Exploiting New Bar-Coding and allied Technologies for Supply Control and Tracking in the Pharmaceutical Marketplace

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EXCELLENCE THROUGH INNOVATION

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Unit Dose barcodes

- On December 3, 2001 the FDA announced a proposed rule requiring that the National Drug Code (NDC) be bar-coded on all pharmaceutical and biological products,

- "Unit-dose packaging" means a method of packaging a product into a non-reusable container designed to hold a single dosage unit intended for administration directly from that container.

- The FDA announcement stated that it was also examining the requirement for lot number and expiry (expiration) date.

- It must be stated that the FDA do not specify which barcode symbology is to be used. The advantage of a well introduced linear symbols and the existing EAN•UCC system was mentioned.

Unit Dose barcodes

- Which medical products should carry a bar code?
  - The bar code should be present for each individual dose that goes to the patient.
- Bar coding is needed in hospitals and health-systems for the following reasons:
  - Ensuring the accuracy of medication identification
  - Ensuring the accuracy of the medication administration process
  - Improving efficiencies within the medication distribution system in hospitals
  - Reducing the number or medication errors
  - Improving the efficiency of the supply system, including ordering, receipt, storage and dispensing, billing, administration documentation and tracking of drug products

Unit Dose barcodes

◆ Within the area of very small healthcare items, the unit dose items dispensed to the patient at the hospital bedside has a high importance for correct product identification.

◆ The lack of possibilities for automatic identification leads to high manual effort and potential errors during medication, documentation or at the stock control stage. This was an area of concern for the FDA.

The Sunrise date

◆ The Uniform Code Council (UCC) is now more than 30 years old and in its infancy launched the UPC code. The European EAN code followed shortly after it.

◆ The EAN•UCC system helps companies communicate trading information globally, but without a really integrated system.

◆ Most North American can work with only a 12 digit symbol while outside the USA, 12 or 13 is common.

◆ The 2005 Sunrise Date is an initiative from the USA. By 1st January 2005 all USA and Canadian companies must be capable of scanning the 8 and 13 digit EAN codes. Additionally the EAN•UCC recommends the acceptance of 14 digit bar codes.

◆ The EAN•UCC family of 14 digit structures is referred to as the Global Trade Identity Number or GTIN.

About EAN•UCC and GTIN

◆ The GTIN number describes the family of EAN•UCC data structures that uses 14 digits and can be encoded into any type of data carrier, including Radio Frequency Identification (RFID).

◆ At the moment GTIN is only used with barcodes but could be used with other types of data carrier, such as RFID and will be included in the 96 digit electronic product code (ePC).

◆ It is thought that the GTIN will be included in the RFID 96 digit electronic product code (ePC). Additionally, five of the existing bar code symbologies – I2 of 5, code 128, RSS, UCC and EAN already support the 14 digit EAN•UCC structure. RSS stands for Reduced Space Symbology.
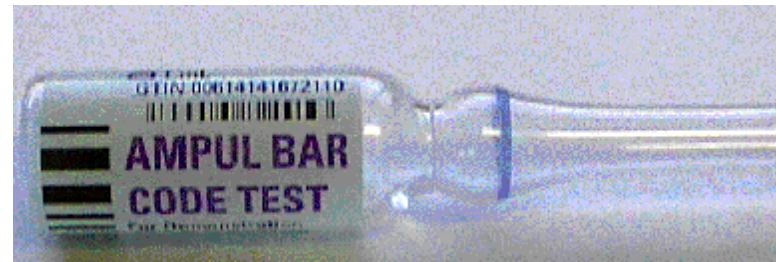
About EAN.UCC and GTIN

Table 1 The relationship between GTIN, legacy terminology, symbologies and use at point-of-sale

GTIN Data structure	Legacy terminology	Symbology	Use at POS
UCC-12	UPC	UPC-A	Yes
EAN.UCC-13	EAN, JAN, EAN-13	EAN-13	Yes
EAN.UCC-8	EAN-8	EAN-8	Yes
EAN.UCC-14	None	RSS Family	Yes
EAN.UCC-14	Interleaved 2 of 5 (I2 of 5) ITF Symbol	Interleaved 2 of 5	Not usually
EAN.UCC-14	SCC-14, DUN-14, UPC case code, UPC shipping container code, UCC code 128, EAN code 128	UCC/EAN code 128 used with application identifiers	Not usually

Source: Pira International

RSS 14 Bar Code

◆ The UCC developed, patented and placed the Reduced Space Symbology and Composite 2D barcode component in the public domain in November 1999.

