

**Unique Identifikation for
control and documentation of clinical processes
ISO conform & UDI compatible**

Unique Patient ID

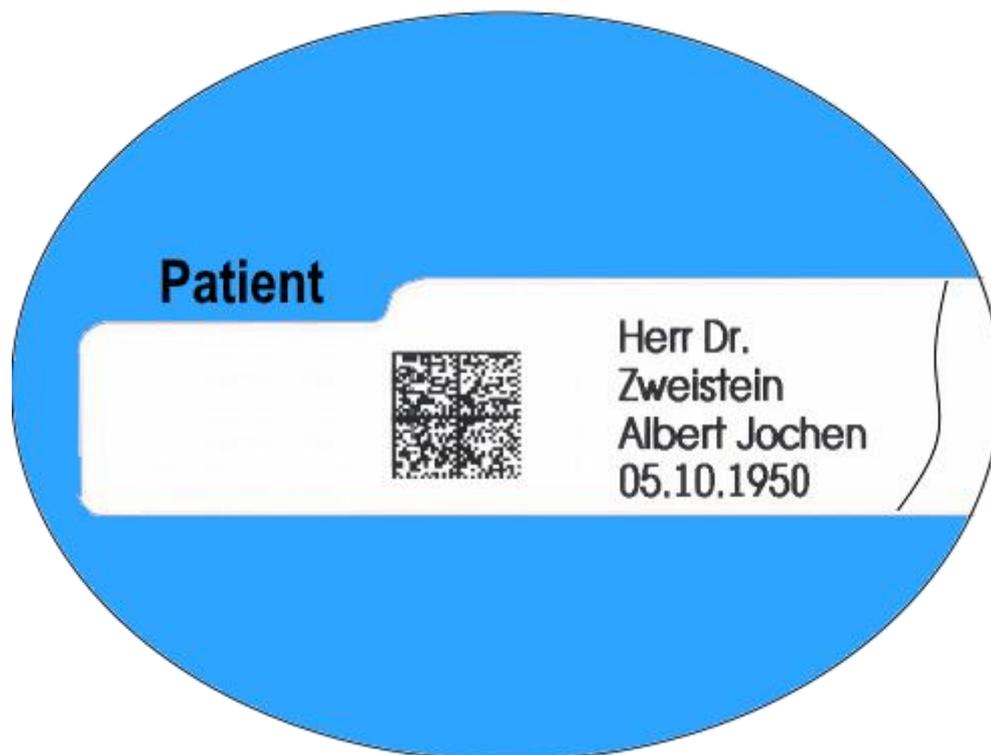


Fig. 1) Excerpt of a patient wrist band, source Universitätsklinikum Jena, Germany

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2. Unique Identification in a Hospital by help of Data Identifiers (DIs) flagging the content of codes

The Healthcare Barcode (HIBC) represents the classical structure for unique product codes since 1986. It has capacity for the traceability attributes of medical devices for unique identification along the supply chain up to the point of use in the hospital. But the hospital has the requirement to label internal items too, like patient wrist bands, sterilization containers, equipment, locations, to name some. For that purpose, ISO standards provide the means for internal unique labelling interoperable and free of overlapping with all other codes flooding in from outside. The means are the ISO/IEC 15418 GS1 Application Identifiers and ANS MH 10.8.2 Data Identifiers commonly used for supply chain management and item tracking. AIs are numeric, DI's are alphanumeric, both are flagging the content of the data elements being applied to in a barcode or RFID tag.

This specification focuses on the application of data elements that are provided with an ASC data identifier, since key elements can be carried alphanumerically from existing systems, e.g. patient IDs, location identifiers, etc. Data identifiers are ideally suited for unambiguous encoding of alphanumeric data elements avoiding the risk of confusion between codes from different sources. Data elements without such identifiers don't feature such a secure data capture independent of ERP systems or sub-systems being used.

