EUROCODE IBLS

International Blood Labelling System

TECHNICAL SPECIFICATION

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DOCUMENT MAINTENANCE SUMMARY

The technical specification of the standards of Eurocode IBLS was published from 1998 to 2010 in versions 1.0.0 to 1.4.0 as the guideline “Eurocode Symbology and Data Structures” on the website www.eurocode.org. These versions have been archived by the Board of Eurocode IBLS e.V.

Date	Action	Summary
2010-09-15	Renaming of the *Guideline* as *Technical Specification*, upgrading of technical details	- to continue version history of the technical specification beginning with V2.0; (V2.0 based on guideline V1.4.0, to which tissue coding elements were added)
2010-01	Version 2.0	new Chapter 5: “Single European Code” (SEC) was added

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Content

1. Introduction

Various documents which indicate how coding and traceability can be standardized internationally have been published with the assistance of the International Organization for Standardization (ISO). One main element of these coding systems is formed by the data and application identifier, whose structure is determined by a joint document of the ISO and the International Electrotechnical Commission (IEC). ISO/IEC 15418 [1] specifies sets of Data Identifiers and Application Identifiers for the purpose of worldwide unique data identification and determines the organizations responsible for their maintenance. In accordance with this document, Eurocode IBLS e.V. is responsible for the maintenance of data structures following the primary identifier “!”.

2. Eurocode IBLS e.V.

Eurocode International Blood Labelling System e.V. (Eurocode IBLS e.V.) is a non-commercial, registered society in accordance with paragraph 21 of the German Civil Code (Bürgerliches Gesetzbuch, BGB) and a non-profit organisation under German Tax Law.
The society was founded in 1998 with the primary goal of creating and maintaining standard coding structures for the safe exchange of products of biological origin for application in human medicine, such as blood products and cells, tissues and organs. The top priority was to ensure a unique and unmistakable internationally-recognised code corresponding to EU Directive 2002/98/EC [2] which could be employed for a minimum period of 30 years. During the development of the code structures, the technical committee of Eurocode IBLS e.V. has incorporated current ISO and other standards
The aims and the regulations of Eurocode IBLS are described in the statutes under www.eurocode.org.

3. Eurocode Data Identifiers

3.1. Data Identifier (DI)

A specified character (or string of characters) that defines the general category or intended use of the data that follows.
Note: ASC MH10 Data Identifiers have a format of one alphabetic character alone, or one alphabetic character prefixed by one, two or three numeric characters [3].

Section I, Data Identifiers, lists a Category “0” as Special Characters Not Assigned or Control by ASC MH1 10/SC 8. These characters, in a leading position of the data structure, are sometimes referred to as system identifiers, denoting a data structure maintained by the organization claiming this system identifier [3].

3.2. System Identifier

Various system identifiers are registered in the following standards:

- ISO/IEC 15418, part ANSI MH 10.8.2 [1]
  Data Identifier and Application Identifier Standard, Annex “K” System Identifiers
- DIN V 66403 [4]
  Information technology - Automatic identification.

System identifiers identify registered characters uniquely as such.

3.3. Primary Identifier

Primary identifier means that the system identifier is the first character of a data element. Alphanumeric characters (A…Z, 0…9) in first position are used to differentiate the data elements of the system. For all Eurocode data elements the registered system identifier is the special character "!" (Exclamation mark).

Important Notes: The character "!" will never be used as data.

3.4. Secondary Identifiers

Alphanumeric characters (A…Z, a…z, 0…9) in second position are used to differentiate the data elements of the system.

4. Eurocode Data Elements for blood, cell and tissue products

Eurocode uses a Secondary Identifier following the Primary Identifier “!” (see 3.2) to distinguish between different data elements.

4.1 Unique Product Identification Number (UPN) for blood products (for organs, tissue and cell products see 4.2)

Important Notes:
It is absolutely imperative that product units be uniquely labelled. Thus every product (even when originating from one donation event) must be either given a new UPN or flagged as being a split product (see 4.1.4)

A numeric digit (0…9) following the primary data identifier "!" specifies a data element to be a UPN. The digit functioning as Secondary Identifier is also the first digit of the 3-digit country code.

