

RFID and Standards Update

Medical Device Supply Chain Council



**JOHNSON & JOHNSON
MEDICAL DEVICES & DIAGNOSTICS
FRANCHISES**

Cordis[®]
a Johnson-Johnson company

DePuy
a Johnson-Johnson company

ETHICON
a Johnson-Johnson company

 **ETHICON ENDO-SURGERY, INC.**
a Johnson-Johnson company

 **LIFESCAN**
a Johnson-Johnson company

 **Ortho-Clinical Diagnostics**
a Johnson-Johnson company

Topics

RFID Activity in Healthcare



Vendor Activity

FDA Activity



DoD Activity

Standards Activity



Auto-ID Primer ("on a page")

Data

- Product identifier
- Lot no., Expiration date
- Unique identifier ("Serialization")
- Etc.

Carrier

- Bar Code
- RFID "Chip"
- Etc.
- Hardware to decode ("read")



Standard

- What data is included
- How data is organized
- How to decode data



Presentation

Assumptions

Bar Coding and RFID complement each other

When considering bar coding, RFID, and labeling; drugs and devices are different

The healthcare supply chain is different from the fast moving consumer goods | retail supply chain

Standardization reaps more benefit in the long run than proprietary solutions do in the short run



Current Status

Medical Device companies are researching and piloting RFID



Vendors are selling RFID to healthcare



Vendor Profile

Small and regional

Funded with Venture Capital

Market to consolidate

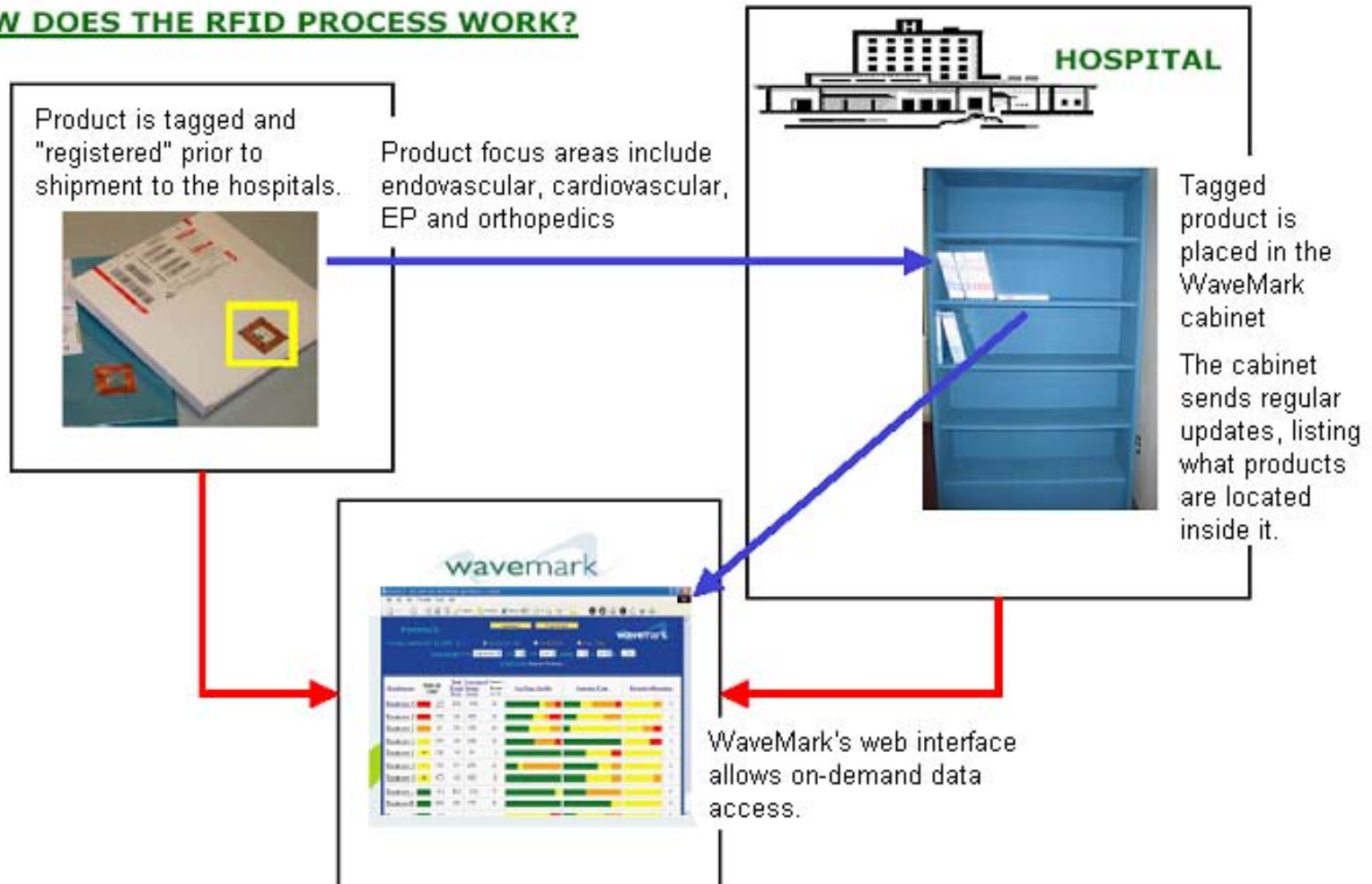
- Symbol Technology acquires Matrix
- Lockheed acquires Savi
- Pfizer invests in SupplyScape