DI's may additionally be embedded in a syntax defining the structure by help of a system identifier. Such unique codes are already in wide usage for unique marking and identification of surgical instruments, probes, vials, wrist bands, etc. but also for identifying incoming shipments of any kind.

Finally, the ASC DI's and thus unique data elements are carried in automatically readable codes. We have linear barcodes available like ISO/IEC 15417 Code 128, 2d-symbologies and RFID as well for specific applications. Most recommended symbols include ISO/IEC 18004 QR code and ISO/IEC 16022 Data Matrix. The smallest DataMatrix can reach up to approx. 3x3mm or even shaped rectangular with the "DMRE" variation. The term "Unique Identification Mark (UIM)" is also used for this purpose (see Chapter 4).

3. Code structures and concatenation of data elements in one code

Depending on the item to be encoded, only one data element might be required, for example a unique serial number for a sample tube. Other codes are intended to carry multiple data elements, for example, patient wristbands with attributes to the patient ID, such as case number and name(s).

If it is necessary to encode several data elements in one code, then the syntax is recommended: „DIN 16598 Syntax keyboard and Web compatible encoding of data elements in machine readable symbols applied with ASC Data Identifiers “. This structure uses only printable characters that are also present on the keyboard, so keyboard compatibility is given for scanning.

In the syntax DIN 16598, the system identifier is " ." (dot) identifying codes applied with data identifiers. The separator to concatenated data elements and between each additional data element is the Circonflex (^). The difference between code structures with one and more data elements is explained in a) and b) below.

a) Code structure with one data element applied with DI

The data string is starting with the system identifier " ." (dot) according to DIN 66403, followed by the specific ASC DI, which describes the meaning of the data element, followed by the specific value.

System identifier	Data Identifier	Value
SI „ . “	DI	Data

b) Struktur bei aneinandergereihten Datenelementen

If data elements are to be concatenated, then the character Circonflex (^) is used as a separator:

System identifier	Data Identifier	Value	Separator	Value	Separator	Value	etc.
SI „ . “	DI	Data	^	Data	^	Data	...

For examples see chapter 5.

Note: For concatenating data elements, each with its own DI, the "plus sign (+ “) has traditionally been used as a separator. However, the " + “ also has other meanings in some cases and "DIN 16598" uses the character "Circonflex (^) as a separator to avoid confusion. " ISO/IEC 15434 "Syntax for High Capacity Media" is also available as syntax but it is not keyboard-compatible and is only recommended for codes with large data volumes and/or multiple structure types in one code.

4. Unique Identifikation Marke – “UIM¹”

A UIM consists of a data element with unique serial numbers, and is intended for the smallest codes and a minimum space, e.g. for surgical instruments. A UIM includes SI " ." and DI "25S" in a standardized sequence, which describes the data element in "unique serial number":

The DI “25S“ is defining the unique sequence as follows: DI, followed by the code of the Issuing Agency (IAC), e.g. QC for EDCi, providing the Company ID (CIN) of the labeller, followed by the registered CIN of the labeller, e.g. UKLJ, and terminated by the Serial number , e.g. 1234567890 .	
The complete sequence for encoding is:: <SI><DI> <IAC><Labeller’s CIN><Serial number>	Encoded with Data Matrix
< . . ><25S><QC><UKLJ><1234567890>	 .25S QCUKLJ1234567890

The example sequence ".25S QC UKLJ 1234567890" represents a globally unique serial number for encoding in a data carrier as a barcode, 2D (DataMatrix) or RFID.



Fig. 3) Sample of a Data Matrix and emblem for an embedded RFID tag.

If additional data elements are required to be add to this serial number, they can be added and separated by Circonflex " ^ " in accordance with the syntax DIN 16598.

5. Globally unique Patient ID with Data Identifier “25H”

Already at the year 2010, the data identifier "25H - Globally Unique Personal ID" was registered on request of health care providers. This DI performs ideal for unique marking of patient wristbands, especially for applications with different locations and decentralized systems. The sequence of DI "25H" guarantees not only internal, but also global uniqueness.

