FAQ for the UK NHS

NEURAXIAL (ISO 80369-6)

CONNECTORS CHANGEOVER

Last Updated: 2017-06-29

Note that there are some UK devolved administration-specific issues which are dealt with at the end of this document.

General questions related to the UK

1. What is a small-bore connector?

- A small-bore connector is a connector with an inner diameter of less than 8.5mm used to connect medical devices, components and accessories for the purposes of delivering fluids or gases.

2. What changes are coming to small-bore connectors?

- The International Organisation for Standardisation (ISO[1]) has developed a suite of standards for small-bore connectors, known as ISO 80369 series. These standards provide design and performance specifications for a range of connectors which can be used for different medical device applications (see table below) and which have been shown to reduce the risks of cross-connections between applications.

80369 part	Use/Application	Common Name
-2	breathing systems and driving gases	
-3	enteral applications	ENFit
-4	urethral and urinary applications	
-5	limb cuff inflation	

[1] ISO (International Organization for Standardization) is the world's largest developer of voluntary International Standards. It has published more than 19,500 International Standards covering almost all aspects of technology and business and has members from 163 countries.

-6	neuraxial applications and major regional anaesthesia	NRFit
-7	intravascular or hypodermic applications	Luer

3. **When will the changeover take place ?**

- The NHS England Small Bore Connectors Clinical Advisory Group worked with the Devolved Administrations, including the Welsh Non-Luer Connectors Reference Group (WNCRG), as well as Scottish and Northern Ireland representatives on a coordinated date for UK NHS introduction of the new devices.
- **The intention was to start in April 2017, although it is now (June 2017) clear that most manufacturers are already significantly delayed, with some starting rollout in Aug 2017, and other s delayed until early 2018.**
- A communication is available on the AAGBI web site: https://www.aagbi.org/safety/non-luer-small-bore-connectors

4. **Will non-Luer new medical connectors have distinct names?**

- Connector naming is not included in the ISO 80369 series of standards. Therefore, companies are free to name the new connectors as they choose.
- An industry organisation known as GEDSA and members of the ISO joint working group have proposed the use of the name “NRFit” (pronounced ‘ner-fit’) for the new connectors used for neuraxial and major regional applications. NRFit is a name that will be used to identify devices that comply with the ISO 80369-6 standard.

5. **Why is industry adopting the new ISO neuraxial connector?**

- The standard small-bore connector in the medical device field for many years has been the Luer connector. Because the Luer connector was such an effective and reliable design, it has been used in many different types of device applications, such as vascular, enteral, respiratory, epidural, and intrathecal. The consequence of this has been that devices that were never intended to be connected together can, in some circumstances, allow the fatal wrong route administration of fluids and gases such as the delivery of toxic chemotherapy drugs into the spinal canal.
- The NPSA (National Patient Safety Agency - now dissolved) published a series of alerts in 2009 and 2011 requiring the UK NHS to use non-Luer devices for neuraxial bolus doses and infusions. This was partly successful with many English Trusts adopting proprietary systems for chemotherapy use in particular. Other Trusts and the Devolved Administrations of Wales, N Ireland and Scotland decided to wait for the ISO standard to be published.
- As well as preventing the delivery of IV drugs into the neuraxial space, use of the ISO 80369-6 connectors will also prevent wrong-route delivery of neuraxial medicines (such as bupivacaine) intravenously.

6. **What are the implications of these new standards?**

- Unique connector designs promote better patient safety and helps ensure that connectors for unrelated applications are incompatible. This reduces the chances of wrong route injections and infusions and the harm and death associated with these incidents.
- Syringes used for intravascular and hypodermic access will no longer be interchangeable with neuraxial syringes. For manufacturers and suppliers this may cause temporary inconvenience as procedure packs may be more difficult to customize. Clinicians need to be aware of what extra items they use which will in future need to be 80369-6 compliant, as those will need to be ordered specifically (for example three-way taps, epidural filter caps and manometers etc) : as pulling those from intravenous supplies stock will no longer suffice.
- Pharmacy departments preparing medicines for intrathecal and epidural use (for example, aseptic preparation of intrathecal chemotherapy preparations) will also have to ensure they have appropriate stocks of syringes, syringe caps, filling devices, filters and other equipment necessary to fill and dispense using the new connectors.

