



Compliance of the Boehringer AUTOVAC® Systems With AABB Standards and Guidelines

Models 7904, 7904R, 7910, 7910R, 7910RL, 7910LF, 7924, 7926

All Boehringer AUTOVAC® systems have been designed and developed specifically for intraoperative and postoperative autologous blood salvage and conform to all the applicable standards and guidelines of the following documents. Individual points that are pertinent to the use of the AUTOVAC® Systems are discussed for each standard or guideline.

Standard: Standards for Perioperative Autologous Blood Collection and Administration, 2nd Edition, AABB

Section: **5 Process Control**

Item: 5.1.4 Sterility *“The perioperative program shall employ methods that provide maximum assurance of a sterile component. Sterile and pyrogen-free equipment and solutions shall be used.”*

Boehringer: A violation of the ‘system integrity’ would indicate a potential loss of system sterility. When used in accordance with product instructions, the AUTOVAC® System maintains complete system sterility. Please reference the table below regarding the individual components of the AUTOVAC® System. All Boehringer Autovac products are pyrogen free.

Potential Source of Contamination	AUTOVAC® Model	Method of Contamination Prevention
Product Transfer into the Sterile Field	All	All Autovac’s are packaged to allow for safe and easy transfer into the sterile field.
Y-Connector for drain attachment	7910(all), 7924, 7926	Sterile field in the OR and use of sterile technique by the physician and/or surgical team.
Vacuum port on the canister cap	All	Integral check valve to prevent back flow of air into the infusion module and a sterile barrier filter for redundancy.
Spike port on the Infusion Module blood bag	All	The spike port cap protects sterility until use and the spike port is designed for use with a standard infusion set to maintain a sterile fluid path.

Standard: Standards for Perioperative Autologous Blood Collection and Administration, 2nd Edition, AABB

Section: 5R-A Handling, **Storage and Expiration**

Item: *“Intraoperative blood recovered without processing:”*
Expiration: 6 hours from start of collection”

Boehringer Models 7904 and 7904R Transfusion of collected blood from the AUTOVAC® shall be completed 6 hours from the start of collection.

Standard: Standards for Perioperative Autologous Blood Collection and Administration, First Edition, AABB

Section: 5R-A Handling, **Storage and Expiration**

Item: ***“Shed blood under postoperative or posttraumatic conditions with or without processing:”***
Expiration: “6 hours from start of collection”

Boehringer Models 7910(all), 7924(all) and 7926(all): Transfusion of collected blood from the AUTOVAC® shall be completed within 6 hours of initiating collection. After 6 hours, the line to the AUTOVAC® blood bag should be clamped off between the bulb and the bag. Where appropriate, the bulb can then be used as a passive drainage device and subsequent drainage should be discarded and not transfused.

Should there exist a clinical need to continue collection for transfusion beyond the designated expiration time, i.e. significant drainage volume over a short period of time, the primary physician must be informed. There may be other factors that require the attention of the physician. At this point the AUTOVAC® is a closed and sterile system that can continue to collect and infuse for as long as clinically necessary as directed by the primary physician.

Standard: Standards for Perioperative Autologous Blood Collection and Administration, First Edition, AABB

Section: 5.4.1 Patient Identification

Item: *“There shall be positive identification of the donor-patient and the blood container.”*

Boehringer: All Boehringer Autovac systems provide a patient identification label to enable identification and start/end times for collection and administration.

Standard: Standards for Perioperative Autologous Blood Collection and Administration, First Edition, AABB

Section: 5.4.3 Minimization of Air Embolism

Item: *“The perioperative program shall have processes and procedures that minimize the risk of air embolism.”*

Boehringer: All Autovac models contain a 170 micron filter to retain potentially harmful particles. Because of the attached bulb, AUTOVAC® models 7924 and 7926 employ an integral anti-air embolism valve to prevent air from being infused into the patient in the case of inadvertent misuse of the system.

Standard: Standards for Perioperative Autologous Blood Collection and Administration, First Edition, AABB

Section: 5.4.5.1 Administration Protocol

Item: *“Perioperative components intended for transfusion shall be transfused through a filter designed to retain particles potentially harmful to the donor-patient.”*

Boehringer: All Autovac models contain a 170 micron filter to retain potentially harmful particles. The potential for insoluble fats in orthopedic wound drainage exists. AUTOVAC® models 7910RL, 7910LF, 7924 and 7955 employ a patented AUTOWICK™ for the removal of insoluble fats and methyl methacrylate.