◆ The EAN•UCC Composite Component Symbology was developed specifically to identify small items.

RSS 14 Bar Code

RSS-14
(01) 00614141000012

RSS-14 Truncated
(01) 00614141000012

RSS-14 Stacked, 2ml vials
(01) 00614141000012

RSS-14 Stacked
Omnidirectional Produce &
healthcare (OTC)
(01) 00614141000012

RSS Limited
syringes
(01) 00614141000012

RSS Expanded
(01) 00614141000012

RSS Expanded Stacked
Variable Measure
(01) 00614141000012
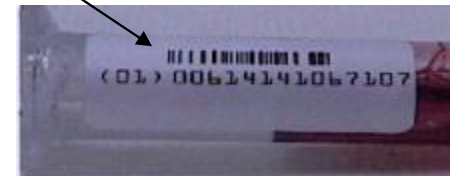
RSS 14 Code

◆ The RSS code can be used as a linear symbol alone or with an additional composite symbol.

Linear barcode like EAN/UPC or RSS

Two-dimensional component
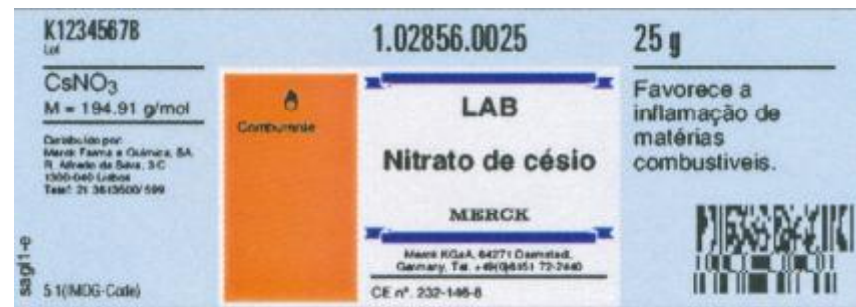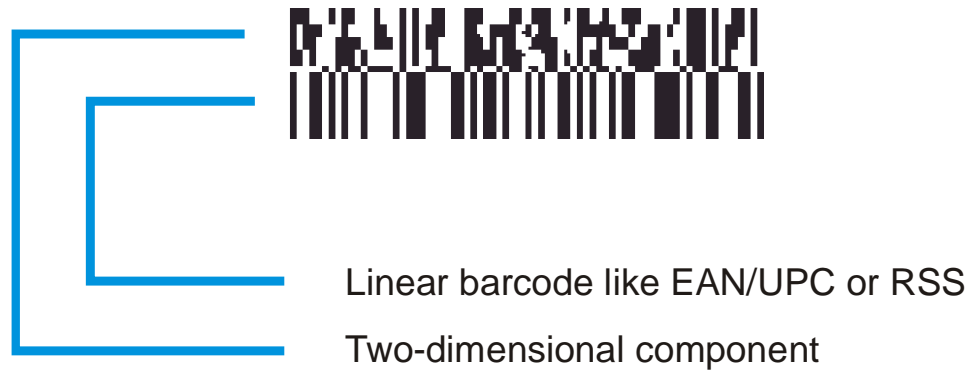
RSS 14 code

◆ Any item may also contain this Composite Component if space allows it. At the discretion of the manufacturer, the Composite Component will contain additional information related to the product. It is recommended to use the Composite Component to adopt the expiry date and the lot number, because this is legally required information, at least as human readable information on the Item or package.

