DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Medical Software

Regulatory and Legal trends

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DITTA Chair
COCIR Secretary General

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Workshop on Friday 22 November 2013

World Health Organization

Devices are turning into software

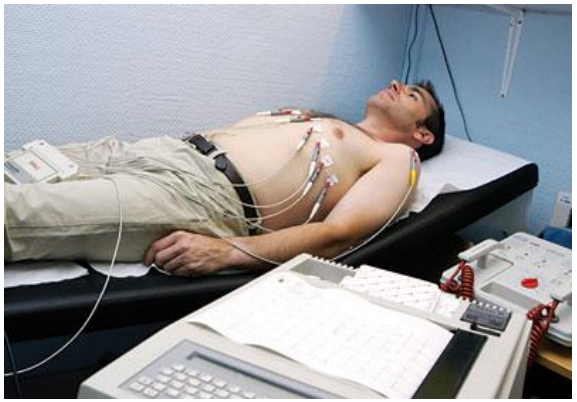
Medical functions

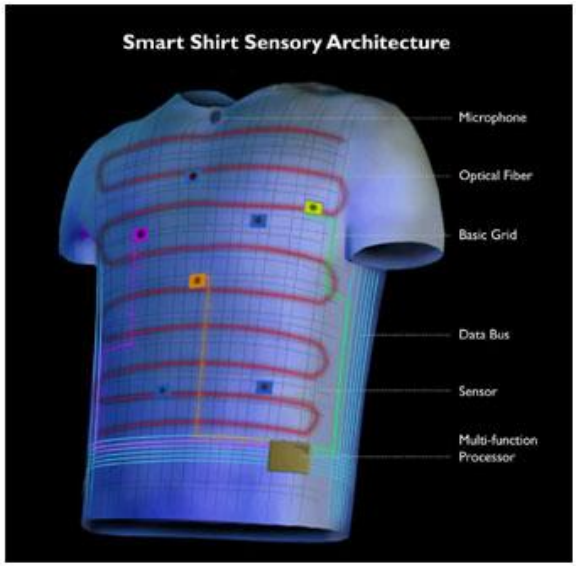
Past: performed by medical device hardware

Now: performed by software running on or connected to medical hardware

Future: performed by software running on technological platforms

STETHOSCOPES BECOME ELECTROCARDIOGRAMS BECOME SMART CLOTHING





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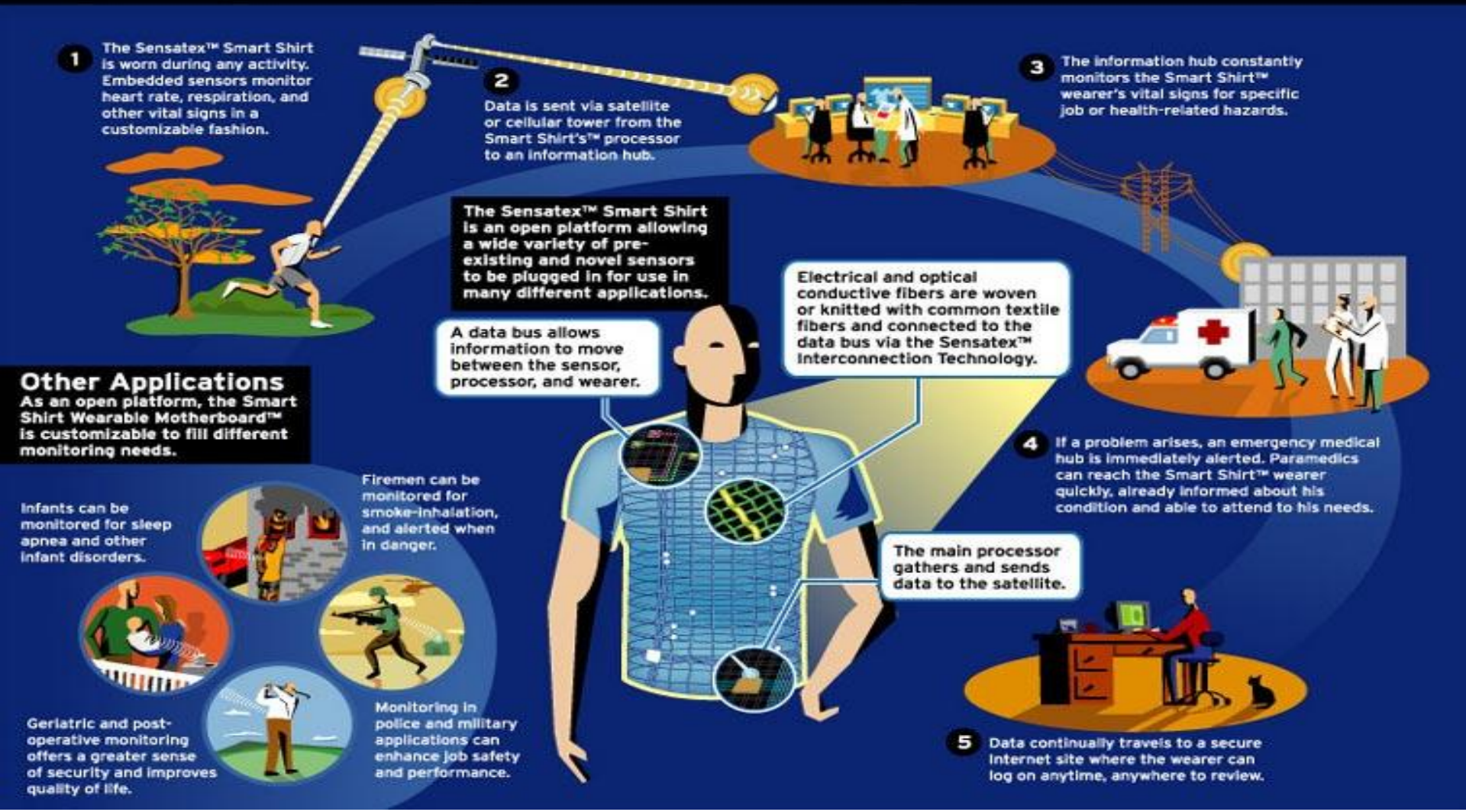
Sensatex™ Smart Shirt

