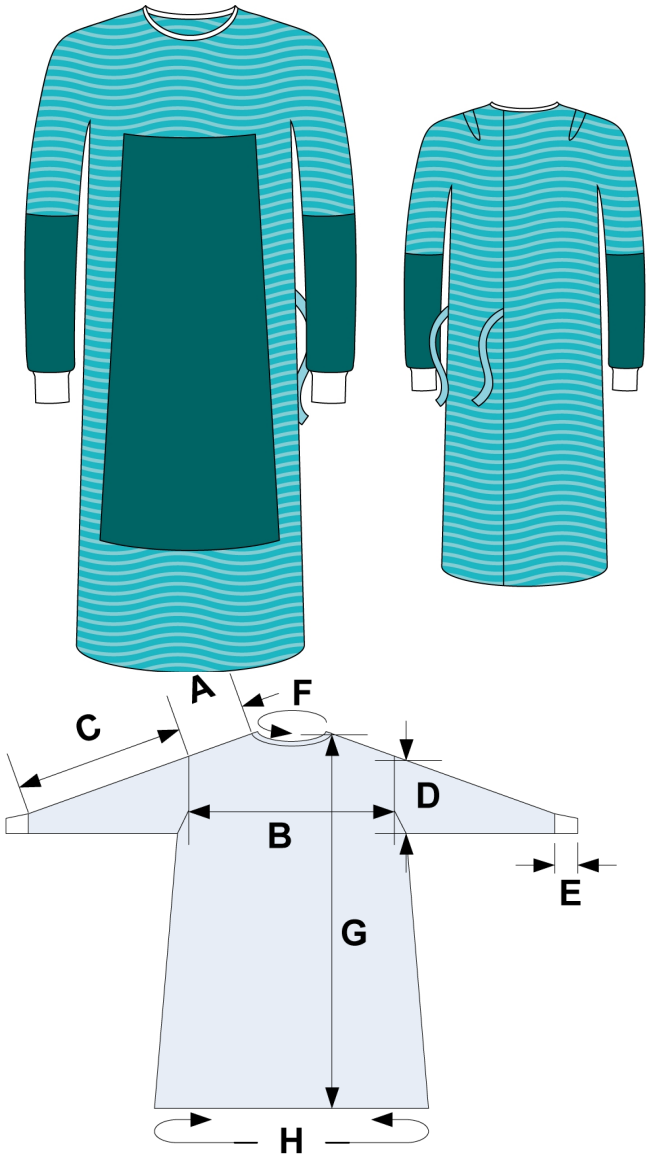
690005 Surgical Gown ULTIMATE HP



Size And Description XL-L

Dimensions (in cm) see image 2

A Shoulder: 26
B Chest: 60
C Top sleeve: 59
D Armhole: 30
E Sewn cuff: 8

F Neck: 66

G Highest length at shoulder: 148

H Circumference: 170

Other information	Product sheet is available in MRM 4 removable labels for easy traceability
Sterile	Yes
Color	Blue
Country Of Origin	Thailand
Sterility barrier quantity	1
Dispenser Box Quantity	14
Transport Box Quantity	28
Pallet Quantity	560
Standard	EN 13795 High Performance EN 13795 ANSI/AAMI PB70:2003 Level 3 ISO 11607-1 ISO 10993 ISO 14001 ISO 14971-1 ISO 9001 ISO 13485 ISO 13485
Label Of Standard	EN 1041 CEE 93/42 ISO 15223

Material data

Material composition

Gown Body and Sleeves	SMS fabric consisting of polypropylene fibres
Front Reinforcement	Polyethlylene plastic film (breathable)
Sleeve Reinforcement	Polyethelene plastic film, viscose/polyester
Cuff	Polyester

Product performance according to EN 13795

Characteristic	Unit	High Performance			
		Requirement		Product Performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration - Dry	CFU	Not required	≤ 300 a	-	5**
Resistance to microbial penetration - Wet	BI	6.0 b, c	Not required	6.0*	-
Cleanliness - Microbial	CFU/100cm2	≤ 300	≤ 300	<300	<300
Cleanliness - Particulate matter	IPM	≤ 3.5	≤ 3.5	1.5**	1.5**
Linting	Log 10 (lint count)	≤ 4.0	≤ 4.0	1.6**	1.6**
Resistance to liquid penetration	cm H2O	≥ 100	≥ 10	> 110	Shoulder seam: 19 Fabric: 74
Bursting strength - Dry	kPa	≥ 40	≥ 40	120*	120*
Bursting strength - Wet	kPa	≥ 40	Not required	122*	-
Tensile strength - Dry	N	≥ 20	≥ 20	29 (CD) sleeve seam, 34 (CD) fabric	34 (CD)
Tensile strength - Wet	N	≥ 20	Not required	32 (CD)*	Not applicable

a) Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.
b) The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 BI are probably not different, materials varying by more than 0,98 BI probably are different (The 95% confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives).
c) BI = 6,0 for the purpose of this standard means no penetration. BI = 6,0 is the maximum achievable value.

Remark:
log (10) CFU ≤ 2 means maximum 300 CFU.

* For both Critical and Less Critical product area the lowest identified average value for concerned product area has been reported.
** For both Critical and Less Critical product area the highest identified average value for concerned product area has been reported.

(labreport: 20110923-001, PD-400802, PD-398377)

Additional test

Characteristics	Units	Test Method	Product performance/Critical area	Product performance/Less critical area

Repellency				
Spray impact	g *	AATCC 42	Sleeves and front: 0.0	Shoulder seam: 0.1
Alcohol Repellency Rating	1-10 **	WSP 80.8	10	10
Strength				
Tear, MD	N **	ASTM D5733	Not available	Fabric: 25
Comfort				
WVTR (water vapor transmission rate)	g/m2/24hrs **	ASTM 6701	3000 Sleeves nonbreathable	72000
Air Permeability	m/s **	ISO 9237:1995	Front not applicable test Sleeves nonbreathable	0.43
Frazier Air Porosity	ft3/min **	ASTM D737:96	Front not applicable test Sleeves nonbreathable	54

* < better
** > better

Instruction Intended Use	Surgical Gowns are single use, disposable, fluid repellent garments intended to be used as sterile by operating room personnel during surgical procedures to protect both the patient and the operating room personnel (users) from the transfer of micro-organisms, body fluids and particulate material.
Sterilization Method	Ethylene Oxide
MDD Classification	Class I Sterile
CEMark Certificate	01966
Instruction Storage	Mölnlycke Health Care recommends that BARRIER products are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed. Storage facilities for products only protected by the sterility barrier should be kept under conditions where low level of particulate air contamination prevail, so that it would not constitute a risk to the patient when the package is opened and the product is used.
Instruction Disposal Waste	Non-hazardous waste used BARRIER products and sterility barriers should, in the majority of cases, be classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineration. BARRIER products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems. The new BARRIER packaging system complies with the Packaging Waste Directive of the European Union.
Environmental Impact	At Mölnlycke Health Care we have a long-standing commitment to make our activities have as little effect as possible on the environment, without compromising the efficiency and reliability of our products and services. A sound

	environmental practice is a priority in our production and at our sites around the world.
Shelf Life	5 years