7. What connectors are affected by the ISO 80369-6 (NRFit) connector standard?

- 80369-6 applications involve the use of medical devices to administer medications to and take samples from neuraxial sites (central nervous system including intracranial and spinal canal such as epidural and intrathecal), major peripheral nerve local anaesthetic blockade and continuous wound infiltration. This includes anaesthetic delivery, monitoring cerebro-spinal fluid (CSF) pressure, and removing CSF for therapeutic or diagnostic purposes.
- It should be noted that there are risks from delivering neuraxial medications intravenously, such as bupivacaine, and whilst the ISO connector will address the near-patient misconnection risk of attaching a neuraxial giving set to an IV cannulae, there is still the risk of misconnecting the reservoir (i.e., the infusion bag) to an IV line as presently they all use the same spike connector. Work is underway within ISO to design connectors for the reservoir end, but this is still a few years away.

8. **Who developed the new ISO 80369-6 connector design?**

- This new connector design was developed by ISO through the combined global effort of clinicians, regulators, test houses and industry. The initial design came from a UK anaesthetist, Dr Philip Bickford-Smith.
- The ISO 80369-6 connector has undergone a rigorous validation process including computer aided design (CAD) misconnection tests, laboratory leak testing and human factors and usability assessment.

9. **Why should we adopt the new 80369-6 connector?**

- The ISO 80369-6 connector provides a simple way to reduce the risk of neuraxial misconnections which in turn should improve patient safety.
- The new connector reduces the chance of an unintentional cross-connection with any other connector intended for non-neuraxial routes.
- In some countries, the legal systems expect clinical staff to take all reasonable steps to mitigate the risk of cross-connection incidents, and therefore may expect clinical staff to use devices that use these application specific connectors.
- Non-adoption of the new connectors may expose clinical staff and organisations to legal challenges if further wrong-route incidents take place which could have been prevented by use of ISO 80369-6 compliant devices.
- Because industry is adopting the new standard, it is expected that at some time in the near future, Luer versions of neuraxial devices such as spinal needles will no longer be available.
- Note that wrong-route injections and infusions continue to take place in the UK NHS.

10. **What makes the new ISO 80369-6 connector different from the current Luer system?**

- The new ISO 80369-6 connector looks like a Luer connector, but is about 20% smaller and has a unique design that reduces the risk of cross connection with other connectors developed under the same series of standards, especially with Luer connectors. There is one visible difference: slip males will have a collar surrounding the connector, as currently only seen in Luer locking versions.

11. **When will the new ISO 80369-6 connector be available?**

- Neuraxial devices with the ISO 80369-6 connector are expected to be available starting Q3 2016 in the U.S., Canada and other markets.
- The UK is expecting to start the deployment of these devices from April 2017. This date was discussed and agreed between industry and the NHS England Small Bore Connectors Clinical Advisory Group.
- The ISO 80369-6 connector should be introduced into use with minimal disruption. Timing is subject to change pending regulatory agency clearance and each manufacturer's readiness. In Europe, manufacturers may need to involve their Notified Body before devices are available. Check with your supplier representative for precise timing and device-specific details.
- The April 2017 date is thought to be the earliest the industry marketplace will offer a complete range of equipment solutions.

12. **How will the new ISO 80369-6 connector be introduced into my healthcare organisation?**

- This will vary throughout the UK. See the country-specific sections at the end.

13. **How is industry coordinating their efforts ?**

Industry are working both on their own and through GEDSA and BAREMA There is general agreement to:

- Develop and execute a coordinated communications initiative
- Use a common brand name for the ISO-80369-6 connector – NRFit.
- Use the same time frame to introduce neuraxial devices with the new connector

As of Jan 2017, most of the key suppliers are aligned with the this initiative.

