

## ISO 80369-5

### Blood Pressure (Limb Cuff Inflation)

- Connector test protocol and validation tests with respect to interconnectability and functionality are complete
- The standard is expected to publish by the end of 2015

## ISO 80369-6

### Neuraxial Devices

- Standard work is in ISO, Geneva
- Efforts to delay the implementation of CA Mandate Bill AB 1847 has passed through multiple steps and is awaiting the Governor's signature. A successful resolution will push the deadline to January, 2017.
- The standard is expected to be published by the end of 2015

## ISO 80369-7

### Intravascular (IV) or Hypodermic

- DIS complete
- Validation testing is underway
- FDIS submission still to happen
- The standard is expected to publish in early 2016

## When Will it Come into Effect?

ISO 80369-1 is published and active currently. There are several requirements that can be followed to ensure non-interconnectability with connector sets based on criteria outlined within the standard. Determining the exact time the 80369 sub-standards will come into effect can be a difficult task as they are still under development. Our team is on the front lines in the development of these standards, allowing us great insight to when these standards will be released. We will be updating our website regularly to when these changes will occur as we get more information.

## How Does it Impact Me?

Compliance with the ISO 80369 standard may require major changes on the part of medical device manufacturers. In the next few years, if these standards are approved it could mean new designs, new parts, new moldings and updating or replacing millions of components. The 80369 standard series will eventually define connector set geometries for specific applications, meaning new connectors will be needed to replace luers in a multitude of areas. Nordson MEDICAL has taken a very active role in the development of these standards to help reduce the impact of this change on our customers.

## How Can I Prepare?

While the standards have not yet been completely established, the main precaution that medical device manufacturers can take to help prevent any future problems is to stay up-to-date on ISO 80369 news. Nordson MEDICAL is one of only a few connector companies worldwide actively participating on ISO 80369 committees. To keep the medical device community apprised of new developments, we have chosen to provide information in one web location. Nordson MEDICAL has set up an online resource to help medical device OEMs stay informed of the changes and updates to this standard.

To read the latest updates, subscribe to alerts, and view related resources, go to Nordson MEDICAL's online resource at [i8.nordsonmedical.com](http://i8.nordsonmedical.com).