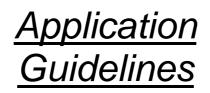
# HIBC BARCODE for Industry and Health Care







2002-11-11

## DOCUMENT MAINTENANCE SUMMARY

This document has had the following changes since the latest update by EHIBCC TC 2001-05-21.

Date	Action	Summary
2002-04-08	correction	EHIBCC logo at front page
2002-04-08	corrections	Editorial corrections
2002-04-08	add	Foot note to section 2.1
2002-04-08	add	Section 8: Introduction to the technical part
2002-04-08	add	Section 12 Quality: Grade 3 "as a minimum"
2002-04-08	add	Section 19 MITL and glossary: reference to ISO 15394
2002-04-08	add	Glossary: License Plate reference ISO/IEC 15459
2002-11-11	exchange	Logo and address F+O against SPECTARIS

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## 1 Introduction

## Foreword

by Heinrich Oehlmann, EHIBCC TC

HIBC Bar Code was developed 1984 as a solution for world wide product tracking. That time Code 39 was the best symbology available for carrying alpha numeric data. It was recognized quickly that automatic data capture by Barcode avoids errors and speeds up logistical processes. Light pens have been used mostly for scanning the code first. But the technology of Barcode entered very fast in new dimensions as Laser beam scanners have been developed, CCD-scanners, powerful decoders and printers. Now not only Barcode is in use, but in addition to it other innovative technologies are available such as 2-dimensional symbologies and RFID. The good news is. that HIBC as a data structure is still valid without any change still offering the features of capability, safety and compactness for unique identification of any kind of products. Today HIBC seems to experience a phase of another spring being refreshed by adoption of small label solutions and supported by its connected FACT Data Identifier structure for unique transport labeling under the same company identity as for the products of the sender. It is a pleasure to see, that HIBC labels are attached to medical devices, pharmaceutical products, X-ray films, chemicals, dental products, documents, gold and silver plates, but also on items of the electronic industries and on many others. Please use the services of EHIBCC offering a life system available for everybody.

The Hague, Oct. 30, 2000

#### Foreword

by Dierk Bellwinkel, FIDE/VDDI/SPECTARIS

In 1992 the VDDI ran a pilot project and demonstrated that a barcode system in the dental field is inevitable. At the same time it determined which system would be the most favorable solution for the dental market.

The result was extremely convincing and the VDDI presented the HIBC barcodesystem during a special seminar to its member companies as well as those of the European dental industry, FIDE. Besides the dental industry the European dental dealers, ADDE, participated in the seminar and they were also convinced of the significant savings and security potential of the system. Honestly, who can flawlessly record and transmit all the data about all the many processing stations and record each individual, single product, no matter how many variations exist of it? It is necessary to provide a possibility to trace back all relevant data concerning manufacturing, storage, order processing and dispatch in case of a return shipment.

We had to wait a long time for the final breakthrough since the external pressure grew slowly over the last few years and it is now finally strong enough to force a reaction.

- Legal requirements demand product marking, external and internal mechanisms to trace the products as well as observation of the product in the market (guidelines about active implants 90/385/EWG, medical devices 93/42/EWG, in-vitro-diagnostica in 98/69/EC as well as the German medical devices law, MPG).
- Quality management systems require the manufacturer to provide a consistent control and Traceability mechanism for the products.

• Future legal developments within the health system will insist on consistent quality management (QM) regulations all the way from the producer to the consumer of medical devices.

The VDDI pilot project tested existing barcode systems and clearly favours the HIBC system for the following reasons:

- The HIBC code is reflected in the FACT standard as CEN-EN 1571 and ANSI standard and will be integrated in the ISO standard in 1997.
- HIBC is able to use all alpha-numeric signs as well as special signs.
- Data can be presented in an individual manner.
- The length of the data is variable.
- A number of legally required markings can be covered. A 2 dimensional printout of the barcode makes use possible on even the smallest packaging units.
- The manufacturer can continue to use his own product numbers.
- The HIBC system is able to integrate individual product and manufacturer numbers of other standardized barcode systems.
- The necessary hard and software is state-of-the-art.

Its flexibility and variability makes the HIBC system the most favourable solution for the dental market including all fields of logistics.

More and more countries and markets become aware of these advantages. The USA and also various EC countries are already using the HIBC for medical devices.

A VDDI workshop confirmed the decision for the barcode system HIBC again in the beginning of 1996. This brochure has been printed in order to publish this decision as well as the advantages of HIBC. It describes the concept and is accessible to all users and interested parties as a general guideline.

Dierk Bellwinkel Cologne, June 2000 VDDI, SPECTARIS, EUROM VI

## 2 Why is HIBC the best system

There are different way's to write an information in Barcode fonts. But for purposes of building tracking and tracing systems in open supply chains only two systems apply being referenced in actual CEN & ISO standards. This is the FACT Data Identifier system with its compressed HIBC syntax and the EAN Application Identifier system. All together meet under one umbrella, the Norm ISO/IEC 15418. This are syntax to be used to carry data for automatic data capture and of course there are some differences in features which are worth wile to compare before choosing one or the other.

## 2.1 Comparison HIBC, FACT, EAN

Comparison between features of HIBC, its global FACT structure, EAN structure and "no standard structure"

Standard	HIBC	FACT	EAN	without	
				standar	
unique	+	+	(+) <sup>1</sup>	-	
compatible with each other	+	+	+	-	
carries tracking data	+	+	+		
product code alpha/num., variable	+	+	-		
compressed, space saving & save	+	-	-		

**The HIBC system is optimized** for unique product identification as a part of the ANSI/FACT Data Identifier Standard.

Key outstanding features are:

- 1. World wide unique since 1987
- 2. Compressed data structure for unique product identification
- 3. Symbology independent, capable for standard Barcode, 2D and RFID
- 4. Capable for users product alpha numeric codes up to 13 characters
- 5. Maintained by EHIBCC Technical Committee and its industries members
- 6. Used in several market segments such as Health Care, Precision Mechanics & Optical Industries, Chemical Industry, Electronic Industry, etc.

**For manufacturers and labellers** it is of vital importance for implementing a tracking system to use the existing numbering scheme rather than to change product codes which would need changes at the marketing side as well as with the customers. The best system is the system which is easiest and cheapest to implement. Barcode shall be a tool for optimisation and for gaining best benefit. It has to be amortised within one or two years. The HIBC system is designed not to change a numbering system but just as a medium to carry existing item information for safe automatic data capture.

## 2.2 Who supports HIBC solutions

Selection of organisations supporting HIBC bar code				
ADDE/BVD	Association for Dental Trade, Europe			
EHIBCC	European Health Industry Business Communication Council			
EUCOMED	European Association Medical Devices			
EUROM VI	European Association for Precision Mechanics & Optics, Medical			
	Technology			
FIDE	Association of Dental Industries, Europe			
SPECTARIS	Association for Precision Mechanics & Optics, Germany			
HIBCC	Health Industry Business Communication Council, USA			
HIDA	Health Industry Distributors Association, USA			
HOPE	Hospitals of Europe Association			
VDDI	Association of Dental Industries Germany			
VDZI	Association of Dental Laboratories, Germany			

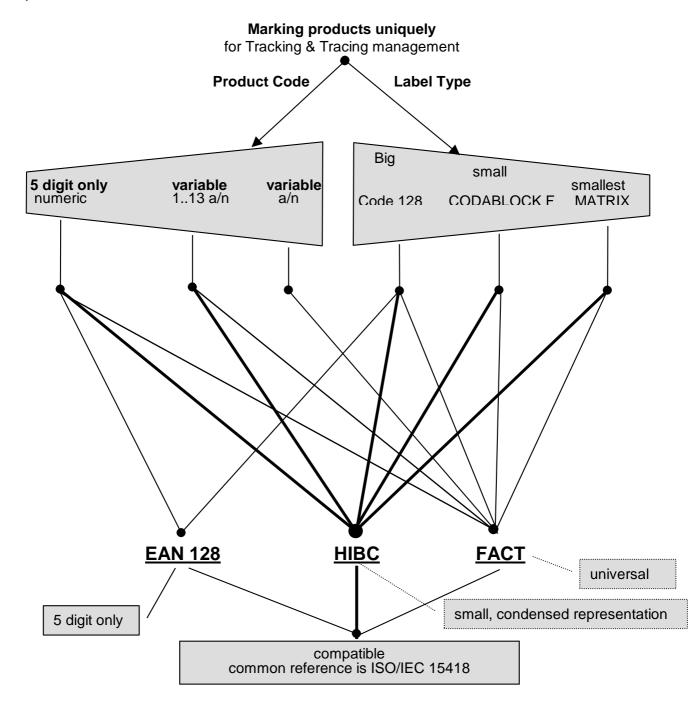
Selection of organisations supporting HIBC bar code

<sup>&</sup>lt;sup>1</sup> EAN 128 is unique only if scanner or computer is able to process the special character FNC 1

etc.