The Smart Shirt Wearable Motherboard™ is a flexible, wearable open platform that can be customized to monitor vital signs, external impact, and other data through sensors woven into its fabric. Here's how the system works:



Source: http://ldt.stanford.edu/~jeepark/jeepark+portfolio/cs147hw8jeepark.html

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Keep regulations platform independent

Software running

- On general purpose computing hardware
- On medical hardware
- In the cloud

The platform shouldn't matter to determine if software is a medical device and what regulatory class it fits into. The intended use and the risk should determine that.

- Still we find regulations specific for software running on certain platforms (e.g. European MEDDEV, FDA mobile app guidance…)
- Software as a Medical Device (see draft IMDRF on SaMD) -> platform independent

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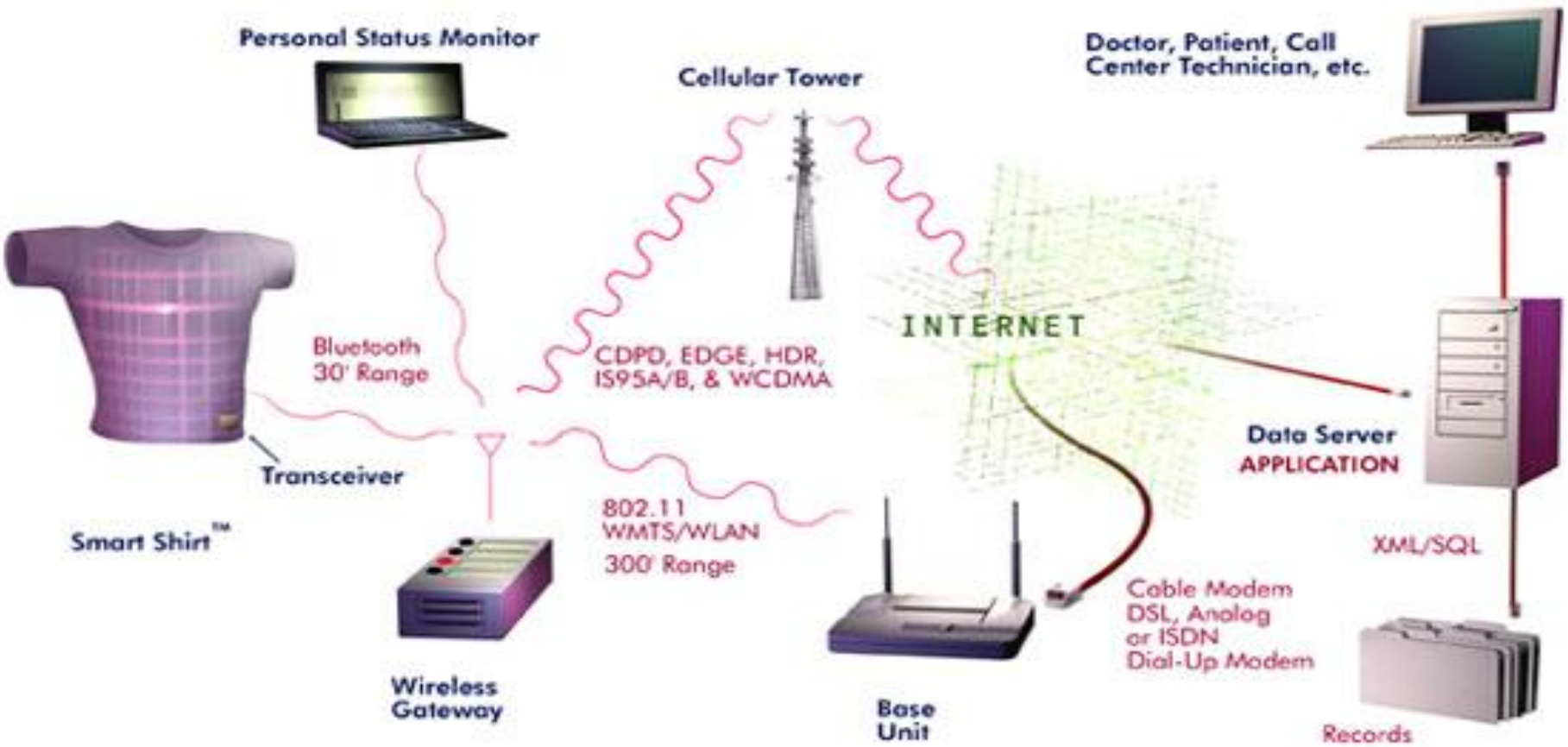
Platform Implementation

