RFID Product Labeling

The New Generation of Automatic Identification

October 5, 2017
AMDM

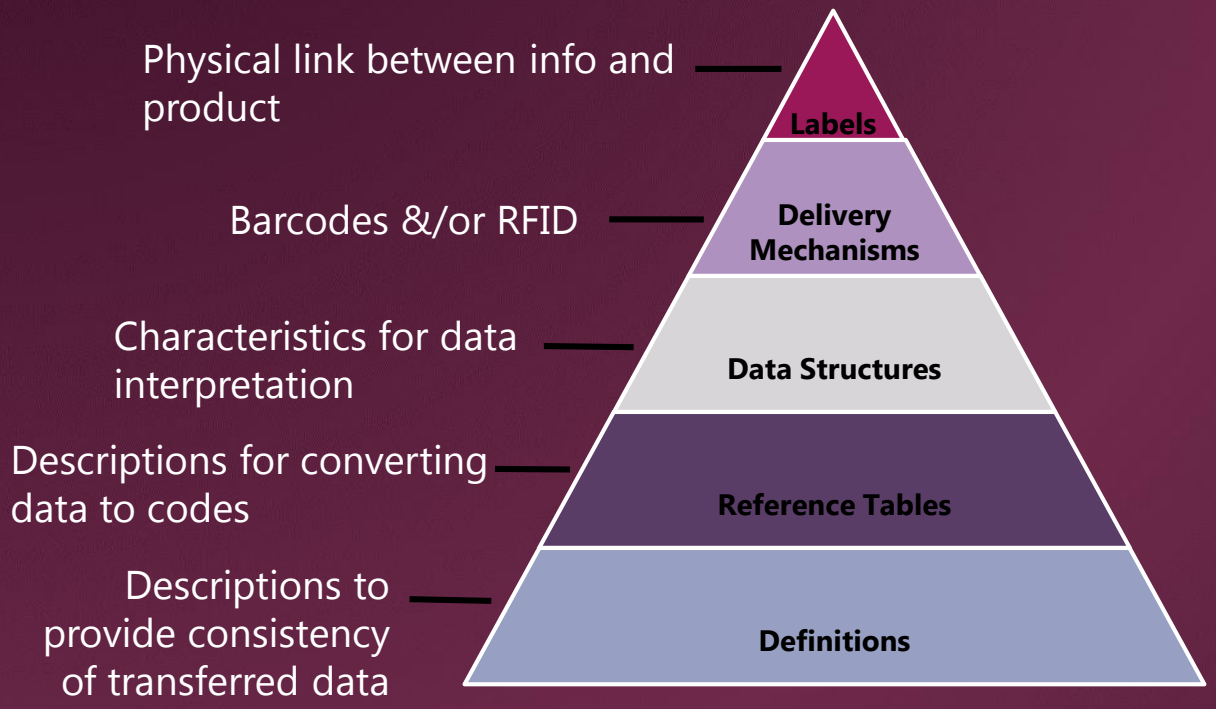
Agenda

- Compliance and Regulatory Environment
- Label Design
- Workflow Analysis
- Automatic Identification
- Consumables of Value

Compliance Driving Change

ISBT-128

Global standard for ID, labeling, and information transfer of human-origin medical products