#### 2.3 Decision chart for finding the most suitable system

The chart may help to find the proper system. Off course, "no standard" in terms of data syntax, will never enable uniqueness of anything in open supply systems. So, first decision would be to go with a standard rather than to stick to non identified numbers. Next decision would be worth wile to do, to stick to a "5-digit only" product code for all of the products. If this is the easiest way to encode it in Barcode either the EAN-System would do it or the FACT system and also its embedded HIBC structure.



If product codes are not 5 digit but variable or alpha numeric, than the FACT and HIBC system applies. But FACT data elements are discrete elements and need some space for the code. Optimization is offered by HIBC only by data compression which is a condensed representation of the data. This is the reason, that HIBC is the best system for unique product marking. Furthermore 2-dimensional symbologies might be used for small or smallest labels, or even electronic labels for invisible labeling in the near future if the RFID technology is available once widely.

#### 3 Barcode for supply chain management

Logistics is steered by information. The more precise and error-free this information is available, as correct and safe are the processes steered by it. A barcode-marked product can be identified quickly and clearly anytime and anywhere. Identification works via electronic devices and thus excludes human errors.

What can be clearly identified any time can also be traced back along the logistic chain anytime. This process is called tracking and tracing and describes all advantages an automatic identification system for steering and tracing can offer. Barcode is presently the optimal solution for the constant availability of data all along the logistic chain.

Barcode meets all marking requirements resulting from legal regulations in the health sector, including expiry dates. The integration of quantity details permits the steering of individual articles as well as complete batches or transport units. Finally, by using barcode, it is possible to integrate further information like batch or serial numbers in the product marking. This leads to advantages during the control of incoming and outgoing material, as well as for the correct steering of return shipments.

Advantages for the complete logistic chain through the use of automatic identification are:

- 1. correct and error-free data recording
- 2. direct communication between electronic unit and physical unit (product, receipt,...)
- 3. real time reaction
- 4. batch steering
- 5. steering of transport units
- 6. control of expiry dates
- 7. easier control of incoming and outgoing materials
- 8. steering of return shipments

The barcode marking can start at any point within the logistic chain. To reach the optimum output of the system it is necessary to start as early as possible in the material flow. Ideally this would be the automatically readable marking of the raw materials. When entering the production plant a product can be marked with a barcode which identifies it during the process from storage to dispatch.

Examples for successful use of barcode can be found in the pharmaceutical, electronic, car and chemical industries as well as the consumer goods industry. Here, the use of barcode is limited to manufacturer and part numbers, since this industry uses EAN as a barcode system.

#### 4 HIBC barcode for common use in industry & health care

HIBC originally was developed for health care industries such as medical devices, pharmaceutical products, etc. Due to the outstanding features HIBC bar code is used for unique product marking in different market sectors.

Since the German dental industry has a high export share, it needs to be able to utilize an internationally standardized barcode system.

Companies, which only intend to code minimum information, like manufacturer and part numbers can use the so-called primary code. All other information can be left out if traceability is not needed but unique manufacturer and product identification only. The socalled secondary code is reserved for the variable information important for traceability systems. It carries the information like expiry date, charge, serial numbers etc. In all cases all necessary information is available in one place and in electronically readable form.

Companies that fall under the medical devices law can easily cover the requirements concerning marking and Traceability with the HIBC code.

The HIBC meets all these requirements. Thus, an extremely flexible market solution is available.

The special advantages of the design of the HIBC code in short are the following:

- 1. alpha-numeric structure
- 2. different part number systems can be accommodated
- 3. computer-based connection of primary and secondary code
- 4. optimal use of space because of different code designs
- 5. international explicitness

#### 5 HIBC barcode for distribution and trade

While for the industries marking of individual products and tracing of the packing units is the most important aspect, distributors and dealers will have to realise an extremely flexible concept. Here, the main emphasise is on the movement of the goods, i.e. the delivery from industry to dealer as well as the material flow within the company, from storage to dispatch to the consumer. What adds to the aspect of flexibility is the fact that the products do not necessarily originate exclusively from the local industries, which already decided in favour of the HIBC code, but from all over the world including different market sectors like the pharmaceutical, electronic, chemical industries and others.

Automatic identification of

- product
- packaging unit
- handling unit consisting of different, sometimes individually marked products
- dispatch unit

will in future be of vital importance for all, for distributors as dealers which have to guarantee trouble-free order processing (and possible complaints).

Therefore, it would make sense for the dental dealers to start examining the possible symbologies and data structures of the barcode early.

The goal is a consistent optimisation of all administrative and logistic relations between all parties involved to make the decisive step to cost-saving processes. The information flow accompanying the goods along the logistic chain of the dealers will sooner or later need to be connected to an industry-wide information exchange system, like the EDI project (Electronic Data Interchange).

Prerequisites are:

The barcode accompanying the goods

- is clearly readable
- can be processed error-free on an electronic basis
- works without bilateral agreements
- works without manual intervention
- works across company borders

The area of application for dealers includes:

- scanner-based control of incoming goods, making it possible to automatically compare the incoming goods to the corresponding dispatch notes which could be transferred via EDI, for example.
- Integration of the external transport system (carriers...).
- The precise and automatic inventory control including control of expiry dates
- The precise and automatic commissioning of customer orders and possible delayed shipments

HIBC also offers valuable support in building up a quality management system. Since dental dealers are becoming more interested in systematic quality management systems, the corresponding goals will be easier to reach with an automatic marking system.

Main goals are:

- Increasing the reliability of deliveries
- reducing transport and delivery times
- eliminating mistakes
- high transparency of current status of goods
- fast processing of complaints

The HIBC offers important prerequisites to guarantee a complete information flow along the logistic chain.

Securing identification of goods during external transportation

When manufacturer products are packed into transport units, the product labeling is no longer visible. It is therefore necessary to mark the transport units uniquely as well.

Since the transport units can contain different products, it is necessary to have <u>one</u> clear and superior mark for the dispatch unit.

The HIBC code of the manufacturer can not only be used on the product directly but also on the Transport unit. This is embadded within the specifications of the Multi Industry Transport Label EN 1572 (MITL) and its upgrade ISO 15394 (see technical part).

## 7 HIBC Applications

Typical applications out of different industries

- Hospital of Leiden HIBC provider standard
- INTEL unique Item labeling
- Johnson & Johnson medical devices product marking
- KODAK film product marking
- HERAEUS unique marking precicious metal
- STRYKER marking implant products
- VITA marking teeth products
- IVOCLAR marking dental products
- DENTAURUM marking chemical & dental products
- MANGRIOTIS, Greece automatic data capture for distribution
- DMG tracking and tracing suppliers and own products
- ... and many others around the world



# BARCODE in Health Care

## Application Guidelines

## **Technical Recommendations**



#### 8 HIBC Application Guideline Technical Part

The Technical part of the HIBC Application Guidelines is targeting to the HIBC data structure for product marking. It contains valuable selection criteria for symbologies and hints to printing labels. It contains also the part "Multi Industry Transport label explaining how the HIBC Identification code is useful for marking shipping units and relevant items for global supply chain management purposes.