Business cases vary



Vendor Focus : POU | create customer demand

HOW DOES THE RFID PROCESS WORK?



Vendor Focus : meet customer demand



FDA and RFID

Recent Activity and Assumptions

FDA understands the “primer” -- the relationship of data and carrier and database

FDA providing 21 point guidance to DoD

FDA active in EPCglobal standards development

FDA interested in medical device serialization

FDA met with Advamed and GS1 HUG members :
Medtronic, Johnson & Johnson, and Baxter April 2006



What we heard from FDA



Ensuring the Safety of Marketed Medical Devices

Dan Schultz, MD

Director, Center for Devices and Radiological Health

January 4, 2006

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What we heard from FDA

Adverse Event Reporting Challenges

- Adverse events are widely under-reported by users
- Numerous reports with inadequate information about how the device was used and what may have caused the problem
- Difficulty in identifying the specific device involved
 - Health care providers generally do not document device use in patient records
 - Devices lack unique identifiers
 - Manufacturers continually produce modified versions of their products.
 - Device firms are often purchased by other companies
- Devices are often used “off-label”
- Shift to home use
 - Non-professionals are using these products



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How we currently overcome the challenges

“Health care providers generally do not document device use in patient records”

Cypher™ RX REF CXS33350 Expanded Stent ID/mm **3.50** Unexpanded Stent Length/mm **33** LOT W0197999 9999-01

Cypher™ RX REF Cat. No. **CXS33350** Balloon-Expandable Stent System

SAMPLE

View product Instructions for Use (IFU), Patient Information Booklet, and Implant Card at www.cypherusa.com or call 1-800-781-0282 to request copies.

Pressure atm	Stent I.D. (mm)
6	3.13
7	3.23
8	3.32
9	3.40
10	3.47
11 (1115 kPa)	3.52 Nominal
12	3.57
13	3.61
14	3.64
15	3.67
16 (1621 kPa)	3.70 Rated
17	3.73
18	3.76
19	3.79
20	3.82

Diagram dimensions: 33mm length, 3.50mm diameter, 137cm total length, 35mm segment, 2.9F (.95 mm) and 2.3F (.75 mm) side branches, .014" (0.36 mm) thickness, .067" (1.70 mm) Min. Guiding Catheter ID.

LOT W0197999 Use By 9999-01 STERILE EO Method of Sterilization: ETO

Cordis Corporation P.O. Box 025700 Miami, FL 33102-5700 USA Assembled in the USA with International and/or Domestic Parts.

Label No. SB 153-9478.4/LB/CXS333500.11 pi-prod01/2006.003270 Storage temperature: 25°C

Peel & apply



How we currently overcome the challenges

“Devices lack unique identifiers”

We have historically identified electronic medical equipment by serial numbers. We have selected certain single use devices to be serialized because they are prime targets for counterfeiting and diversion. Products are either identified by serial number or lot number. If sterilized, product expiration dating is also bar coded.



