

# two-part quality system for irradiation system confidence

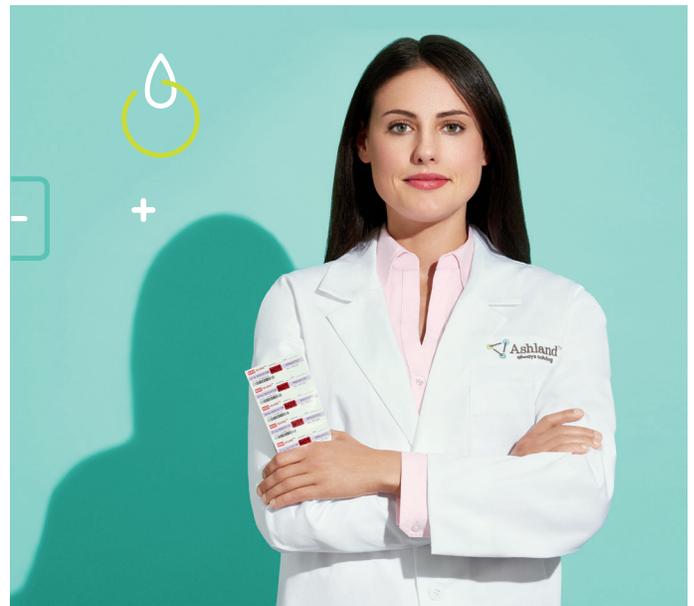
## rad-sure™ blood irradiation indicators

### Indicators for positive visual identification of irradiation

Transfusion-associated graft-versus-host disease (TA-GVHD), a rare complication of blood transfusion, is usually fatal. Patients in certain clinical categories, including bone marrow transplants, solid tumors and acquired T cell defects, are at greater risk of developing TA-GVHD. TA-GVHD can be prevented by the irradiation of cellular blood products prior to transfusion.

Ashland developed Rad-Sure blood irradiation indicators to provide positive, visual verification of irradiation. When attached to blood products, Rad-Sure Type XR 15 Gy, Type XR 25 Gy, Type 15 Gy and Type 25 Gy blood irradiation indicators show whether the blood products have been irradiated or not. Before a blood product and its attached indicator are irradiated, the indicator reads, "NOT IRRADIATED."

After the blood product and its attached indicator are irradiated, the word "NOT" in the indicator window is obscured and the indicator reads, "IRRADIATED." Rad-Sure blood irradiation indicators only indicate that irradiation has occurred. They should not be used as dosimeters to measure the dose delivered by the irradiator.

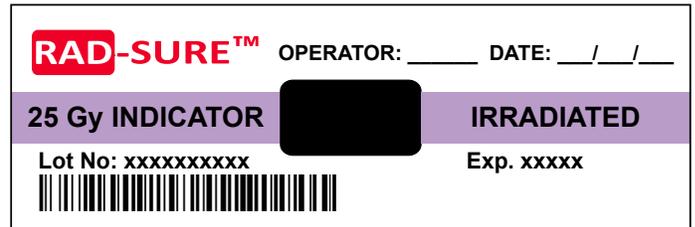
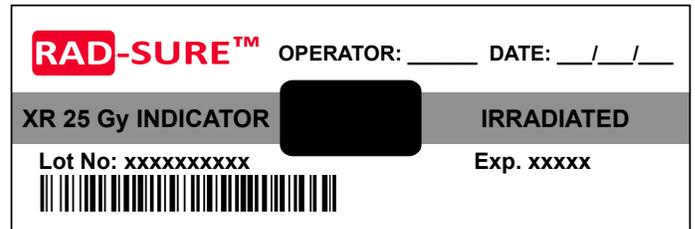


Rad-Sure Type 15 Gy and Type 25 Gy blood irradiation indicators should only be used with irradiators having cesium-137 or cobalt-60 radiation sources, or other sources producing radiation of equal or greater energy. Rad-Sure Type XR 15 Gy and Type XR 25 Gy blood irradiation indicators should only be used with x-ray irradiators that utilize x-rays generated from 160kVp sources that are filtered through 0.38 mm of copper, or 150kVp sources that are filtered through 1 mm of aluminum.

### Rad-sure blood irradiation indicators are FDA-listed medical devices

Registration	Listing number	Description
FDA	A976736	Rad-Sure™ Type 15 Gy, Type 25 Gy, Type XR 15 Gy, and Type XR 25 Gy

Examples of Rad-Sure Type XR 25 Gy and Type 25 Gy blood irradiation indicators before and after irradiation



In addition to the above, French, and Polish versions of rad-sure are available.

