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. /2010-09-20

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
Revision 2003	Completion of dimension for QR Code
Revision 2010-09-20	Add HIBC serial number and change minimal dot size for HQ print, add reference to ISO/IEC DTR 29158 Direct Part Mark (DPM) Quality Guideline

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for smallest item marking

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Content

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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 .
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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 DTR 29158	Direct Part Mark (DPM) Quality Guideline
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	2009-05-27, 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.

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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 18 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.

System Identifier (SI)	Labeler Identification Code (LIC)	Product Code	Package index	Sepa-rator	Flag SN	Serial number	Chec k
+	Eaaa	18an	1n	/	$+	18an	1an
Sample							
+	E999	123456	0	/	$+	AB345678	J

Sample concatenated Unique Item Code with data above:	**+E999123456/$+AB345678J**

If the product code is not required for building an UIM, than a single data element can be constructed by help of the Data Identifier “25S” followed by the sequence: Issuing Agency for Company Codes (LH is registered for HIBC), followed by the Company Identification Code (Labeler Identification Code –LIC), followed by Serial number.

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Table 2 - Structure of a Unique Item Number applied with Data Identifier (DI)

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**	

The single data element “25SLHE999AB345678” is unique as well but does not include product information.

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 for Direct Product Marking (DPM). For High Quality prints (geometry and contrast) the minimal “X” dimension shall be X=0,17mm as lowest.

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.

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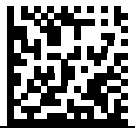
Table 3) Datamatrix growth with the number of data and data set

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

8.3.1. Rectangular option of Datamatrix

Datamatrix might be printed square or in a rectangular format

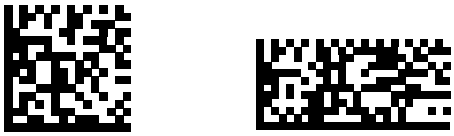
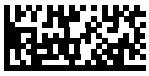


Figure 1) Datamatrix square format 16x16 versus rectangular format 12x26

Rectangular codes of Datamatrix is growing with the data volume as well but with different steps. Three sizes are shown with the table below for most likely use with UIM's.

Table 3.2) Sizes of rectangular Datamatrix

Examples rectangular format	Modules	Data capacity (incl. control characters)	
		numeric	**alpha numeric**
	8x32	20	13
	12x26	32	22
	12x36	44	31

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

QR and Micro QR code are potential symbologies for unique marking as well.
Both are regular options for marking products according to HIBC standard.

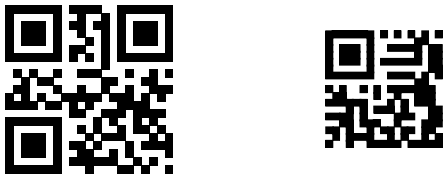

Figure 2) Example of QR Code and Micro QR (enlarged)

9.1. Parameter requirements of QR Code

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

9.2. “X” dimension

Nominal dot dimension “X” of QR Code is 0,38 mm, standard resolution is 0,25mm. Lower resolutions need special considerations for printing and scanning. Such special consideration is given to small products marking by the specification of the minimum "X" dimension below.

9.3. "X" dimension for smallest size applications

The minimum “X” dimension for Reduced Space item marking shall be 0,2 mm for Direct Product Marking (DPM). For High Quality prints (geometry and contrast) the minimal “X” dimension shall be X=0,17mm as lowest..
Similar to DATAMATRIX, the Dot Matrix of a QR-Code depends on the number of data to be carried. The matrix grows with the number of data encoded in the symbol. Datamatrix includes a compaction feature for numeric data, increasing the capacity for numerics.

Table 3.1 QR Code Dot matrix growth with the number of data and data set

examples (not to scale)	QR type	modules	Total capacity of encoded characters	
			numeric	alphanumeric
	Micro QR	15x15	18	11
	Micro QR	17x17	30	18
	QR	21x21	34	24
	QR	25x25	63	38

(NOTE: For larger symbol sizes see ISO/IEC 18004)

10. Headers of World wide Unique Identification Mark (UIM)

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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 advise 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 direct marking the specification applies “ISO/IEC DTR 29158 Direct Part Mark (DPM) Quality Guideline”.
For laser direct marking the specification of the scanner to be used should be considered as well with focus on parameters for recognition of 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.

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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. 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 to 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 shows a HIBC code with 6 digit article number and 8 character long serial number (in total 23 characters).