FDA 21 CFR 809 IVD Products

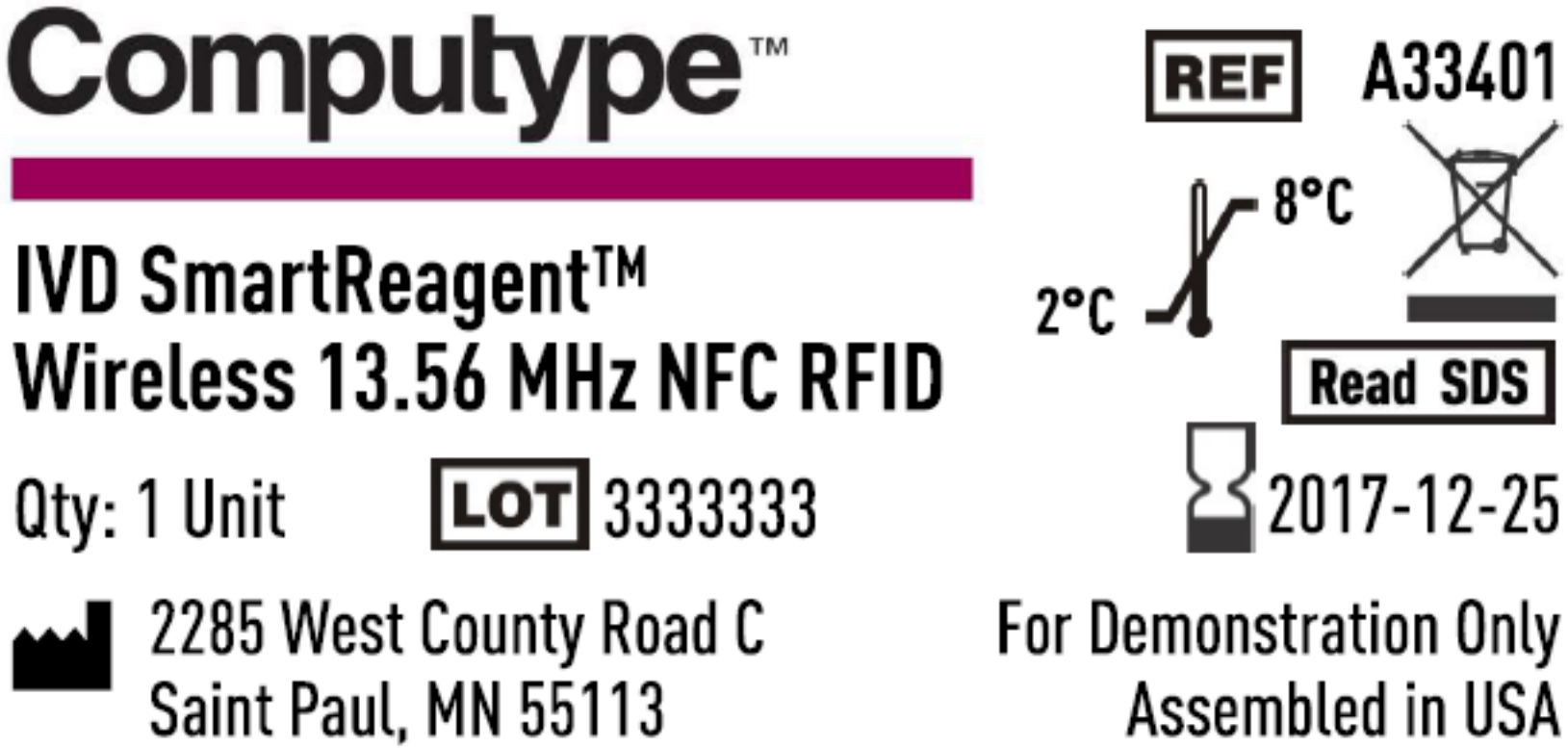
Labeling Requirements for Reagents

- Immediate Container
- Inserts and Outer Packaging
- General Purpose and Equipment

IVDR

- Unique Device Identifier
  - UDI–PI – Serial number, lot number, date
  - UDI–DI – Model of device
- UDI Carrier - RFID with Linear or 2D Barcode
- Labels and Instructions for Use

