



Status Report Work Team 'Instruments & Implants Marking'

Paris, France - September 20th, 2006
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The global language of business

www.gs1.org

„Analysis of the necessity of marking instruments and implants.“



Core questions : Right level of track & trace and which data do we need ?

course
of action
March 2006

- concentrate on instruments (later implants)
- clarify processes, requirements, business drivers
- discussion level of track & trace
- define the necessary data
- possible data carriers



WT activities so far

get information

- ❑ **Conference calls**
- ❑ **Personal interviews of hospitals (CSSD) or sterilization service providers**
 - questionnaire (which process step – information – level – for what ?)
 - approx. 30 interviews in 7 countries (EU, US, AP)
- ❑ **Site visits**
 - Hospital Europ. George Pompidou, Paris F : DataMatrix
 - Hospital Bichat, Paris F : RFID pilot
 - Decontamination Centre, Chorley UK
 - Central Manchester Hospital + Manchester Children's Univ. Hospital, UK
 - Health Edge, Stockport UK

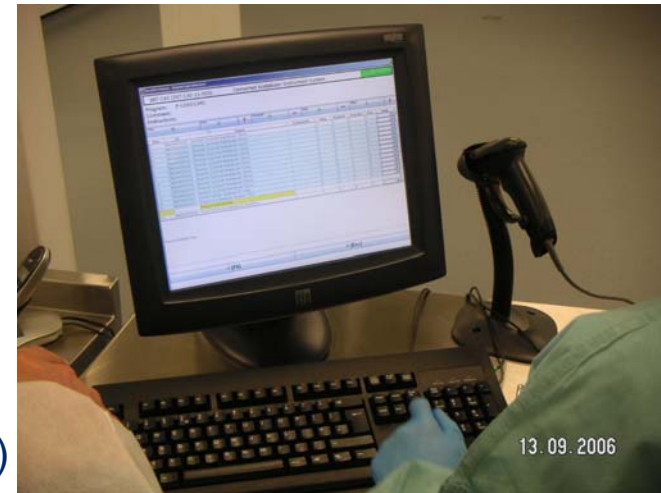


Decontamination Centre Vernon Carus, Chorley UK

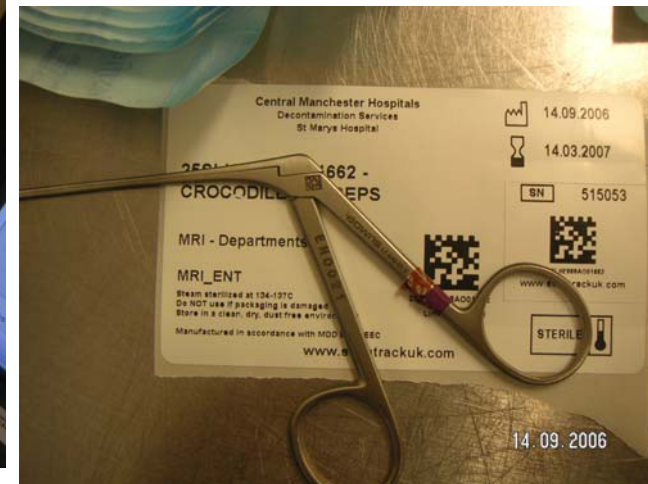
- first operating Super Centre in the UK
- capacity 1.5 mill. trays/year
- provide 3 hospitals, further will follow soon
- currently T+T on set level realized



- **IMS software SAVANT**
- **possible data carrier**
 - RFID (125 khz)
 - Dot Peen (matrix, 10 char)
 - Bar code / DataMatrix
- **subsequent marking**



- **laser bonded marking**
 - size 2.9 x 2.9 mil
 - subsequent marking (2-3€ per item)
- **SCAN Track software**
 - T+T on instrum. level possible, diff. CSSD work steps tracked on set level



- **link to patient file by removable labels (set level)**



❑ **CSSD Service provider**

- 60.000 trays per year / 2.000 loaner sets

❑ **IMS software ,Fingerprint‘**

- data carrier direkt marking : → currently the best ,Dot Peen‘ technology
- subsequent marking
- Internet based solution for T+T of loaner sets
 - via ‘www‘ access to set content !!!