#### 9 Product marking

In order to label products unique the most flexible and compatible and secure standard is recommended for marking products with Barcode, which is the HIBC code today. HIBC (Health Industry Bar Code) was introduced in USA 1984 and in Europe 1987. It is a compact data structure combining the Product Code with manufacturer identification, Charge/Serial reference and optional informations as expiration date.

The HIBC code defines a "primary code" and a "secondary code". Where the primary part of the full code contains the labeler identification LIC (Labeler Identification Code) and the product code number PCN applied with a packaging indicator, the secondary part contains the tracking information with Charge/Serial number, expiration date and optional quantity references.

The HIBC data structure is symbology independend, where Barcode standards are recommended which fulfill the criteria of capacity, space and safety. Where the Barcode Code 39 is still recommended since the invention of the Code, Code 128 offers higher density within numeric sections. Where small space is available only, the 2-dimensional option of Code 128 is recommended since 1996, this is CODABLOCK F for small packages.

#### The data elements for encoding in Barcode:

ID mark for the HIBC Standard Labeler/location identification code Product/article code	the plus sign "+" 4 digit a/n, issued by EHIBCC variable 1 to 13 digit a/n, issued by the supplier
Unit of measure	1 digit numeric
Quantity	optional 2 or 5 digit numeric
Expiration date	different formats as Julian calendar, as
	YYMM, etc.
Charge/Serial number	variable 0 to 13 digit
Security elements:	
Check digit	1 digit Modulo 43
Link character	1 digit Modulo 43 for connecting separated primary and secondary code properly
Data concatenation	CODABLOCK structure to concatenate separated Barcode rows for space optimization reasons

The HIBC specification is available with the EHIBCC offices in Europe and with HIBCC in USA.

The HIBC Standard recognizes the integration of UCC/EAN product codes if such article numbers are used for Point of Sales applications in order to avoid dublication of labeling. Scanning HIBC and UCC/EAN clear recognition is achieved for both data elements, but no link nor plausibility for the Traceability information is provided using UPC or EAN 13 Barcode as a product code. Using UCC/EAN128, the EAN/UCC regulations need to be considered for this fixed length numeric article numbering system. Coexistence of both HIBC and UCC/EAN system enables the access to the benefit of Automatic Data Capture in general, but to the advantage of flexibility and compactness by help of the HIBC code.

#### 10 HIBC Code in Detail

HIBC Code builds Traceability out of the primary data segment and the secondary segment. The HIBC format encodes a "+" always as the recognized identifier of the HIBC Supplier Data Structure.

#### 10.1 HIBC Primary data structure

The primary data structure contains an indication of the labeler of the item, the item, and the packaging level. A check character is applied , used as a link if the secondary data are carried in a separate Barcode.

After the proceeding ",+" a 4 character Labeler Identification Code (LIC), a 1 to 13 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single-digit Check and Link Character (L) is encoded.

With the variable 1 to 13 digit alpha/numeric product code, manufacturer oriented codification builds the "one" reference through out the logistical processes.

The following data elements apply for use:

Field Descriptor	Field length	(F)ixed leng (V)ariable le	•
+	1	F	HIBC Supplier Labeling Flag Character "+"
I	4	F	Labeler Identification Code (LIC) is alphanumeric and the first character is always an alphabetic character.
Р	1-13	V	Labelers Product or Catalog Number (PCN) alphanumeric data.
U	1	F	Unit of Measure ID 0 through 9:, where 0 is for unit-of-use items.,1 to 8 are used to indicate different packaging levels above the unit-of-use, 9 is used for variable quantity containers where the quantity information is encoded optionally with the secondary symbol.
L	1	F	Check and Link character L . Applies only if secondary data segment is encoded in a separate symbol, calculated from the above characters according the standard Code 39 Modulo 43 check digit calculation.

Illustration of a primary data segment:

## <u>+ E234 MEDIX12Y 0 L</u>

Check/Link Characte	er (L)	1 digit
Unit of Measure	(U)	1 digit, numeric*
Product or Catalog Number	(PCN)	1 to 13 digit, a/n
Labeler Identification Code	LIC)	4 digit, a/n
HIBC Supplier Flag Character		1 digit ("+")

#### 10.2 HIBC Secondary Data Structure

The secondary data segment is responsible for the Traceability of products. The secondary code might be printed separately of the primary data segment, connected with the Link character L or

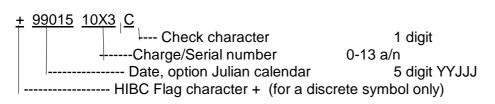
in one common Barcode following the primary segment. In this case no Link character is needed, but a separator is to be add for automatic recognition. The same rules apply if primary and secondary segment is encoded in the 2-dimensional Code 128 extension CODABLOCK F.

The secondary data structure is variable and flexible, allowing recognition of manufacturers codification mechanisms.

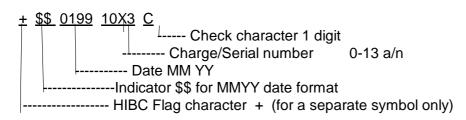
The format for the HIBC Secondary Data Structure, who maximum length is 33 characters, follows:

Field Descriptor	Field length	Field description
+	1	HIBC Supplier Labeling Flag Character "+" is applied, if the Secondary data segment is printed with a separate Barcode, but not used if Primary and Secondary element is concatenated as one*
R	1,2 or 5	Quantity/Date Reference Identifier. The following rules apply by help of "Numeric, \$ and \$\$ indicators: <u>Numeric:</u> If the character of the secondary segment is numeric, than R is a fixed length 5 digit Julian date. No quantity or Lot/Batch/Serial number is present. \$: If the first character is a "\$" and the second character is alphanumeric, than the quantity and date fields are not used. Only a Lot/Batch/Serial number is present. \$\$: If the first two characters are "\$\$", than the next digit specifies quantity and date field format.
Q	0, 3 0r 6	Quantity field format indicator followed by two-digit or five- digit quantity, for use after the "\$\$".
D	0 or 5-9	Date field, for use after the "\$\$" (includes the date field format indicator)
В	0-13	Charge/Serial (Batch) Number field
L	1	Link Character: Duplication of the last character from Primary data element. L applies only, if the Secondary data element is printed as a separate Barcode symbol. L does not appear, if Primary and Secondary fields are printed as one Barcode symbol.
С	1	Check character, calculated from the above characters according the standard Code 39 Modulo 43 check digit calculation. The check calculation includes the primary data segment, if encoded with the same symbol as one Barcode as linear or 2-dimensional.

The Secondary Barcode is capable to adopt different formats according to the table below. As sample a Secondary code with a Julian date is chosen as the most compact form.



Another sample but with the date format MMYY followed by Lot number:



## 10.4 Table Secondary data structure

HIBCC Code 39 or Code 128 Secondary Data Formats									
#	HIBCC Flag	Qty. Format Char.	Quantity Format	Exp. Date Flag	Expiration Date Format	LOT Field	LINK Char.	Mod 43 Check Char.	Example Data
1	+				YYJJJ	LOT	L	С	+952713C001LG
2	+\$					LOT	L	С	+\$3C001LV
3	+\$\$				MMYY	LOT	L	С	+\$\$09953C001L7
4	+\$\$			2	MMDDYY	LOT	L	С	+\$\$20928953C001LJ
5	+\$\$			3	YYMMDD	LOT	L	С	+\$\$39509283C001LK
6	+\$\$			4	YYMMDDHH	LOT	L	С	+\$\$4950928223C001LP
7	+\$\$			5	<b>AA111</b>	LOT	L	С	+\$\$5952713C001LD
8	+\$\$			6	YYJJJHH	LOT	L	С	+\$\$695271223C001LI
9	+\$\$			7		LOT	L	С	+\$\$73C001 <i>L</i> Y
10	+\$\$	8	QQ		MMYY	LOT	L	С	+\$\$82409953C001LL
11	+\$\$	8	QQ	2	MMDDYY	LOT	L	С	+\$\$82420928953C001LX
12	+\$\$	8	QQ	3	YYMMDD	LOT	L	С	+\$\$82439509283C001LY
13	+\$\$	8	QQ	4	YYMMDDHH	LOT	L	С	+\$\$8244950928223C001LS
14	+\$\$	8	QQ	5	<b>AA111</b>	LOT	L	С	+\$\$8245952713C001LR
15	+\$\$	8	QQ	6	YYJJJHH	LOT	L	С	+\$\$824695271223C001LW
16	+\$\$	8	QQ	7		LOT	L	С	+\$\$82473C001 <i>L</i> 5
17	+\$\$	8	QQ				L	С	+\$\$824 <i>L</i> P
18	+\$\$	9	QQQQQ		MMYY	LOT	L	С	+\$\$90010009953C001LH
19	+\$\$	9	QQQQQ	2	MMDDYY	LOT	L	С	+\$\$90010020928953C001LT
20	+\$\$	9	QQQQQ	3	YYMMDD	LOT	L	С	+\$\$90010039509283C001LU
21	+\$\$	9	QQQQQ	4	YYMMDDHH	LOT	L	С	+\$\$9001004950928223C001LZ
22	+\$\$	9	QQQQQ	5	<b>AA111</b>	LOT	L	С	+\$\$9001005952713C001LN
23	+\$\$	9	QQQQQ	6	YYJJJHH	LOT	L	С	+\$\$900100695271223C001LS
24	+\$\$	9	QQQQQ	7		LOT	L	С	+\$\$90010073C001L1
25	+\$\$	9	QQQQQ				L	С	+\$\$900100 <i>L</i> L

Note: The Link Character L is the same as the calculated Link Character in the associated Primary Symbol

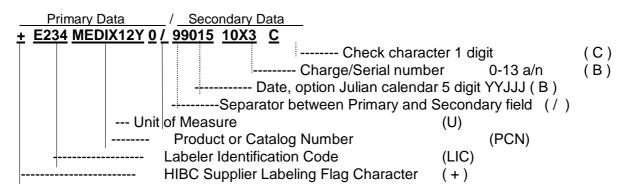
#### 10.5 Concatenation of Primary & Secondary Data

Concatenation of Primary and Secondary data element allows printing both Primary and Secondary Code in one symbol.

Since Traceability is given only, if the two data elements are available together one Barcode with both data elements is the most safe way of encoding product data. In this case the Link character (L) is replaced by the "/" as a separator, but no second HIBC flag "+" is needed nor the repeated Link prior to the final check character (C) at the end of the one symbol.

## 10.6 Sample of a complete HIBC code for encoding in one Barcode Symbol

The HIBC structure allows to encode Primary and Secondary data in one symbol. This is very useful for encodation in 2-dimensional symbologies.



Where Code 39 or Code 128 applies for lower data volume and large label sizes, the 2dimensional extension of Code 128 CODABLOCK F applies for high data volume and small label sizes.

Samples might be drawn according to the application, to find the proper label design.

## 11 Barcode Symbologies.

The HIBC Data Structure is build to be symbology independent to be carried by a selection of Barcodes.

Suitable are alphanumeric symbologies, where the recommended standards are Code 39 (European Norm, EN 800), Code 128 (EN799) and its 2-dimensional extension CODABLOCK F.

## 11.1 Code 128

Code 128 is designed to encode all characters of the alphabet including the full ASCII character set of 128 characters in capital and small letters. Furthermore the Code 128 allows compression for numeric sections of a data string which is larger than 4 characters an printed in even pairs. Different to the 2-Bar code Code39, the Code 128 consist of different Bar sizes.

For numeric data contents Code 128 promises advantages against Code 39 in building smaller Codes. If the code size exceeds the label sizes, the 2-dimensional option of Code 128 is recommended to use.

## 11.2 CODABLOCK F

CODABLOCK F is a structured concatenation rule which applies for more than one row of Code 128. Each row of a Code 128 Block contains a row indicator, so the message is to be rebuild after scanning the rows easily. A long Code 128 field might be cut at any length, where the rest of the message is attached below or above. By help of this easy method a HIBC code might be put on very small space on a label, where the normal linear Barcode would not fit. Standard printers and readers just shall be updated with the concatenation rules, but will continue to use the standard Code 128 symbology according EN 799.

## 11.3 Code 39

Code 39 is a Barcode which is designed for encodation of 43 characters with the characters of the alphabet, the numeric 0-9 and some special characters as +, \$, being used within the HIBC structure. Each character is build out of a 3 out of 9 Bar combination, where 3 Bars of 9 are bigger than the other 6, with a ratio between 2:1 and 3:1.

## 11.4 7.4. Code EAN 13 or UPC

Code EAN 13/UPC is partly applied to consumer products. In order to avoid relabeling, the HIBC recommendations allow to use it, if the 5 digit numeric code is meeting the requirements of the users. But it is to be pointed out, that the use of any EAN 13 or UPC code in conjunction with a separated charge/serial or badge code does not inbuild the security of a full HIBC code.

## 11.5 Code EAN 128

Code EAN 128 is same as Code 128 but applied with EAN data content. It appears mainly in conjunction with consumer products where the 5 digit article number requires additional tracing information.

## 11.6 MATRIX Code

Matrix Code is a pixel oriented symbology for very small symbols compared with linear Barcode. Two standards are available for future use, its DATAMATRIX and QR CODE.

#### 12 BARCODE QUALITY

The print quality of Barcode symbols is subject of a quality control to ensure proper function through out the supply chain from supplier to the point of use. The Test Specifications for printing Barcode Symbols are available for measuring the quality. The specification is accepted as European Norm EN and in the process to become an ISOIEC standard (ISO/IEC 15416).

The standard covers Code 39, Code 128 and CODABLOCK F.

The principle of the specification is to generate a Quality Grade for judgement of a printed Barcode. A Barcode Verifier is needed for the test procedure. The test equipment takes the relevant measurement values of different criteria as contrast, etc. Out of this an overall quality grade will be calculated. There are two tables available, one alpha Grade table (specified by ANSI) and one numeric CEN Grade table (specified by CEN), which have relevance to each other.

Numeric range	Alphabetic grade	Mapping	
4	А	3,5 to 4,0	best
3	В	2,5 to 3,49	
2	С	1,5 to 2,49	
1	D	0,5 to 1,49	
0	F	Below 0,5	fails

The EHIBCC Technical Committee recommends Grade 3 for printing Barcode symbols as a minimum.

#### 13 Data security

Within the HIBC structure security is implemented by means of check calculation for closed symbols and with the linkage mechanism to concatenate separate Barcode symbols building the Traceability code only if the appropriate data segments which belong together are scanned together, but rejected if not properly fitting. The check calculation for both symbol check and linkage check is the standard code 39 modulo 43 procedure, even being used if the data are encoded in Code 128 or CODABLOCK in addition to the symbologies own check. This is to enable external checks after scan within the computer systems or if the HIBC data are used for manual key entry.

Both, symbology independent data structure and check calculation guarantee highest security, even if the full information is spread in more than one row of Barcode. Even split in 2, 3 or 4 rows of Barcode, the message will always be transmitted as the one secure HIBC Traceability code, using the approved hard and software.

## 14 HIBC Bar code samples from big to small

#### "Same data content, different label sizes: from big to small"

HIBC 21 digit printed for different sizes of labels Data content: **+A99912345/99015Y0X3C** 





CODE 39, two rows linked by the check digit "L"



CODABLOCK F, 2d extension of Code 128, size a.) 10mil / 0,25mm



CODABLOCK F size b.) 10mil / 0,25mm



CODABLOCK F size c.) High Density 6mil



+A99912345/99015Y0X3C

QR MATRIX Code for fast processes, 10mil

■30 ■30 +A99912345/99015Y0X3C

DATAMATRIX Code, 10mil

+A99912345/99015Y0X3C

If only smallest space is available, Matrix Code might be used. The sample above shows QR-Matrix Code for fast processes and DATAMATRIX as practical solutions for the future. The technologies are available today for error free data capture even on smallest products.