¹ Die Norm UIM ist als DIN 66401 über www.DIN.de beziehbbar

The sequence of the "Globally Unique Personal ID" is structured as follows:

	SI	DI	Issuing Agency Code (*IAC)	Registered CIN (Hospital ID)	Serial number
System Identifier	.				
Globally Unique Personal ID		25H			
Code of the Issuing Agency			QC (e.g. EDCi)		
Code of the labeller (Hospital)				ABCD	
Serial number					<u>1234567XYZ</u>

*IAC=ISO/IEC 15459-2 IAC of the Issuing Agency for the registered CON of the labeller.

Resulting data element for encoding with a linear or wd-barcode or RFID:

•25HQABCD1234567XYZ

The system identifier is not shown in the code interpretation line, but the DI is placed in parentheses for visual recognition:

(25H) QC ABCD 1234567XYZ.

Coded in a symbol, read by a scanner and transmitted via an interface, the computer recognizes the exact meaning and content, namely ASC-DI structure, sequence "Unique Personal ID" and the data content with the serial number.

As the size of a DataMatrix with module size X=0,3mm and applied with the above unique patient ID will result in the size of 5,4x5,4mm:



(25H)QCABCD1234567XYZ

Fig. 4) Globally unique Data Matrix code for patient wrist bands

Note for experts: Instead of the system identifier ". " header and the format "06" of syntax ISO/IEC 15434 can also be selected, which indicates the use of DI's in the multiple syntax.

If the clinic has codes for patient wristbands and for staff cards, name badges, etc., the personal ID can be applied with corresponding attributes of the database. Accordingly it is possible to put an attribute in the ID, e.g. a "P" in front of the serial number for patients, e.g. an "I" for internal staff or an "E" for external staff, etc.. The table below shows potential solutions to this:

	DI	IAC	Clinic ID	internal ID	Serial number	Unique data element
Patient	.25H	QC	EHOS	P	<u>1234567XYZ</u>	.25HQCEHOSP1234567XYZ
Personal internal	.25H	QC	EHOS	I	<u>1234567XYZ</u>	.25HQCEHOSI1234567XYZ
Personal external	.25H	QC	EHOS	E	<u>1234567XYZ</u>	.25HQCEHOSE1234567XYZ

6. Data Identifiers for IDs and attributes for person/patient wrist bands

a) Wristband and data

A wristband in a clinic is used to identify a person, whose reference must be unique in the clinic's system, but also distinguish from other codes. In addition, a person ID can not only be unique within one system, but also globally unique across departments and institutions and their centralized/ decentralized systems. For this purpose, the functionality of the "DI's" was described at the beginning using the example of the unique serial number with "DI 25S".

The category "H – Human Resources" is used specifically for personal identification. The table below contains an excerpt of the list of Data Identifiers for encoding as single data element or concatenated with other data elements according to DIN 16598.

DI	Definition according to ISO/IEC 15418, part ASC MH10.8.2)
1H	Personal ID / Employee Identification Code assigned by employer .1H772812X14
3H	Personal ID ID, mutually agreed .3H1281011PQ18
5H	Family name / Last Name .5HMUSTERMANN
11H	First name and middle initial .11HOTTOKAR-W
25H	Globally unique personal ID (Patient ID) applied with "Issuing Agency Code" followed by "Hospital ID" and net value of the personal ID, e.g. as serial number .25HQCKLNK01234567XYZ
12S	Document number., case number .12SQCKLNK987XY77Z14
nY	For internal definition, if no standard DI is available or desired, e.g. 10Y for maintenance processes, 11Y für xxx, etc.) .10Y09X4321B

For the complete DI list, see ISO/IEC 15418 / Part ANS MH10.8.2 (Bibliography/Sources)

b) Concatenation of Data elements of a patient wristband

For the concatenation of data elements within one code, the syntax DIN 16598, according to chapter 3, is used.