- ❑ **strongly support the definition of a harmonized instruments marking system based on GS1 Standards**

- ❑ **Different opinions regarding the necessary level of track + trace**
 - set level vs. single instrument level
 - mix - e.g. on instr. level only for selected products (crucial, expensive, ...)
- ❑ **We have business needs for track + trace on single instrument level**
- ❑ **Different business drivers for track + trace / direct marking**
 - patient safety → frequently for crucial instruments (CJD infection)
 - personnel costs → concerns all instrum. (replace high qualified staff in CSSD)
- ❑ **Most suitable work steps for track + trace issues :**
 - PRE-DESINFECTATION → completeness set
 - INSTR.CHECK and ASSEMBLING → identity individual instrument
- ❑ **Hesitant willingness to invest on hospital side**
 - appropriate IT infrastructure (HW, SW) → prerequisite for effective T+T
 - link CSSD documentation to patient file by removable labels
- ❑ **Not all instruments can be marked !** → with currently available technologies

Method of resolution : 4-Level-Concept



Level 1 : Track + trace on set level



- human-readable code on set
- human-readable code on instrument
- paper-based set list



Set name : xxxxxx

<u>Art.no.</u>	<u>Prod. Name</u>	<u>Qty</u>
XX00R	scissors	5
SF9958	clamp	2
VHG22D	spreador	6
GX2005	mallet	2
...		



Level 2 : Track + trace on set level



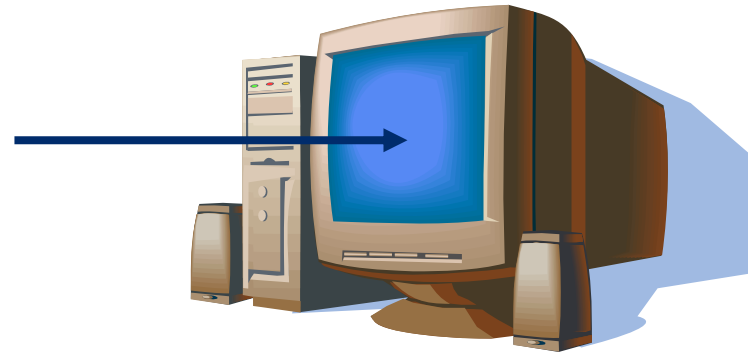
- human + machine-readable code on set
- human-readable code on instrument
- IT-based set list (bill of materials)



Set name : xxxxxx Set ID : 4022...

<u>Art.no.</u>	<u>Prod. Name</u>	<u>Qty</u>
XX00R	scissors	5
SF9958	clamp	2
VHG22D	spreador	6
GX2005	mallet	2

...

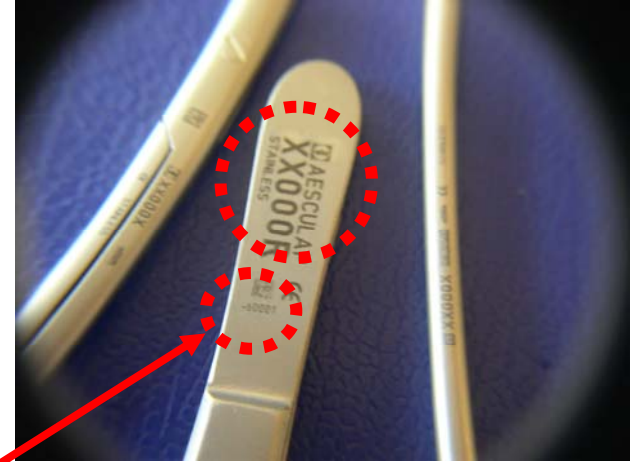




Level 3 : Track + trace on instrument level 'indirect'



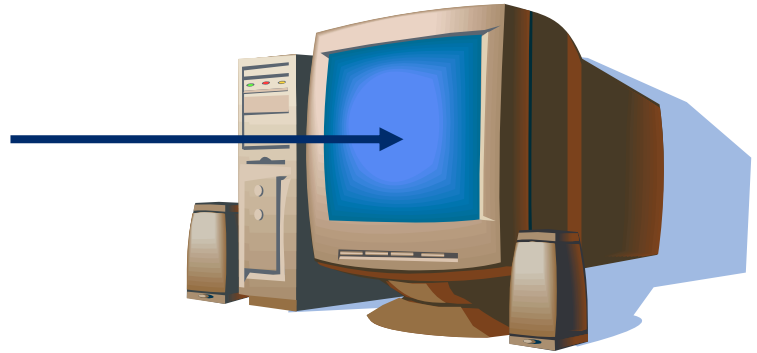
- human + machine-readable code on set
- human-readable code on instrument
- qualified IT-based set list



Serial No.

