



EXECUTIVE SUMMARY OF AUTOMATIC IDENTIFICATION AND DATA CAPTURE (AIDC) ROLE IN IMPLEMENTATION OF THE UDI RULING

Automatic Identification and Data Capture (AIDC) technologies, also referred to as **Automatic Identification Technologies (AIT)** are all around us. Our modern economy wouldn't function as well as it does without it. Retail stores everywhere rely on AIDC so that even children understand the ability to glean data from the barcode on toy packaging. In fact, UPC barcodes have been made into toys and games. Nearly everyone at one time or another has used AIDC while trying to speed their grocery store exit through the self-checkout line or stood and watched as a cashier has scanned item after item placed in front of them.

AIDC technologies include a wide range of solutions, each with different data capacities, form factors, capabilities, and "best practice" uses. While everyone is familiar with the UPC barcode, there are other forms of AIDC which are routinely used but the users may not fully appreciate the functionality of the technology. The common vehicle EZPass is a great example. EZPass is a form of AIDC, in this case radio frequency identification (RFID), that automatically collects and moves data. Barcodes, RFID, contact memory buttons and many other forms of AIDC all serve to address specific data collection and data use needs. AIDC technologies also include mobile computing devices that facilitate the collection, manipulation, or communication of data from barcodes and RFID tags as well as through operator entry of data via voice commands.

UDI Background

Medical devices are an integral part of the Global Health Care System. Advances in devices and implants has led to a longer and improved the quality of life for countless patients. However, not all patient interactions with medical devices have proven to be trouble-free. Recalls, adverse events, and post-market surveillance of medical implants have been cumbersome, and are marginally effective in the healthcare industry. Documenting and identifying which patient has what implant has been accomplished through mainly human data entry.

Regulatory Response to Track & Traceability of Medical Implants:

- Unique Device Identifier (**UDI**): In 2012 the FDA enacted the [UDI](#) final rule which requires that every medical device must bear a unique identification marking (device identifier and production identifier) as the first stage in developing an AIDC enhanced medical device tracking system. By mandating UDI's, the FDA is better able to detect adverse events, reduce counterfeits, improve product recalls, and enable a robust post-market surveillance program. All lifesaving and life supporting medical devices which are intended to be re-sterilized are required to bear permanent human and *automated markings* to satisfy the UDI requirements. Further, the FDA has opined that their preference is the use of AIDC technology to collect the device UDI at the point of care. UDI's were designed to identify each individual medical device. Similar track and trace provisions are included in the EU [MDR](#) and [IVDR](#).
 - Undertaking such an aggressive and multi-stakeholder global effort has been daunting. There have been multi-stakeholder committees formed to develop industry standards and utilization throughout the supply chain up to the point of implant. Automated



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programs are beginning to become more common-place for tracking medical devices from the manufacturer to end user. However, documentation at the point of implant has been the most problematic for accurately matching patients to their specific implants. Even though most of the procurement of medical devices are capable of automation for the surgical documentation of patients. However, today this process is primarily *manual*, and prone to human data entry errors.

- The Office of the National Coordinator for Health Information Technology (**ONC**): The [ONC](#) has mandated that UDIs will be included as part of the EHR's Common Clinical Data Set (CCDS). The intention of the mandate is to ensure a patient's CCDS will follow the patient throughout their life as they encounter providers in different healthcare systems. Access to the standardized CCDS allow clinicians the ability to accurately identify a patient's medical implants and associated safety characteristics.
- The Centers for Medicare & Medicaid Services (**CMS**): [CMS](#) has mandated that UDIs be included in claims forms and expects the data to be captured via AIDC technology and transmitted electronically. Gathering data from claims, EHRs, and registries will help to monitor the efficacy of medical devices as well as use the data to improve patient outcomes and lower the cost of healthcare. Today, the FDA estimates that approximately 50,000 serious adverse events related to medical devices are reported each year, resulting in some 3,000 deaths. The inclusion of UDIs would allow for accurate post-market surveillance, identification of trends, recalls and ultimately lead to better patient care.
- National Evaluations System for health Technology (**NEST**): [NEST](#) is the work product of the accurate collection of implant UDI in the healthcare industry. The objective of NEST is to more efficiently generate better evidence for medical device evaluation and regulatory decision-making. The linchpin of all the above programs (UDI, ONC, CMS & NEST) is the accurate labeling/marketing, collection, and inclusion of Unique Device Identifier information on every medical implant.

In June of 2017 the FDA announced guidance to industry that there would be a one-year delay, to November 26, 2018, in the enforcement of requirements for drug manufacturers to mark (serialize) drugs at the package level. The reasons for the delay cited by the FDA are manufacturers and others in the supply chain being adequately prepared to implement the systems needed for drug tracking despite the 4-year advanced notice between the law being signed and its effective date.

AIDC technologies are low cost, with either existing barcode readers or nominal investment to upgrade readers, equipping the healthcare supply chain to enable use of serialized labels on pharmaceuticals. AIDC technologies are well understood in the healthcare and the logistics supply chain given their ubiquitous use. AIM North America believes that our country cannot afford to delay further or weaken the provisions of the UDI Ruling.

HOW AIM NORTH AMERICA CAN HELP

AIM North America is trade alliance comprised of Automatic Identification Technology (AIT) suppliers

Education · Advocacy · Standards

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and manufacturers dedicated to raising awareness about AIT and encouraging the adoption of AIT policies within U.S. government agencies and the U.S. government contractor community. Our members may be competitors in the marketplace, but each of our members is a patriot and American taxpayer, dedicated to helping the U.S. government and public health stakeholders improve the way they do business by adopting AIT.

AIM North America serves as conduit to bring industry and government together to foster the exchange of information. This exchange provides clarity on the implementation of technology to achieve business process improvement goals.

We welcome the opportunity to provide independent advice on policy, technology, and implementation of standards through hands-on demonstrations, seminars, webinars, whitepapers, and case studies.

The AIM North America can be found at: www.aim-na.org