

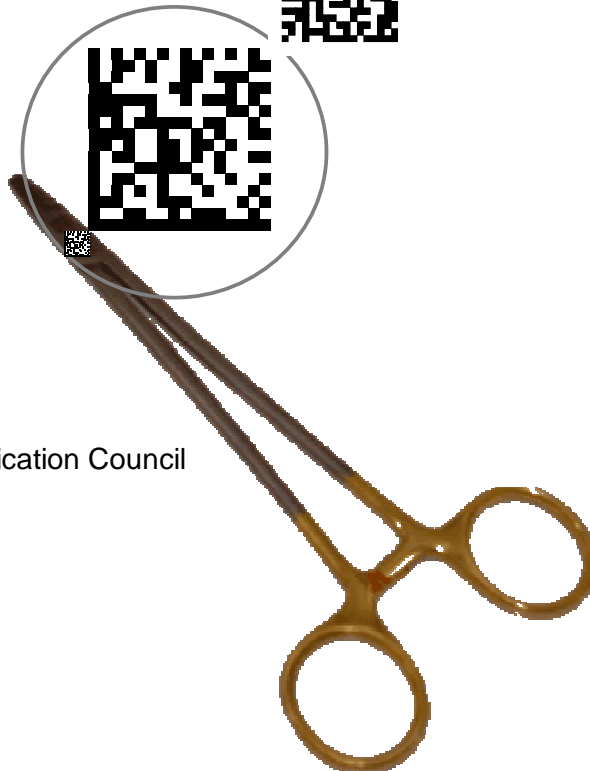
HIBC solution

The World Wide Unique Identification Mark (UIM)

for Medical Devices

ISO powered EHIBCC standard

Standard specification developed by EHIBCC TC
for small items and instruments
as addendum to the HIBC Standard and Guidelines



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Rev. 2002-12-20

Maintenance of the ISO powered standard specification

The world wide
Unique Identification Mark (UIM)
for Medical Devices

The standard specification is subject of maintenance undertaken by the EHIBCC Technical Committee.

Comments out of practical experiences and current developments of related technologies under ISO will be considered for upgrading the specification by the TC.

Any comment or question should be passed to the chairman of EHIBCC TC.

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Table of revisions and updates

Revision 2002-10-24	Draft for the experts group
Revision 2002-11-21	add "spectral contrast" in appropriate paragraphs and editorials
Revision 2002-12-20	Document approved and issued

HIBC solution

for smallest item marking

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1. Foreword

EHIBCC (the European Health Industry Business Communication Council) and HIBCC (Health Industry Business Communication Council - USA) are worldwide acting associations recognized by CEN, ANSI and ISO as standards bodies. EHIBCC and HIBCC develop and maintain standards and recommendations for Health Care logistics and communication. The work of preparing the specifications is executed by the technical committees consisting of members and technical experts. The members have interest in wide spread use of the standards to achieve best efficiency in supply chain environments.

The specification for reduced space item marking by a world wide Unique ID Mark was prepared by the EHIBCC Technical Committee. It is ISO powered by taking use of related ISO Standards for achievement of world wide functionality and interoperability with other industries standard solutions.

2. Introduction

This specification constitutes an add on the HIBC Guidelines for cases where standard sized solutions do not full fill the requirements. The solution is flexible enough to meet the general requirements for smallest items such as instruments, probes as any kind of parts with the need to be traced.

For identifying serial numbers uniquely it is not sufficient just to encode the number as a single string. As with the HIBC code, uniqueness is achieved in conjunction with the HIBC Primary code. This is a good solution for marking items with enough space, but smallest items need special solutions. The HIBC Technical Committee worked out such a solution for effective and economic use not only for Health Care but also within and between industry sectors .

The Working Group preparing this Committee Draft has participation of the following individuals representing the named organizations

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3. Scope

The EHIBCC Application Guideline for Smallest Item Marking specifies the methodology to enable unique identification, tracking and tracing for smallest items. It provides specific recommendations for world wide uniqueness of parts, but also for selecting the appropriate 2D symbology. The current specification will not change the HIBC Guidelines for Standard labeling normal and small products but is entitled as an add on for the specific task of direct marking.

4. Normative references

The following referenced documents are indispensable for the application of this document.

