

Cardiosave Fluid Ingress Protection

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Learning Objectives

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- Evaluate the potential causes of fluid ingress into the intra-aortic balloon pump (IABP) and assess the clinical implications
- Explain the meaning of Ingress Protection (IP) ratings and describe procedures used in IPX testing
- Compare and contrast the fluid protection features of the Cardiosave Hybrid and Cardiosave Rescue
- Demonstrate the correct application of Cardiosave Transport Protective Covers to ensure optimal device protection

Topics Covered:

- Fluid Ingress Protection Ratings
- IPX Testing
- Cardiosave Hybrid and Rescue Fluid Protection Changes
- Cardiosave Transport Covers

Cardiosave

Introduction

- Current state: Clinicians use the IABP pole to hang the arterial flush solution
- The IABP pole has been a contributing factor for fluid entering the pump and damaging the internal components
- What has changed?
 - The IABP IV pole has been removed
 - New designs have been added to protect the IABP from fluid entering the pump, known as fluid ingress protection



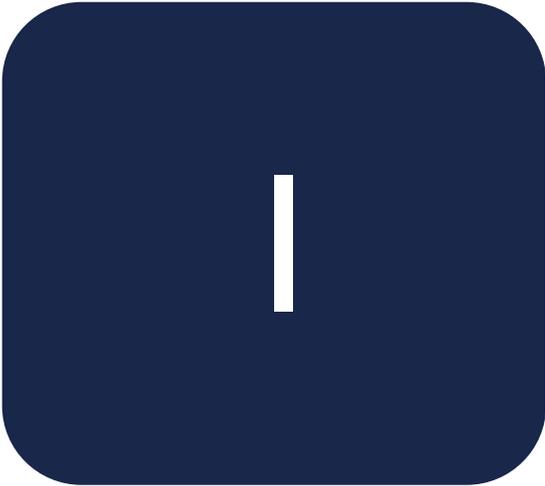
Fluid Ingress Protection

Definition

- Medical equipment must resist spills, cleaning agents, and bodily fluids
- Fluid Ingress Definition:
 - Unintended fluid entering a device
- Fluid Ingress Protection:
 - Involves design features (like seals or enclosures) to block fluid entry
- Ingress Protection Ratings:
 - IP (Ingress Protection) Ratings classify how resistant a product is to solid and liquid intrusion