Beyond Compliance

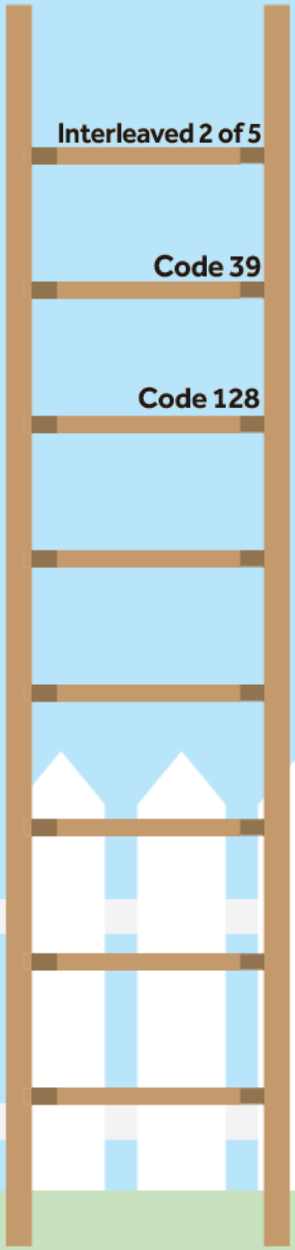


Watch the bar, mind the gap

It's all about bars and the spaces in between.

- **Start and stop characters –** these grouped patterns of bars and spaces tell the scanner where the code starts and ends. They also tell the scanner which symbology is to be scanned.

- **Check characters –** these are placed in the barcode at a predetermined position (usually at the end). They're related mathematically to the rest of the characters, and help confirm that the correct data has been decoded



Is it a fence or a ladder?

Barcodes can be orientated in two different ways:

Picket fence – where the code is arranged vertically, like a picket fence.

Step ladder – you guessed it, when the code's bars lie horizontally, it's called a step ladder.