◆ Automatic handling of this data facilitates many maintenance and documentation duties. Within the Composite Component the secondary information is structured according to the rules of the EAN•UCC 128 Application Identifier Com

Linear barcode like EAN/UPC or RSS

Two-dimensional component
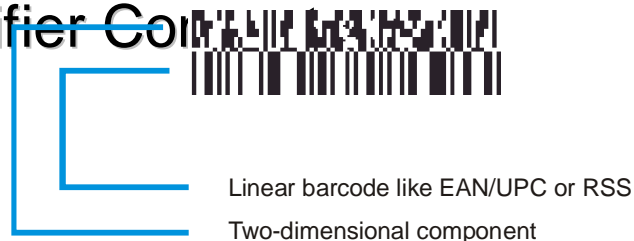
RSS 14 code

UPC-A Composite

6 14141 01234 3

EAN/UCC-128 Composite

(01)03212345678906
(21)A1B2C3D4E5F6G7H8

RSS-14 Composite

(01)03612345678904(11)990102

RSS Limited Composite

(17)050101(10)ABC123

(01)04012345678901

RSS-14 Stacked Composite Composite

(01)03412345678900(17)010200

RSS-14 Stacked Omni

(17)050101(10)ABC123

(01)04012345678901
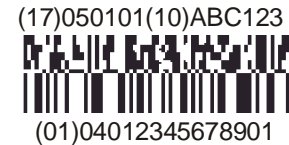
RSS 14 code

Laser Printed Composite code

RSS-Limited
6.7 mil, 0.493 in.
NDC 1234-5678-90

030823112ASDASW123

(01) 1 031234 567890 3

Label 0.75" x 2.00" by

Clopidogrel Bisulfate
Tablets 75 mg

Complete RSS Code

Data Matrix code

◆ Additionally to the UCC solution the Health Industry Business Communications Council (HIBCC) made its own proposal.

◆ The HIBCC preferred solutions for small healthcare items are PDF417 or the Data Matrix Code.

◆ Some reasons stated by the HIBCC for the adoption of Data Matrix are because it is a better barcode than RSS. The following page shows the advantages of Data Matrix codes.
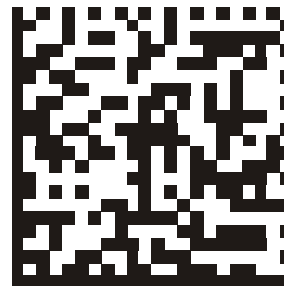
Data Matrix code

- ◆ **Size** - Data Matrix symbols as small as 2 mm can be accurately printed and read. RSS will not fit on all unit-of-use packages.

- ◆ **Print Quality** - Data Matrix can be decoded with as little as 20% contrast. RSS, like all linear barcodes, requires a higher level of print quality and contrast.

- ◆ **Readability** - Data Matrix can be marked directly on any surface including reflective materials such as foil packaging associated with some unit-dose blister packs.

- ◆ **Error Correction** - Data Matrix symbols employ Reed-Solomon error correction. RSS has no error-correction capability.

- ◆ **Scaleable** and **omni-directional** reading.

RFID

- Radio frequency identification involves fitting a small radio transmitter to the packaging component or the completed pack. 'Smart labels' are based on radio frequency identification (RFID) technology. Each contains a tiny silicon chip and an aerial; this is commonly called a 'tag' which can send information to a radio base station.

- RFID has applications far outside pack identification, moving into fields of pack authentication, prevention of counterfeiting, theft and protection against parallel imports.

- Magnified image of actual tag found in the Gillette Mach3 razor pack.

RFID

|	2002	2003	2004	2005	2006
Industry tag sales 15,000 (billions of units)	2	3	7	30	
Tag price to highest volume users	0.40c	0.30c	0.20c	0.10c	0.05c
Industry reader sales (million units)	0.1	0.2	0.5	1	2
Reader electronics price	$500	$250	$150	$100	$70

RFID

◆ The real position today however is that tags for low volume application still cost around 50 - 80 cents and are not dropping in value by any significant amount.

◆ It should be understood that the silicon chips are is not the issue or the limiting factor here. Semiconductor companies are very good at manufacturing billions of microchips. They can make the chips small enough that, in very high volumes (30 billion or more), the cost of each one falls to 1 US cent.