The following example will illustrate a code with concatenated data elements, here a globally unique person (patient) ID, DI "25H" applied with the attributes Surname, DI "5H", First name DI "11H" and case number, DI "12S":

<•>< 25HQCKLNK01234567XYZ<^>5HMUSTERMANN<^>11HOTTOKAR-W<^>12SQCKLNK987XY77Z14,

oded string: •25HQCKLNK01234567XYZ^5HMUSTERMANN^11HOTTOKAR-W^12SQCKLNK987XY77Z14

Human readable interpretation is printed without the control characters but with DI's in brackets:

(25)HQCKLNK01234567XYZ(5H)MUSTERMANN(11H)OTTOKAR-W(12S)QCKLNK987XY77Z14



Fig. 5) DataMatrix of a patient wrist band applied with the above data.

Resulting measure of the Data Matrix of fig. 5 is 8x8mm with Data Matrix module size of X=0,25mm.

c) Coding of „tremas (umlaut)“ e.g. for names

See annex 12).

7. Option “Blood Group ID” encoded with a wrist band

EUROCODE IBLs, the "International Blood Labelling System", maintains the labelling standard for blood products with all specific characteristics. This also includes the identifiers for blood groups. The system identifier for the system is the exclamation mark "!". If a specific data element, such as blood group, is to be incorporated into the patient ID as an additional characteristic, then this can be done by stringing together the data elements "Global Unique Personal ID" + "Blood Group ID". According to the rules for stringing together data elements with DI's, the plus sign "+" can be used as a separator.

The EUROCODE standard specifies the corresponding data format under Chapter 1.2 "BLOODGROUP (RED CELL ANTIGENS)". From this, the excerpt shows some options as follows:

- ! = Primary data identifier for a EUROCODE 128
- R = Secondary Data Identifier, carrying attributes “abcd”

“abcd” values are numeric {0-9} defining the blood groups in detail (see list below)

a	AB0;TABLE: 0= no result; 1 = A; 2=B; 3=AB; 4= 0; 8 =0h (Bombay); 9 = special
b	Rh; TABLE: 0=no result; 1=D pos.; 2=D neg.; 3=D weak; 4=D partial; 8=--dd--; 9=special
c	Rhesus subgroups; TABLE: 0 = no result; 1 = CcEe; 2= CCee; 3 = Ccee; 4 = ccee; 5=ccEe; 6= ccEE; 7 = CcEE; 8=CCEE; 9 = CCEe.
d	Kell and/or Cw; TABLE: 0= no result; 1 = K pos.; 2= K neg.; 3 =C w pos ; 4=C wneg; 5=Kell pos,Cwpos; 6=Kell pos, Cw neg; 7 = Kell neg, Cw pos; 8 = Kell neg, Cwneg; 9= special

EXAMPLE of a Blood Group code as a single data element flagged by “!":

Data element	Description of blood group
!R1131	the red cell antig. of the unit A Rh pos (D pos) CcD.ee Kell pos

Patient ID and blood group encoded in one code

To the unique Patient ID „25HEHOS1234567“ blood group “!R1131” shall be add. For this case both data elements will be concatenated and structured according to DIN 16598 syntax:

SI	DI	Patienten-ID	Separator	Eurocode ID “blood group“
•	25H	QCEHOS1234567XYZ	^	!R1131

Data string for encodation of patient ID with blood group: .25HEHOS1234567^!R1131

Note: For countries where the ICCBBA ISBT code is used for labeling blood products, the ISBT format can be used instead of the Eurocode format (see standard ICCBBA ISBT 128)

8. Other unique code constructs, e.g. with DI "25S"

There is a variety of items within and around a hospital that need to be uniquely identified, recorded and documented. This includes equipment, inventory, spare parts, etc. If these are not already clearly marked, the clinic can do so itself. Same registered CIN as for a unique personal ID can be used for generating all other unique code for clinical applications. With the help of the "25S" data identifier, unique serial numbers can be assigned to practically all items to be individually marked and identified. The unique serial number then serves as a reference to the item with equivalent entries in the database.