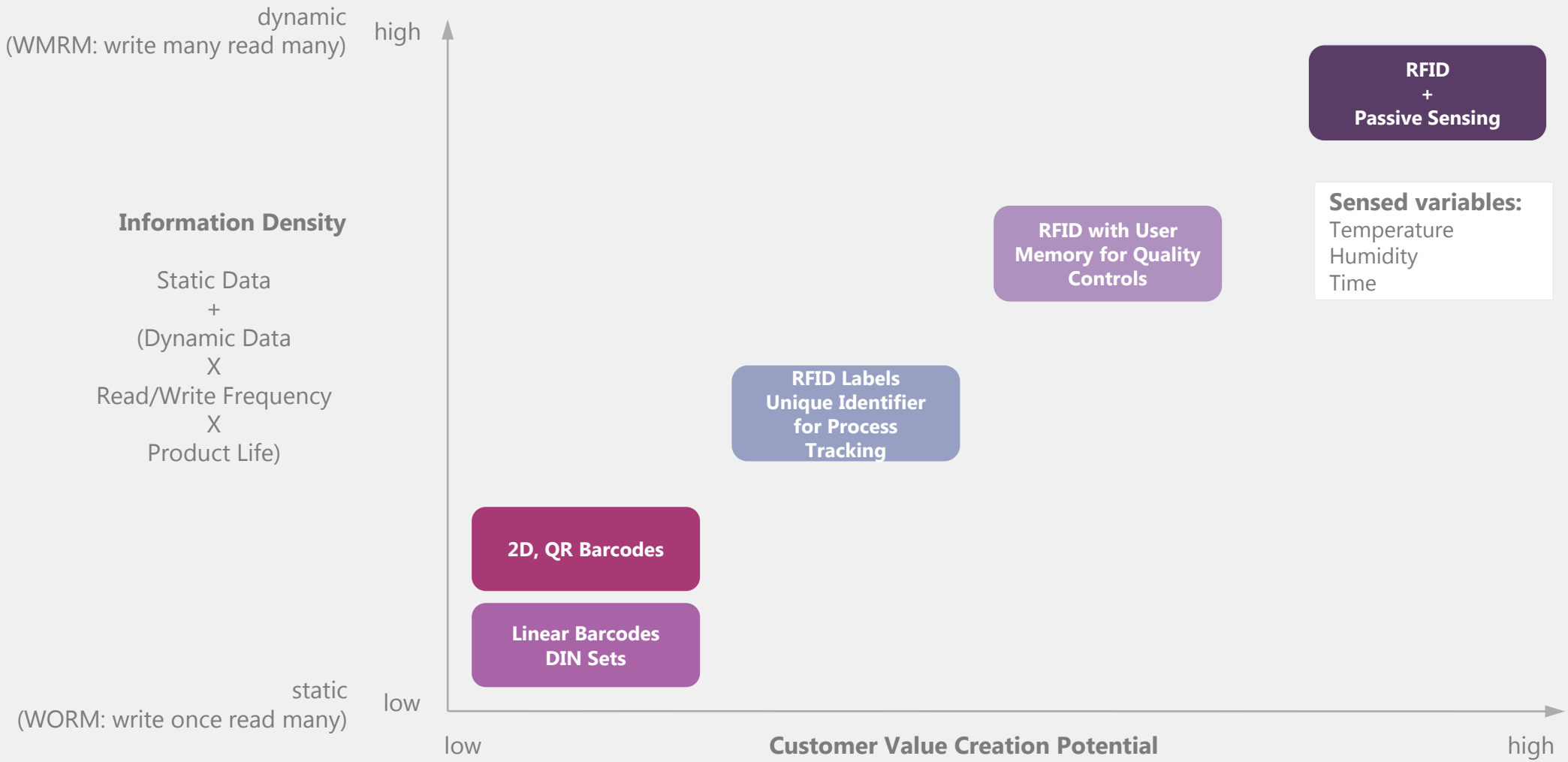
Computype™

Datamatrix:

Each symbol is made up of:

- A perimeter 'quiet zone'
- A border comprising two solid edges and two dashed edges
- Data cells inside the board which are dark or light

The Spectrum of Automatic Identification Possibilities



RFID System Types

	Low Frequency	High Frequency	Ultra-High Frequency	Super High Frequency
Operating Frequency	Typically 125 or 134KHz	13.56 MHz	Around 900MHz	Can be over 3GHz
Data Transfer Rate	2-4 Kb/S	10-20 Kb/S	20-150 Kb/S	150+ Kb/S
Affected by Common Opaque Materials (Metal and Water)	Low or No Impact	Highly Impacted	Significantly Impacted or Blocked	Significantly Impacted or Blocked
Read Range	Up to approx. 3 feet	Up to approx. 3 feet	Up to approx. 20 feet	Longest