!	**ccc**	**iii**	**nnnnnn***nnnnnn*

!	exclamation mark	primary identifier
ccc	3 digits numeric	three-digit country code acc. ISO 3166-1 [5]; the digit in the first position is the secondary identifier for the UPN
iii	3 digits numeric	centre code (national regulation)
nnnnnn*nnnnnn*	6-12 digits numeric (national regulations)	consecutive product number (including flags and check character)

4.1.1 Country code (ccc)

The international country code defined in ISO 3166-1 [5] (3 numeric digits) is adopted by Eurocode as country code. A numeric digit at the position of the secondary identifier indentifies the data element to be a UPN.

4.1.2 Centre Codes (iii)

Centre codes are determined within each country involved and underlie national agreements or regulations. The rules for centre codes must be accepted by the Eurocode-IBLS Board and they must be published on the website http://www.eurocode.org/tables/center/index.html.

4.1.3 Consecutive Product Number

The length of the consecutive product number varies from 6 to 12 numeric digits depending on national agreements or regulations. The rules for consecutive product number must be accepted by the Board of Eurocode-IBLS and subsequently published on the website www.eurocode.org.

Note: The following three elements of the Consecutive Product Number are not specified in Eurocode and thus underlie national agreements or regulations. However, their use is recommended to improve safety and ensure easier handling.

- Specification of *decade* and *year* at the beginning helps to ensure that codes remain unique over 30 years.
- The use of flags before the recommended check character makes it easier to distinguish product units from one donation event (see 4.1.4).
- The introduction of check characters at the end of the consecutive product number increases the total security of data transmission (see 4.1.5)

4.1.4 Split and Pool products/ Flag

The single-digit flag number offers the unique labelling of up to 9 products (splits) originating from one donation event.
Two examples:
0 = whole blood → 1 = RBC, 2 = plasma, 3 = buffy coat → 4 = irradiated RBC;
0 = PLT Triple-Apheresis → 1 = 1.split, 2 = 2.split, 3 = 3.split → 4 = 1.split irradiated).
Pool products are assigned a new consecutive product number or an available flag of one of the original products. For split series which include more than 9 products it is necessary to create a new UPN. In both cases it is important to ensure that the number of the original product is uniquely assigned to all end products, and that all end product numbers can be used to identify the original product and the associated donor.

CAUTION: The use of flags changes the check character, so that products derived from one donation event are only identically labelled in terms of the characters appearing before the flag.

4.1.5 Check Characters

Although the use of check characters is subject to the agreement or regulations of individual countries, Eurocode highly recommends the usage of the check digit MOD 11,10 according to ISO 7064 [6]. The check function must cover the entire string of numeric digits making up the data elements. Check characters must never be trimmed at any step of processing, transfer or storage. The user guideline for the check character is available at www.eurocode.org.

4.2 Donation Identification or Unique Product Identification Number (UPN-T) for organs, tissue and cell products (for blood products see 4.1)

The UPN-T corresponds to the Donation Identification Number according to Annex 7 of the EU Directive 2006/86/EC [7].

!	T	cc	iiiiii	nnnnnnnnn

!	exclamation mark	primary identifier
T	letter “T”	secondary identifier: UPN-T
cc	2 digits alpha	country code acc. ISO 3166-1 [5]
iiiiii	6 digits numeric	centre code (national regulation)
nnnnnnnnn	9 digits numeric (national regulations)	consecutive product number (including check character)

4.2.1 Country code (cc) and Centre Codes (iiiiii)

Country and Centre Codes are administered and published by the Eurocet Registry [8]. Eurocode adopts as country code the international country recognition code corresponding to ISO 3166-1 [5] that use two alpha characters.

4.2.2 Consecutive Product Number

The length of the consecutive product number varies from 6 to 9 numeric digits (0…9) and is determined by each nation. It is recommended that the decade and year be inserted at the beginning, and that check characters (see 4.2.3) be used at the end of the consecutive product number. The rules for consecutive product number must be accepted by the Eurocode-IBLS Board and published on the website www.eurocode.org
A new UPN-T must be used for split products issuing from one donation event. Here it is important that the numbering of the original product be clearly assigned to all end-product units so that, if necessary, the original product and donor can be identified from the split product label.