#### 14.1 The Label

Tracking and Tracing concepts based on Lot numbers need accurate data for the purpose of proper processing and documentation. Individual labeling is the common solution, where the actual data are transmitted from the computer system to a printer, which converts the Traceability data both in eye readable text for users and in Barcode for safe and Automatic Data Capture. For product labeling mostly marketing information's as colored graphics and text are to be combined with the black and white coded information.

Common practice shows that preprinted marketing information gives space for on demand logistical information and Barcode, where preprint in color is supplied with lot information right with the production process while packaging. With this method, the label takes over the important function as a data carrier to be used through out the logistical chain.

For Traceability function the label needs to carry the manufacturer ID, the product code, the lot number as a minimum, but the expiration date as a legal requirement for plenty of products. This are the variable data for on demand and individual print at least on lot basis. Due to the available printing technologies even Graphics might be printed on demand instead of preprinting it before.

#### Barcode for labels:

Barcode needs to be integrated in to the design of the label but also the quality specifications are to be considered as for Bar sizes, contrast, quiet zones, etc. The related Norms are available for the standards being used, where the Norm for the Barcode Quality "Barcode Test Specifications, EN 1635" applies for

CODE 39, Code 128 and CODABLOCK.

#### Barcode color:

Ideally Barcode is printed black on a white label, but the necessary contrast between Bar and Space of a code might be achieved even if colored labels are used. This is depending on the color of the reading device which is typical for 633 to 680 Nano Meter, where some reflection is possible even with black bars on red ground, but never with red Bars on black ground. The recommendations are to use black on white, but tests might be necessary to execute with appropriate Barcode verifiers.

#### Barcode height:

The height of a Barcode may not be printed below 15% of the value of the Barcode length to achieve comfortable reading performance. If 2-dimensional Barcode extension is used the hight could be smaller, but not less than 8 times the Bar widths.

#### Bar width:

The nominal Bar width is recommend as for 0,25 mm, but shall not be smaller than 0,19 mm.

#### Length of the Barcode:

The flexibility of the symbology independent HIBC structure enables flexible label design not using the security, even if the Barcode is to be shortened due to small label sizes. The HIBC Barcode is printable in different forms for fitting to a given label length:

- a. One field of Barcode as Code 39 or Code 128 containing both Primary and Secondary segment, if the length of the code fits to the label size.
- b. If the above Code exceeds the label size, the to data segments might be printed as 2 single Code fields as Code 39 or Code 128, where the data are concatenated by the Link character
- c. If the above 2 Barcode fields or one of them still exceeds the label size, the Code 128 shall be used, cutting the symbol at the required length, encoding the full information in a Block of more than 2 rows of Barcode using the CODABLOCK structure to keep the message together for reading.

#### **Barcode selection:**

a simple recommendation for the label designer:

Code 39 is always useful if label size is sufficient Code 128, if numeric compression is appropriate CODABLOCK F, if the Barcode needs to be adapted to spaces of sizes, where the above do not match.

The attached form "Label Design" may help to design the smallest and smallest label of series of products.

## 15 Printing Techniques

The most appropriate technique is the Thermo Transfer Technology for printing labels with Barcode on demand, special for projects of 1 serial number per product.

## 15.1 Thermo Transfer Printing

This technology is very precise in printing smallest dot and Bar sizes at continues quality as for text, graphics as for Barcode.

The resolutions for smallest dots are typically specified for 0,125mm (200DPI, 8D/mm) or less (0,084mm -300DPI, 12D/mm). Printing tolerances are very low by means of the print head technology, where the dots transfer the print to the media from a fixed positions to each other. The color is transferred to paper or plastic materials by heat through carbonated ribbon as a macro burn in process. Thermo Direct (TD) print mode might be chosen for labels with short life time. In this case the thermo sensitive label material generates the print in place of the ribbon of the Thermo Transfer mode (TT), but the image is not scratch nor UV resistant for TD printed labels.

Thermo Direct or Thermo Transfer printer are available as continuos operations as on demand printer for single labels as for integration in automatic systems. The control is managed by workstations or network systems through appropriate interfaces.

## 15.2 Laser printer

with appropriate resolutions of better than 200 DPI are very useful for printing page sized formulas, work sheets, delivery notes, etc. in office environments. Office Laser printers are not useful for small adhesive labels, because the glue will damage the system immediately merging out of the paper treated by heat. Continuos quality is a problem as well due to no toner control during the printing process.

## 15.3 Matrix Printer

do not allow equal continuing quality by the mechanical operation and uncontrolled consumption of ribbons. Therefore Matrix type printers are not recommended for High Quality on demand print as for product labels.

## 15.4 Ink Jet printer

This technology is in a developing process of optimization, but the usage for Barcode of High Density is limited due to the physical dot transfer of the Ink. Resolutions of adequate systems allow dot sizes above 0,3 mm, but the quality depends from three components: Print media material, Ink and process. Integration would need great experiences in technologies and packaging processes.

## 15.5 Automated Labeling

Automatic Label Applicators are useful for labeling products at the end of a production line to print actual serial or charge numbers in line as text, graphics and Barcode. Such a system contains of a industrial print engine, a dispenser for applying the label to the product and the interface to the computer originating the data. Print engines as Thermo Transfer systems guarantee proofed quality even for small labels.

## <u>16 The data structures for Tracking, Tracing and Documentation within the</u> <u>supply chain</u>

Within a complete supply chain a series of information will be generated, building the basis for Tracking and Tracing systems. Information's are presented in different form and symbologies related to the different stations from birth of the product up to the point of use. Using standards, any form and any interpretation is useful be connected to related information levels. Global standards both of data structures and carrying media as Barcode enable communication even between different market segments or branches.

The following chart show applied data structures carrying data segments to the next logistical point building a complete chain of information within a material flow process.

Row material: "Standards" of suppliers Identification of material and Stocking: Supplier, FACT Standard processes: FACT Production: FACT ID for product/Charge,... Stock: FACT plus Product Code ID Picking: FACT, Product Code, Charge Shipment: Add MITL Transport: MITL EDI Electronic Communication EDIFACT Transport: MITL Distribution: MITL+ Product Entry: Product Code+FACT for in-House Stocking: Product Code+FACT Point of use: Product, Charge, FACT Identification of material and Back-Tracing: Product code, Charge processes: FACT Recall/Re-shipment: Produt Code, Charge

The chart might be the basic model for working out logistical Tracking and Tracing concepts.

FACT is the term for a data structure being used widely within different industries in connection with Automatic Data Capture. The FACT standard will be included in the new ISO standard "Data Application Identifier Standard" as the UCC/EAN identifiers as well being in preparation since 1996 with the appropriate ISO committee. MITL stands for Multi Industry Transport Label which includes the use of both of the above data structures. As Product standards different structures are in use, where only a few allow tracking and tracing by use of Barcode. Those are the HIBC-Code, the ISBT and EUROCODE, the FACT system based Product codes, the UCC/EAN128 system (but not the EAN 13 nor UPC).

Electronic transmission of logistical information is in practice by use of the EDIFACT data structure.

The transition from one logistical point to the other of material and its related information is easy to document if the standard data structures are used with the chance of combining information encoded in one standard with the information carried in another form. This coexistence of different forms of information with its proper interpretation enables different industries and partners to communicate which each other on global world wide levels and enables international Tracking and Tracing concepts. The ANSI/FACT data identifiers in conjunction with the HIBC-Product code is an important tool for such systems, combined with other codification forms as described above.

Marking at the transition point from raw material to finished products for unique identification of the products right at the production.

The specific product data are build out of the individual components of raw material and process data, to be documented carefully for related quality control and reproduction of the processes. The above chart contains the transition point C to D, where new data elements are created together with the new product. This point shall be considered for investigation, whether an internal step might be approached or common data structures might be used already in order to identify items and processes uniquely.

As a starting point typical references for data capture within the production flow might be selected and applied with the related ANSI/FACT identifiers. The table shows the related Data Identifier as a flag for the Data Element:

Work order number	W
Employee Identification Code	1H
Location/production line	1L
Date YYMMDD, or	1D, or
Item ID Code assigned by the supplier	1P
Charge/Serial Number-Traceability Code	1T
Quantity	Q
etc.	