Understanding IP Ratings



I

I = Ingress



P

P = Protection



X

3rd Number = Protection
against solids

- Rated 0-6
- If X is listed, it means the device was not tested



Y

4th Number = Protection
against liquids

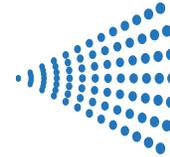
- Rated 0-9

IP Rating Examples



IPX0

No protection



IPX5

Protection against water jets



IPX1

Protection against vertically falling water drops



IPX7

Protection against immersion in water



IPX3

Protection against spraying water at an angle



IPX9

Protection against high pressure, high temperature water jets

IPX Testing

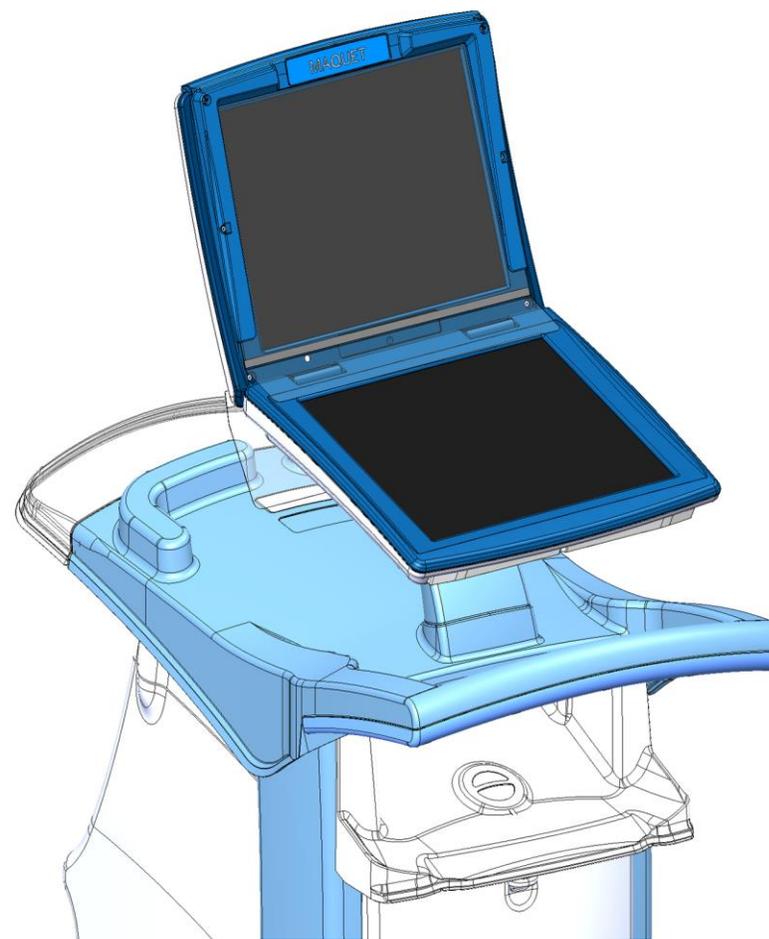
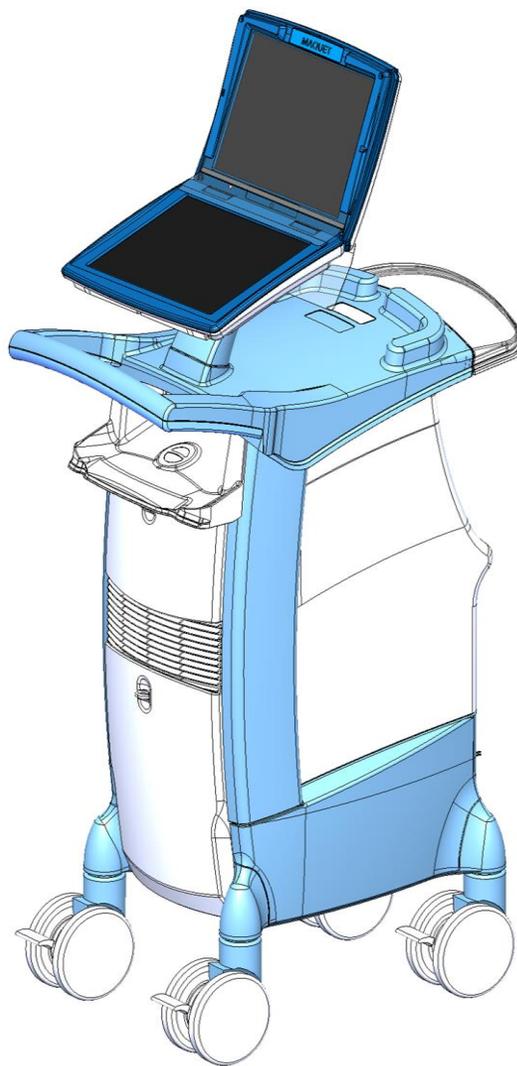
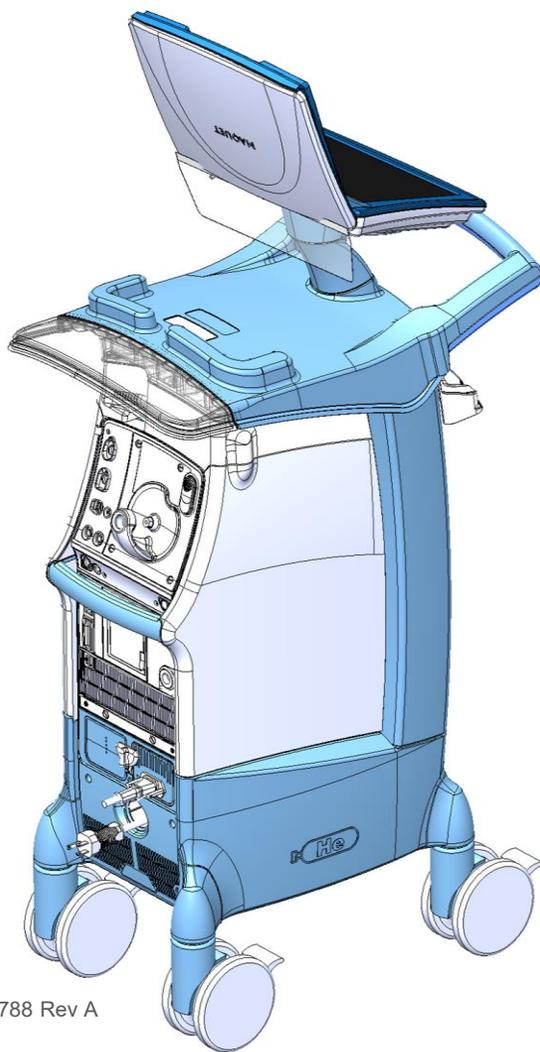
Test Details

- IPX testing involves exposing a product to controlled water exposure to determine its resistance to water ingress
- Includes:
 - Setup: Device is mounted on a rotating platform to ensure uniform exposure from all directions
 - Spray Nozzle Configuration: Spray nozzle is positioned 200-300 mm from the device, simulating real-world splashing conditions
 - Test Duration: Water pressure is regulated to ensure consistent spray intensity
 - Minimum of 5 minutes per square meter of the device's surface area
 - Post Test Evaluation: Device is inspected for water ingress, electrical functionality, and structural integrity