4.2.3 Check Characters

Although the use of check characters is subject to the agreements or regulations of individual countries, Eurocode highly recommends the usage of the check digit MOD 11,10 acc. ISO 7064 [6]. The check function must cover the entire string of numeric digits of the UPN-T. Check characters must never be trimmed at any step of processing, transfer or storage of the UPN-T. The user guideline for the check character is available at www.eurocode.org.

4.3 Product Code

Product codes serve to classify product properties in order to help the user make the correct choice of product. Three secondary identifiers help to distinguish between products intended for international, national or internal usage.

4.3.1 International Application

Product codes for international use are assigned by Eurocode's technical committees according to medical expertise and following requests from Eurocode members.

!	P	nnnnnn

!	exclamation mark	primary identifier
P	letter “P”	secondary identifier: international product code
nnnnnn	6 digits numeric	1st numeric digit specifies the product group; the next 5 digits are consecutive and given by Eurocode [1]

[1] All product groups and products are listed in the product code tables and the product codes catalogue on www.eurocode.org.

4.3.2 National Application

Product codes for national use may follow agreements or regulations of individual countries, and must be made accessible via www.eurocode.org. The national codes should include the 3-digit country code according ISO 3166-1 [5] at the beginning.

!	Q	**nnnnnn***nnn*

!	exclamation mark	primary identifier
Q	letter “Q”	secondary identifier: national product code
ccc	3 digits numeric	country code acc. ISO 3166-1 [5]
nnn*nnn*	3-6 digits numeric	national regulation

4.3.3 Internal Application

The product code for internal use is not controlled and published by Eurocode IBLS and has to be kept secret by the centre that has adopted this code.

!	q	n…n

!	exclamation mark	primary identifier
q	letter “q”	secondary identifier: international product code
n…n	alphanumeric	centre controlled

4.4 Donor Number

The donor number serves to uniquely identify the donor. The form of the donor number will vary according to the various specifications of country and centre codes used for blood products or organs, tissues and cells.

4.4.1 Blood Donors

!	S	ccc	iii	nnnnnnnn	p

!	exclamation mark	primary identifier
S	letter “S”	secondary identifier: donor number
ccc	3 digits numeric	country code acc. ISO 3166-1 [5]
iii	3 digits numeric	centre code (national regulation)
nnnnnnnn	8 digits numeric	consecutive donor number
p	1 character	check character (starting after “S”)

The use of country code, centre code and check digit correspond to the specifications described under the UPN (see 4.1). The consecutive donor number is assigned by the donation establishment according to internal regulations.

4.4.2 Organ, Tissue and Cell Donors

!	S	cc	iiiiii	nnnnnnnn	p

!	exclamation mark	primary identifier
S	letter “S”	secondary identifier: donor number
cc	2 digits alpha	country code acc. ISO 3166-1 [5]
iiiiii	6 digits numeric	centre code (national regulation)
nnnnnnnn	8 digits numeric	consecutive donor number
p	1 character	check character (starting after “S”)

The use of country code, centre code and check digit correspond to the specifications described under the UPN-T (see 4.2). The consecutive donor number is assigned by the donation establishment according to internal regulations.

4.5. Blood Group (Red Cell Antigens)

The specification of red cell antigens is restricted to four of the most important systems for clinical use: ABO blood group, Rhesus factor D, Rhesus antigens CcEe and Kell antigens. Further information on antigens is not encoded and must be transmitted by means of plain text.

