

**Unique  
Reduced  
Space  
Instrument Marking 3x3**

*the answer to identification problems of surgical instruments.*



**Why Unique Item Codes for each individual instrument.**

Continuously increasing legal requirements as demand for efficient processes in Health Care raise the issue of unique instruments tracking rapidly. Marking medical products are subject to European regulations globally developed and bounding for all parties involved. Surgical Instruments are small, usually made from special metal and are subject of hard treatment during the live cycle. Nevertheless they need to be processed as any other medical products under conditions of legal rules and additional quality processes, even if difficult to realise.

- National and international regulation require documentation for unique item tracking
- Unique identification of each single instrument is necessary for documentation at the process of Sterilisation, Point of use, maintenance and inventory control

For identifying serial numbers uniquely it is not sufficient just to encode the number as a generic single string. Cross institutional uniqueness can be achieved just with Company ID, article number and individual variable data. The Health Industry Barcode (HIBC) provides such a solution since the 80's as a sound solution for marking items with enough space. Meanwhile additional recommendations have been developed by EAN/UCC as well, but smallest items need special solutions. In October 2002 the HIBC Technical Committee worked out such a solution for effective and economic use determined not only for restricted Health Care purposes but also for use within and between industry sectors, where ever small instruments may occur.

**The problem**

- Instruments are made out of special metal materials, difficult to apply consistent marking.
- Surfaces are small sized, its difficult to find enough space available for marking
- Instruments are treated hard during the live time, markings get endangered to become destroyed. Just human readable characters course errors capturing data for documentation purposes.

- To day's standard Data structures such as Health Industry Barcode (HIBC) and EAN/UCC wear the overhead of the article number which is not absolutely necessary.

**The solution**

- Automatic Identification for error free data capture is the right answer compatible to state of the art item management
- Short but world wide unique data structure limits overhead
- Capacity for numeric and alpha numeric numbering schemes for more than 10<sup>11</sup> items (100.000.000.000).
- MATRIXCODE offers small labelling capability in combination with a Unique Data Structure. It allows automatic data capture with scanners.
- Laser technology is suitable for direct marking metal instruments.
- HIBC Guidelines for Unique **Reduced Space Item Marking** set the rules for global cross institutional functionality.

**The HIBC solution for Unique Reduced Space Instrument Marking**

The solution is based on the compressed HIBC data structure determined for encodation with quite different data carriers, such as MATRIX codes. Since the original HIBC code for a serial number is proceeded by the article number always to achieve uniqueness, simple rules have been found to avoid the article number for reduced space marking purposes:

- Take the HIBC Labeller Identification Code, add the Serial Number of the instrument and encode it in a Matrix Code according to ISO rules and appropriate Data Identifier.

According to ISO rules uniqueness can be provided with the Data Identifier (DI) "25S", taken from the ANSI/FACT list of global Data Identifiers, referenced with ISO/IEC 15418.

The Data Identifier "25P" proceeds a unique serial number, where uniqueness is guaranteed following the sequence:

- take the Data Identifier "25S",
- add the Issuing Agency Code "LH" (ISO/IEC 15459),
- add the HIBC Labeller Identification Code "LIC",
- complete it with the Serial Number of the item

The result is a compact but unique data set constructed according to the table below:

<b>25SLHE999AB345678</b>	Unique Item Code
25S	DI for unique serial no.
LH	IAC for EHIBCC
E999	by EHIBCC issued LIC
<b>AB345678</b>	Serial Number issued by labeller


In comparison the so generated serial number is slightly shorter than a complete HIBC code where an article number and other additional information is embadded.


- Unique HIBC Code full size with article information: "+E999123456/\$AB345678L"
- HIBC-DI short Code: "25SLHE999AB345678"

Finally the symbology is to be chosen for encoding the unique serial number in a space saving way. The best choice is to use a MATRIXCODE according to ISO/IEC 16022 or 18004 which is Datamatrix and QR Code and its Micro code option. Both are suitable for smallest space marking.

**What do you get: A world wide unique Instrument code**

Any character avoided saves some space as well, that is the reason for generating the smallest data string possible in conjunction with selecting smallest symbologies.

