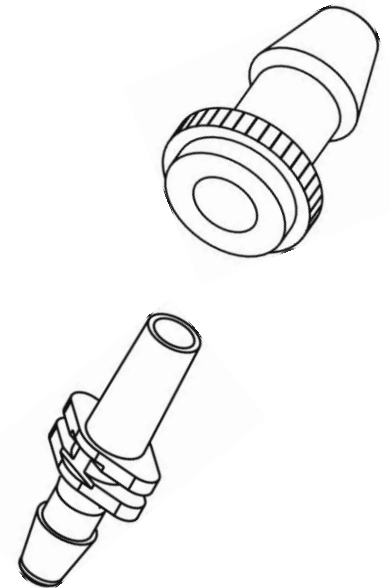


ISO Standard 81060

- The **International Organization for Standardization (ISO)** is an international standard-setting body composed of representatives from various national standards organizations
- In order to sell medical products internationally, Welch Allyn must be in compliance with ISO standards

ISO 81060 Standard eliminating Luer-Locks and Luer Slips

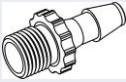
- New **ISO standard 81060** eliminates all luer-lock and luer slip compatible connectors from all devices (because they are a “Universal” Connector and used commonly on many different device types)
- This is due to misconnection issues between different devices that can pose **serious patient safety risks** (ex. Connecting an IV line to a blood pressure pump).
- ISO 81060 has clauses that specifically prevent the use of luer connectors in the standard.
 - ISO Standard 81060 **has** been officially published and in order to comply with ISO 81060 and maintain our CE mark, we can not sell cuffs that have a luer-lock or luer-slip compatible connector on it.



How does this impact Welch Allyn

- Great news – FlexiPort **IS** Compliant. All FlexiPort standardized customers are all set because FlexiPort is a unique design that is only compatible with our Cuffs
- Certain Connectors that Welch Allyn provides are not **currently** compliant to the standard, however the chart on the next slide shows how we have brought those connectors into compliance to meet the standard
 - The next slide will be available via KC as a file - you may send to customers on request

Common Connectors used by Hospitals

Connector Type	Device Side	Cuff Side	WA Getting to Compliance	What Hospital Should do
FlexiPort	 ✓	 ✓	Nothing (already meets standard)	Nothing (already meets standard)
Screw	 ✓	 ✗	Modified the cuff side screw to no longer function as a luer slip. It is still backwards compatible to work with device side screw connectors but NOT luer slips. Customer Part numbers will remain the same	Customers using the cuff side screw as a threaded connector do not have to do anything Customers that were using the cuff side Screw as a luer-slip will need to change their device side connector from a luer slip to a threaded screw using part # 5082-161 (or they could convert to FlexiPort)
Bayonet/HP	 ✓	 ✓	Nothing (already meets standard)	Nothing (already meets standard)
Locking/MQ/Subminiature	 ✓	 ✓	Nothing (already meets standard)	Nothing (already meets standard)
Luer-Lock	 ✗	 ✗	Discontinuing this connector option (can not be modified as luer-locks can no longer be used)	Switch to a compliant connector option such as the Female Tri-Purpose which is part # 5082-100
Tri-Purpose/luer-Slips	 ✓  ✗	 ✗	Modifying the cuff side tri-purpose to no longer function as a luer slip or luer-lock. Will be backwards compatible to only work with Welch Allyn device side Tri-Purpose (5082-100). Customer Part numbers will remain the same	For devices that use a traditional male-luer slip, they will need to convert the device connector to the Welch Allyn Female Tri-Purpose connector, part # 5082-100
Neonatal Cuffs (luer-slips)	 ✗	 ✗	Released new Neonatal Cuff connectors that are compliant	Change device side connectors to the Welch Allyn compliant connector and buy new Neo cuffs with the compliant connector

