

GOWN PROTECTION LEVELS

ANSI/AAMI PB70 Standards recognized by the FDA



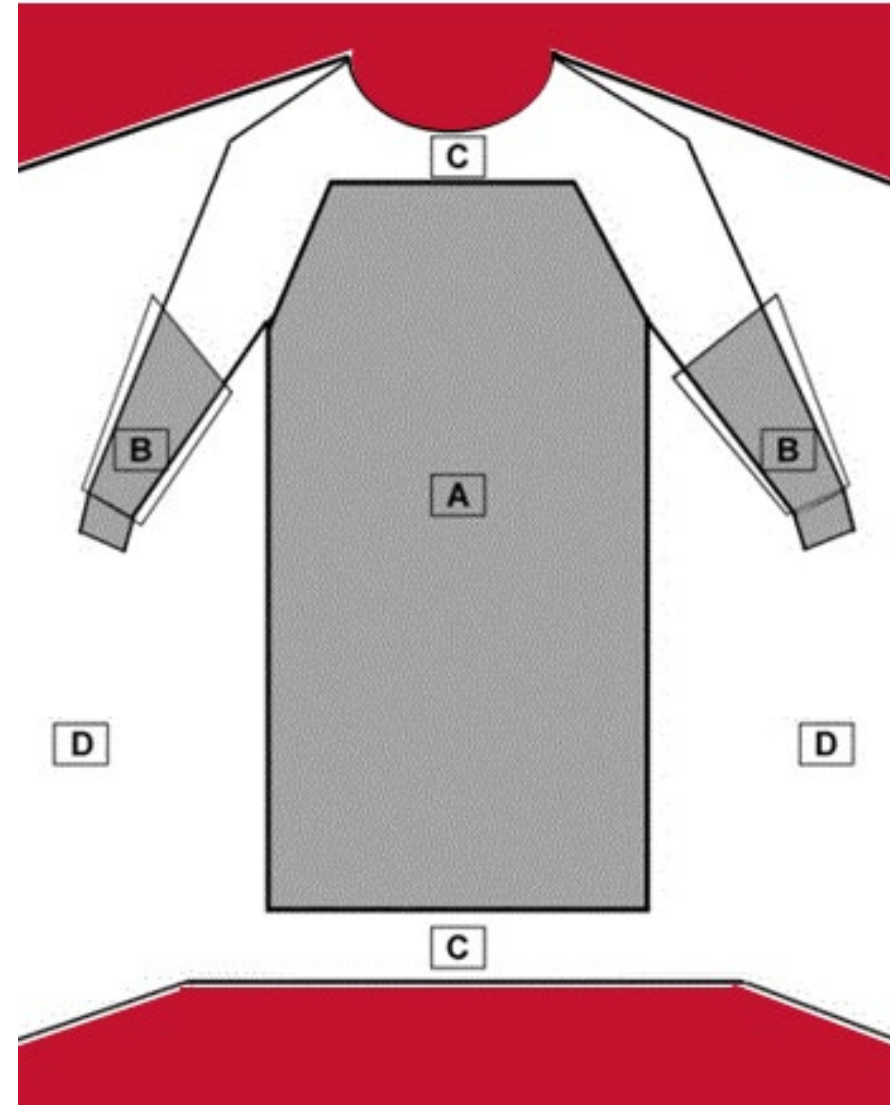
ANSI/AAMI PB70 Standards Classifies a gown's ability to act as a barrier to penetration by liquids or liquid-borne pathogens based on four levels. The critical protective zones for surgical and non-surgical gowns are defined differently by the standard. While the critical zones designate different protective areas for the different gowns, the levels of protection are the same for both surgical and non-surgical gowns

		DESCRIPTION	APPLICATION
CLASS I NON-SURGICAL	Level 1	<ul style="list-style-type: none"> Used for MINIMAL risk situations Provides a slight barrier to small amounts of fluid penetration Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance. 	Basic daily patient care, Standard hospital medical unit
	Level 2	<ul style="list-style-type: none"> Used in LOW risk situations Provides a barrier to fluid through splatter and some fluid exposure through soaking Two tests are conducted to assess barrier protection performance: <ul style="list-style-type: none"> - Water impacting the surface of the gown material - Pressurizing the material 	Blood draw from a vein, Suturing, Intensive care unit, Pathology lab
	Level 3	<ul style="list-style-type: none"> Used in MODERATE risk situations Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2 Two tests are conducted to test barrier protection performance: <ul style="list-style-type: none"> - Water impacting the surface of the gown material - Pressurizing the material 	Arterial blood draw, Inserting an IV, Emergency Room, Trauma
CLASS II SURGICAL	Level 4	<ul style="list-style-type: none"> Used in HIGH risk situations Prevents all fluid penetration for up to 1 hour May prevent VIRUS penetration for up to 1 hour In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus. If no virus is found at the end of the test, the gown passes. 	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods

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GOWN CRITICAL ZONES

Critical Zones are defined as the areas where direct contact with blood, bodily fluids, and other potentially infectious material is most likely to happen (Areas A and B). For surgical gowns, this includes the fabric and the construction (sleeve seams, front tie attachment) in areas A and B. The entire gown (Areas A, B, and C), including seams but excluding cuff, hems, and bindings, is required to have a barrier performance of at least Level 1. The back of the surgical gown (Area D) may be non-protective. AAMI liquid barrier standards also apply to surgical drapes.



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