Unqie Datamatrix code:  25SLHE999AB345678

Unique Micro QR code:  25SLHE999AB345678

## Reduced Space Instrument Marking in brief

### The advantages

- Non-ambiguity - no overlapping with other numbering schemes: local - national - world wide.
- Uniqueness protected by ISO rules.
- Alpha numeric numbering scheme for high volume of items compatible to HIBC standard.
- Efficient solution both for unique identification as for automatic inventory control.
- Reduced Space size of 3,3x3,3mm
- Micro Space size for short numbers 2,8x2,8mm
- ISO/IEC Symbolologies & Data Structure global use.

### Parameters for Reduced Space Item Codes

All parameters for Reduced Space Instrument Marking are in line with the normative references, The parameters for the Matrixcode symbol requires special parameters to achieve the required size for fitting to the application.

To achieve a most dense code but keeping uniqueness for interoperability between different responsibilities the special Parameters for Reduced Space Item Marking are:










1. Data characters to be encoded incl. overhead:  
max 17 characters
2. Serial number alpha numeric: max. 11 n or 8ch. an  
+ capacity numeric only: up to  $10^{11}$  items  
+ capacity alpha numeric: up to  $36^8$  items
3. Pixel size "X": 0,38, 0,25 and reduced size of 0,2mm per dot
4. Achieved symbol sizes 3,3x3,3mm, 2,8x2,8 for Micro codes

### Recommended equipment for marking small metal items:

- Laser Marking provides the technique for high resolution marking on different kind of surfaces, such as metal of any kind.

### Recommended readers for reduced space resolution:

- CCD Scanners suitable fore the parameters above. State of the art scanners available: Fixed mount scanners for easy handling by placing the symbol to a scan window for quick recognition.

Samples of DATAMATRIX symbols	X0,38	X0,25	X0,2
HIBC Article + Serial n. +E999123456/\$AB345678L			
DI Serial n. + HIBC LIC 25SLHE99912345678901	 6,1 <sup>2</sup> mm	 4 <sup>2</sup> mm	 3,3 <sup>2</sup>
Samples of Micro QR Code symbols	X0,38	X0,25	X0,2
25SLHE99912345678901	 6,5 <sup>2</sup> mm	 4,25 <sup>2</sup>	 3,4 <sup>2</sup>

## **HIBC Solution for Supply Chain Management.**

Where the HIBC solution for regular item marking has proved to be efficient for marking medical products since years, HIBC solution for reduced space instrument marking completes the options available for supply chain management in Health Care logistics. It is based on latest standards and practical experiences with applications in industry and health care.

### **Normative references**

HIBC Application Guidelines 2002-04-08, EHIBCC/FIDE/SPECTARIS  
ISO/IEC 16022 Bar Code Symbology Specification-Data Matrix  
ISO/IEC 18004 Bar Code Symbology Specification-QR Code  
ISO/IEC 15424 Information technology – Automatic identification and data capture techniques – Data Carrier Identifiers (including Symbology Identifiers)  
ISO/IEC 15418 EAN.UCC Applications Identifiers and FACT Data Identifiers  
ISO/IEC 15459 Automatic Identification and Data Capture Techniques – International Specification - unique identifier for transport units  
ISO/IEC 15415 Bar Code Print Quality Test Specification - Two Dimensional Symbols  
ANSI MH10.8.2 Data Application Identifiers  
ANSI HIBC 2Health Industry Supplier Labeler Standard

Contacts:

#### **EHIBCC-D**

D-06618 Naumburg, Koesener Str. 85,  
phone +49 3445 78114-0  
fax +49 3445 770161  
info@HIBC.de, www.HIBC.de

#### **EHIBCC**

**European Health Industry Business  
Communication Council,**  
NL-2596 AM Den Haag, Josef Israelslaan 3  
phone +31 70 3244754, www.EHIBCC.com

*Supporting organisations:*

#### **AIM-D**

D-68623 Lampertheim, Akazienweg 26  
phone: +49 6206 13177, fax +49 6206 13173

#### **SPECTARIS e.V.**

**Association for optical, medical and mechatronic technologies**

D-50858 Köln, Kirchweg 2  
phone +49 221 948 628-0, fax +49 221 48 34 28

Eurodata Council Stichting  
D- 06618 Naumburg  
phone +49 3445 78116-0  
www.EurodataCouncil.org



*Please call for information: Heinrich.Oehlmann@HIBC.de, www.hibc.de, +49 3445 78114 0*