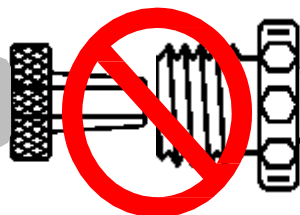


August 5, 2015

As required for compliance to the latest ISO Standard (ISO 81060-1), components of blood pressure measurement systems are no longer allowed to be supplied with luer-lock or luer-slip compatible connectors. As a result, the following product changes have been implemented on blood pressure cuffs and aneroid gauges.

SCREW Configurations:**FlexiPort -1SC & -2SC configurations****Trimline 1 & 2-tube screw configurations (including Neonatal cuffs) Private Labeled 1 and 2-tube screw configurations:**

1. The female screw connector used on the above referenced cuffs traditionally had an internal lumen profile that would allow insertion and capture of a male luer slip connector. We have eliminated that feature in all Screw type connectors to be compliant to ISO 81060. This has not affected the ability to mate with device side (male) screw connectors.



2. Trimline disposable and reusable cuffs with female luer slip connectors have been discontinued.
3. Neonatal Cuffs with male luer connectors remain available in the US and other non-CE countries.

What do Customers need to do:

If a customer was using the cuff side screw connector as a luer slip, they will need to change the connectors on their Device hoses to the mated-screw connector which is part # **5082-174** (10 per bag). If the facility/hospital has many devices that need to be changed, they can contact their Field Sales Representative to discuss other options, for example, converting to the FlexiPort connector which is compliant to the ISO 81060 standard and Welch Allyn's conversion team can assist them with the change of their connectors.

TriPurpose (TP) Connector:

The Female Luer Slip and Female Luer Lock capabilities of the TriPurpose connector are being removed in two phases. The first phase of the change resulted in a reduction to the inside diameter of the TP connector which now prevents insertion of male luer-slip and luer-lock connectors. Once tooling changes are complete, the outside male threads that comprise the “lock” feature of the female luer lock will also be removed. The TriPurpose connector is now a “UniPurpose” connector, but the TP code in all part numbers will remain unchanged.



Phase 1 (Completed): Cuff side TP Connector looks unchanged but female luer profile has been removed.



Phase 2: Once tooling changes are complete, Male Luer Lock thread will be removed leaving only the TP Male screw that mates with the device side female TP connector

What do Customers need to do:

Customers that were using the tripurpose cuff side connector as a luer-lock or luer slip can change their device side connector to the female Tri-Purpose connector which is part # **5082-100** (10 per bag). The 5082-100 is compatible with the redesign of the cuff side tri-purpose connector.

DS65 & DS66 (Trigger Style) Aneroid Gauge:

Welch Allyn has replaced the Male Luer Lock connector with the Female Tri-Purpose connector on all DS65 and DS66 Trigger Style Aneroid Gauges



Before
Luer-Lock Male



After
TP Female

What do Customers need to do:

Customers that have devices with the luer-lock fitting can change their device side connector to the female Tri-Purpose connector which is part # **5082-100** (10 per bag).

Classic Handheld Gauge:

The Tycos Classic Hand gauge has a male luer on top of the gauge, where the BP hose connects. We had to stop selling cuffs with the female luer connector due to the ISO Standard. We also had to modify the TriPurpose connector: the outside male threads that comprise the “lock” feature of the female luer lock will also be removed. The TriPurpose connector is now a “UniPurpose” connector, but the TP code in all part numbers will remain unchanged. The modified TP connector will not fit on the Classic Gauge now.



Gauge



Adapter

What do Customers need to do:

Customers will have to put the above adapter on their gauge to connect to our TP connectors on our cuffs. Welch Allyn will have a stock of adapters that we can send out to customers using the Classic Handheld gauge. Customer Service Rep will collect the below information and fill out a manual ship form. Once they have that completed, they will obtain the connector(s) from Jamie Bruno and mail them out.

Name of Facility

ATTN: Person and Department

Street Address

City, State, Zip

Quantity Needed

SAP Process:

1. Create RMA
2. Short Text: Luer Connector Adaptor
3. Subject Code: Done
4. Material field: 5098-03
5. Long Text: Customer requested adaptor. “NO YR Required. This is not a complaint because it is regarding customer request for new adaptor per ISO Standard (ISO 81060-1).
6. Give customer RMA number for reference, set expectation they will receive adaptor within 5 business days.

For those interested in the specific clauses in the new ISO standard, these are listed below:

Subclause 7.2.6 Tubing connectors

This requirement addresses the known hazards associated with cross-connections. There is a demonstrated unacceptable risk associated with the use of Luer connectors with patients, including neonatal patients, in the cuffs and tubing. Three-way adaptors are readily available in the clinical environment, so that a reverse Luer connector affords very little protection from this risk.

7.2.6 Tubing connectors

Tubing connectors, if provided, shall incorporate a means of preventing accidental disconnection. Tubing connectors shall not be equipped with a connector that connects with a connector complying with ISO 594-1 or ISO 594-2.

Normative references

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment —*

Regards,

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