Set name : xxxxxx Set ID : 4022...

<u>Art.no.</u>	<u>Prod. Name</u>	<u>Serial No.</u>	<u>Qty</u>
XX00R	scissors	74550	1
XX00R	scissors	74551	1
VHG22D	clamp	38957A49	1
....			

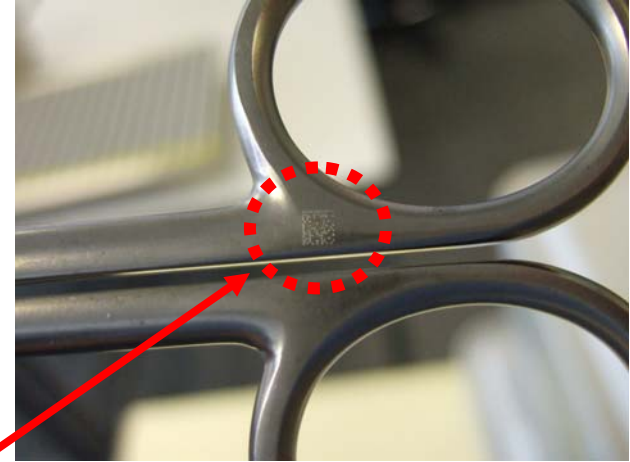




Level 4 : Track + trace on instrument level 'direct'



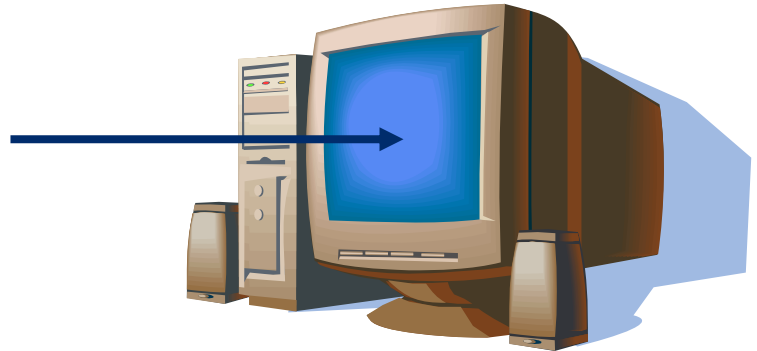
- human + machine-readable code on set
- human + machine-readable code on instrument
- qualified IT-based set list



Serial No.

Set name : xxxxxx Set ID : 4022...

<u>Art.no.</u>	<u>Prod. Name</u>	<u>Serial No.</u>	<u>Qty</u>
XX00R	scissors	74550	1
XX00R	scissors	74551	1
VHG22D	clamp	38957A49	1
....			





How to move forward ?

What is the right level of track + trace ?