!	R	abcd

!	exclamation mark	primary identifier
R	letter “R”	secondary identifier: blood group
abcd	4 digits numeric	encoding of antigens (see below)

digit	**a** **ABO** blood group	**b** **Rh-D gene**	**c** **Rh-CE gene**	**d** **Kell antigen**
0	no result	no result	no result	no result
1	A	Rh pos. “..D..”	Cc..Ee	K pos.
2	B	Rh neg. “..d..”	CC..ee	K neg.
3	AB	D weak “..D^{weak}..” [1]	Cc..ee	KK
4	O	D partial “..$D^{partial}$..” [2]	cc..ee	Kk
5	-	-	cc..Ee	kk
6	-	-	cc..EE	-
7	-	-	Cc..EE	-
8	Oh (Bombay)	-	CC..EE	-
9	special	special [3]	CC..Ee	special

[1] Rh pos as a donor and as a recipient of red cells
[2] Rh pos as a donor; Rh neg as a recipient of red cells
[3] Rh-D and Rh-CE-gene controlled.

Examples:
"!R3240" encodes the red cell antigen profile "AB Rh neg ccddee (K ?)"
"!R1122" encodes the red cell antigen profile "A Rh pos CCD.ee K neg"

Notes:
"A Rh_{null} --dd-- K neg", "A Rh pos --D.-- K neg", "A Rh pos CCD.-- K neg" or other rare Rh mutations should all be encoded as "!R1902", specifying the exact Rh group by plain text only.

4.6 Date and Time values

Collection and expiry date can be encoded either with or without an indication of time. The time of irradiation as an additional vital indicator of shelf-life can be included here. For international exchange of products, insofar as time values are necessary, the difference between local and UTC-time should be included (see 4.6.6).

4.6.1 Collection Date with Time

!	D	yyyy	mm	dd	hh

!	exclamation mark	primary identifier
D	letter “D”	secondary identifier: collection date and time
yyyy	4 digits numeric	year
mm	2 digits numeric	month
dd	2 digits numeric	day
hh	2 digit numeric	hour (local time)

4.6.2 Collection Date without Time

!	C	yyyy	mm	dd

!	exclamation mark	primary identifier
C	letter “C”	secondary identifier: collection date
yyyy	4 digits numeric	year
mm	2 digits numeric	month
dd	2 digits numeric	day

4.6.3 Expiry Date with Time

!	F	yyyy	mm	dd	hh

!	exclamation mark	primary identifier
F	letter “F”	secondary identifier: expiry date and time
yyyy	4 digits numeric	year
mm	2 digits numeric	month
dd	2 digits numeric	day
hh	2 digit numeric	hour (local time)

4.6.4 Expiry Date without Time

!	E	yyyy	mm	dd

!	exclamation mark	primary identifier
E	letter “E”	secondary identifier: expiry date
yyyy	4 digits numeric	year
mm	2 digits numeric	month
dd	2 digits numeric	day

EXAMPLE: !E19970304 encodes the expiry date of the unit: 4 March 1997

4.6.5 Irradiation Date and Time

!	B	yyyy	mm	dd	hh

!	exclamation mark	primary identifier
B	letter “B”	secondary identifier: irradiation date and time
yyyy	4 digits numeric	year
mm	2 digits numeric	month
dd	2 digits numeric	day
hh	2 digit numeric	hour (local time)

4.6.6 Time Difference to UTC (Universal Time Coordinated)

This coding element is intended for products which require an indication of time in hours, and which are exchanged through diverse time zones. The 2-digit time difference is introduced directly after the other time formats.

!	G	x	hh

!	exclamation mark	primary identifier
G	letter “B”	secondary identifier: time difference to UTC
x	“+” or “-“	positive or negative difference
hh	2 digit numeric	hour difference between UTC and local time

Example for products (e.g. stem cells) collected in Germany and dedicated for application in Washington State: !D2004083016 and !G+02 means collection date and time is 30th of August 2004 at 16:00 in Germany (local daylight saving time), equivalent to 30th of August 2004 14:00 UTC and 30th of August 2004 at 07:00 in Washington State (Western Pacific daylight saving time).

4.7. Centre-controlled Entity Identification Number (EIN)

The Entity Identification Number can be used by centres for the unique and unmistakable identification of additional entities, for example documentation on quality control systems.

Tip: In order to distinguish between diverse classes of entities, an additional internal identifier can be inserted after the centre code.