The above Identifiers help marking and recognizing the data elements uniquely. Capturing the data elements properly is the basis for creating the related product identification with product code, involved charge and other data as packaging information. The product data will be used as for users eye readable as text and graphics as for automatic data capture by Barcode. The design of both text and Barcode is a matter of the marketing approach, where the appropriate product code will be selected as the machine readable information.

According users experiences the HIBC code offers the best features for traceable products specially in the area of Health Care just by its flexibility.

Out of the above data elements, identified by the ANSI/FACT method, the translation into a HIBC product code is executed by help of the systems data base to generate a traceable product code:

Manufacturer ID Code	- fixed value(name) stored in the data base
Product code, variable 1 to 13 digit - o	ut of data base linked by the work order
	"W"
Expiration Date	<ul> <li>generated out of production date</li> </ul>
Charge/Serial NR.	- generated out of data base as of location
	"1L"and date"1D"

By means of this data a product will be traceable back to the production and beyond, if the data base is filled with the related data. Where the Charge/Lot number enable backward Traceability, an encoded expiration date enables external control at the point of use at time of use.

The method of using identifiers for every data element being in use with material flow processes any information can be encoded safely for secure data capture again building logistical quality systems.

Using data identifiers for building a logistical information system a one to one relation can be achieved between material flow and flow of data and its proper in time documentation, so its an engineering tool being useful as internal as for the external business partners.

## 18 HIBC at the point of use in the Hospital

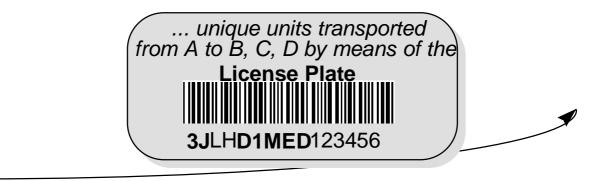
#### 18.1 HIBC Provider Standard

The origin of HIBC Barcode was in Health Care. Still the main application is the use for supply chain management in Health Care. Where the HIBC Supplier Standard covers unique marking of items on the way to the Patient, there is an extended specification available for optimising the internal Hospital processes. This is the HIBC Provider Standard. With it, HIBC offers the solution for secure data processing Hospitals. The HIBC Provider Standard for Hospitals is available from EHIBCC as support for implementation.

## 19 Multi Industry Transport Label, MITL

The Multi Industry Transport Label was developed by the European Normalization Committee (CEN) in 1996 on request of the industries in order to create unique references for logistical processes of transportation in line with the developments of the business processes on Electronic Data Interchange (EDI) level.

The European Norm is EN 1573 referencing to the related Data Structures EN 1572 and EN 1571. The core of a MITL is the Unique Identification Number of a Transport Unit, specified under EN 1572 and called "License Plate" according the function making a Transport Unit unique as a car is. The 1996 development by CEN was adopted and upgraded by ISO in 2000 under ISO 15394 for MITL and ISO/IEC 15459 for the License Plate Barcode.



The mandatory element of a MITL is to be represented in Barcode for error free and unmistakable identification internationally. Transport related information might be transmitted via Electronic Data Communication using the License Plate as the unique reference between message and unit. For situations without Electronic Data Interchange optional data elements are specified to be Bar coded as supplier and customer references, content information and routing information. Even to carry a subset of an EDI message might be carried by the label in Barcode.

The uniqueness of a Transport Unit is build according a hierarchical structure, managed and maintained by the Netherlands Normalization Institute (NNI), Delft, as the executing organization on behalf of CEN. The NNI registers issuing agencies of user groups, the agency registers the labeler as user member, applying its own unique serial number to the string of data. This is how to build a License Plate, which has got identifiers to be recognized as such in an open environment. User organizations may issue member reference numbers without an extra fee to be used for building License Plates (EHIBCC EDIFICE, ...). If the potential user is not a member of an organization which supplies the service of unique numbering concepts, he may buy a number from one ore another paying a fee. Nevertheless the responsibility for achieving uniqueness is with the labeler, not with the organizations which make membership numbers available.

Some organizations issuing Ident numbers for its members:

Chemical Industry (CEFICE), Electronic Industry (EDIFICE), Health Care (EHIBCC), Consumer Industry (EAN), Transport (FIATA), etc.

#### Users of the HIBC Barcode are in the position to use the individual Label Issuer Code (LIC) not only for product identification but also for building License Plates for international uniqueness under CEN and ISO terms without extra fee.

The concept of the Multi Industry Transport Label (MITL) is an effective standard in Europe since October 1996, since 2000 it is ready for world wide use as an ISO standard.

## <u>The construction of a Unique Identification Number for a Transport Unit</u> (License Plate):

The specified technical basis is EN 1572 referring to the Data Structure according to EN 1571, where the appropriate Data Identifiers are listed. The symbology independent ID's for identifying a License Plate is included in the FACT part of the list of Data elements. The Identifier for a License Plate within this FACT list is a "J". According the specification EN 1572 it is followed by the Issuing Agency ID, followed by the individual serial number issued by the labeler. In addition to it 4 optional categories of packing levels are considered as with or without reference to an EDI message:

Detailed illustration in brief:

"J" is the protected Identifier for a License Plate,

- options 1 to 4 are specified to mark different categories of units
- 1J: lowest packaging level (unbreakable unit)
- 2J: highest packaging level, consisting of more than one sub packages (1J's)
- 3J: as 1J, but referencing to an existing EDI message for more information

4J: as 2J, but with reference to an EDI message

**JC100** is the Identifier for License Plates using EAN ID's, as an additional option for building fixed length License Plates, based on EAN Location Codes.

<u>The hierarchical structure of a License Plate:</u>

according to EN1571 1J 2J 3 J	Organisations registered with NNI, e.g.: LH: Healthcare LE: Electronic 0-9: EAN	Registered ID number of the Labeler	Serial Nr. of Unit, issued by Labeler
]C100	LF: Transport,		

"Licence Plate" example for the area of Health Care to achieve continued uniqueness from product to Transport Unit for quality processes.

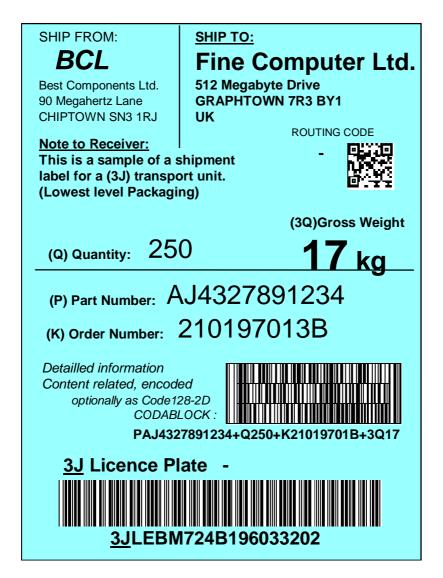
Selection ,1J'' identifying unbreakable shipment units without relation to an EDI message versus ,3J'' ID for relation to EDI.



"Licence Plate" with relation to an EDI message would read: **3J**LHE999123456X

#### Example of a Multi Industry Transport Label (MITL)

The example shows the different sectors of the label, where the mandatory sector is the License Plate (EN 1572 – ISO/IEC 15459). Additional sectors are reserved for human readable information. Another optional sector shows informative data safely encoded in the 2-dimensional option of Code 128, CODABLOCK. Optional routing information for the transporter is illustrated encoded by help of the Quick Response Matrix Code "QR" for fast scanning in automatic processes.



The data structure is build according the FACT part of EN 1571 and ISO/IEC 15418. The Data elements are clearly to be identified, where the "3J" Code specifies a License Plate of a lowest transport package, where a EDI message exists related to it. A transport unit build of several sub "3J" units would be marked with a "4J" identifying highest packaging level. Further information is encoded using specific identifiers for the appropriate data elements as "Q" for a Quantity element, "3Q" specifying weight, "P" part number and "K" customer reference. The 2-dimensional stacking rules of Code 128 allow concatenating of complete messages. Another optional symbology for this purpose is PDF 417. The forwarder may need specific information for routing the units, adequate symbologies are needed for automated processes of fast sorting. The example shows the squared QR-Matrix Code being designed for fast scanning. Another option would be the symbology MaxiCode. Those options require agreement between the partners involved in the process to achieve full functionality in addition to the mandatory information for open access, the License Plate.

