White Paper

UDI **IMPLEMENTATION** AND THE ROLE OF SCALABLE **VISION SOLUTIONS**

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Introduction – UDI Overview

Unique device identification (UDI) is a method used to mark and identify medical devices within the healthcare supply chain. The Food and Drug Administration (FDA) in the United States, the European Commission and other regulators have made patient safety a strategic priority by developing legislation to ensure the proper identification and subsequent traceability of devices.

A UDI code consists of various identification components. Whether they go by generic names as specified by the FDA or specific ones as standardized by GS1, the information is similar. The Device Identifier section is a 14-digit code representing the country of origin, the manufacturer, and product type. The Production Identifier or Application Identifier section includes the device's manufacturing and/or expiration date, the lot or batch number, and the item serial number, when required.

UDI (FDA) = DI 1 + PI 2 3 4
DI = Device identifier (Fixed)
PI = Production identifier (Many options)

UDI (GS1) = GTIN 1 + AI 2 3 4
GTIN = Device Identifier (Fixed)
AI = Application Identifier (Many options)

(01) 10857674002017
(17) 141120
(10) 1234AB
(21) 10987654d321

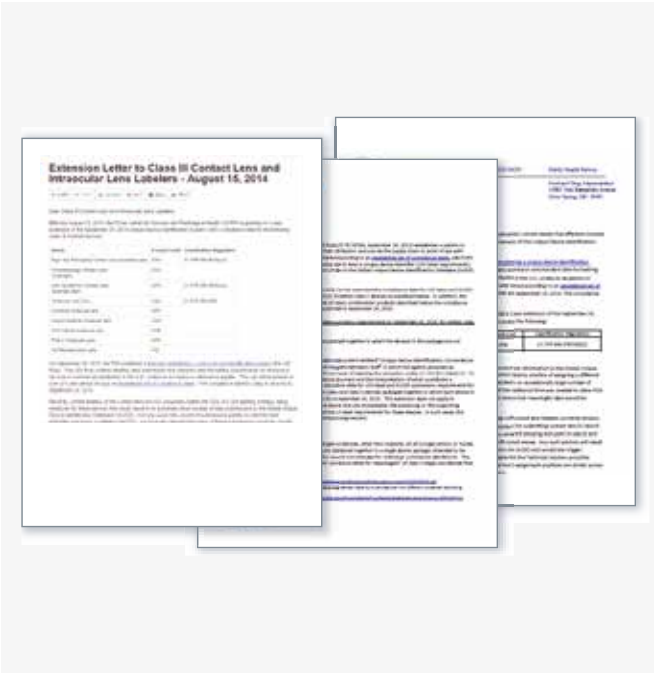
1 (01) Global Trade Item Number
2 (17) Expiration Date
3 (10) Lot/Batch Number
4 (21) Serial Number

Figure 1. UDI Components: UDI Structure.

Current UDI requirements for most medical devices do not yet call for a unique item-level serial number, so most UDI codes will typically stop at the batch number for the time being. However, according to current safety regulatory trends in various industries, item-level serialization might be required in the near future.

The implementation of UDI is somewhat complex as regulations vary from country to country, and not only depend on where the medical devices are produced, but also where they are distributed. The identification requirements in Europe differ from those in the US and other regions. In addition, the deadlines to comply with legislations are also different, depending on device classification and country. And sometimes, even within a single country, there can be differences. For example, the FDA lists a number of exceptions and extensions to compliance.

As a result, UDI is like a moving target with diverse requirements that will change and evolve over time. So as a manufacturer of medical devices producing and/or distributing products in one or several countries, how do you go about ensuring that your company will be able to comply with and adapt to changing requirements, without disrupting business every time?



The Role of Vision Solutions in UDI

Vision solutions are the key to meeting UDI requirements efficiently. Not only do they provide manufacturers with the edge needed to navigate the changing medical device landscape, they optimize the entire UDI process on a daily basis.

UDI codes and direct part marks need to be assigned and printed, but they also need to be inspected and verified. This includes the devices themselves, flexible web, labels and packaging.