◆ There are, however, significant limitations to the technology today. RFID does not have an unblemished record on reliability. There are also the factors of cost, competing international standards, privacy concerns, and a variety of technology barriers. Metal and liquid will shield the tag and prevent reading, also tags in close proximity cause mutual interference.

RFID

◆ The engineering challenge is assembling billions of tags by attaching a metal aerial electrically to a microchip (which is about the size of a full stop on a page of your conference folder). This has to be done accurately, the adhesive has to set quickly and the bond has to be strong enough to ensure that the aerial to chip connection lasts for the lifetime of the tag.

◆ But RFID provides, at least in theory, robust, non-contact, non-line-of-sight capabilities for automatically distributing comprehensive information. The concept gives real benefits in product tracking, including the encoding of security and batch / date codes. Non-contact, non-line of sight product identification has significant applications in our industry, moving into fields of pack authentication, prevention of counterfeiting, theft and protection against parallel imports.

Mass serialization and anti-counterfeiting

◆ The counterfeiting of medications is a particularly insidious practice. Drug counterfeiters not only defraud consumers, they also deny ill patients the therapies that can alleviate suffering and save lives.

◆ A combination of rapidly improving "track and trace" technologies and product authentication technologies will provide a much greater level of security for drug products in the future. Use of mass serialization to uniquely identify all drug products is the single most powerful tool available to secure the drug supply chain.

Counterfeit Drug Cases are Increasing
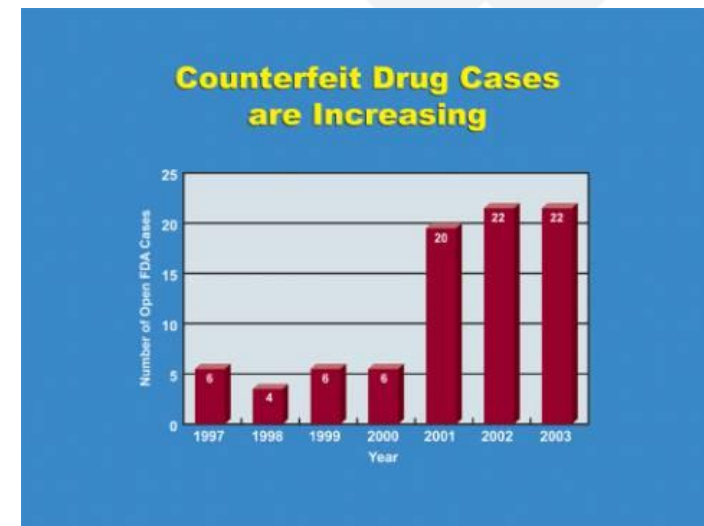
Mass serialization and anti-counterfeiting

◆ The FDA themselves stated recently that 'RFID was cited as being the technology with the strongest potential for securing the supply chain but that it was not ready for widespread commercial use with pharmaceutical products.' However, with the number of counterfeiting occurrences increasing, what can be reliably introduced today? What is required is a *transitional strategy* for manufacturers to use immediately and eventually transfer the concepts to RFID.

◆ One approach is the use of printed numeric codes for mass serialization. The codes can just be sequential. Or a second approach, which has a stronger element of built-in security, is the use of apparently randomly generated numbers obtained from a method such as *public-key cryptography*.

Mass serialization and anti-counterfeiting

◆ Manufacturers involved in the program of feasibility studies concerning business uses of RFID, including GlaxoSmithKline and Pfizer, say they will begin shipping packages with RFID within the next year to 18 months. Pfizer will use RFID on its drug Viagra, which is one of the most popular and most counterfeited medicines. GSK will pick for the program at least one of its six drugs designated by the National Association of Boards of Pharmacies as being susceptible for adulteration, counterfeiting, or diversion.

◆ Purdue Pharma of Stamford has already started working with RFID. In November it began shipping 100-tablet bottles of its painkiller Oxycontin with RFID tags to two of its largest customers.

Mass serialization and anti-counterfeiting

- Due to industry's current initiatives, mass serialization and RFID technology is likely to be adopted according to the following timeline.