!	Y	ccc	iii	n…n

!	exclamation mark	primary identifier
Y	letter “Y”	secondary identifier: EIN
ccc	3 digits numeric	country code acc. ISO 3166-1 [5]
iii	3 digits numeric	centre code (national regulation)
n…n	up to 30 characters	centre controlled

4.8. Packaging Volume (in ml)

!	V	nnnn

!	exclamation mark	primary identifier
V	letter “V”	secondary identifier: packaging volume
nnnn	4 digits numeric	volume in ml

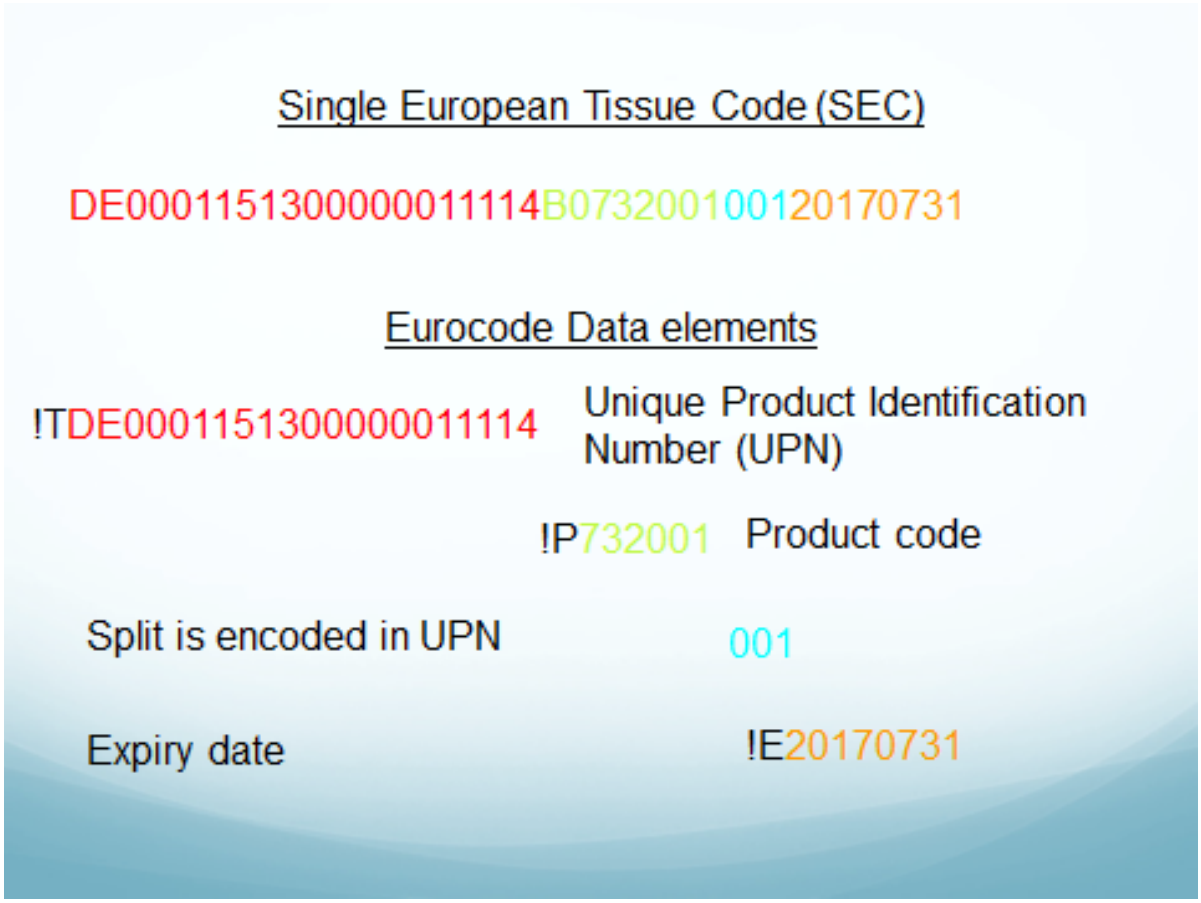
Example: !V0050 = packaging size of 50 ml

5. Single European Tissue code (SEC) and Eurocode data elements

European Directives 2004/23/EC and 2006/86/EC set out the requirement of a single European coding system to identify and label tissue and cell products in the EU. Requirements which cover the full definition of the SEC, indications on its application, as well as obligations of the tissue establishments, Health Authorities and the European Commission have been adopted by Directive 2015/565 and should be transposed into the national legislation by 29/10/2016.