Through state-of-the-art optical character recognition and verification (OCR/OCV) techniques, vision solutions automate the inspection and verification of human-readable codes, as well as 1D and 2D codes according to ISO/IEC standards – including grading. They can even inspect and verify packaging integrity as well as confirm content.

In addition, vision solutions can also include serialization and aggregation functions, which go beyond printing and verifying a unique identifier. These processes also entail data exchanges with government databases, and even if this is not required now, it will be the next step in regulation compliance a few years down the road. Indeed, medical device safety requirements are expected to be subject to additional legislation, similar to the requirements that are currently being imposed on pharmaceuticals.

Therefore, implementing vision solutions now to help with today's UDI requirements also allows you to be ready for subsequent serialization and Track&Trace requirements later on. Although it is not necessary to get a full-fledged solution and pay for functions you do not need right away, considering an upgradeable architecture that allows you to add on more functions in the future provides several benefits.

Upgradeable Architectures

The main benefit of upgradeable architectures resides in the fact that you don't have to start over with a new system every time requirements change. The scalability of these architectures means you can start off with a very basic system with a single camera and then build on it as much or as little as needed. The image below illustrates the extent to which a vision system can evolve.

In fact, simply by adding or upgrading system platforms, you can go from simple item verification all the way to a centralized system with serialization and full Track&Trace capability. This includes the warehouse and connections to government databases, making devices traceable throughout the supply chain.

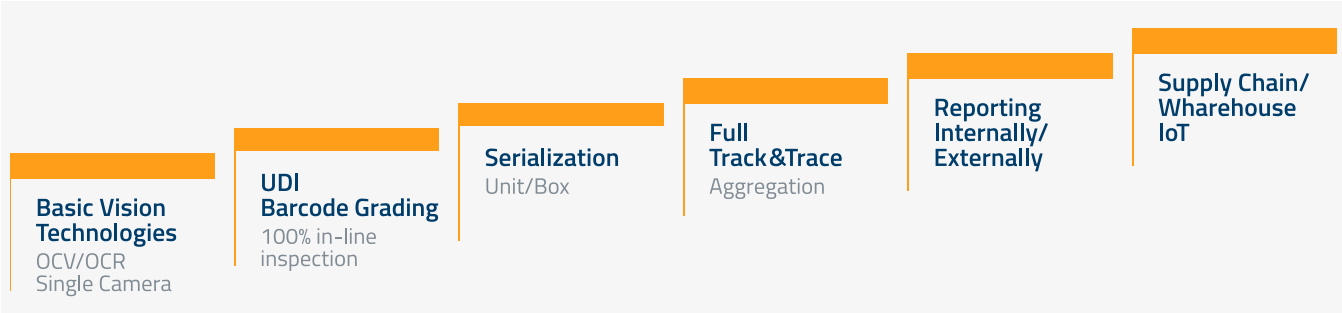


Figure 2. The evolution of systems with an upgradeable architecture.

Local vs. Centralized Solutions

As you may have deduced, the more functions are added, the more centralized the architecture becomes and the more connectivity it requires.

If we start at the beginning, a **local** solution means that the system is installed at the line level and simply controls vision hardware devices such as cameras, printers and scanners. The data is stored locally and there's no IT connection to your ERP/ MES/serial number provider.

A **centralized** system means that there is two-way communication between the line level and other IT business levels above it, so an IT connection is required.

When serialization is involved, the label layout has to be updated for each product, as the information is variable. The line controller will then need to receive data from a centralized system or serial number provider.

The next section covers centralized architectures more extensively and discusses how the different platforms are linked to business infrastructure.

Centralized Architectures

Centralized solutions can be customized and built based on a company's level of IT integration and degree of automation of the packaging workflow.

The illustration below shows a typical centralized architecture with the different business IT levels.