### Ordering Information

Rad-Sure blood irradiation indicators		
Version	Product code	Packaging
Rad-Sure 15 Gy - blood irradiation indicators	831377	200/Box
Rad-Sure 25 Gy - blood irradiation indicators	831379	200/Box
Rad-Sure XR 15 Gy - blood irradiation indicators	831396	200/Box
Rad-Sure XR 25 Gy - blood irradiation indicators	831398	200/Box

# dose-map™ dosimetry system

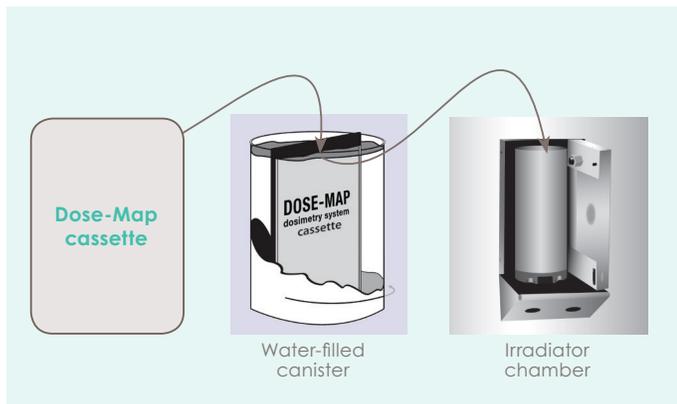
## Accurate, quantitative 3-D dosimetry for blood irradiators

The Dose-Map dosimetry system for blood irradiators is based on an instant-imaging film medium that darkens in response to ionizing radiation. The film has been extensively characterized and calibrated every 12 months with exposures provided by the University of Wisconsin Radiation Calibration Laboratory. The system is capable of measuring the absorbed dose in a blood irradiator canister with an estimated accuracy of  $\pm 5\%$ .

Dose-Map dosimetry system is designed to measure most commercial blood irradiators that contain a cylindrical canister and use either cesium-137 or cobalt-60 as the gamma ray source.

The Dose-Map dosimetry system cassette is placed into the irradiation canister and the canister is filled with water. The cassette/water “phantom” is then exposed using the same irradiation cycle that would be used for blood products (See Exhibit 1).

Exhibit 1



Upon return to Ashland, the cassette is disassembled and the entire film (See Exhibit 2) is analyzed using a flatbed scanner and software designed specifically for film dose analysis. All measurements are indexed to alanine, an internationally recognized dosimetry transfer standard, which is incorporated into each cassette. The measurement of the alanine pellet is performed by NIST.

The final report (see Exhibits 3 and 4) issued to the customer consists of:

- A dose distribution chart showing the centerline, left edge and right edge of the canister.
- A color-coded dose contour plot showing the distribution of absorbed dose in the canister.
  - Minimum and maximum axial dose
  - Minimum and maximum dose

## Ordering Information

**dose-map dosimetry system**

Call customer service at 1 800 622 4423 with the following information:

- Make/model/serial number of blood irradiator
- Inside dimensions of canister
  - Inside diameter
  - Inside height
- Name and address of person to receive report