How we currently overcome the challenges

“Manufacturers continually produce modified versions of their products”



Mod Code 01
Ethicon®
3-0
Silk Suture
Black, Braided

How we currently overcome the challenges

“Device firms are often purchased by other companies”

One Equity Partners

INVESTMENT APPROACH PROCESS PORTFOLIO TEAM NEWS CONTACT HOME

For immediate release: May 27, 2003 [Back to Press Releases](#)

ONE EQUITY PARTNERS TEAMS WITH MEDEX TO ACQUIRE JOHNSON & JOHNSON'S ETHICON ENDO-SURGERY DIVISION

Addition of intravenous catheter business allows Medex to provide complete system solutions

DUBLIN, Ohio (21 May 2003) – Medex, Inc. has acquired the worldwide Vascular Access business of Ethicon Endo-Surgery (a Johnson & Johnson Company). This acquisition positions Medex as a leading global provider of critical care products. The transition, expected to be complete within twelve months, includes Medex assuming responsibility for Vascular Access manufacturing operations in Connecticut, Mexico and Italy to support existing Vascular Access business operations.

Although terms have not been disclosed, total annual revenues for Medex are expected to reach \$300 million for this coming year.

The Vascular Access business is a leading provider of peripheral intravenous catheters and includes the PROTECTIV® and ACUVANCE® Safety I.V. catheters and OPTIVA® and CATHLON® conventional I.V. catheters.

smiths

Welcome to Medex / Smiths Medical - Redirect Page

Medex, a well respected name in the manufacture and supply of critical care and alternate care medical products has been acquired by Smiths Medical.

Used in both acute and alternate care (community) settings for a variety of therapeutic, diagnostic and long term procedures, **Medex** markets and sells critical care systems and products to over 5,500 hospitals, healthcare systems and alternate healthcare settings in more than 75 countries world-wide.

Together, **Smiths Medical** with **Medex** offers a comprehensive portfolio of innovative and clinically focused solutions to meet your needs.

 **medex**

To view your **Medex** products, visit: www.smiths-medical.medex.com

May 2003 then December 2004



What also we heard from FDA

Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program – Synopsis and Recommendations

2. Develop World Class Data Sources and Systems

We must assess the ability of our current structure to identify postmarket medical device problems and explore new ways to gain access to richer health care data.

As part of this effort, we will champion the development of a system to provide unique device identification, a standardized and globally accepted nomenclature for devices, and mechanisms and incentives for device users to include this information in healthcare records.

C·D·R·H Center for Devices and
Radiological Health



What also we heard from FDA

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G·M·D·N

Global Medical Device Nomenclature



An Added Complication ...

New requirement to include on labels "the respective code of an internationally recognized generic medical device nomenclature" (Annex II, 13.3 b):

The MHRA already intends asking "why?"; if there is a compelling argument as to why this should be done, they will propose one nomenclature should be used (they will suggest the obvious one to use - GMDN = the Global Medical Devices Nomenclature).

However, the codes may be too broad to be meaningful, and there may be medical devices which cannot be coded using GMDN. Please let me know of any examples where this may pertain (and any compelling arguments why the principle in itself is a bad idea – perhaps in terms of practicality).

Info on GMDN can be found at:

BHTA summary of possible effects of EU proposals to revise the Medical Device Directive – 11 Jan 06
British Healthcare Trade Association
MHRA - Medicine and Healthcare Products Regulatory Agency

G·M·D·N

Global Medical Device Nomenclature



Summary

What we wanted FDA to hear

Product Identification / coding schema should be accepted worldwide

System should be carrier independent

Implementation should be over a multi-year timeframe

Issues of data ownership must be resolved

To work, system would require widespread healthcare provider participation



Summary

What we wanted FDA to hear

“Country-specific requirements for labelling text, content, or the format of labels or labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.” (1)



Department of Defense and RFID

Department of Defense active with EPCglobal

Department of Defense requires tags on several classes of non-medical goods

DMLSS (Defense Medical Logistics Standard Support forms RFID workgroup

DoD issues interim requirement

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 211 and 252

RIN 0750-AF31

Defense Federal Acquisition Regulation Supplement; Radio Frequency Identification (DFARS Case 2006-D002)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule with request for comments.

SUMMARY: DoD has issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to include additional commodities and DoD locations that require package marking with passive radio frequency identification (RFID) tags. The rule requires contractors to affix passive RFID tags at the case and palletized unit load levels when shipping packaged petroleum, lubricants, oils, preservatives, chemicals, additives, construction and barrier materials, and medical materials to specified DoD locations.

DATES: *Effective date:* May 19, 2006.