14. **If we use Neuraxial parts from another manufacturer's set, how will we know the products will work together?**

- As long as the connectors have been produced in compliance with the ISO standard, then it is expected that the devices will connect together effectively and safely.
- All major neuraxial device manufacturers are expected to comply with the proposed new ISO standards to help ensure neuraxial components fit together as a system.
- Many compatible devices will be marked with the NRFit label or with the standard number (ISO 80369-6).
- For clinician convenience, some items, such as syringe plungers, are expected to maintain the yellow colour seen in most proprietary non-Luer syringes in current use.

15. **Is it mandatory to transition to the new ISO 80369-6 connector?**

- There is no legal requirement to make the transition. However, there is an expectation that all UK organisations providing NHS funded care will implement the new connectors, in line with the NPSA safety alert of 2011 (NPSA/2011/PSA001).
- Organisations which fail to change to non-Luer connectors may find themselves exposed legally if a wrong-route incident occurs and they have not used devices which may have prevented that incident.
- As the ISO 80369 series is stimulating a global change in connectors on neuraxial devices, it is expected that eventually all suppliers will have moved to the ISO 80369-6 connector, and Luer-compatible neuraxial devices will be rare.

16. **When will the neuraxial devices with current connectors be discontinued?**

- Discontinuation of items is at the sole discretion of manufacturers. For precise timing of item discontinuation, contact your supplier representative. The Luer connector for neuraxial devices will be phased out of hospitals on varying timelines.
- Hospitals using the Surety connector should check with their suppliers if there is a date after which their devices will no longer be available with the Surety connector.
- It is important to understand that some devices, such as spinal needles, are presently used for non-neuraxial applications, such as amniocentesis and joint injections (sometime called 'off-label' use). The use of long needles with a Luer connector will still be required by these specialists (for example, orthopaedic surgeons) after the change to 80369-6 connectors, and some manufacturers have declared their intent to market such devices to meet clinical needs. You should therefore start contacting the suppliers of the

needles you presently use and ask them what plans they have for long needles with Luer connectors in the future. There is a risk that clinicians undertaking some clinical procedures may find there is no suitable device available after the withdrawal of Luer-based spinal needles from the healthcare setting. If there is no alternative option a clinician may decide to use the ISO 80369-6 devices off-label i.e. for a purpose other than that what it was intended by the manufacturer. The MHRA has published guidance on off label use of medical devices including considerations and recommendations for clinicians. You should also ensure that you follow your local governance and risk management procedures, which may include documenting the usage in your local risk register or local governance system.

- Liaison with the specialist clinicians who use spinal needles 'off label' should also be undertaken to ensure that they understand the change and what options will be available to them post-change.

17. **Will there be new Catalogue numbers for the new 80369-6 devices ?**

- Introduction of new items and related issues such as new item numbers are at the sole discretion of manufacturers. For precise answers relative to new item introductions, contact your supplier representative.
- In the UK, clinical incidents have already arisen over confusion between proprietary neuraxial connector devices and standard Luer devices, resulting in delays to treatments. It is therefore anticipated that many manufacturers will use product codes that allow individuals to distinguish easily between Luer, ISO 80369-6 devices to avoid such incidents.
- In parts of the UK, where proprietary non-Luer connectors are already in use, the codes will also be different, and there will be need for additional vigilance in these settings.

18. If applicable, when will the new catalogue numbers be available and how will we know when to order the new devices ?

- Introduction of new items and related issues, such as new item numbers, are at the sole discretion of manufacturers. For precise answers relative to new item introductions, contact your supplier representative.

19. Will there be a price increase?

- Pricing is at the sole discretion of device manufacturers.
- Some manufacturers involved in supplying proprietary non-Luer systems in the UK have kept their prices stable.

20. **Will there be a standard colour for the 80369-6 connector?**

- Colour-coding is not included in the ISO 80369 series of standards. The standards will only address the shape and size of the new connectors. These engineering controls make it unlikely that two unintended connectors will fit together. While you might see a consistent colour used for devices with neuraxial connectors, it is not a requirement.

There is, however, a trend in parts of the world to use the colour yellow to indicate neuraxial routes. This feature would be provided for convenience, not safety.