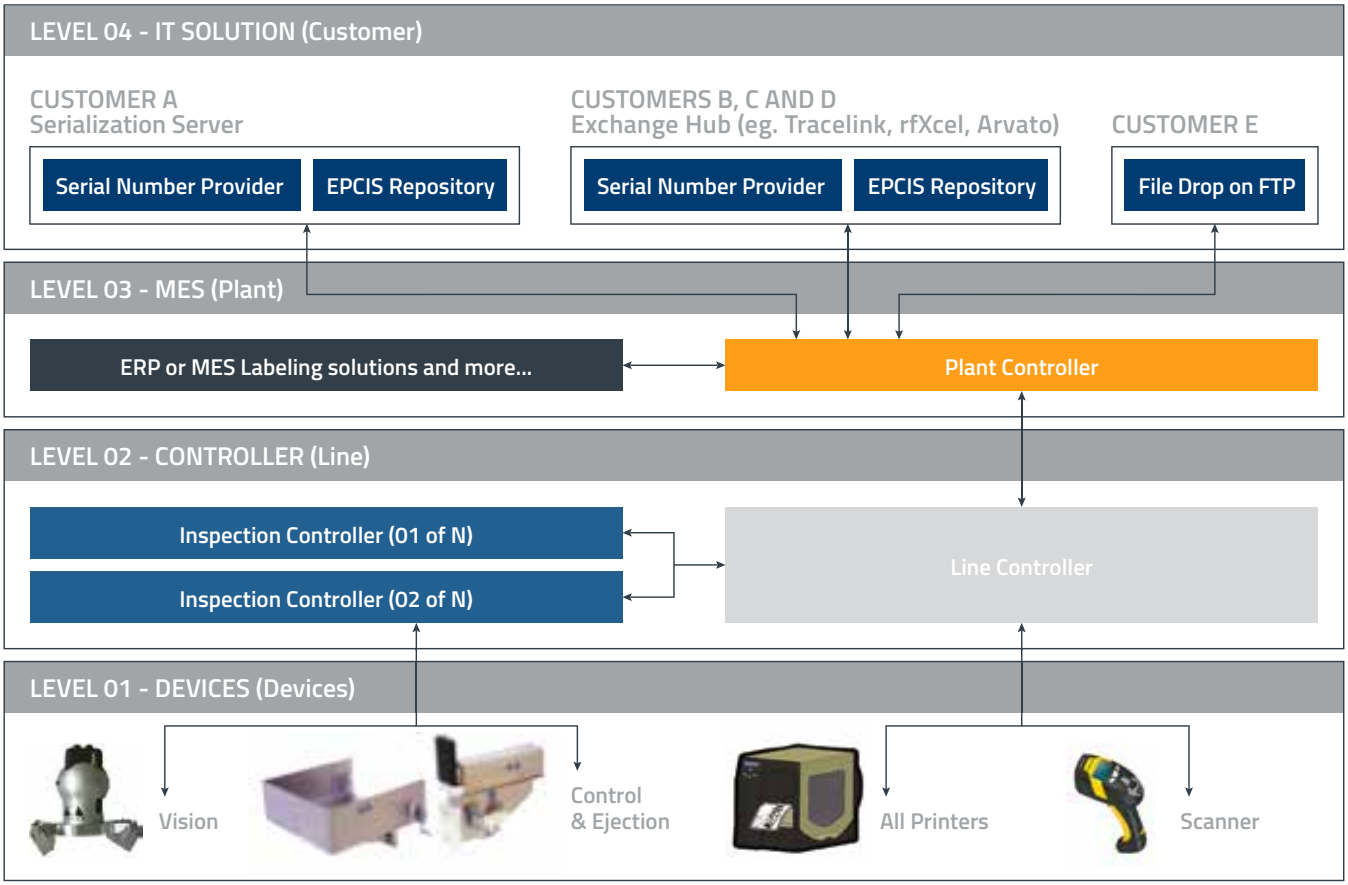


Figure 3. Centralized architecture diagram.

This architecture includes three main platforms:

- The **INSPECTION CONTROLLER** is at Level 2 or line level. This system is local and controls the vision devices. It can send and receive input/output signals to control a rejection station for example.

- The **LINE CONTROLLER** is also installed at Level 2, but it has an IT connection to Level 3 or 4 to connect with the ERP/MES, serial number provider or centralized plant controller. It also communicates with Level 1 devices like printers and scanners.