Table 4) Symbol sizes with X-dimension 0f 0,2mm per dot and a HIBC code of 23 characters

	ID	LIC	Product/ Article code	Package index	Sepa-rator	Flag for SN	Serial number	check
structure	+	Eaaa	1-18	1n	/	$+	1-18	1an
example	+	E999	123456	0	/	&+	AB345678	J
Concatenated data sting			+E999123456/$+AB345678J					

Unique HIBC code	Capacity with size of 3.6x3.6 mm: SN 8an or 11 digit	Symbol dimensions with X=0,2 mm	Beispiele
+E999123456/$+AB345678J	8 an ≈ 36^8 ≈ 2901 billion or 11 n ≈ 10^{11} ≈ 1111 billion	Datamatrix 18x18 modules: 3,6 mm x 3,6 mm	
		QR-Code 25 x 25 modules: 5 mm x 5 mm	
Note: *For the sample the HIBC primary sequence was selected followed by a serial number. Other sequences and max. capacity see ANSI HIBC 2.3 or HIBC guidelines.*			

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Symbol sizes are depending from both data content and dot size “X”. The table below shows same data content but sizes of codes with 3 different dot sizes.

Table 5) Samples HIBC data with nominal, standard and reduced space resolution

	Unique HIBC Code sample with 6 digit product code and 8an serial number for a 18x18 Datamatrix	+E999123456/$+AB345678J	**Data Matrix mm**	**QR mm**
1	**Nominal Size** resolution of X=0,38mm	+E999123456/$+AB345678J	 **6.8x6,8**	 **9,5x9,5**
2	**Standard size** resolution of X=0,25mm	+E999123456/$+AB345678J	 **4,5x4,5**	 **6,25x6,25**
3	**Reduced Space** size resolution of X=0,2mm	+E999123456/$+AB345678J	 **3,6x3,3,6**	 **5x5**

14.2. Symbol 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 6 Samples high density resolution matrix and DI "25S" structure

UIM samples applied with DI “25S”	**Number of** characters for the samples	**Capacity for serial numbers** ≈ **Billions**		**Code, dot matrix and size with X 0,2mm**		
				Datamatrix	**QR code**	**Micro QR**
25SLEIBM12345678901	19	11n	≈ 10^{11} ≈ 1111	16 x 16 3,2 x 3,2mm	21 x 21 4,2 x 4,2mm	17 x 17 3,4 x 3,4mm
25SLEXYZAB345678	17	8an	≈ 36^{8} ≈2901	16 x 16 3,2 x 3,2mm	21 x 21 4,2 x 4,2mm	17 x 17 3,4 x 3,4mm
25SLEY99ABC	11	3an	≈ 36^{3} = 47.989	14 x 14 2,8 x 2,8mm	_	15 x 15 3,0 x 3,0mm
25SLEY991234	12	4n	≈ 36^{4} ≈ 1.7	14 x 14 2,8 x 2,8mm	_	15 x 15 3,0 x 3,0mm

Note: *Other symbol sizes than based on X-diemension of 0,2mm are not illustrated and subject of calculation dot size x number of dots of the matrix (e.g. Matrix 16x16/dot 0,2mm: 16x0,2=3,2mm)*

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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 to large, the appropriate "X" dimension should be chosen. If still to 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 DATAMATRIX symbols
and its capacity for data and serial numbers

Structure	sample data	modeules/dimensions	Datamatix size
HIBC data structure with 6 digit product code & **serial number of 8an**	+E999123456/$+AB345678J	**nominal** 18x18 X 0,38mm	 6,8x6,8mm
HIBC data structure with 6 digit product code & **serial number of 8an**	+E999123456/$+AB345678J	**standard** 18x18 X0,25mm	 4,5x4,5mm
HIBC data structure with 6 digit product code & **serial number of 8an**	+E999123456/$+AB345678J	**reduced space-small** 18x18 X0,2mm	 3,6x3,6mm
DI+HIBC LIC structure with **serial number 11n** **(or 8an)**	25SLHE99912345678901	**reduced space - smallest** 16x16 X0,2mm	 3,2x3,2mm
DI+HIBC LIC structure with **serial number 3n** **(or 2an)**	25SLHE999123	**reduced space - micro** 14x14 X0,2mm	 2,8x2,8mm

Note: *Equvalent QR symbols are not illustrated with the table but subject to same calculation principle of nr. of modules x dot size..*

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**

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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.

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- **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.

- **symbology**

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.

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- **"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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Figure 3) HIBC Unique Identification Mark (UIM) applied to a surgical instrument (UIM enlarged)

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