SEC requires data elements which are described by Eurocode already. These data elements can be used to complete SEC:

- Unique Donation Identification in SEC correlates with Unique Product Identification Number for organs, tissue and cell products (UPN-T) in Eurocode (see 4.2),
- Product Number in SEC correlates with Product Code in Eurocode (see 4.3.1) In SEC the Eurocode Product code is characterized by a preceding “B” as identifier and a Zero “0” is inserted between B and the Eurocode Product Code to fill up from six to seven digits
- Split number in SEC is part of the UPN-T in Eurocode, thus in SEC three “001” digits are intended for the numbering of split products
- Expiry date correlates with Expiry Date without time (see 4.6.4)



6. Delivery Mechanisms and Concatenation

Eurocode data elements can be indicated in plain text and included in diverse Bar Code formats both individually as well as in concatenation. Storage on RFID chips is currently unsupported, although the primary data identifier “!” for Eurocode will be registered for RFID applications in the near future.

6.1 Eye-Readable Text

The full string of data elements including the primary identifier “!” must be adopted in eye-readable text. Different data elements must be separated from one another by blank spaces or listed vertically in order to improve readability.

6.2 Bar Codes

A Bar Code is an optical machine-readable representation of data, whereby the encoded data structures can be read automatically, quickly and accurately. Due to the high reliability of bar code reading in comparison to the key-entry of data, the use of Bar Code technologies is strongly recommended for the exchange and application of products intended for patients.
Various types of Bar codes are available. Eurocode highly recommends the use of the linear Bar code format “Code 128” or the 2-dimensional Bar code format “Data Matrix”.

Important Note:

All data elements included in the Bar Code must also be written in plain text underneath the Bar Code.

6.2.1 Code 128

Code 128 is a linear Bar Code format designed to encode all characters of the alphabet including the full ASCII character set of 128 characters in capital and small letters. Code 128 provides excellent density for all numeric data and good density for alphanumeric data and thus ensures a reliable reading of the Bar Code. Furthermore, Code 128 allows compression for numeric sections of a data string, which is longer than 4 characters; these are printed in numeric pairs, thereby saving space and facilitating the reading of the code with standard Bar Code readers. This is very useful for longer data elements such as UPN, UPN-T, donor number and OIN.

Important Note:
The Bar Code must comply with the industry standard ISO/IEC 15417: 2007(E): Information technology - Automatic identification and data capture techniques - Code 128 Bar Code symbology specification [9].

6.2.2 Data Matrix

A **Data Matrix** code is a two-dimensional matrix Bar Code consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or raw data and the usual data size is from a few bytes up to 2 kilobytes. The length of the encoded data depends on the symbol dimension used. Error correction codes are added to increase symbol strength; even if partially damaged, they can still be read. A Data Matrix symbol can store up to 2,335 alphanumeric characters. Thus, various data elements of Eurocode could be concatenated in one 2D-Bar Code, while the discrimination of the elements is given by the primary identifier “!”.

Example: "!2767029954637285!P100300!C19991227!E20000103!R3152" represents a blood product having the UPN 2767029954637285, product code 100300, collection date 1999-12-27, expiry date 2000-01-03, and red cell antigen code 3152.

Important Note:
The Bar Code must comply with the industry standard ISO/IEC 16022 Information technology - International symbology specification - Data Matrix [10].

6.3 Bar Code quality requirements

6.3.1 Print Quality

To ensure proper function it is necessary that various quality requirements are met when Bar Codes are printed, e.g. regarding bar widths, contrast, quiet zones, etc. The following test specifications are available to provide quality control in the printing of Bar Code Symbols:
- ISO/IEC 15416 “Bar code print quality test specification - Linear symbols” for Code 128 [11]

- ISO/IEC 15415 “Bar code print quality test specification - Two-dimensional symbols” for Data Matrix [12].

