



New ISO standard for NIBP
Cuffs connectors: ISO 80369-5

How does it affect your Blood Pressure Cuffs?

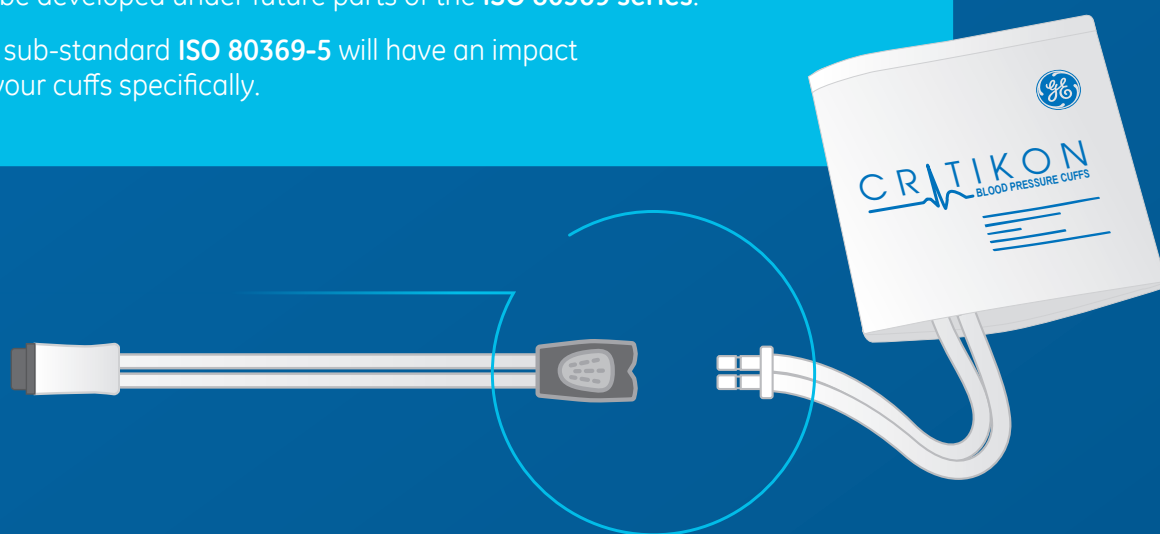
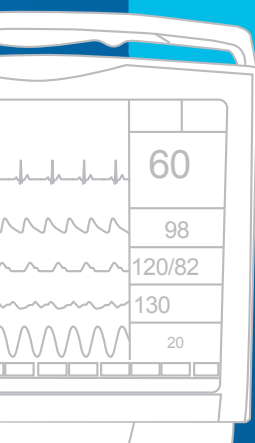
The GE solution for NIBP Cuffs

WHAT IS THE ISO 80369 STANDARD?

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ISO 80369-1: this document provides the methodology to assess **NON-INTERCONNECTABLE** characteristics of SMALL-BORE CONNECTORS based on their inherent design and dimensions in order to **reduce the RISK of misconnections** between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS as specified in this document as well as those that will be developed under future parts of the **ISO 80369 series**.

The sub-standard **ISO 80369-5** will have an impact on your cuffs specifically.



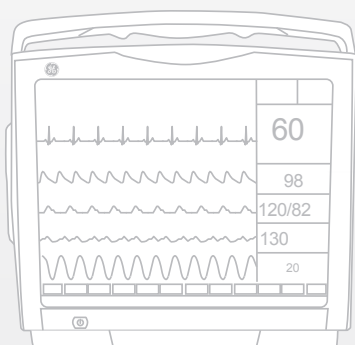
By being compliant with ISO 80369-5 limb cuff inflation standard for blood pressure cuffs, many organizations choose to move toward this new worldwide standard –bayonet-style¹ connectors whose tight dimensional specifications will help reduce the probability of a misconnection.



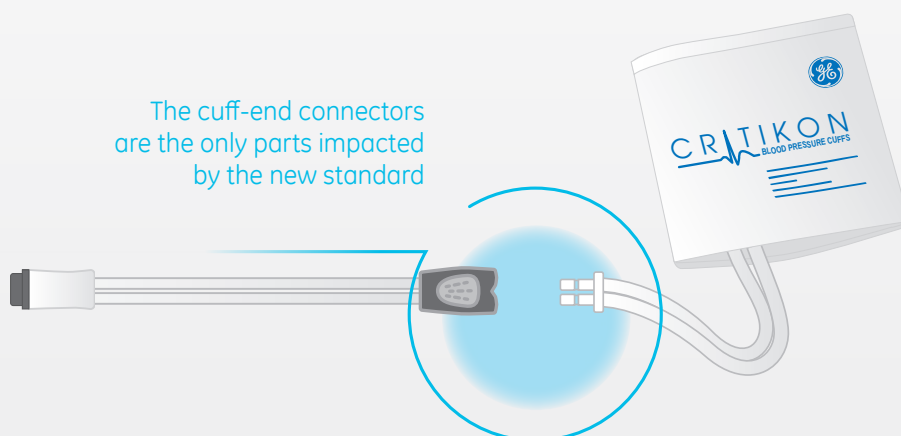
A STRONG LEGACY ACCESSORY OF GE

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As a pioneer in non-invasive BP (NIBP) monitoring for more than 40 years, GE understands your priorities. The state-of-the-art technology used in the manufacturing process ensures that CRITIKON® blood pressure cuffs always meet highest quality standards. We offer a wide selection of BP cuffs – from long lasting reusables to convenient disposables designed to support your infection control efforts. With GE CRITIKON BP cuffs, you can confidently care for patients in virtually any care setting.