New Neonatal Cuffs for ISO

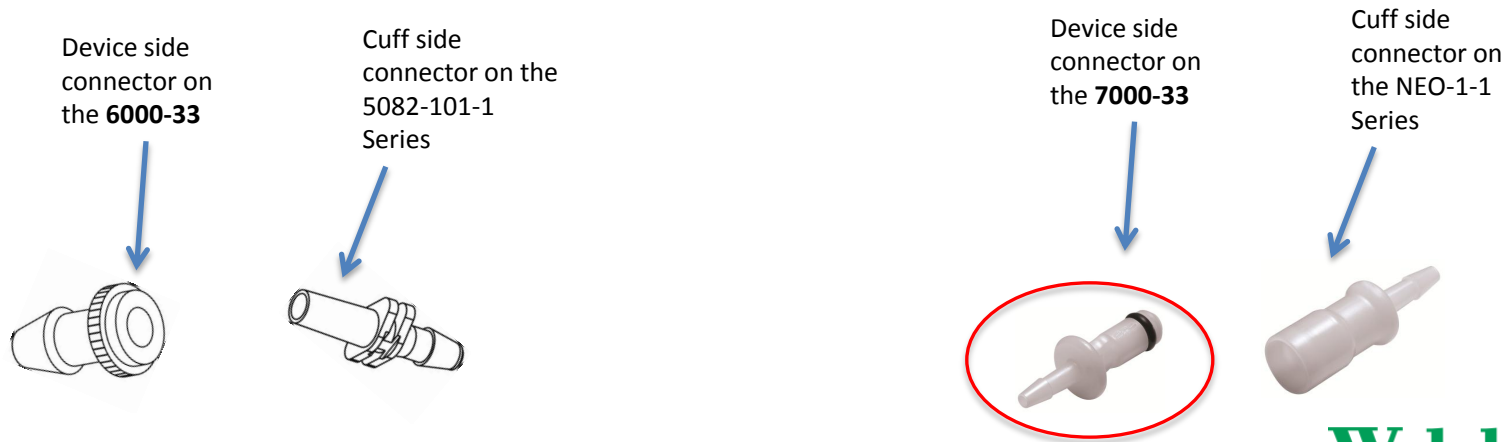
- New connector that meets ISO standard (no change to the cuffs themselves, just a new connector option)
- Will be available in one and two-tube versions on:
 - Welch Allyn Soft (CE marked, **already released**)
 - Trimline Soft (not CE marked, will be released Q4 2015)
 - Trimline Vinyl (not CE marked, will be released Q4 2015)
 - Cardinal (not CE marked, will be released Q4 2015)

Example Part Numbers	
NEO-1-1	CUFF, NEO 1,1-TUBE,WA SOFT DISP,ISO 10/BX
NEO-1-1TLS	CUFF, NEO 1,1-TUBE,TL SOFT DISP,ISO 40/CS
NEO-1-1TLV	CUFF,NEO 1,1-TUBE,TL VINYL DISP,ISO 40/CS
30502110SP	CUFF,NEO 1,1-TUBE,CARD SOFT,ISO 40/CS



CSM and CVSM Neonatal Hoses

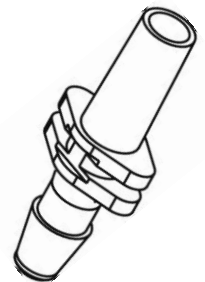
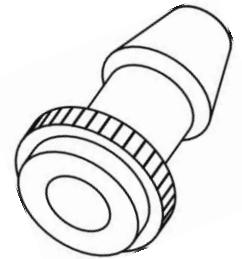
- The CSM and CVSM can use the same neonatal hose.
- We have a version that still has the old luer slip and a new version that has the ISO compliant connector.
- Customers can choose between both options for CVSM and CSM.
 - **6000-33**: still uses the luer-slip style connector and will work with the 5082 series Neonatal Cuffs (ex. 5082-101-1)
 - **7000-33**: uses the new ISO compliant Snapquick connector, customers would have to use the new Neonatal cuffs (Neo-1-1)



Internal Use

What you may hear from Customers

- I ordered the DS66 – now it doesn't work with my other cuffs. We never had this problem before.
 - Reason: Welch Allyn has replaced the Male Luer Lock connector with the Female Tri-Purpose connector on all DS65 and DS66 Trigger Style Aneroid Gauges
- The connector on my BP cuff is different
- The cuffs are missing the lips on the inside of the connectors and the interim holes are smaller



What you should do if you hear something like this from a customer

Before replacing any product, or creating a complaint:

- If possible, verify the part number the customer ordered or has in hand
- Check if the part number is in the material list in the file ***Elimination of Luer Compatibility ISO 81060 Update***
- Refer to **What do Customers need to do** sections
 - For customer satisfaction (if customer pushes back or claims they should not have to purchase additional connectors) you may send replacement connectors out at **no charge**
 - Make sure customer understands what they need to purchase for next time
- You may send ***Elimination of Luer Compatibility ISO 81060 Update*** and ***Common Connectors used by Hospitals Slide*** to customers if needed