ISO/IEC 2382	Information Technology — Vocabulary
ISO/IEC 15415	Bar Code Print Quality Test Specification - Two Dimensional Symbols
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 16022	Bar Code Symbology Specification – Data Matrix
ISO/IEC 18004	Bar Code Symbology Specification – QR Code
ISO/IEC 15459	Automatic Identification and Data Capture Techniques – International Specification - unique identifier for transport units
ANS MH10.8.2	Data Application Identifiers
ANS HIBC 2	Health Industry Supplier Labeler Standard
HIBC Application Guidelines	2002-04-08, EHIBCC/FIDE/SPECTARIS

5. Data Content and Requirements

The data content shall enable unique identification of a single item on a world wide basis. For marking items with enough space standard HIBC data structure will offer full tracking information. For minimized overhead the article number might be split off for smallest data length by help of the Data Identifier (DI) "25S". Applied with the DI "25S" a serial number becomes unique just by the proceeding Issuing Agency Code and Labeler Identification Code prior to the number itself. The appropriate Data Identifier has been selected out of the list of registered Data Identifiers (DI's). The full specification for use of the DI's can be found in the American National Standard MH10.8.2. Using standard Data Identifiers as either the "+" for HIBC data structure or "25S" for Unique Serial Numbers the solution becomes compatible with all other standard data elements and numbering schemes. The implementation of the standard is supported by state of the art technology Data set is alpha numeric A-Z, 0-9.

5.1. Human Readable Information for encoded data elements

Human Readable Information shall be add as serial number for the item.

6. Item Identification

Item Identification may be assigned by either the Supplier or the Provider or Customer, who ever might be responsible for uniqueness of the item. It shall contain the registered code for the responsible company and the individual serial number of the item. Existing numbering schemes might be used without change but applied with the Data Identifier sequence prior to the plain data. Unique Item Number and Matrix Symbol will build the world wide Unique Mark.

6.1. Unique Item Number

A unique item number is a unique code assigned by the labeler to an item for its lifetime. It consists of the appropriate DI, the company code (LIC) and the individual Serial Number (SN) for the item.

The appropriate Data Identifier to build a unique item number is the "+" for standard sized item codes, but DI "25S" for small item marks, which is the combined IAC/LIC proceeding the serial number assigned by the labeler.

The appropriate Issuing Agency Code (IAC) is "LH", assigned for EHIBCC. It follows the Labeler Identification Code (LIC). The serial number for the item completes the Unique Item Number.

As maximum 13 characters are specified for product as for lot/serial number in according with the standard. For space saving features full use of the capacity is not recommended, but limitations to 11 digits or below, according to the required size. To achieve a small item code, the recommend length of the serial number is not longer than 8 characters alpha numeric or 11 digit numeric not including the control characters with flags, company, etc.

Table 1 - Structure of a Unique Item Number structured with HIBC primary & secondary code. As data content a 6 digit product code is selected and a 8 character serial number.

Data Identifier (DI)	Labeler Identification Code (LIC)	Product Code	Package index	Sepa- rator	Flag SN	Serial number	Chec k
+	Eaaa	13an	1n	/	\$	13an	1an
Sample							
+	E999	123456	0	/	\$	AB345678	L
Sample concatenated Unique Item Code:				+E999123456/\$AB345678L			

Table 2 - Structure of a Unique Item Number

Data Identifier (DI)	Issuing Agency Code (IAC)	Labeler Identification Code (LIC)	Serial number
25S	LH	Eaaa	8an
Sample			
25S	LH	E999	AB3456789
Sample concatenated Unique Item Code:		25SLHE999AB345678	

7. Data Carriers.

7.1. Data Carrier Selection

Matrix code selection shall be in accordance with the related ISO Standards. The two-dimensional symbologies permitted by this standard are:

- Data Matrix ECC 200 (reference: ISO/IEC 16022)
- QR Code (reference: ISO/IEC 18004)

The choice of use 2D symbols shall be agreed between trading partners. When implementing this standards, the reader output string should include the appropriate Data Carrier Identifier as set forth in ISO/IEC 15424.

Special Reduced Space features for direct marking requires selecting of most dense parameters for both printers and readers.

8. DATAMATRIX ECC 200 (ISO/IEC 16022)

Parameter requirements

One key parameter is the dot size of a matrix code. This is the "X" dimension.

8.1. "X" dimension

Nominal dot dimension "X" of Data Matrix ECC 200 is 0,38 mm, standard resolution is 0,25mm. Lower resolutions need special considerations for printing and scanning.

8.2. "X" dimension for smallest size applications

The minimum "X" dimension for Reduced Space item marking shall be 0,2 mm.