Cardiosave IPX1

Fluid Ingress Protection



Rescue Configuration

Fluid Ingress Protection

- In Rescue configuration (transport), the pump console is not protected from fluid and is rated IPX0
- Transport Protective Covers were developed to protect the pump console from fluid
 - Transport Protective Covers are rated IP33
- Use of covers is **required** when the pump console is removed from the cart, including:
 - During out-of-hospital transport
 - During in-hospital relocation
- Covers are single-use only and should be disposed of after each use

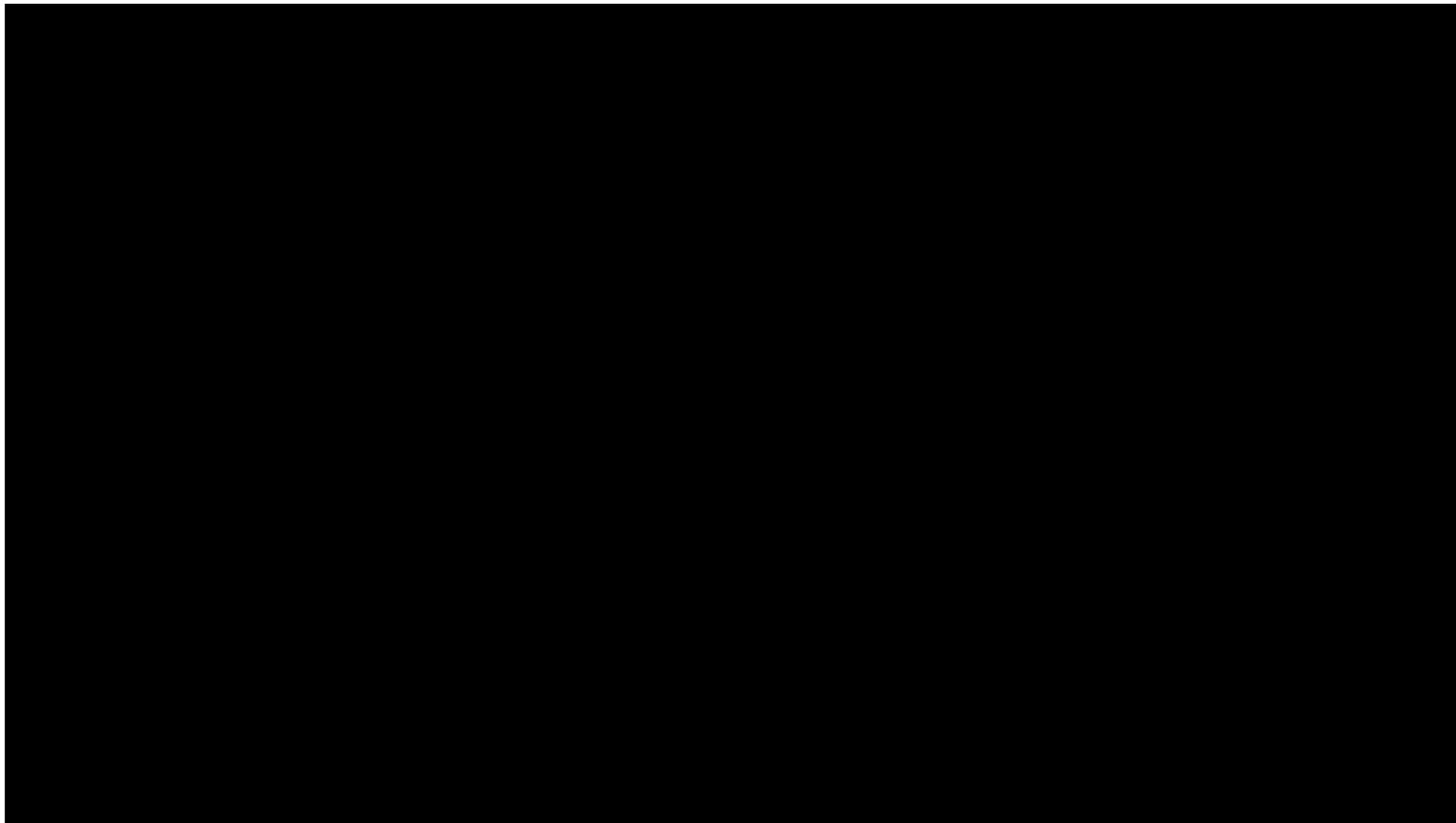


Cardiosave Rescue

Pump Console + Transport Protective Covers = IP33



Cover Application Video



Summary

- IP Rating
 - Hybrid: IPX1
 - Rescue (pump console) with Transport Protective Covers: IP33
- Implications
 - Greater usability in challenging environments
 - Met stringent medical device standards
 - Improved durability





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