Combined Small Area & Wide Area Wireless Monitoring Application



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Medical Devices Regulations

(blue, top recommended in session and in overall ranking, yellow, from general overall ranking)

- **WHO and GHTF to take lead in the use of medical device regulation area for pre-market and post-market guidance**
- WHO and GHTF to convince the government to have harmonized standard in different countries
- GHTF to promote more support to assist countries to develop harmonized mechanism in particular areas beyond WHO justification
- **WHO to facilitate opportunities for capacity building based on cooperation between regulatory authorities**
- Promote an exchange system for information on regulatory action
- Facilitate experience sharing and a meeting for device regulators every two years
- **WHO should encourage international databank for adverse events in addition to national databases and exchange of information**
- WHO to facilitate capacity building for PMS and adverse event reporting plan in low income countries
- WHO to develop a programme for adverse event reporting on medical devices

Applying the same core principles

- **Independence:** independent advisory committee and assessment by academic group
- **Scientific basis:** scientific evidence and evaluation
- **Transparency:** evidence and process published on-line; open committee meetings
- **Inclusiveness**: Broad stakeholder consultation incl. patients, industry and professionals

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Regulation

Regulation on Medical Device:

- **About 30% of countries has developed framework for regulation**
- **About 30% of countries are only partly regulated for medical devices**
- **The Rest – either developing a framework or not yet having regulation.**

Some Concerned Areas

- Manufacturers' desire to simplify / standardize premarket submissions or approval to market
- Patients anticipate timely accessibility for the required MD / technology
- Management Systems such as procurement or donation guidelines and Maintenance Procedures
- One Nomenclature System – for effective market surveillance, safety management and risk management.

References.
Resolution 60.29 Health Technologies of the WHA

Urges Member States:

- **(3) to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;**

WHO resources

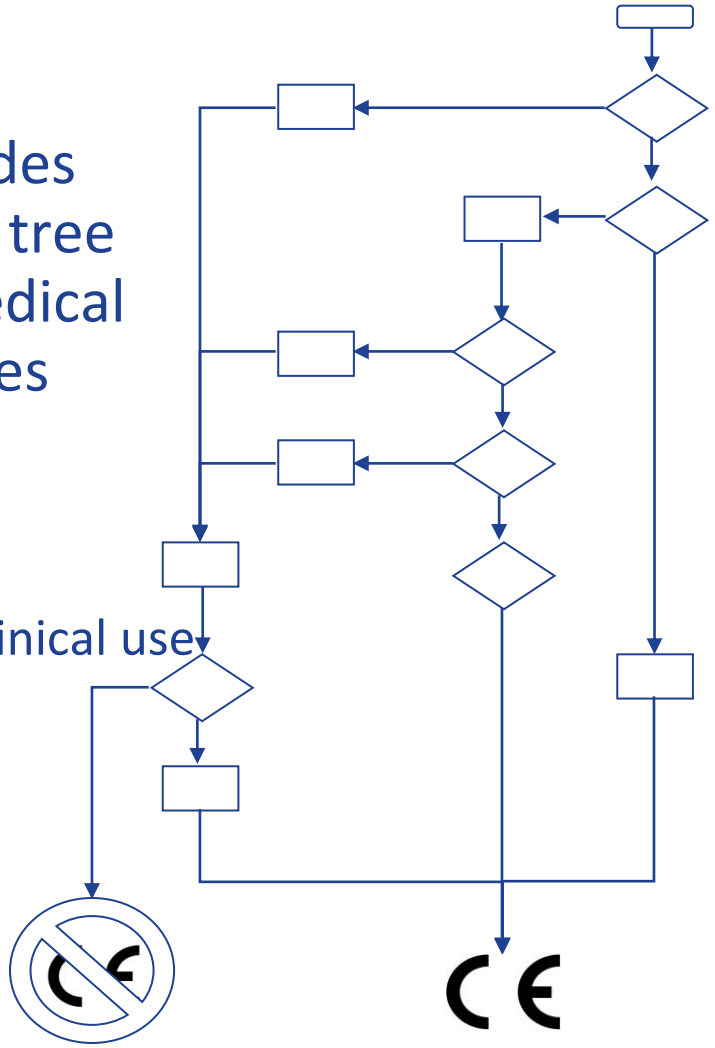
- "A Guide for the Development of Medical Device Regulations (2001)" provided a framework to assist member States in establishing regulatory programs for medical devices.

- "Medical Device Regulations: Global overview and guiding principles (2003)" also provided guidance to Member States wishing to create or modify their own regulatory systems for medical devices.

Open versus closed regulatory system

Some regulatory systems use product codes (China, US), other systems use a decision tree (Europe) to determine if software is a medical device, yet others use legislative guidances describing the exceptions (Canada…):

- Blood Bank Software
- Medical Device Data System
- Calculator/data device processing module for clinical use
- Drug dose calculator
- Medication reminders
- Medical image storage device
- Medical image communications device
- Image processing system



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Leveraging Standards to Develop Software

Product Codes:
+ descriptive
 - code overlap, not innovation-proof

Decision Tree:
+ future proof
- interpretation issues

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Current landscape of health standards

	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
Human enters information	✗	✗	✓
Medical device sends information	✓	✓	✓

	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
Human enters information	✗	✗	i
Medical device sends information	✗	i	✓

Countries known to regulate stand alone software with medical purposes:

Australia, Brasil, Canada, China, EU, Morrocco, Taiwan and Singapore

	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
Human entered information	✗	✗	i
Medical device sent information	✗	✗	i

ROW	Stand Alone Software with medical purpose		
	communicates	stores	communicates, stores + changes or creates
Human enters information	✗	✗	i
Medical device sends information	✗	✗	i

✓ regulated

✗ not regulated

i It depends

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IMDRF definition for SaMD

➔ draft IMDRF on Software as a Medical Device
➔ a definition that stays close to the medical device definition

+ simple, no or few interpretation issues, future proof
- casts larger net (but not necessary a larger regulatory net)

IMDRF software risk types

	Acute care situations	Urgent care situations	Routine/ chronic care situations	General Lifestyle/ wellness care situations (informational)
Immediate/ direct	A1	B2	C2	D2
delayed indirect/ action	A2	C1	D2	E2
informative	B1	D1	E1	E3

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Enforcement discretion or regulatory control based on risk type?

What it could look like for Country X:

	Acute care situations	Urgent care situations	Routine/ chronic care situations	General Lifestyle/ wellness care situations (informational)
Immediate/ direct	Control	Control	Control	Discretion
delayed indirect/ action	Control	Control	Discretion	Discretion
informative	Control	Control	Discretion	Discretion

Each country has the freedom to decide which SaMD risk types to control. IMDRF software community will provide a toolbox with suggested controls

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Map regulatory classification on SaMD risk type

Past:

➔ GHTF regulatory classification rules were made with hardware in mind (rules are used in Europe, Canada, Australia…)

Now:

➔ Old-world classification rules difficult to apply to software

➔ The same type of software is sometimes assigned a different regulatory class

➔ Leads to discrimination at tender level

Future:

➔ Each country to map SaMD risk type to regulatory class

➔ see draft IMDRF on SaMD risk framework

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THANK YOU !

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