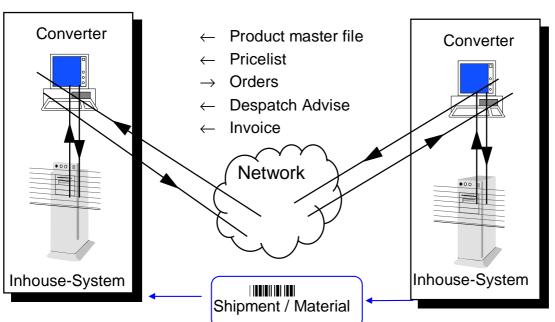
## 20 EDI within the logistic chain

There is a direct connection between Barcode and EDI if messages refer to logistical processes, they can support each other. Therefore the EDI-system is described briefly in this brochure.

EDI is the abbreviation for Electronic Data Interchange and stands for the electronic interchange of messages and information of any kind. An international standard called UN/EDIFACT (Electronic Data Interchange For Administration Commerce and Transport) is available for structured and recurrent business transactions like orders, order confirmations, dispatch notes, invoices and many more. The objective of using EDIFACT is the direct transfer of messages between the operating IT-systems of customers and suppliers without any manual handling of data and without using paper in between the process. The messages are available immediately for further data processing and the possibility of mistakes in information transfer is reduced dramatically.

XML will be a complementary solution to EDIFACT for transmitting the information to partners electronic mail boxes.

Avoidance or at least automation of non value adding activities in the supply chain leads to cost savings and to better ratios in the administration of processes.



## **Dealer**

<u>Manufacturer</u>

#### Components of EDI

As mentioned above EDI and barcode complement one another as shown in the following example:

An order is transferred electronically to the supplier and starts the order processing. An order confirmation is resent to the customer in order to make a first electronic order-check possible. Only exceptions have to be handled.

The shipment of the order is advised electronically. This enables the customer to check the details again, to plan the receiving capacities, and to organize the warehouse. The dispatch advise ideally contains detailed information about lot numbers, expiration dates of the shipped products and detailed packing information.

The Barcodes on the boxes and on the products themselves make the information about the physical shipment easily electronically available. The connection of both - barcode and EDI information guarantees highly automated degree of the receiving process at the customer's. The transaction is finished by the electronic invoice what makes another automation step possible to avoid manual work.

The reference between such a EDI message and shipment is the so called "License Plate" as the Unique Identity of a Transport Unit (see chapter 16, Multi Industry Transport Label). The unique reference to a product is a Product Code, build according the HIBC rules and consisting of manufacturer ID and article number. Both "License Plate" and Product Code get a data element identifier for transmission via EDI. The Bar coded data element being scanned and transferred to the EDI interface acknowledges the physical transaction for quality data processing.

Every message can be filed electronically.

To sum up the connection of EDI and barcode offers many different ways to rationalize the information processing between the partners of the supply chain.

To gain these advantages a work group of dental dealers and manufacturers supported by the VDDI was set up to work on the implementation of UN/EDIFACT in the dental branch. The VDDI provides interested persons with some more information about the work group and the addresses.

#### 21 Appendix

#### 21.1 Sources for Standards and Specifications

HIBC StandardHIBCC and ANSI<br/>Health Industry Business Communication Council<br/>5110 N.40th Street, Suite 250<br/>Phoenix, Arizona 85018<br/>Tel: + 602 381 1091

EHIBCC European Health Industry Business Communication Council NL-2596 AM Den Haag, Jozef Israelslaan 3 Tel: + 31 70 3244754, Fx: +31 70 3242522, Info@EHIBCC.com

HIBC-D Region Deutschland, Österreich, Schweiz D-06618 Naumburg, Kösenerstraße 85 Tel: 06081 961070, Fx: 06081 961072, Info@HIBC.de

#### **Barcode Standards**

D-10772 Berlin 30, Burgrafenstraße 6 Tel: 030/ 2601-1260, Info@DIN.de	CODE 128 Standard EN 799	
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CODE 39 Standard EN 800 DIN

2D-Extension CODABLOCK F AIN

AIM USS Standard and Norm Francaise HIBC-D, AIM-D, AIM-Europe, AFNOR

AIM-D

Industrieverband für automatische Identifikation und Betriebsdatenerfassungssysteme e.V. D-68623 Lampertheim-Neuschloß, Akazienweg 26 Tel: 06206 13177, Fx: 13173

AIM-Europe Automatic Identification Manufacturers UK-Halifax HX3 6DR, Haley Hill, The old Vicarage Tel: +44 1 422 368368, Fx: +44 1 422 355604

AFNOR Association Francaise de Normalisation Doc. Norme Francaise FD Z 63-322 F-92049 Paris la Defense, Tour Europe, Cedex Tel: +33 1 4291 5555

FACT Data Identifier Standard ANSI, DIN

## 21.2 Glossary of terms

ANSI	American National Standards Institute 11 West 42 <sup>nd</sup> St., New York, NY 10036, USA Tel: +1 212 642 4900, Fax: +1 212 302 1286
ANSI/FACT	Data Identifier Standard developed in USA early the 80 <sup>th</sup> now in short FACT Standard (see below). ANSI is the responsible maintenance association for FACT.
Barcode; Bar CodeAn array	of parallel rectangular bars and spaces arranged according to the encodation rules of a particular symbol specification in order to represent data in machine readable form. (see symbology)
Code 39	alpha-numeric Barcode symbology (HIBC-proofed) for encodation of 43 characters as the numerics 0-9, 26 alpha and 7 special characters. Every character is constructed in a 3 out of 9 Bar arrangement, each consisting of 2 different Bar sizes as 3 wide Bars out of 9 in total. As Bars are both valid, black Bars and the white gaps.
Code128	alpha-numeric Barcode symbology (HIBC approved) for encodation of 128 characters as numerics, alphas as capital and small letters and control characters. Different to the fixed character length of Code 39 is the optimization feature of Code 128. The encodation rules allow the interpretation of pairs of numeric digit gaining space for series of numeric numbers within the code. The symbology describes 4 different Bar sizes for creating the character values.
CODABLOCK 2-	dimensional extension of linear symbologies as Code 128 (HIBC approved) for forming a code block according the given size of the label, stacking single rows and concatenating the data elements. Forming Code 128 rows according the label sizes by using the CODABLOCK rules allows coding of long messages even on small labels without changing the data content. Printing and reading is enabled by state of the art equipment without extra costs compared with linear "one line" equipment.
DIN	German Normalization Institute (Deutsches Institut für Normung, Berlin)
EAN 13N	umeric Barcode symbology, carries a 7-digit EAN membership number, issued by EAN Internationals national offices, a 5 digit article number and a one digit numeric check digit (0-9). EAN 13 was developed in the 60 <sup>th</sup> for point of sales cash register applications but does not include Traceability information. Variations are the 8 digit EAN 8 and the American Universal Product Code UPC with its own variations.