- The centralized platform is the **PLANT CONTROLLER**, which is installed at Level 3 on a server. It can have multiple IT connections to communicate with all the production lines, the ERP/MES system, the serial number provider and other plants or customers.

Figure 4. Plant controller and its relation to other elements.

In the graph above, we clearly see the plant controller as a single entry point — all the data exchange is managed by this system.

The main features of a plant controller are:

- Serial Number Management and Database (EPCIS)
- Process Order and Recipe Storage
- Central Configuration Point
- Network Isolation (L3)
- Open Architecture

The above was a brief overview of a centralized architecture. In the sections below, we will describe the key features of each controller and clarify the functions of each platform.

- **INSPECTION CONTROLLER**

  Located at the line level, the inspection controller is the brain behind the vision system. There's usually one inspection controller per packaging level.

  The software it contains offers a wide range of vision inspection tools required for OCR/OCV inspection, dimensioning and in-line grading. Inspection controllers are configurable and scalable to future needs.

  With this controller, recipes are entered manually and data is stored locally. Some of the key functions of the inspection controller include product identification and traceability, as well as barcode grading. Using this controller for these functions mitigates human error.

- **LINE CONTROLLER**

  Also located at the line level, the line controller drives the line (compared to the inspection controller, which controls the vision system). And when applicable, the line controller is also the brain behind serialization.

  In terms of functionality, the line controller connects to the ERP or MES system and provides complete lot management capabilities. It controls all line elements such as printers, scanners and inspection controllers. It also manages serialization, aggregation and Track&Trace operations, providing efficient access to production data and line performance information.

  This access to information also allows you to generate complete production reports. For example, the serialization data and timestamps allow for various types of batch reports. You can also create reconciliation reports with serial number information, performance reports and statistical info, such as rejects, all of which help improve overall equipment effectiveness (OEE).

Figure 5. Examples of production reports.

- **PLANT CONTROLLER**

The centralized plant controller (located at Level 3) manages several packaging lines and acts as a real-time data aggregator. It manages broken flows and multiple open lots, allowing you to control all your packaging lines from one central location.

This controller can be installed on your current IT infrastructure or in a stand-alone cabinet, with unlimited web-based access to the system. The plant controller is the single point of entry for all packaging lines, so no need to go from line to line. It requests or receives process orders from the ERP system and allocates them to the local packaging lines. It also has recipe creation and batch flow configuration capabilities to make the entire process more efficient.

The centralized architecture and software platforms described above are the core of a scalable solution and all the long-term benefits it can bring. These advantages become clearer by understanding the basic principles of serialization and Track&Trace, discussed in the next section.

Serialization, Aggregation and Track&Trace

As discussed above, UDI is the first step in device identification. The goal of regulatory agencies is to ultimately be able to identify and track the whereabouts, origin and authenticity of each item anytime, anywhere. This means identifying each individual item and associating it with its primary, secondary, tertiary packaging level, pallet, and so on, throughout the supply chain. All this data must be scanned, logged and verified. Then, if must be sent to various databases and accessible at all levels, including distribution level. So as you can see, UDI is really just the beginning of the process.

So let's take a look at each of the main processes.

SERIALIZATION

As mentioned earlier, current UDI requirements mostly stop at batch-level identification. When serialization is involved, it goes one step further in that a unique identifier is given to each individual unit, not just the batches. This is referred to as item-level serialization and each unique identifier code is stored and verifiable.

There are different mediums available for serialization, such as linear barcodes (1D), Data Matrix (2D) barcodes and RFID tags. In addition, UDI information often has to be printed as human-readable text as well.

Once products are serialized, it is then possible to include aggregation.

Figure 5.Types of serialization mediums.

AGGREGATION

Aggregation goes even further, as this is the process that associates each unique serialized unit to its subsequent packaging levels, which also have their own unique serial numbers. So, ultimately, when a large case or pallet is delivered to its final destination, just by scanning the outer serial number, the recipient knows exactly what's inside.

For example, let's say there are 12 medical devices. Each item is identified and then combined/packed into a bundle. The bundle is also serialized and associated with its contents. In common industry jargon, this is referred to as aggregating the 12 "children" to a "parent".