Department of Defense and RFID

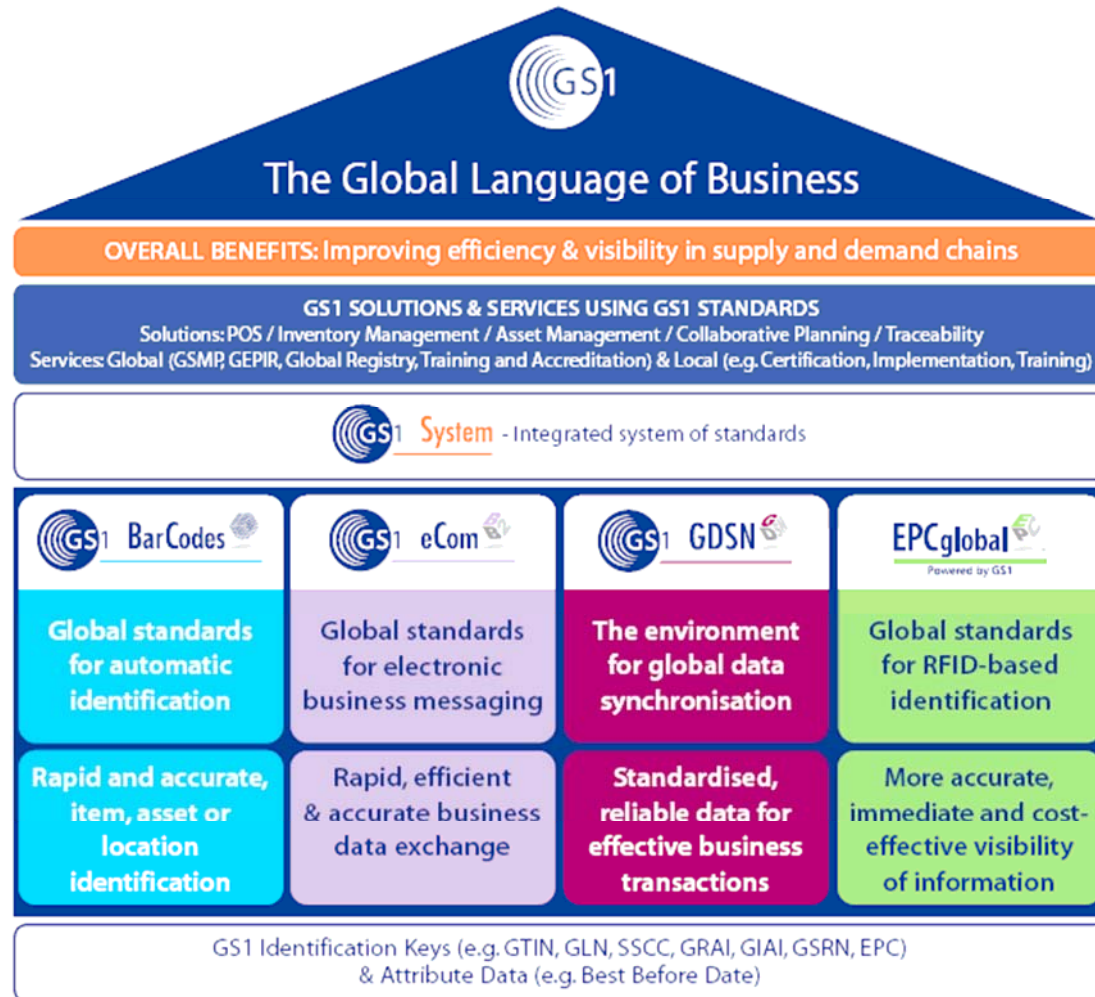
DoD interested in item level tagging

Navy Medical Pack Up Kits (PUKs)