- **January - December 2004 -** Performance of mass serialization feasibility studies using RFID.

- **January - December 2005 -** Mass serialization of <u>some</u> pallets and cases of pharmaceuticals.

- **January - December 2006 -** Mass serialization of <u>most</u> pallets and cases of pharmaceuticals likely to be counterfeited and <u>some</u> pallets and cases of other pharmaceuticals.

- **January - December 2007 -** Mass serialization of <u>all</u> pallets and cases of pharmaceuticals, mass serialization of <u>most</u> packages of pharmaceuticals.

- One such numeric code system which is being implemented today is the Italian Vignette code.

Italian Vignette tracking

◆ The Italian government have for many years provided individual pharmaceutical cartons with an external, peal-off vignette label containing a single bar code.

◆ As an anti-counterfeiting control and for improving the supply chain security to the end user, the Italian government has recently made law a modification to this vignette label. A new,unique, progressive 2/5i code is to be added.

◆ The Product code value plus the Progressive Interleaved 2/5 code value equals the Serial Number of the label.

◆ The plan is the complete elimination of losses due to theft and/or counterfeiting, this currently accounts for some 6% of the total pharmaceutical turnover.

NOME
Commerciale
A026089108
TITOLARE DELL'AIC
1234567789

Italian Vignette tracking

◆ All data collected during the packing and tracking operation will be stored in a database, the construction of which allows the assignment of a unique identity to each product shipment, so that its contents can be identified at any time.

◆ For the time being the information in the database can be reproduced in list form; its design will however accommodate an online connection for upload of data to a central computer at the Italian Ministry of Health in the future.