The sequence of the unique serial number is structured like the unique personal ID, but not with DI "25H" at the beginning, but with DI "25S" instead:

	DI	Issuing Agency	issued labeler code	serial number
DI defining the data element sequence	25S			
IAC e.g. "QC" for Issuing Agency EDCi		QC		
Registered CIN of the labeller (hospital)			e.g. EHOS	
Serial number				12345678YZ
The data modules:	25S	QC	EHOS	12345678YZ
Data element applied with System Identifier „.“ ready for encodation in a data carrier of the choice, siehe chapter 9).	.25SLHCODE12345678YZ			

9. Data carrier

A number of optical and radiofrequency technologies are available as data carriers. The selection might be done according to available space and specific requirements. Linear barcodes as Code 39 or Code 128 have traditionally been used for wristbands, but today 2d-symbols dominate in these applications for reasons of size and security. DATAMATRIX is in trend, but among other codes, the QR code can also be used. RFID, e.g. for wristbands, is also a valid option or 2d-symbol and RFID as hybrid solution.

The examples fig. 6) below shows the unique patient ID ".25HLHEHOS1234567XYZ" encoded in 3 different symbols: in code 128, DATAMATRIX and QR code.

DATA MATRIX ISO/IEC 16022	QR ISO/IEC 18004
 .25HLHEHOS1234567XYZ	 .25HLHEHOS1234567XYZ
CODE 128 ISO/IEC 15417	
 .25HLHEHOS1234567XYZ	

Fig. 6) One Patient ID, 3 different symbols

10. Patient ID encoded in a RFID tag



Since a described unique patient ID is structured independently of technology, it can also be carried in an RFID transponder.

An invisible RFID chip contained in a wristband is indicated with the RFID emblem according to ISO/IEC 28160 and printed jointly with the information and optional optical codes, like DataMatrix + RFID in hybrid technology.

Appendix 11) shows excerpts of how data are "written" into an RFID transponder. Further details for the implementation can be found in the relevant RFID standards, such as ISO/IEC 15961 RFID data protocol: data encoding rules and logical memory functions".

For the user, the RFID read/write device takes over the conversion into the RFID specifics for data transmission via radio wave.

Fig. 7) illustrates multiple data carrier, e.g. on a wrist band to satisfy different reading spots and interoperability, also back-up:

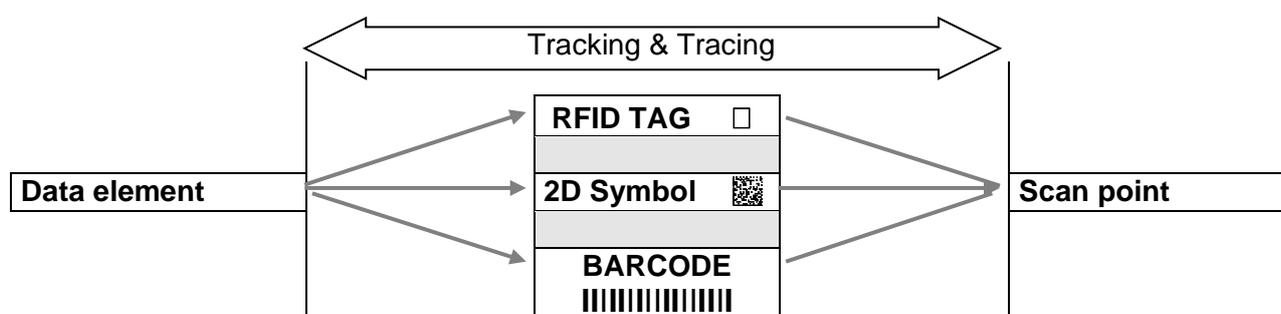


Abb. 7) Different data carrier on one item, e.g. wrist band.

The recommended frequency for RFID for wristband application is 13.56 MHz, specified according to ISO/IEC 18000-3.