8.3. Dot Matrix

The Dot Matrix of a DATAMATRIX Code depends on the number of data to be carried. The matrix grows with the number of data encoded with the symbol. Datamatrix includes a compaction feature for numeric data, increasing the capacity for numerics.





samples enlarged	dot matrix	data capacity	
		numeric	alpha numeric
	14x14	16	10
	16x16	24	16
	18x18	36	25
	20x20	44	31

Table 3 Dot matrix growth with the number of data and data set

8.3.1. Rectangular option of Datamatrix

Datamatrix might be printed square or in a rectangular format

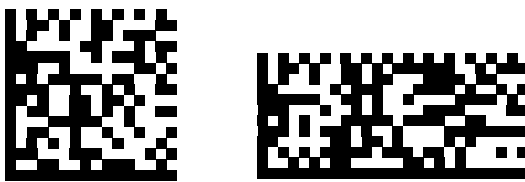


Figure: Datamatrix square format 16x16 versus rectangular format 12x26

9. QR Code (ISO/IEC 18004), Micro QR

QR and Micro QR code are potential symbologies for unique marking as well. Parameters for use of QR Code for Reduced Space direct marking will be added according to demand and appropriate input from experts and user groups.

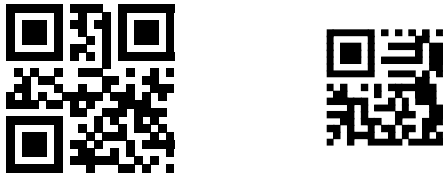


Figure - Example of QR Code and Micro QR (enlarged)

10. World wide Unique Identification Mark (UIM)

The world wide Unique Mark consists of the world wide unique item number with header "+" or "25S" and the Matrix symbol carrying the unique data.

11. Marking by Laser Edging

Laser Edging is the recommended technology for direct marking of parts. Spectral contrast shall enable symbol recognition by the scanning devices. The setting shall be set according to the material of the device to achieve resolution and spectral contrast required by the selected reader.

11.1. Product Responsibility

The manufacturer is responsible for the functionality of its product. Laser edging shall meet the requirements of unique item marking but shall not interfere with the natural functions of the part itself. If Laser Edging is executed by service providers or end users, the manufacturer shall give advice about best parameters of edging.

12. Print quality

In general print quality should be tested in accordance with ISO/IEC 15415 - Bar Code Symbol print quality test specification - two dimensional symbols. For laser direct marking the specification of the scanner to be used with focus on spectral contrast between dots and spaces.

13. Scanning

The scanning device for recognition of spectral contrast of the symbol shall be selected according to application requirements.

The scanner shall be adjusted for resolution suitable for symbol "X" Dimension of 0,2mm.

14. User Guidance for selecting symbol sizes

Symbol sizes depend on the numbering scheme and available space. The samples below may assist in finding the most sufficient solution which may fit to the application.

Rules for finding the appropriate selection:

- A) No space problem for direct marking items:
Select standard HIBC data structure and nominal symbol resolution of 0,38mm.
- B) Space reduction with standard HIBC structure:
Select Space Reduced Resolution of 0,2mm
- C) Smaller size required:
Select DI "25S" data structure with Reduced symbol resolution 0,2mm
- D) Smallest Micro Size required:
Limit the numbering scheme to the shortest numeric data string possible, e.g. 4 digit numeric serial number only

14.1. DATAMATRIX symbol sizes with Standard HIBC data structure

The HIBC data structure includes all necessary data elements for product tracing. It is suitable for use with DATAMATRIX for applications where linear Barcode or even stacked CODABLOCK F is too large. The actual size depends on the length of the article number of the item as of the serial number. The examples with nominal and reduced space resolution below show a HIBC code with 6 digit article number and 8 character long serial number.




1	Data Identifier (DI)	Labeller Identification Code (LIC)	Example Product Code	Package index	Separator	Flag SN	Serial number example	Check	
	+	E999	123456	0	/	\$	AB345678	L	
	Unique HIBC Code sample with 6 digit product code and 8 digit serial number for a 18x18 Datamatrix			+E999123456/\$AB345678L					
1.1	Nominal Size with resolution of X=0,38mm: 6,8x6,8mm			+E999123456/\$AB345678L					
1.2	Standard size with resolution of X=0,25mm: 4,5x4,5mm			+E999123456/\$AB345678L					
1.3	Reduced Space size with resolution of X=0,2mm: 3,6x3,6mm			+E999123456/\$AB345678L					

Table 4: Samples HIBC data with nominal, standard and reduced space resolution (graphics not to scale)

14.2. DATAMATRIX symbols sizes with reduced space DI structure





Symbol sizes with DI structure of unique serial number with DI "25S" + HIBC Labeller Identification Code (LIC).