The principle of these specifications is to generate a quality grading to allow judgement of a printed Bar Code. A Bar Code Verifier is needed for the test procedure. The test equipment measures the values of relevant criteria such as contrast, allowing an overall quality grading to be calculated.

Numeric range (CEN specification	Alphabetic grade (ANSI specification)	Mapping	Quality
4	A	3.5 to 4.0	Best
3	**B**	**2.5 to 3.49**	**recommended by Eurocode**
2	C	1.5 to 2.49	
1	D	0.5 to 1.49	
0	F	below 0.5	fails

2D Data Matrix Symbols should achieve a 3.0/08/650 grade level according to the ISO 15415 print quality specification for 2-D matrix symbols.

6.3.2 Integration in labels

Bar Codes must be integrated into the design of the label while maintaining the quality specifications described above. The label design, based on national regulations or agreements, must provide some minimum information about the product unit, such as UPN or UPN-T, product code and expiry date. For blood products it is also necessary to indicate the blood group.

6.3.3 Bar Code colour

Bar Codes should be printed on black or white labels.

6.3.4 Bar Code height

The height of a Bar Code may not be lower than 15% of its length in order ensures ease of reading. If 2D-Bar Code extension is used then height can be smaller, although not less than 8 times the bar width.

6.3.5 Bar width and length

0.25mm is the recommended nominal bar width, although this may be reduced to a minimal accepted value of 0.19 mm. Every data element of Eurocode can be printed in one Code 128 Bar Code. Concatenation of various data elements should be done in a Data Matrix.

6.4 Technique of Bar Code printing

The most suitable technique for printing Bar Code labels on demand is Thermal Transfer Technology, especially for projects of one serial number per product.

6.4.1 Thermal Transfer Printing

This technology is very precise at printing the smallest dots and bar sizes at a permanently high quality, as for text, graphics as Bar Codes. The resolutions for the smallest dots are typically specified at 0.125 mm (200 DPI, 8D/mm) or smaller (0.084 mm – 300 DPI, 12D/mm). Printing tolerances are very low by means of the print head technology, whereby dots are transfer from the print ribbon to the media at a fixed position to each other. The ink is transferred to paper or plastic materials by heated pixels through carbonated ribbon as a macro burn-in process. As an alternative, Thermal Direct (TD) printing can be chosen for labels, which only require a short lifetime. Here a temperature-sensitive label coating generates the required image instead of being applied by a ribbon as in Thermal Transfer (TT), although the resulting image from TD printing is neither scratch nor UV resistant.
Thermal Direct or Thermal Transfer printers are available as on-demand printers for single labels, for continuous operations or can be integrated in automatic systems. Control of the printing process is managed by workstations or network systems through appropriate interfaces.

6.4.2 Laser printer

Laser printers with resolutions of better than 200 DPI are very useful for printing page-sized forms, worksheets or delivery notes, etc., in office environments. However, office laser printers cannot be used to print small adhesive labels as the adhesive coating melts during heating and thus damages the equipment internally. Maintaining print quality can also be a problem due to a lack of toner monitoring during the printing process.

6.4.3 Matrix Impact Printer

Due to their mechanical operation and uncontrolled consumption of ribbons, matrix impact printers do not provide continuous high quality. They are therefore not recommended for the high quality, on-demand printing necessary for product labels.

6.4.4. Ink-jet printer

Although this technology is constantly developing, its usage for high density Bar Codes is limited due to the physical size of ink dots. The resolution of some systems bring dot sizes close to 0.3 mm, but the quality depends on three components: the media to be printed, the ink and the underlying process.
Integration would need great experiences in technologies and packaging processes. More experience with this technology and packaging processes would be required to make use of ink-jet printers in the production of Bar Codes.

6.4.5. Automated Labelling

Automatic Label Applicators are useful for labelling products at the end of a production line in order to print actual serial or charge numbers as text, graphics and Bar Code. Such a system includes an industrial print engine, a dispenser for applying the label to the product and an interface to the computer, which supplies the data. Print engines such as Thermo Transfer systems guarantee quality even for small labels.

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