21. **Does this new system require that devices using the Luer connector become obsolete?**

- The Luer connector will still be used for intravascular and hypodermic access and now has its own standard in the ISO 80369 series – ISO 80369-7 (this was previously a separate ISO standard, ISO 594).
- It is, however, expected that availability of *neuraxial devices* using Luer connectors will decline rapidly because of the significant patient safety benefits associated with a connector which will not cross-connect with Luer. One of the most effective ways to comprehensively reduce the risk of misconnections and enhance patient safety is to ensure that connectors of different delivery systems (i.e., neuraxial and intravascular) are not compatible.

22. Will there be adapters for different kinds of syringes?

- There will be no adapters. Syringes will be supplied with the application specific connector.

23. Is there any specific action required for pharmacy departments ?

- Yes. Pharmacy departments undertaking pre-filling of syringes for neuraxial/intrathecal use (such as those for spinal chemotherapy, antibiotics and pain management) will be using new ISO-compliant neuraxial-specific syringes, and should instigate a formal, documented change control process which covers changes to policy, worksheets (which will in future need to be be specific regarding the connector on the syringe), training, and awareness . This must be managed locally as part of a multidisciplinary approach.
- Due to the potential change in handling and connecting the new devices, it is recommended that pharmacy departments undertake broth fills as part of the initial validation run for ISO 80369-6 compliant devices.
- Pharmacy departments should also ensure that they have appropriate evidence to support any storage requirements they have for the new syringes. This could be produced by industry or by the departments themselves.
- As of December 2016, we are aware that Intervene and B.Braun intend to supply neuraxial syringes and were in the process of commissioning stability and storage validation studies with UK NHS laboratories. The protocol agreed by UK production and QA pharmacists is available on the PASG website.

- Pharmacy departments using bulk-sterilised syringes (from companies such as Helapet, MicronClean, AMD and Ecolab) should ensure their supplier has a plan of action to make the ISO 80369-6 syringes and ancillary equipment available prior to implementation or ensure that they can make alternate arrangements. The current main supplier, BD, will not have product available in time for the April 2017 target date.

- See next question for information on elastomeric and cassette devices.

24. Will elastomeric and cassette delivery devices for analgesia be affected ?

- Yes. Elastomeric devices and cassettes for epidural/regional use will need to have an ISO 80369-6 (NRFit) connector on the line that connects to the patient. We believe that some suppliers will be ready in Q2 2017, although timescales for all suppliers are not yet fully understood.
- **Elastomeric devices**: Eventually the filling port on elastomeric devices for epidural/regional use should also be ISO-compliant but timescales from industry are not yet available.
- **Cassettes:** Because cassettes are filled through the administration line there is no separate requirement for a filling port on these devices. Small scale filling of these cassettes for epidural/regional use could be carried out using NRFit syringes. However, for larger scale batch production this may present an issue for aseptic units (NHS or commercial) using automated filling pumps until the filling lines used in these pumps become available with an ISO compatible connector for connection to the cassettes.
- We advise NHS and commercial aseptic compounding units, using automated filling pumps to fill these devices for epidural/regional use, to raise this issue with their pump manufacturer. Whilst initially this will only be a problem for cassette filling, in the longer term it will also apply to elastomeric devices for epidural/regional use when the manufacturers of these devices change the filling ports from luer to NRFit connectors.

25. Are there any specific actions for EBME/Medical Physics departments ?

- Yes. If your hospital uses syringe drivers for intrathecal or epidural infusions, you will probably have to set the driver up for one of the new designs of neuraxial syringes.

26. What about specialist areas of anaesthesia such as Caudal injections ?

- At present anaesthetists in the UK use IV devices to undertake Caudal injections (such as a non-ported IV cannula or hypodermic needle). In future, accessing the neuraxial/epidural space with these Luer devices may be classified as ‘off-label’. The solution is to use a specific caudal device utilising the ISO 80369-6 connector, but at the time of writing no such device is available. Until industry manufacture such a device, organisations providing NHS funded care should manage the risk through their risk register.