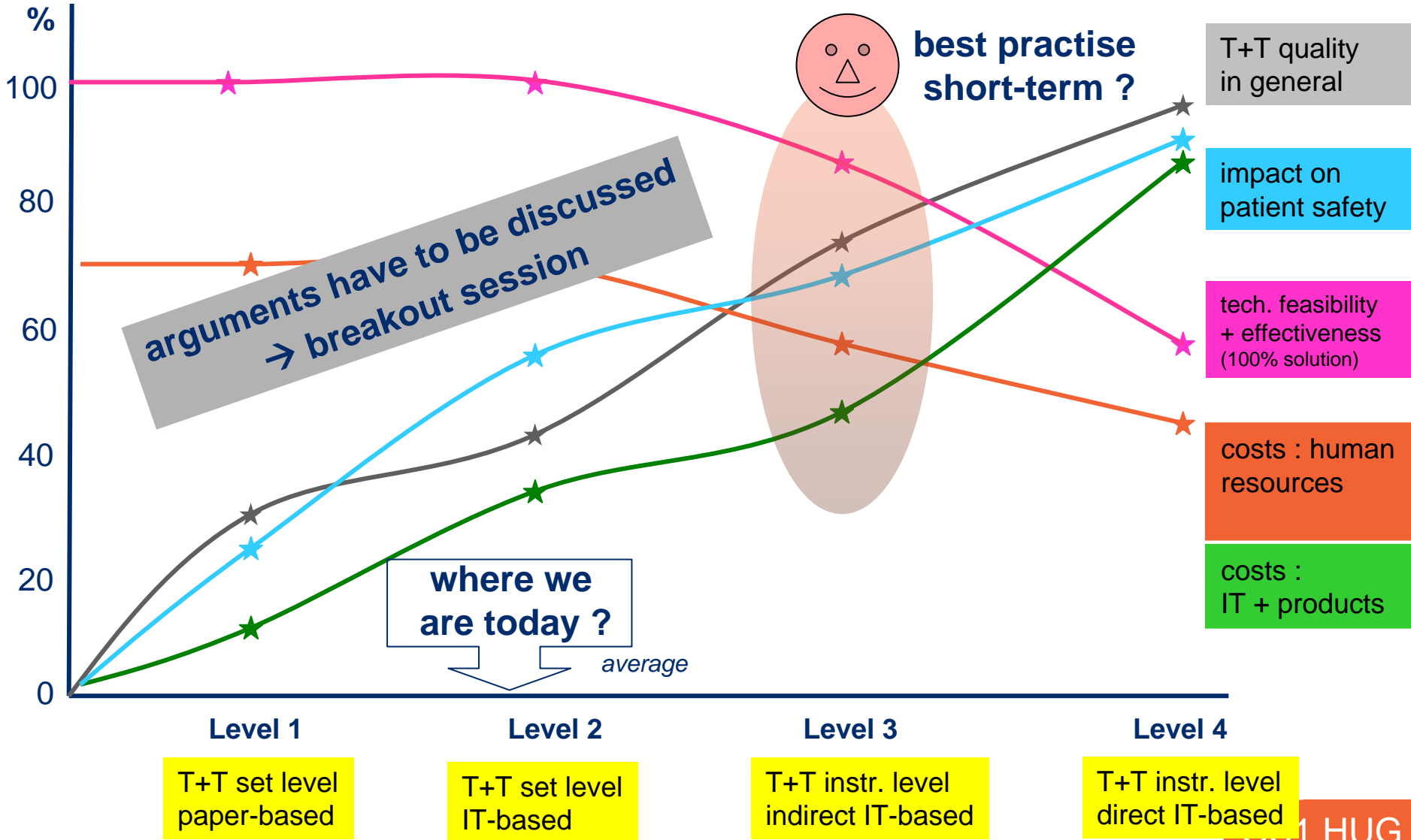
- ❑ Answer : It depends on ...
- ❑ Legal bodies, hospitals or sterilization service providers will decide it individually !

What can we do ?

- ❑ **Make the characteristics of the different levels transparent**
 - description (Excel spreadsheet) – visuals of the characteristics (next slide)
- ❑ **Describe business needs regarding product identification**
- ❑ **Discuss data concept for the different levels (set / instrument)**
 - become part of new WT's 'Auto ID Data' + 'Serialisation' → short-term



Level 1 – 4 : Characteristics / different views





Breakout session (Sept. 21st)

- ❑ **Complete and finish the description '4-Level-Solution'**
 - Excel spreadsheet
 - consideration of comments from WT members
- ❑ **Complete and finish the visualized chart of characteristics**
 - PPT chart with graphs → arguments behind diff. views
- ❑ **Describe business needs for sets / instruments ID**
 - required data
 - discuss currently existing GS1 solutions
(e.g. **GTIN+serial no.** vs. **GIAI** or **anything new** ?)
 - important influence factors (e.g. space issues)

Short-term : Sunset separate WT 'Instruments + Implants'



Thank you for your attention !

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