The application will set the necessary numbering scheme of numeric or alpha numeric data. The size of the symbol will depend on the data volume and the chosen resolution. Choice of specific serial number schemes for length and content might be selected from the table below in conjunction with necessary resolution.

Table Samples of nominal resolution matrix with HIBC DI "25S" structure

2 DATAMATRIX symbol sizes with nominal resolution of X 0,38mm										
	DI	IAC	LIC	capacity			serial no. examples	DotMatrix mm	Unique SN	
1	25S	LH	Eaaa	8an	36^8	>100Mlrd	AB345678	16x16 6,1x 6,1mm	25SLHE999AB345678	
2	25S	LH	Ennn	11n	10^11	<100Mlrd	12345678901	16x16 6,1x 6,1mm	25SLHE99912345678901	
3	25S	LH	Eaaa	2an	36^2	1.269	AB	14x14 5,3x5,3mm	25SLHE999AB	
4	25S	LH	Ennn	3n	3n	999	123	14x14 5,3x5,3mm	25SLHE999123	

Table 6 Samples high density resolution matrix and HIBC DI "25S" structure






3 DATAMATRIX symbol sizes with resolution of X 0,2mm										
	DI	IAC	LIC	capacity			SN examples	Dot Matrix mm	Unique SN	
3.1	25S	LH	Eaaa	8an	36^8	>100Mlrd	AB345678	16x16 3,3x3,3mm	25SLHE999AB345678	
3.2	25S	LH	Ennn	11n	10^11	<100Mlrd	12345678901	16x16 mm	25SLHE99912345678901	
3.3	25S	LH	Eaaa	2an	36^2	1.269	AB	14x14 2,8x2,8mm	25SLHE999AB	
3.4	25S	LH	Ennn	3n	3n	1.110	123	14x14 2,8x2,8mm	25SLHE999123	

(graphics not to scale)

15. Selection criteria for world wide unique ID Marks for small items

In order to find the optimal sized solution for marking small items the maximum space available for a symbol should be defined first. Next step might be to define the required structure and length of the serial number of the item. A sample should be generated with full HIBC data content with product code and serial number. If this is too large, the appropriate "X" dimension should be chosen. If still too large, the space reduced data structure with DI "25S" in conjunction with reduced space resolution should be selected. If the full serial number would not fit to the space, the serial number might be shortened down to micro size.

Table 7 - Illustration nominal to micro sized symbols and its capacity for data and serial numbers

Structure	sample data	size	symbol
HIBC data structure with 6 digit product code & serial number of 8an	+E999123456/\$AB345678L	nominal 18x18 X=0,38, 6,8x6,8mm	
HIBC data structure with 6 digit product code & serial number of 8an	+E999123456/\$AB345678L	standard 18x18 X=0,25,	
HIBC data structure with 6 digit product code & serial number of 8an	+E999123456/\$AB345678L	reduced space-small 18x18 X=0,2	
DI+HIBC LIC structure with serial number 11n (or 8an)	25SLHE99912345678901	reduced space - smallest 16x16 X=0,2	
DI+HIBC LIC structure with serial number 3n (or 2an)	25SLHE999123	reduced space - micro 14x14 X=0,2	

15.1. Scaling

Matrix symbols allow flexible scaling of sizes, so any size could be achieved between nominal and high density resolution according to available space. The golden rule of determination the appropriate size is:

- **As large as possible, as small as necessary, but not smaller than 0,2mm**

16. Annex Glossary of terms

- **ANSI**

American National Standards Institute

- **ANSI/MH 10**

An ANSI accredited committee responsible for the development of American national standards on unit-load & transport-package sizes, package testing standard, definitions & terminology, standardization of unit-load height, sacks & multi-wall bag standards, coding & labeling of unit-loads.

- **ANSI/MH 10/SC 8**

An ANSI accredited committee responsible for the development of American national standards on the coding and labeling of transport packages and unit loads, product packaging, and radio frequency identification for returnable containers. ANSI/MH 10/SC 8 serves as the U.S. Technical Advisory Group (TAG) to ISO TC 122.

- **ASCII**

American Standard Code for Information Interchange: a computer code, as described in ISO 646, consisting of 128 alphanumeric and control characters, each encoded with 7 bits (8 including parity check), used for the exchange of information between computerized systems.

- **character**

See Character Set, Data Character, Symbol Character, Human Readable Character.

- **character set**

The total range of letters, numbers, and symbols that can be encoded in a particular symbology. See Code Page, Code Set.

- **CIN**

Company Identification Code, assigned by an Issuing agency (see IAC) under the rules of ISO/IEC 15459.

- **coded character set**

A set of unambiguous rules establishing a character set and the relationship between the characters of the set and their byte values.