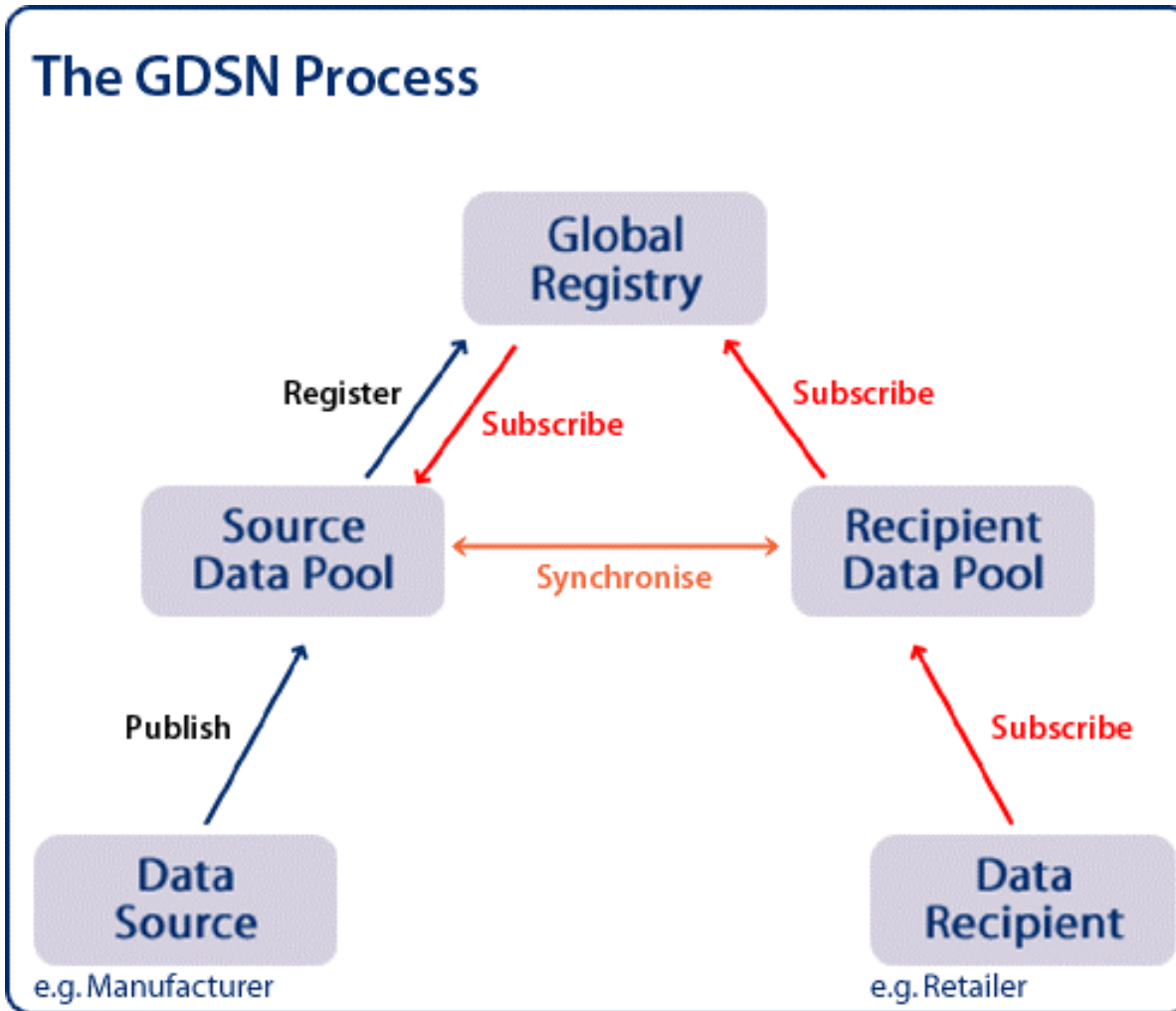
The Navy Medical Pack Up Kit (PUK) project at Fleet Hospital Support Office (FHSO) Cheatham Annex establishes and maintains visibility of medical equipment that provides life-saving and critical services (twelve surgically intense medical procedures) to include casualty receiving, an intensive care/medical-surgical unit, operating rooms, a laboratory and a radiology unit. AIT facilitates rapid part location within both warehoused and deployed Emergency Medical Units (EMUs). Phase 1 culminated in an EMU mobilization, transport, and deployment demonstration via the Navy's new High Speed Vessel (HSV) and the 463L pallets. The demonstration shows how centralized asset management and "on-demand" mission specific EMU deployment, using multiple AIT/RFID technologies can be applied to mobile hospital modules and components to provide greater flexibility, increased readiness, and immediate use of EMU upon deployment. Multiple technologies are used with component parts/packages labeled with linear and 2D barcodes, passive and semi-active RFID tags, along with CMBs. The project successfully created and captured essential data, passing and viewing the same data during buildup, assembly, maintenance, deployment, recovery, teardown and reconstitution processes. The project also completed AIT integration with Defense Medical Logistics Standard Support System (DMLSS) for batch processing, deployed EMU Delta marking over 13,000 items of equipment, tracked equipment convoy using Iridium Modem with GPS, and achieved \$500K savings per deployment in reduced transportation costs.