27. What about highly specialist areas such as implantable pain management systems ?

- Implantable reservoirs and vascular access ports usually use special non-coring needles, commonly known as Huber point needles . They are used to penetrate the skin and the septum of a reservoir or access port underneath the skin. If these ports are connected to the neuraxial system, then theoretically the Huber needle should use a

80369-6 hub. As a result of their highly specialised nature, the production of such devices is at the discretion and control of the manufacturers. It is unclear whether industry will have these available in the near future, and therefore plans should be made to manage these devices through the risk register initially.

28. How will training be provided ?

- Training is expected to be coordinated by the local hospital groups in conjunction with Procurement.

- When planning the training programme for the deployment of ISO 80369-6, we recommend that you train your acute pain management teams first, as in many hospitals it is this group who train ward staff.

29. Do we need a Plan B in case we encounter problems with the new ISO compliant devices ?

- A phased rollout within an organisation would mean that Luer or proprietary non-Luer devices were still available in the organisation if necessary, especially in the early stages when it is more likely that issues would be encountered. It may be prudent to keep a supply for the first few weeks. The expectation is that the risk with ISO should be lower than with the previous proprietary connectors as it is a single design. Issues should be reported on a case by case basis and risk assessments made to decide on continuing use of the ISO system where required.

30. Is there any documentation which would help my organisation deploy these new devices ?

- Yes. A HOWTO document has been authored by two clinicians involved with the deployment of Surety devices in NHS organisations in England. It is available at this link: https://goo.gl/mERxFo

31. Are External Ventricular Drains (EVDs) covered ?

- Yes. The clear intent in the UK from the original NPSA alert was that EVDs would be covered. The February 2011 Newsletter (Page 4) clarifies this.
- In addition the Scope of ISO 80369-6 states:
    - *NOTE 1 Sites for the neuraxial application include the spine, intrathecal or subarachnoid space,* ***ventricles of the brain,*** *and the epi-, extra-, or peri-dural space. Neuraxial application anaesthetics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the branchial plexus blocks or single nerve blocks. Neuraxial application procedures include continuous infusion of wounds with local anaesthetic agents.*

- As of September 2016, it appears unlikely that EVDs will be available with the new connectors alongside the rest of the ISO compliant equipment and Trusts, Health Boards

and other providers of NHS funded care should initially manage through their risk register. Industry have signaled their intent to make ISO compliant EVDs available but we do not have anticipated timescales as yet. [June 2017 update: there are still no timescales available for EVD's]

32. Should spinal needle introducers use the new connector ?

- In the UK the consensus has been that a non-Luer connector (in this case, an ISO 80369-6 connector) on the introducer both prevents the wrong route injection of IV drugs (which would be possible with a Luer connector) and allows the clinician, in rare circumstances when they may accidentally pierce the dura with the introducer, to deliver spinal medication if necessary.
- The alternate view is that it should have no connector (for example, a Sise introducer).
- Luer 80369-7 connectors should not continue to be used on introducer needles once ISO 80369-6 has been deployed, because it introduces the risk of giving IV medications spinally if the introducer pierces the dura.

Questions specific to the NHS in England

1. **How will the new ISO 80369-6 connector be introduced into my healthcare organisation?**
   - There is no central co-ordination of introduction to specific organisations through the NHS in England. Each organisation will be responsible for establishing its own multidisciplinary group to facilitate the introduction process.
   - Most major manufacturers have adopted the ISO 80369-6, NRFit system. The intention, therefore, is to be able to simply change your current device, Luer or proprietary non-Luer, to a new device with the NRFit connector from the same manufacturer. This may require waiting past the April 2017 initiation date if your specific manufacturer will not be ready at that time.
   - April 2017 is the date, from extensive industry meetings, when we believe the marketplace will contain a full range of essential compliant devices. They are unlikely to be from a single manufacturer and may not contain your current supplier. It will, however, allow organisations wanting to change their devices to do so from that date onwards if the devices available meet with clinical acceptance.
   - There is guidance on establishing a multidisciplinary group (HOWTO document), including projected timescales required available from OAA, AAGBI and BAREMA
   - Individual industry members and the BAREMA special interest group, accessed via www.barema.org, will be in a position to guide their customers to appropriate device availability and advise on the levels of support they can offer to facilitate a smooth transition in each clinical area.
   - Device issues should be logged using your current organisations reporting system and referred to the MHRA.