The same applies to subsequent packaging levels such as shipping cases and pallets. So, in the end, by scanning any parent package, the information related to the children inside is readily accessible.

This aggregation process is also what enables true Track&Trace capabilities, which again go one step further.

TRACK&TRACE

Track&Trace consists of two things. First, there is tracking, that is, the capability of recording and accessing the last observable location of a unique item (where, when and who scanned the package). In contrast, tracing consists of being able to access the past history of the item. For that part, shipping events data has to be exchanged between partners in the supply chain.

Serialization vs. Track&Trace

The two most important things that distinguishes simple serialization from Track&Trace are the aggregation process, and the fact that serial numbers are captured when shipped and received.

One important benefit of Track&Trace for patient safety is that it significantly improves the efficiency of recalls. With serialization, it's possible to know if the product is affected by the recall, but it's impossible to know where they are in the supply chain. With Track&Trace, the shipping event information is recorded and accessible.

Beyond regulation and safety, Track&Trace can also bring additional benefits to manufacturing and packaging facilities.

Track&Trace – Benefits beyond Regulation

Upgradable solutions provide numerous benefits and protect your investment from potential regulation updates. Some of the benefits include better production planning and quicker setup time, as you can centralize process orders and recipes.

These solutions provide analytics that allow you to be aware of the overall efficiency of your process, rejection statistics, as well as how long your products stay on the shelves. In the warehouse, it helps control your inventory and track shipping events for better stock management and rotation. You can also better manage recalls, verify returns and control costs, as serialization gives you the ability to track the original rebated cost of products when being returned, which in turn allows you to control the cost and avoid fraud.

Figure 6. Benefits of implementing a Track&Trace solution..

Upgrade Flexibility

Whether you opt for a full-fledged centralized solution or a more simple serialization system, your investment is protected.

When you are ready to upgrade your scalable solution, all you need to do is update the software, as they are designed to be compatible with IT infrastructures and other software components.

Upgrading to a centralized solution allows you to serialize production and be ready for Track&Trace, so you will already know the system when new regulations come into effect and implementation will be much quicker. In addition, once you are serialized, you can track your rework process, and your solution already has ERP connectivity enabling centralization of information and warehouse management capabilities.

With open-architecture systems, you have the flexibility to upgrade to a centralized solution that is ready for Track&Trace, whenever you are, and it can be done step by step. This way, your investment is always protected, and you always have the technology you need at the right time.

Upgradable systems certainly do have their fair share of technical advantages, but you may be asking yourself what these solutions cost.

Securing Your Investment for Future Needs

Of course, each situation or application will be different, but let's take a general look at how a basic system compares to an upgradable solution in terms of cost.

The first thing to keep in mind is that whether a system is upgradable or not, pricing can vary significantly depending on selected components, so the range within the categories themselves is relatively wide.

The most important thing to remember, though, is that sometimes the difference between a basic system and an entry-level upgradable system is negligible. The difference is that if you opt for a basic system now and are forced to upgrade later, you will have to replace all your equipment, which means your initial investment would be completely lost and you would have to start all over again.

In comparison, if you invest a little more in an upgradable system from the beginning, you can then simply upgrade your software as needed, while keeping your original equipment. In the end, if you have multiple lines, the savings are significant.

Conclusion

As shown throughout this paper, upgradable solutions allow medical device manufacturers to protect their initial investment and face any future changes and updates without disrupting business every time and without breaking the bank. This is a sure-fire way to follow the "moving target" that is UDI and comply with changing requirements over time.

Not only is this a smart financial decision, but it helps on the operational front as well. In fact, an upgradable system will also allow you to include modules that will help you in the shift towards smart manufacturing (Industry 4.0) and make all your processes more efficient.

All the components added to an upgradable system can be connected through the Internet of Things. In addition, implementing a scalable system allows you to build a solid relationship with a long-term solution partner that knows your company well and will facilitate the process, every step of the way, thus helping you adapt easily as your business requirements change.

For more details, contact us at:
info@optelgroup.com

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