For encoding the data in RFID, the following RFID standards apply in addition to the standards for building the unique data string, e.g.: .25QHOSP1234567^!R1131

Data element e.g. Patient ID and Blood Group	RFID Standards for carrying the data safely in open requirements
.25HLHOS1234567^!R1131	ISO/IEC 18000-3, 13,56 MHz ISO/IEC 15961,2, 3 data and protocol ISO/IEC 28160 RFID emblem

11. Annex RFID expert information



ISO/IEC 15961 defines the bits and bytes to the transmission protocol from the RFID read/write device to the transponder. The "Application Family Identifier - AFI" is responsible for recognizing the "DI structure". Thus, the "DI structure" with the described data elements of patient IDs, serial numbers, etc. can be stored for data capture fully compatible with the ISO data carriers barcode, 2D code. The following table already gives an insight into how the data are embedded in the memory of an RFID transponder.

Table: Data elements provided with DIs like in a barcode but embedded in the memory structure of a RFID tag.

RFID Tag type	ISO/IEC 15963 & ISO/IEC 7816-6	ISO/IEC 15961, 15962				ISO/IEC 15418 ASC MH10.8.2 DIs	Application data
	Fixed UID with IC manufacturer ID	AFI	AFS	Access method	Data format	DI	Data (examples)
SN	RFID Tag (IC) Manufacturers responsibility	10	1	0	10	25S	LHA23412345678Z
P-ID		10	1	0 or 1	10	25H	QCHOSP1234567

The conversion of bytes into RFID chip-related BIT array is done in 6-bit resolution.

12. Annex encodation of „tremas“ (umlaut)

Tremas (umlauts) in names can be encoded in DataMatrix for the German language as well as for other languages. For this purpose, the "Extended Channel Interpretation" and use of "UNICODE Code Pages" (e.g. Latin-1 ISO/IEC 8859-1) apply.

The specification of the corresponding symbology, e.g. ISO/IEC 16022 Data Matrix, has to be consulted as well prior to implementation.

Fig. 8) is showing an example of encoding the Polish name "Jędrek" in the data field "1H" for an employee ID.



Fig. 8) Example DataMatrix with coded Polish name with ISO8859-2 character "ę".

The table below shows the DataMatrix code words and the corresponding code words in the DataMatrix.

Table: Data Matrix code words, decimal notation and character values of the sample shown with fig. 8

Position	Codeword (decimal notation)	Derandomized Codeword (decimal notation)	Value
1	241		ECI number following
2	5		ECI 4 (CW – 1) : ISO-Latin 2 East Europe
3	231		Latch to Base256 encodation
4	95	8	Binary length of 8
5	29	49	„1“
6	202	72	„H“
7	98	74	„J“
8	151	234	„€“ in ISO-Latin-2
9	167	100	„d“
10	74	114	„r“
11	211	101	„e“
12	111	107	„k“

Source of example fig. 8 and table: Dr. Harald Oehlmann

Note: The specification for a corresponding "decoder interface" for the transmission of umlauts is initialized in the DIN and ISO/IEC committees for AIDC data carrier standardization.

13. Bibliography, sources

- Barcode standards: ISO/IEC 15417 Code 128, ISO/IEC 16022 Data Matrix: www.DIN.de
- DIN 66401 UIM - Unique Identification Mark: www.DIN.de
- DIN 66403 System Identifiers www.DIN.de
- DIN 16598 Syntax keyboard and Web compatible encoding of data elements in machine readable symbols applied with ASC Data Identifiers www.DIN.de
- List of standardized ANS MH 10.8.2 Data Identifiers: www.e-d-c.info/images/documents
- EUROCODE Standard: www.eurocode.org
- ISO/IEC 18000-3 Radiofrequente Identifikation (RFID) HF 13,56 MHz www.DIN.de
- ISO/IEC 15961,2, 3 RFID and protocol www.DIN.de
- ISO/IEC 28160 RFID emblem www.DIN.de