The cuff-end connectors
are the only parts impacted
by the new standard



WHY DO WE CHOOSE TO MOVE TO ISO 80369-5 STANDARD AND SUGGEST YOU DO THE SAME?

TO IMPROVE PATIENT SAFETY – FIRST PRIORITY AT ALL TIMES



The International standard was developed because of patient safety concerns due to accessories misconnections incidents, with catastrophic consequences².

The ISO 80369 series was developed to prevent misconnection between small-bore connectors used in different applications. It ensures correct connections even in complex working environments.



TO PLAN FOR THE FUTURE

The European Economic Area regulatory agency has published ISO 80369-5 in November 2016 for CE Mark countries, and **recommends enforcement** within 3 years of publication, which makes 2019 a critical year of decision making. In order to remain state-of-the-art, **GE Healthcare products will meet this standard across its connectors** and will meet new MDR standard.



TO SIMPLIFY YOUR WORKFLOW AS A LONG TERM BENEFIT

We encourage you to move to **ONE unique new DINACLICK** ISO 80369-5 compliant male and female connectors to simplify BP cuffs connections, drive standardization in all care areas and simplify your clinical workflow.



A real story³:

Blood pressure tubing erroneously connected to iv catheter

An ER patient had an IV heparin lock but no IV fluids had been started. The patient also had a noninvasive automatic BP cuff placed for continuous monitoring. The BP cuff tubing was disconnected when the patient went to the bathroom, when she returned, her spouse **mistakenly connected the BP cuff tubing to the IV catheter and approximately 15 mL of air was delivered to the IV catheter.**

The patient DIED from a fatal air embolus, despite resuscitation efforts

Therefore, In 2000, a task group of the European standards organization CEN proposed a strategy to reduce incidents of accidental misconnection of PATIENT therapy tubing by the use of a series of NON-INTERCONNECTABLE CONNECTORS, differentiated by design, for use in different medical APPLICATIONS. The strategy reserves the use of LUER CONNECTORS solely for use in MEDICAL DEVICES used to access the vascular system or for hypodermic syringes so that they can achieve their intended function.



THE CONVERSION SOLUTION TO DINACLICK ISO COMPLIANT CUFF AND CONNECTORS

The whole range of CRITIKON Blood Pressure Cuffs^{1 4} and equipment air hoses will be equipped with the new **ISO 80369-5 DINACLICK connectors⁵**.

DINACLICK is an innovative adult/pediatric BP cuff connection system that allows healthcare professionals to **have BP cuffs standardization and provides improved workflow by decreasing manual connection time**. DINACLICK is a true dual-tube universal connectivity solution⁶ that is **intuitive** and **easy to use** and **helps to prevent misconnections**.

GE Healthcare's range of CRITIKON cuffs with the new ISO 80369-5 connectors: DURA-CUF reusable cuffs, SOFT-CUF & CLASSIC-CUF limited reuse cuffs and CLASSIC-CUF ISOLATION single patient use cuffs.

You can contact your GE Healthcare representative who will assist you in adopting this new blood pressure cuff patient safety standard.



FEMALE



MALE

THE CONVERSION SOLUTION TO DINACLICK ISO COMPLIANT CUFF AND CONNECTORS



ISO 80369-5 DINACLICK CONNECTORS



CONNECTOR
AIR HOSE AND CUFF



CARESCAPE ONE



CARESCAPE
B850/650/
450 with PDM /
PSM-P modules



B105/B125



CARESCAPE
V100/VC150



1. As the bayonet connector is ISO 80369-5 compliant, CRITIKON cuffs with bayonet connectors continue to be part of the GE range and will remain commercialization.
2. From document : American National Standard. ANSI/AAMI/ISO 80369-05: 2016
3. FDA. U.S. FOOD & DRUG. Example of Medical Device Misconnections.
<https://www.fda.gov/medical-devices/medical-device-connectors/examples-medical-device-misconnections>
4. The range of CRITIKON cuffs with screw, submin, mated submin connectors will no longer have CE mark at the date of November 4th and will be obsolete for sales in Europe.
5. The ISO 80369-1 compliance Cuff connectors (male) are still compatible with new female connectors.
6. For adult and pediatric blood pressure cuffs.
7. The current DinaClick will be made ISO80369-5 and MDR standard compliant in 2020 - 2021.
8. The manufacture of the three connectors has been stopped since November 2019.

GE Healthcare is a leading provider of medical imaging, monitoring, biomanufacturing, and cell and gene therapy technologies.

GE Healthcare enables precision health in diagnostics, therapeutics and monitoring through intelligent devices, data analytics, applications and services. With over 100 years of experience and leadership in the healthcare industry and more than 50,000 employees globally, GE Healthcare helps healthcare providers, researchers and life sciences companies in their mission to improve outcomes for patients around the world.

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