Carton

Shrink

Pallet

Case

Italian Vignette tracking

Cartonner   Shrink Wrap   Case Packer   Pallet
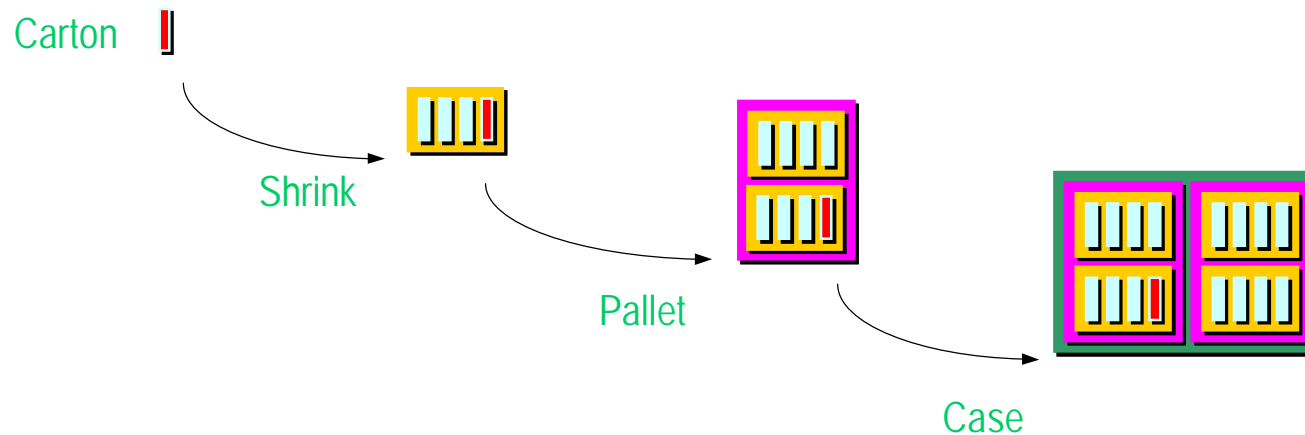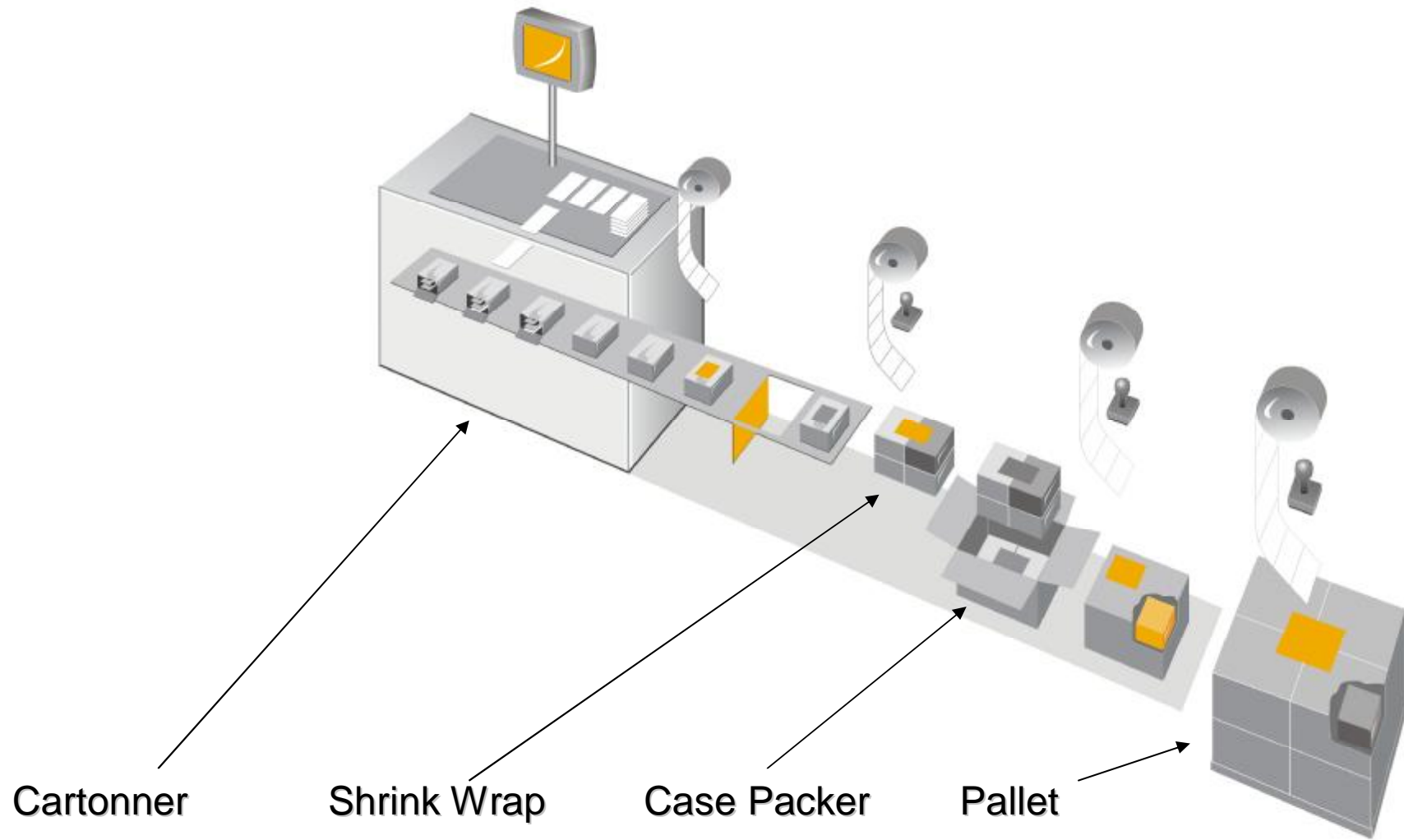
RFID against bar codes

Bar coded Labels	RFID Tags
Inexpensive (but not reusable)	Costly (though potentially reusable)
Reliable to read	Not always reliable to read
Work with virtually all products	Work with most products but have trouble with some (such as those containing metals and liquids)
Can be printed before production or printed directly on items	Must be programmed, applied, and verified individually, and data synchronization is usually required
Must be read one at a time and line of sight is required	Many tags can be read simultaneously and no line of sight is required
Written once with limited data	Can potentially be written multiple times, have higher capacity, and can be combined with sensors
Have a limited read range	Can have a longer read range

Thank you