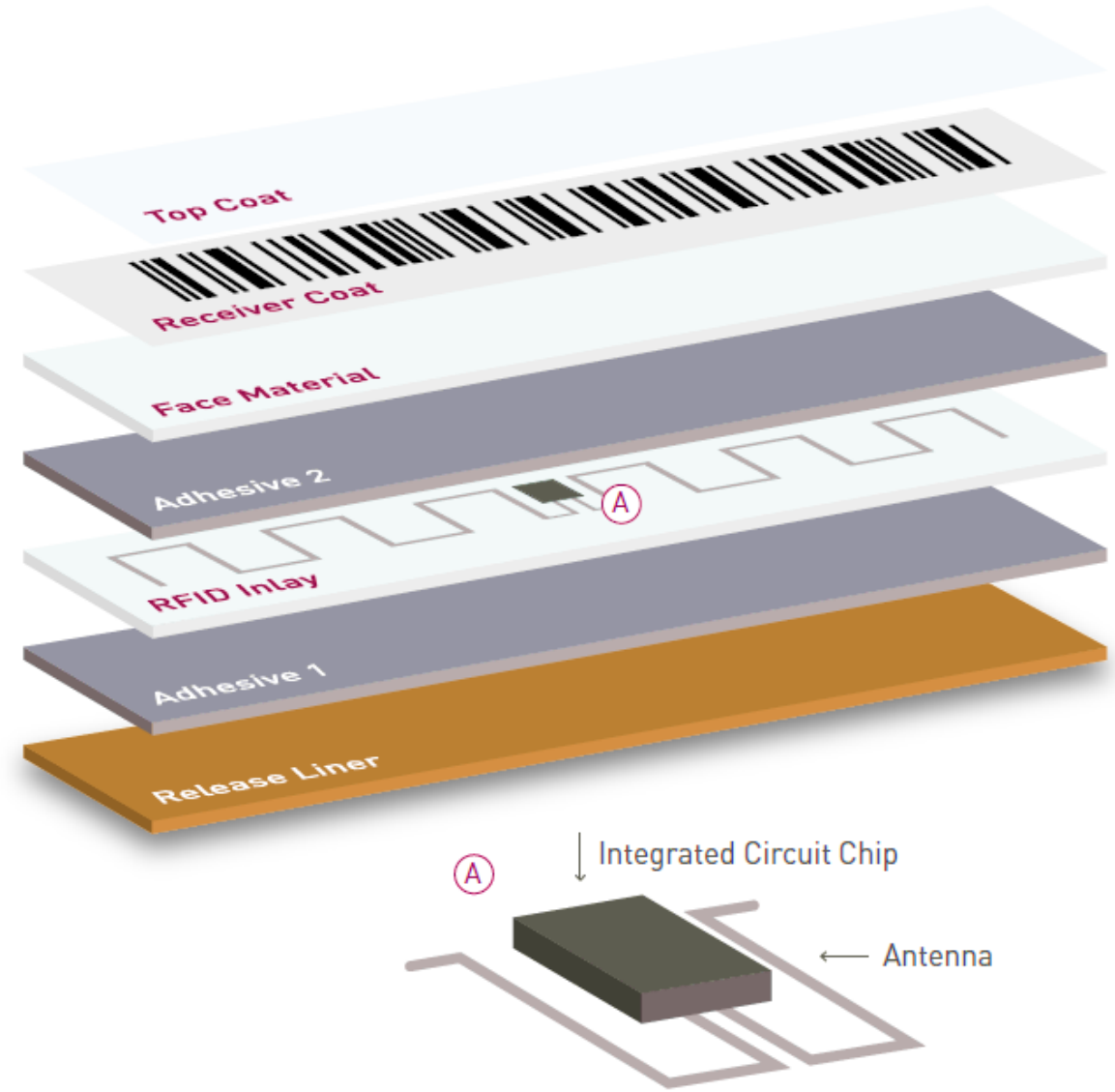
RFID READY

Battery Assisted Tags

	Active	Semi-Active	Passive
Battery powered integrated circuit	X	X	
Onboard Radio Transmitter	X		
Read Range Distance	Best	Better	Good

Hybrid Barcode- RFID

- Variable information, branding, and human readable data for consumables
- Tracking of consumables through the process with multiple scan methods for automated and semi-automated instruments
- System redundancy = reduced downtime and protection of the revenues and profits associated with proprietary consumables



High Frequency (HF) RFID System

RFID System for Diagnostics

RFID Tag or Label

Tagged Consumable

Antenna & Reader

Computer System

Keeper of the data, the tag consists of an integrated chip with onboard memory & an antenna

