk Manager. Ask how to implement an EU regulatory requirement. Work with the system, not against it.
  - Explain the "***Economic Benefits of the Belmont RI-2***" to the HOD (Head of Dept.) and hospital administration. Show the benefits RI-2 so as to justify the price you ask.
  - Perform an in-service to staff to show that the Belmont is a class above Level 1.
  - If no capital budget, consider rental/lease to own programs.
  - If out of budget cycle, consider a placement program against disposables utilization.

FORECAST REQUIREMENTS

- Forecasting is essential due to increased demand, supply chain & transit time changes.
- Link to online forecasting table will be sent out again.
- Please keep your forecast accurate by reviewing by the 1st of every month.

FM Monthly Forecast **Last Update: XX-Feb-2022**

Equipment

Part #	Description	22Q1 Jan-22	Feb-22	Mar-22	TOTAL	22Q2 Apr-22	May-22	Jun-22	TOTAL	22Q3 Jul-22	Aug-22	Sep-22	TOTAL	22Q4 Oct-22	Nov-22	Dec-22	TOTAL	2022 TOTAL
	RI-2, 750 mL/min (120V)																	
903-00039	US English																	
	RI-2, 750 mL/min (230V)																	
903-00039A	US English																	
903-00039A-C	Chinese																	
903-00039A-D	Dutch																	
903-00039A-F	French																	
903-00039A-FI	Finnish																	
903-00039A-G	German																	
903-00039A-I	Italian																	
903-00039A-N	Norwegian																	
903-00039A-P	Portuguese																	
903-00039A-S	Spanish																	
903-00039A-SW	Swedish																	
903-00039A-UK	UK English																	

Part #	Description	22Q1 Jan-22	Feb-22	Mar-22	TOTAL	22Q2 Apr-22	May-22	Jun-22	TOTAL	22Q3 Jul-22	Aug-22	Sep-22	TOTAL	22Q4 Oct-22	Nov-22	Dec-22	TOTAL	2022 TOTAL
	RI-2, 1000 mL/min (120V)																	
903-00037	US English																	
	RI-2, 1000 mL/min (230V)																	
903-00037A	US English																	
903-00037A-D	Dutch																	
903-00037A-F	French																	
903-00037A-FI	Finnish																	
903-00037A-G	German																	
903-00037A-I	Italian																	
903-00037A-N	Norwegian																	
903-00037A-P	Portuguese																	
903-00037A-S	Spanish																	
903-00037A-SW	Swedish																	
903-00037A-UK	UK English																	

Disposables

Part #	Description	22Q1 Jan-22	Feb-22	Mar-22	TOTAL	22Q2 Apr-22	May-22	Jun-22	TOTAL	22Q3 Jul-22	Aug-22	Sep-22	TOTAL	22Q4 Oct-22	Nov-22	Dec-22	TOTAL	2022 TOTAL
903-00006	3-Spike Disposable Set																	
903-00018	3.0 Liter Reservoir (LVR)																	
903-00032	4x4 Disposable Set																	
903-00004	Dual Patient Line																	
903-00022	Patient Line Extension																	

THANK YOU