2. **Will there be new Catalogue numbers for the new 80369-6 devices?**

- Manufacturers are being encouraged to ensure their product codes are easy to distinguish between both Luer and proprietary non-Luer devices already in use across England.
- NHS Supply chain will be in a position to help guide organisations with accessing the knowledge they require to facilitate production selection.

Questions specific to the NHS in Wales

1. **How will the new ISO 80369-6 connector be introduced into my healthcare organisation?**

- In Wales, the introduction is being coordinated by the WNCRG (Welsh Non-Luer Connectors Reference Group) in conjunction with NWSSP procurement and local Health Board representatives.
- The principle being followed in Wales is that clinicians continue to use the same brand and design devices currently in use, where the only difference is that they will have the new ISO 80369-6 connector attached. The aim of this strategy was to minimise disruption during the changeover. As of June 2017, we are now aware that BD will not have 80369-6 compliant product available until sometime in Q2/3 2018.. Most other key equipment manufacturers continue to expect product availability between Aug 2017 and Spring 2018.
- We are planning to wait until all of the essential equipment is available before beginning the implementation.
- Healthcare facilities and providers will also be able to call upon industry to help them with a careful transition plan to replace Luer devices with the new ISO 80369-6 connector.
- Public Health Wales have been funded by Welsh Government to undertake baseline surveillance of neuraxial procedures prior to the changeover, as well as surveillance post-changeover (for 6 months). The aim of this exercise is to ensure that no new risks are introduced for patients and staff with the new devices. All NHS staff involved in the use of these devices should participate in the surveillance exercise. See http://www.wales.nhs.uk/sites3/page.cfm?orgid=457&pid=72625 for information on the surveillance exercise as well as links to access the reporting forms.
- As usual, any device issues should be reported in compliance with the NHS Wales requirements (http://www.wales.nhs.uk/sites3/page.cfm?orgid=465&pid=56203)
- We expect the first Welsh hospital to change to ISO-compliant equipment in Q3 2017.

2. **Will there be new Catalogue numbers for the new 80369-6 devices ?**

- In Wales we are encouraging manufacturers to use significantly different catalogue numbers for Luer and non-Luer devices to help differentiate them in the supply chain and in the clinic.

3. **Are there any risk register templates available ?**

- Yes. Welsh NHS staff can access them from the neuraxial web page

4. **Who do I contact for further information ?**

- You can contact the chair of the WNCRG, Pete Phillips <pete@smtl.co.uk>.

Questions specific to the NHS in Scotland

Who do I contact for further information in Scotland ?

- The lead in Scotland is Terry O'Kelly, consultant surgeon and Chair of the non luer group: <tokelly@nhs.net>
- For Procurement related issues, please contact Alex Little <alex.little1@nhs.net> (Commodity Manager, National Procurement NHS National Services Scotland), Tel: 01698-794525.

Questions specific to the NHS in Northern Ireland

Who do I contact for further information in Northern Ireland ?

- Please see http://www.hscbusiness.hscni.net/services/1908.htm for contacts for Northern Ireland.

RESOURCES

1. A video is available which can be used in training sessions to help increase awareness of the changeover.
2. A HOWTO document with advice on managing a controlled changeover on a hospital by hospital basis.

3. BAREMA Portal with information on individual company information, and links to the HOWTO, FAQ and Video.
4. The Jan 2017 Anaesthesia News has an article on NRFit
5. AAGBI have a page on this topic.

This FAQ is based on an original FAQ coordinated by Rory Jaffe at CHPSO (California Hospital Patient Safety Organization) and GEDSA (Global Enteral Device Supplier Association) including contributions from a number of UK experts. The panel who have edited it for the UK includes Pete Phillips (Chair of the Welsh Non-Luer Connectors Reference Group), Paul Sharpe (Chair of the NHS Improvement Neuraxial Oversight Group), and Matthew Alderman (NWSSP Procurement and member of the WNCRG).