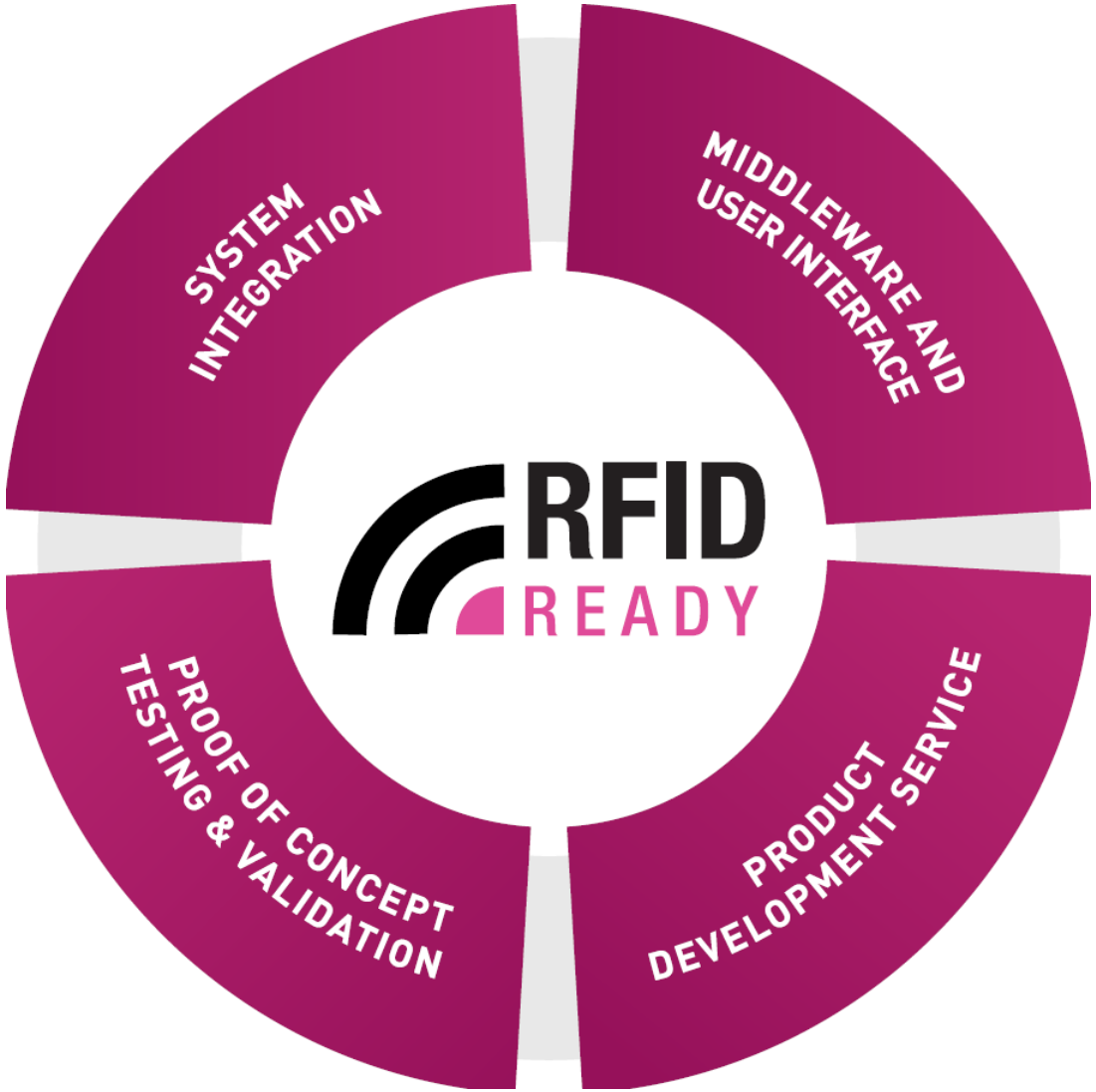
The identified consumable needing to store and track information

The antenna and reader couple together to communicate with the tag and transfer data from the tag to the computer system

The computer system leverages the information available from the RFID data transfer

In cases where NFC is utilized, a Smartphone can take the place of the antenna, reader, and computer!

