

## What is UDI and why it is important for Healthcare

Bar codes have been used for many years in the retail industry and, for logistical purposes, on shipping containers used by manufacturers, including those making medical devices. Today there are revolutionary developments taking place worldwide, which will mean that unique identifiers (e.g. bar codes) will be required to be placed on medical devices. This will have many benefits:

- **Improved patient safety:** making it easier to trace devices and, where appropriate, record which patient they have been used on;
- **Better regulatory control:** more accurate identification of devices if there is a product recall;
- **More efficient business processes:** improved monitoring of usage and costs for both industry and healthcare providers.

This development is known as UDI (Unique Device Identification) which is a requirement for medical devices to carry (on the labelling and in some cases directly on the device) a unique machine-readable identifier. The UDI is a series of numeric or alphanumeric characters created through a global coding standard allowing the unambiguous identification of a specific medical device. It should also be noted that in UDI the word 'unique' does not imply device serialisation. Only certain devices will need to be identified individually rather than by their production lot/batch.

It is only relatively recently that the potential benefits of UDI have become apparent. Today, the authorities both in the USA and Europe are addressing UDI by creating legislation, which will require all medical device manufacturers to mark their products with a unique identifier. The EU will incorporate UDI in the revised Medical Device directives and the US FDA is preparing similar legislation. Both participate with other regional authorities in a group which is working to harmonise requirements for UDI globally. By 2018 all devices will be required to have a unique identifier, although in some countries it is already a regulated requirement, which industry should not overlook.

The devices industry works closely with GS1, a not-for-profit organisation which is the issuing agency for the majority of bar codes used globally, across all industry sectors. GS1 Healthcare has set up a global network of device industry and healthcare professionals to develop specific standards for UDI. This approach is supported by the FDA, the EU Commission as well as authorities in the UK, Australia, Japan, India and an increasing number of other countries.

UDI will undoubtedly bring many benefits and it will also reduce healthcare costs by improving efficiency. However, like so many cost saving initiatives, it will also involve initial up front expenditure particularly by industry. As with any new revolutionary development, there are a number of concerns:

- **Health Systems need to invest and upgrade:** It is vital that authorities worldwide take the necessary steps to ensure that their systems are able to respond. The legislation will be directed only at the manufacturer who will face significant costs in altering production and labelling lines, creating extensive databases (UDID) and support mechanisms. If there is no equivalent high level of awareness and commitment to training and updating equipment on the part of healthcare providers, then the potential benefits of UDI, not to mention the significant investment by industry, will be lost.
- **One Globally coherent UDI:** A product should be identifiable anywhere in the world. However authorities must not 'jump the gun'. Enthusiasm to implement UDI and set up databases (UDID) is commendable but it should only be done with full regard to the developing legislation and to global standards. Local (regional or country) deviation can have a negative impact on supply chain security and efficiency, generates associated unnecessary costs and can create unforeseen risks.
- **Pragmatic Approach:** To take account of the scale of the project, (nearly 500,000 types of products from many thousands of manufacturers, worldwide) it is important that such a wide ranging requirement as UDI is introduced in a pragmatic manner which requires full co-operation between all parties involved.

UDI is a 'key' to improved process and therefore greater safety and reduced costs in healthcare. Without UDI these process will be difficult or impossible to achieve electronically and extremely cumbersome to handle manually, with further risk of inaccuracy due to manual intervention in data entry. For this reason UDI deserves the support of all concerned: industry, healthcare providers and the authorities.

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