GS1 Healthcare Users Group



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CODIFICATION / OUR STRATEGY

- 3. USING THE STANDARD IN EACH LOCAL OR COMMON PLAN
- 4. ASKING OUR SUPPLIERS TO USE THE CODIFICATION OR TO CODIFY THEIR PRODUCTS
- 5. IN A SECOND PHASE, REQUIRING THEM TO CODIFY AND PUT BAR CODES INTO THE PUBLIC MARKETS

UNI.H.A

Single Health e-Catalogue The Big Picture A Phased Approach - Phase 1

18th October 2005

Kim Coates
Project Officer
Health Procurement

NSW HEALTH



GS1 Healthcare Users Group

Working Groups

Communication and Membership

GTIN Allocation Rules

Standards Development

Business Cases for Standards

Instrument Marking

Regulatory Affairs &

Standards Implementation



GS1 Healthcare Users Group

Next Meeting

June 13 - 15, 2006

Medtronic World Headquarters
Minneapolis, Minnesota, USA.



GS1 Healthcare Users Group

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EPCglobal HLS BAG MDWG

First meeting of Medical Device Work Group

Members present include:

Johnson & Johnson

Abbott

Kimberly Clark

Wavemark

Visible Assets



Baxter also has expressed interest



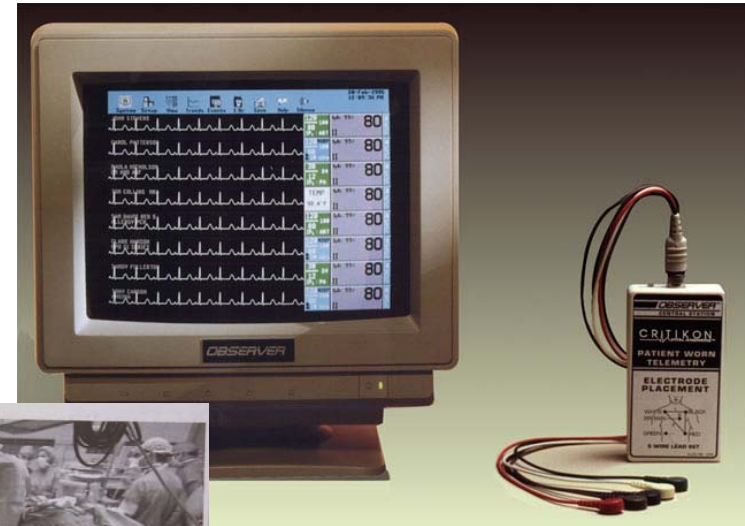
EPCglobal HLS BAG MDWG

Challenges

Unique Environment

Frequency

Data



EPCglobal HLS BAG MDWG

Challenges

Supply Chain Segmentation

By regulation

By frequency

By data

By vendor IP, technology, or business agreement

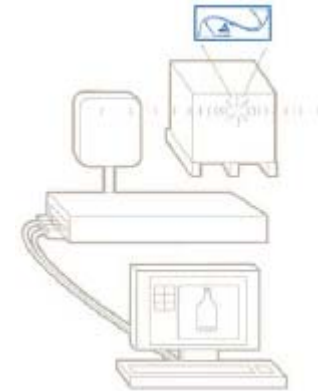


Table 4: RFID Operational Frequencies in Countries

Frequency	Regions/Countries
125 – 134 kHz	United States, Canada, Japan, and Europe
13.56 MHz	United States, Canada, Japan, and Europe
433.05 – 434.79 MHz	In most of Europe, United States (active tags at certain locations must be registered with the FCC), and under consideration in Japan
865 – 868 MHz	Europe
866 – 869 and 923 – 925 MHz	South Korea
902 – 928 MHz	United States
952 – 954 MHz	Japan (for passive tags starting in 2005)
2400 – 2500 and 5.725 – 5.875 GHz	United States, Canada, Europe, and Japan



EPCglobal HLS Business Action Group

Next Meeting

18.-20. Sept. in Duesseldorf Germany



EPCglobal HLS Business Action Group

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What if

Now

If hospital “A” then bar code “A” and RFID tag “A” and data elements “A”

Future

Standard data in a standard carrier to relate to a standard Healthcare data dictionary

Obtain

Worldwide product visibility by unique identifier by product and location

