



# Best Practices Guide for Selecting Automatic Cell Washing Systems



Important guidelines to consider when purchasing a cell washer.

# Important Guidelines to Consider

In order to meet regulatory requirements and to implement best practices for automatic cell washing, there are important considerations for the design and features of a cell washer. The following checklist can help ensure all critical aspects are considered when selecting a device for automatic cell washing.

## U.S. Food and Drug Administration (FDA)

In 21 CFR Sec. 864.9285, the FDA describes an automatic cell washer as an automated cell-washing centrifuge for immuno-hematology used to separate and prepare cells and sera for further in vitro diagnostic testing. The regulatory classification for these devices is Class II, which requires Section 510(k) premarket notification of intent to market the device.

- The cell washing system is designed to separate and prepare cells and sera for further in vitro diagnostic testing
- The cell washing system has 510(k) clearance from the FDA

## AABB

Method 8-9, Testing Automatic Cell Washer, states that "A properly functioning cell washer must add large quantities of saline to each tube, resuspend the cells, centrifuge them adequately to avoid excessive red cell loss, and decant the saline to leave a dry cell button."

- The cell washing system is designed to dispense saline, suspending the cells and then resuspending them in subsequent wash cycles
- The cell washer is capable of centrifuging at an adequate speed and time to separate the cells and form a button at the bottom of each test tube
- The cell washer is designed to decant in a manner that retains cells in the tubes while removing residual saline

The Suggested Quality Control Performance Intervals for Equipment and Reagents in the AABB Technical Manual states that the saline fill volume for a cell washer should be checked weekly.

- The cell washing system has a calibration function that facilitates checking the volume of dispensed saline
- The cell washer calibration can be adjusted when necessary

# Additional Considerations for Best Practices

- The cell washer is programmable, ensuring that facilities can create programs that will meet their needs
- The cell washer is designed to provide precise saline fills
- The calibration process is digital to provide precise control of saline volumes
- The cell washer is designed so that the saline supply can be placed below the unit, eliminating the need for staff to lift the saline
- The cell washer has a low profile that enables laboratory staff to work in an ergonomic and comfortable position
- The cleaning procedure does not require excessive downtime

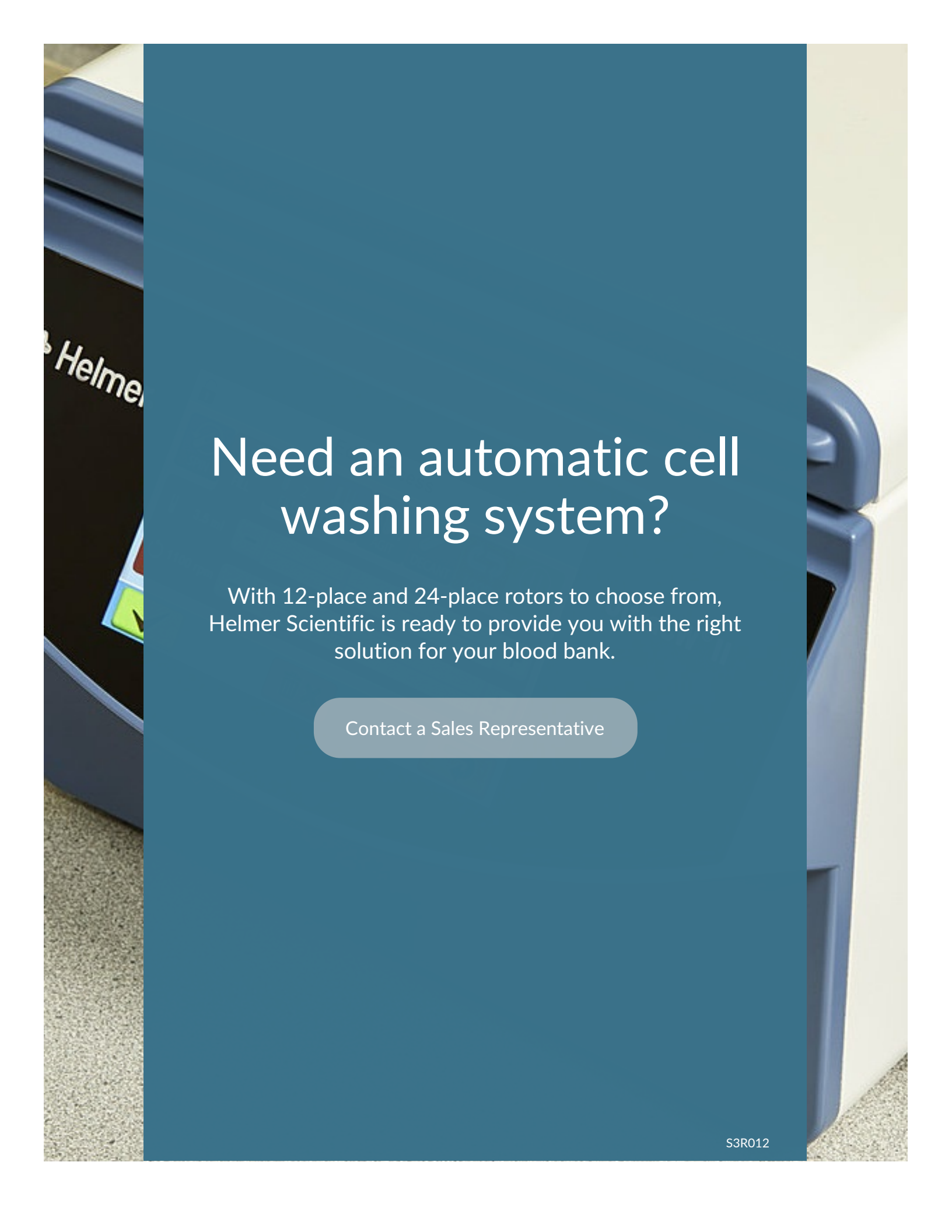
The Automatic Cell Washing System from Helmer Scientific is designed to meet the critical demands of the cell washing process. The use of Helmer cell washers supports hospitals and blood centers in their efforts to meet regulatory requirements. They are also designed to facilitate best practices for automatic cell washing.

#### References:

FDA 21 CFR Sec. 864.9285

AABB, Standards for Blood Banks and Transfusion Services, 30<sup>th</sup> edition

AABB, Technical Manual, 18th Edition

A photograph of a Helmer Scientific automatic cell washing system. The machine is white with blue accents. The brand name 'Helmer' is visible on the side. The machine has a control panel with a yellow arrow pointing down. The background is a solid blue color.

# Need an automatic cell washing system?

With 12-place and 24-place rotors to choose from, Helmer Scientific is ready to provide you with the right solution for your blood bank.

Contact a Sales Representative