	b set of the Code 128 symbology (see above). It carries a special character, the function code one (FNC1), right after the Start pattern. The connected symbology identifier to be transmitted to the computer shall be a ]C1 to identify EAN specific data.
	ectronic Data Interchange, the concept for data communication between computers of trading partners using standard data syntax as EDIFACT.
and Transport The concept	ectronic Data Interchange for Administration, Commerce consists of identifiers for describing data elements for proper interpretation by sender and receiver.
Council, NL-2596 AM Den Ha EHIBC-D, 06618 Naumburg, EHIBCC and EHIBC-D delive	ropean Health Industry Business Communication ag, Josef Israelslaan 3, Tel: +31 70 3244754, Fax: +31 70 3242522. Contact address for the german speaking region: Kösenerstr. 85, Tel: 03445/78114-0, Fax: 3445/770 161. er the service for maintaining the HIBC Code and implementation of the structure in applications of industry and health care in Europe. The association issues the unique Label Issuer Code (LIC) for unique marking of products and shipping units according CEN and ISO rules.
	ginally named as Federation of Automatic Coding Technologies, now the name for the FACT Data Identifier Standard and its maintenance committee under the umbrella of ANSI. FACT is referenced at the European Standard EN 1571, being in process of the ISO standardization. Where the FACT Identifiers are used for encoding information in Barcode, EDIFACT Identifiers tag data elements for electronic data interchange, both include references to each other. The FACT Standard is in use since the 80 <sup>th</sup> in industrial applications of Electronic, Automotive, Transport, etc., to achieve uniqueness in logistical processes. The HIBC Code is a compressed Product Code under FACT categories.
	e Health Industry Barcode (HIBC) was developed 1998 to identify not only article numbers, but also logistical data for tracking and tracing concepts as Date, Quantities, Charge and Serial numbers. HIBC Code is a data structure which is designed for Barcode, but symbology independent. Code 39 and Code 128 are the preferred symbologies together with the 2-dimensional option for small labels, CODABLOCK. The alpha/numeric data structure of high flexibility enables the use of original manufacturer codes for source marking the products without the need of mapping to another structure as a 5 digit numeric EAN article code or customer codes. The HIBC identifier is a "+" sign, included in the identifier list of FACT for international functionality. The specification are available from EHIBCC and associate user communities.
IECInte	ernational Electrotechnical Commission, Geneva.
ISO	International Standardization Organization, Geneva

ISO/IEC JTC 1/SC 31	Joined Technology Committee of ISO and IEC, building the Sub Committee 31 (SC 31) for the tasks of developing standard specifications for Automatic Data Capture and methods. Such tasks given to the group in 1996 are to harmonize the existing standards for Bar coding as symbologies and data structures and to achieve world wide functionality in synchronization with Electronic Data Interchange concepts.
LIC-Number	Labeler Identification Code, 4 digit alpha/numeric Code, issued by EHIBCC for the purpose of unique product and shipment identification and world wide access. The first character of the four is always an alpha character.
License Plate	Synonym for "Unique Number for Transport Units". The License Plate is specified within the Norm EN 1572 and ISO/IEC 15459as a mandatory Barcode of a Multi Industry Transport Label (EN 1573 – ISO 15394). With it not only uniqueness will be achieved for shipments and transports but also references to Electronic Data Interchange messages. An appropriate identifier is registered within the FACT list mentioned above.
	Linear Barcode A one dimensional symbology being constructed linear proceeding from the start pattern to the stop pattern as a one row symbology in terms of a complete but short encoded data segment. The term "linear" was created to define a difference to the latest developments of the 2- dimensional symbologies stacking linear rows to a concatenated symbol block as CODABLOCK does or PDF 417. Linear symbologies are Code 39, Code 128, CODABAR, etc. which don't have logical connections between different rows, based on symbology level as the 2-dimensional symbologies feature.
Matrix code	An arrangement of regular polygon shaped modules where the center to center distance of adjacent elements is uniform. The arrangement of the modules represents data and functions. Typical Matrix type codes are DataMatrix, QR-Matrix Code and MaxiCode.
Modulo 43C	heck calculation for Data segments, as part of the Code 39 specification being used to secure the data. Within the HIBC structure used also to secure the code and for linking two Code 39 or two Code 128 rows of primary and secondary information together.
Multi Industry Transport Lab	el Standard , MITL 1996 approved European Standard for marking transport units uniquely. The mandatory data field is the "License Plate", optional coded data elements are EDI messages and routing codes. The CEN standard EN 1573 of 1996 was adopted and upgraded by ISO in 2000 under ISO 15394.
Symbology	A standard means of representing data in printed or marked machine readable form. Each symbology specification sets out its particular rules of composition or symbol architecture.

Multi-row; stacked symbol ... linear symbologies are limited in length, multi-row stacked extensions (2-dimensional) extend the capacity of a symbol. Symbologies where a long message is broken into sections and "stacked" one upon another. Compare to "linear symbologies". Using the stacking rules of a symbology a message might be cut in to several rows while the message remains concatenated. One example of stacking rows of Code 128 is CODABLOCK. By help of CODABLOCK the code size is adaptable to the label size. Where equipment for linear symbologies is sufficient for printing and reading CODABLOCK as a linear Code, all other stacked symbologies as PDF 417, 16K and Code 49 need special equipment with adjusted features.



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# "One Product One Number"

Barcode is the common reference for a unique product, enabling continuos Traceability through out the supply chain. This unique reference makes it possible, that the distribution partners are able to connect the suppliers ID any time with its own numbering system and database without relabeling the product. Barcode once applied to a product can be used at all logistical movements. Even for the end user it might be very attractive to learn how to get all of the benefits of error free procedures and logistical quality, easy to be achieved using Barcode.

Supporting Associations:

#### VDDI

Association of German Dental Manufacturers D-50836 Köln. Postbox 400663 Tel: +49(0)221/948628-0, Fax: +49(0)221/483428 Info@VDDI.de, www.VDDI.de

## FIDE

Fédération de l'Industrie Dentair en Europe D-50836 Köln. Post Box 400663 Tel: +49(0)221/94862835, Fax: +49(0)221/483428 info@FIDE-online.org, www.FIDE-online.org

## **BVD**

Bundes-Verband Dentalhandel e.V. 50677 Köln. Salierring 44 Tel: +49(0)221/2409342, Fax: +49(0)221/2408670 BVD@Verbandsbuero.de, www.BVDENDAL.de

European Federation of Precision Mechanical and Optical Industries D-50858 Köln, Kirchweg 2 Tel: +49 (0)221/948628-0, Fax: +49(0)221/483428 Info@Feinoptik.de, www.feinoptik.de

## EHIBCC

European Health Industry Business Communication Council NL-2596 The Hague, Jozef Israelslaan 3 Tel: +31 70 3244754. Fax: +31 70 3242522 Info@EHIBCC.com, www.EHIBCC.com Info@HIBC.de, www.HIBC.de

EURODATA COUNCIL D-06618 Naumburg, Kösener Str. 85 Tel: +49(0)3445 78116-0, fx 770161 Info@EurodataCouncil.org, www.EurodataCouncil.org

Responsible for the content: EURODATA COUNCIL, VDDI AK HIBC, Köln, issue 3-e, May 2001

21.3 Request form "Label Design"

Request form "Label Design" for printing samples to be sent to:

## EURODATA/EHIBC Council, Kösener Strasse 85, D-06618 Naumburg Fax: +49 (0)3445 770161

## According to the data specified in this form, samples will be printed and passed back to the sender

(please copy this form if samples for different product variations are required)

It is recommended to print sample labels prior to final package design for a selection of products with different spaces for labeling, containing different data volume as well. The Bar Code samples will help the designer to reserve the necessary space for the automatic readable Bar Code segment on products and packages.

Label Issuer Code	LIC-Number	4 a/n	
Product code	PCN-Number 1	-13 a/n	
Packaging indicator	ſ	1 n	_
Quantity field ( option	onal)		
Exp. date and forma	at		
Charge/Serial numb	ber	1-13 a/n	
Available space for	Bar Code (length x he	eight) mm	x

Available space for Bar Code (length x height)

Sample: 1 code: Length: \_ \_ \_mm Height: \_ \_ \_ mm

Space for the Bar Code with all of the data

Sample: 2 codes (2 rows linked by the check "L") Bar Code total available space for the 2 rows Length: \_ \_ \_mm Bar Code Height: \_ \_ \_ mm

Sample 3: 1 block, 3 rows rows linked by the CODABLOCK-Check total space available Length: \_ \_ \_mm Height: \_ \_ \_ mm

Space for the Primary

and for the Secondary

Space for the complete Code with all of the data

Printing	technology,	available	<u>equipment</u>

Additional information's, requirements, remarks \_\_\_\_\_ Name, Address Phone/Fax, etc. ----------