Exhibit 2



Film to be analyzed

Exhibit 3

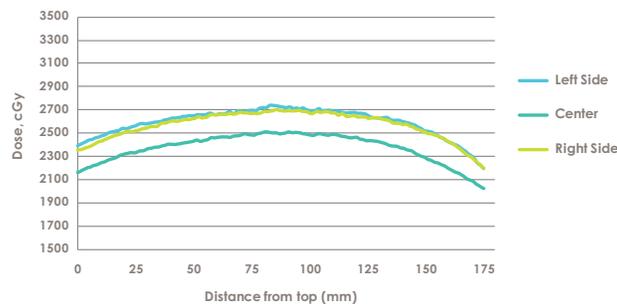
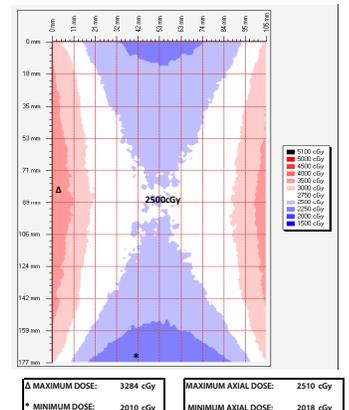
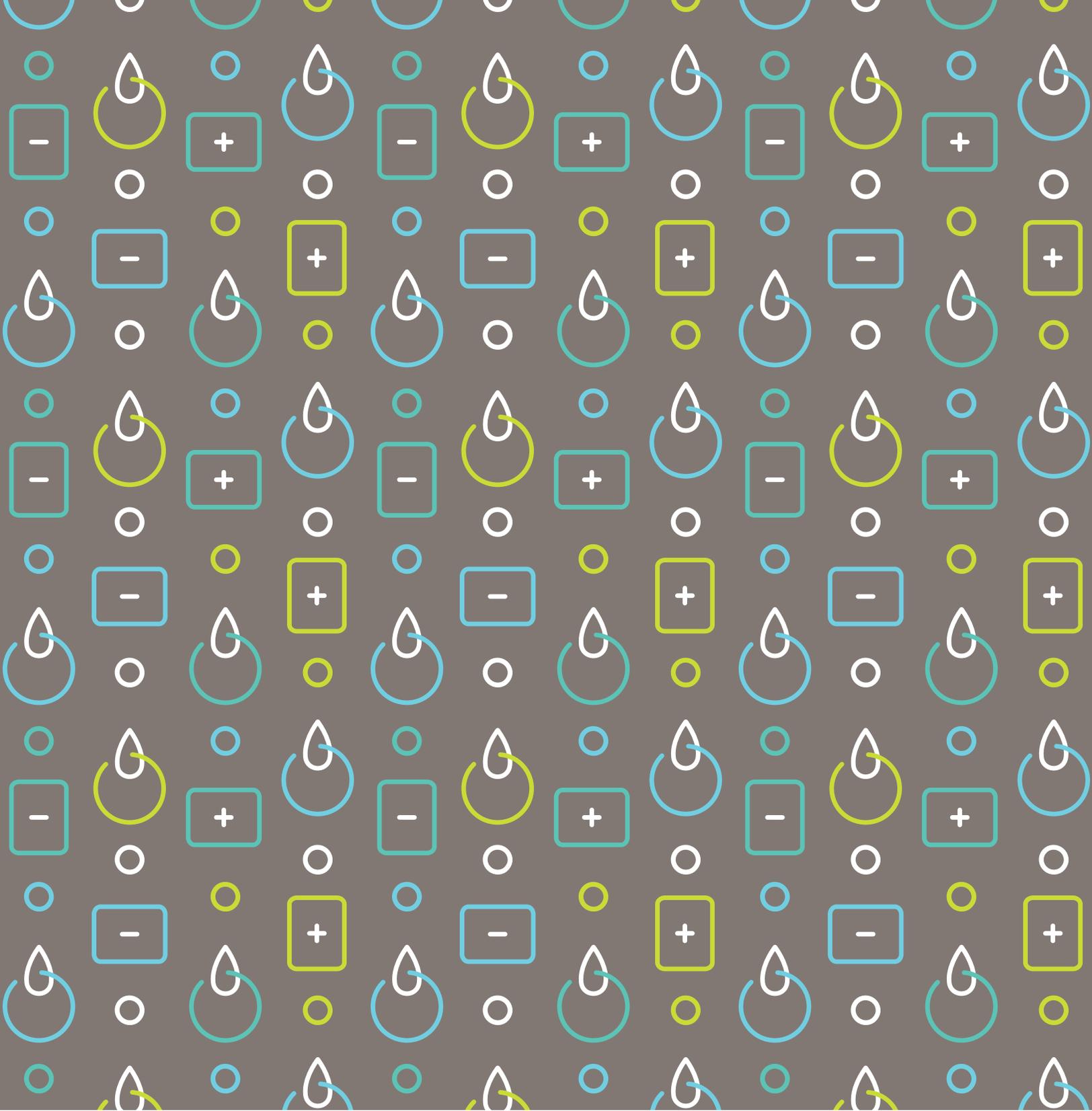


Exhibit 4





**Domestic Orders and Inquiries**  
[AdvancedOrders@ashland.com](mailto:AdvancedOrders@ashland.com)

**International Orders and Inquiries**  
[AdvancedMaterialsOrders@ashland.com](mailto:AdvancedMaterialsOrders@ashland.com)

[ashland.com/contact](http://ashland.com/contact)

® Registered trademark, Ashland or its subsidiaries, registered in various countries  
™ Trademark, Ashland or its subsidiaries, registered in various countries  
© 2018, Ashland / PHA17-1007.1

The information contained in this brochure and the various products described are intended for use only by persons having technical skill and at their own discretion and risk after they have performed necessary technical investigations, tests and evaluations of the products and their uses. Certain end uses of these products may be regulated pursuant to rules or regulations governing medical devices, drug uses, or pesticidal or antimicrobial uses. It is the end user's responsibility to determine the applicability of such regulations to its products.

All statements, information, and data presented herein are believed to be accurate and reliable, but are not to be taken as a guarantee of fitness for a particular purpose, or representation, express or implied, for which seller assumes legal responsibility. No freedom to use any patent owned by Ashland, its subsidiaries, or its suppliers is to be inferred.