- **Data Identifier (DI)**

A specified character string which defines the specific intended use of the data that immediately follows. The identifier shall be an alphabetic character or an alphabetic character preceded by up to three numeric characters as defined by ANSI MH10.8.2, Data Application Identifier Standard. A character (or set of characters) within a machine-readable symbol that defines the general category or specific use of the data that is encoded in the same machine-readable symbol. See ISO/IEC 15418/ANSIMH10.8.2.

- **Data Matrix**

An error correcting two-dimensional matrix symbology, developed in 1989 with finalized design in 1995 by International Data Matrix, capable of encoding various character sets including strictly numeric data, alphanumeric data, and all ISO 646 (ASCII) characters, as well as special character sets. The symbology has error detection and error correction features. The intellectual property rights associated with Data Matrix have been committed to the public

domain. See ISO/IEC 16022.

- **decoder**

An electronic assembly that translates the proportional electrical signals from a scanner into recognizable or computer-compatible data.

- **dot**

A localized region with a reflectance that differs from that of the surrounding surface.

- **error correction**

A mathematical procedure which allows the detection and rectification of errors to take place.

- **HIBC**

Health Industry Bar Code.

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- **human-readable interpretation (HRI)**

The letters, digits or other characters associated with the encoded message and printed adjacent to the bar code or two-dimensional symbol. See “human readable information.”

- **Issuing Agency Code (IAC)**

Code assigned by the Netherlands Standardization Institute for Associations which qualified for issuing Company Identification Codes according to ISO/IEC 15459, such as EHIBCC, etc.

- **Labeler Identification Code (LIC)**

The LIC is registered with EHIBCC under the rules of ISO/IEC 15459 for the purpose of building unique numbers for items and shipments.

- **print quality**

The degree to which a printed optical symbol complies with the requirements which are specified for it, such as dimensions, reflectance, edge roughness, spots, voids, etc., which will affect the performance of the scanner.

- **QR Code**

An error correcting matrix symbology, introduced in 1994 by Denso Corporation, consisting of an array of nominally square modules arranged in an overall square pattern, including a unique finder pattern located at three corners of the symbol. See ISO/IEC 18004.

- **quiet zone**

The area free from interfering markings which must surround a bar code symbol and, in particular, precede the start character and follow the stop character. Also referred to as light margin or clear area.

- **reader**

A device used to capture the data encoded in a machine-readable symbol or other automatic data capture media. Machine-readable symbol readers consist of two parts: the transducer that sends signals proportional to the reflectivity of each successive element of the symbol to the decoder, that examines the signals from the scanner and translates them into recognizable or

computer-compatible data. The decoder itself is sometimes called a reader.

- **resolution**

Measure of the fineness of detail of an image which a piece of equipment can produce or distinguish. The width of the narrowest element capable of being read by the equipment under test.

- **scanner**

An electronic device that converts optical information (e.g. a printed bar code) into electrical signals for subsequent decoding and transmission to a computer. See also Bar Code Reader, Decoder.

- **serial number**

A code assigned by the Supplier to an entity for its lifetime, (e.g., computer serial number, traceability number, contract tool identification)

- **structure**

The order of data elements in a message.

- **supplier**

In a transaction, the party that produces, provides, or furnishes an item or service.

- **symbol**

See bar code symbol.

- **symbol character**

The physical representation of the code word as a pattern of dark and light elements. There may be no direct one-to-one mapping between symbol character and data character or auxiliary character. Decoding through the compaction rules is necessary to identify the data.

- **symbolology**

A standard means of representing data in bar code form. Each symbology specification sets out its particular rules of composition or symbol architecture.

- **symbology identifier**

A sequence of characters, generated by the decoder and prefixed to the decoded data transmitted by the decoder, that identifies the symbology from which the data has been decoded. See ISO/IEC 15424, *International Specification - Data Carrier/Symbology Identifiers*.

- **traceability identification**

A code assigned to identify or trace a unique group of entities (e.g., lot, batch, item, revision/version or serial number).

- **two-dimensional (2D) symbols**

Machine-readable symbols that must be examined both vertically and horizontally to read the entire message. Two dimensional symbols may be one of two types: matrix symbols and multi-row symbols. Two dimensional symbols have error detection and may include error correction features.

- **Unique Identification Mark (UIM)**

A mark consisting of a standard Matrixcode symbol and embedded data for unique item identification.

- **"X" dimension**

1. The specified width of the narrow elements in a bar code symbol. See Z Dimension. 2. The specified width of a single element in a matrix symbol.

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