Solution



6 Ways to Utilize RFID in Diagnostics:

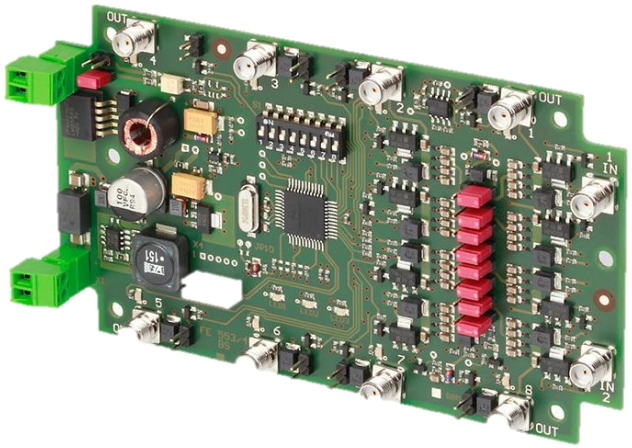
Volume Metrics	Track usage volume of a consumable or cartridge within equipment to enable visibility regarding how many tests or shelf life remains on multi-use consumables
System Controls	When RFID is coupled with a sensor, the ability exists to 'kill' a cartridge or consumable. This rejection technique can be utilized if the consumable is expired or exposed to undesired temperatures
History Log	Environmentally-sensed data like temperature history can be stored on an RFID tag and can be used to determine whether or not a consumable remains approved for use
Audit Trail	For specific applications, it might be necessary to log data usage associated with a consumable. Things like lab ID, date and time values, and sample identifiers can all be logged to a consumable to provide an audit trail
Efficient Reordering	Product ID can be pulled from the RFID tag on a given consumable to streamline web-based reordering
System Verification	RFID can help ensure that the proper consumable is being used in conjunction with it's intended equipment and test counterparts, enabling efficiency and accuracy

Specimen Tracking and Auditing

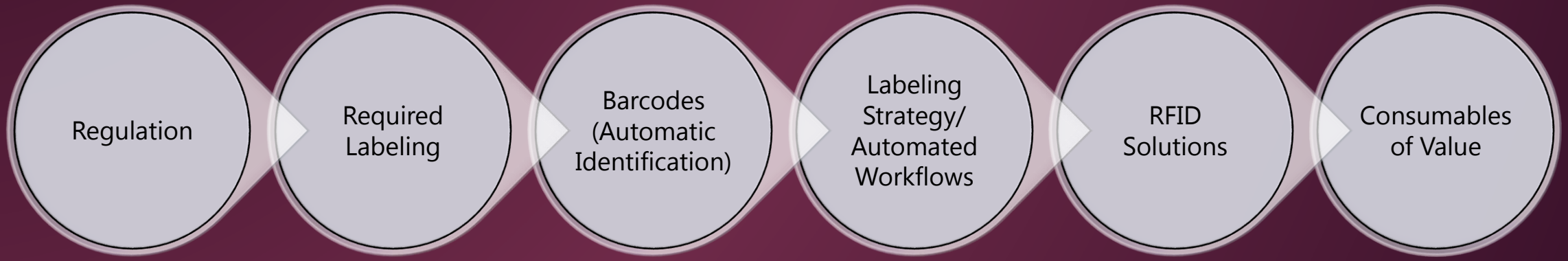
- On-Device Tracking
- Linking Laboratorian, Assay/Analysis, and Specimen
- Chain of Custody
- Accessioning
- Can replace paper requisition
- Mayo Implemented for tissue sample containers as a pilot program. http://www.rfidjournal.com/articles/view?8367/2
  - Reduced discrepancy rate from 10% down to near zero
  - Decreased the amount of time employees spend inputting data for each sample by approximately 50%

Extending the Curve- Future Proofing

- Ensure that the solution lasts the intended life of the consumable/ platform
- Reduce the need for re-qualification, manage end-of-life issues
- Extend the life of the consumables revenue and profit stream with minimal disruption



Summary


Regulation
Required Labeling
Barcodes (Automatic Identification)
Labeling Strategy/ Automated Workflows
RFID Solutions
Consumables of Value

Thank you.

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