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Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution

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This technical bulletin provides an overview of one example use of the flag characters in the *ISBT 128* Donation Identification Number data structure

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Use of the *ISBT 128* Donation Identification for process control

Control of critical points enhances the safety of blood and blood components.

Critical points are, for example, labeling and relabeling of blood and blood components as well as printing and attaching a record to follow specific units of blood or blood components.

This Technical Bulletin describes an example of the use of the flags in the Donation Identification Number for process control of critical points during processing and distribution.

The *ISBT 128* Donation Identification Number Data Structure

The *ISBT 128* Donation Identification Number data structure provides unique identification of each unit of whole blood (or apheresis product) collected anywhere in the world over a one hundred year period.

The Donation Identification Number data structure is:

= α pppp yy nnnnnn ff

where:

“=α” is the data identifier;

“αpppp” is a five-character (one alphanumeric plus four digits) Collection Facility Identification Code;

“yy” is a two-digit year of collection,;

“nnnnnn” is a six-digit unit serial number;

“ff” are two flag numerical characters, (*see* Table 1);

The eye-readable form of the Donation Identification Number will also include a

keyboard data entry check character “K”.

As mentioned above, this publication will deal with the use of the two-digit flag characters for process control. For further information about the other elements of the *ISBT 128* Donation Identification Number *see* the *ISBT 128 Standard: Technical Specification*.

Donation Identification Number Flag Characters

The specific usage of the two *ISBT 128*-specified special (non-data) flag characters “ff” must conform to national guidelines. There are two general types of usage, where the two digits are to be interpreted as either:

- Two-digit special flag characters used for process control, or
- A weighted modulo 37,2 check digit on the entire thirteen character Donation Identification Number. This check character must not be confused with the K check character. The use of the flag characters for this purpose will not be discussed further in this Technical Bulletin.

The flag characters “ff” are non-data characters. They are used to convey specific information other than the unique identification of the blood product.

Two types of flag characters for process control are provided:

Type 1: Process control, where the meaning is defined within the *ISBT 128* standard;

Type 2: Process control, where the meaning is defined at either the national or facility level.

In all cases the following two rules must be observed:

- When not used or not specified, the value of “ff” is to be set to “00”;
- When used, the selected values of “ff” must conform to Table 1.

When Type 1 or Type 2 process control flag characters are used (which means the encoded value of “ff” is in the range 01-59) they must be represented in a nationally specified eye-readable format. This format may either be a numeric, text or other symbol as noted below.

Numeric Format
When printed as a two-digit number the digits should be rotated 90° clockwise to make them visually different from the other data characters in the Donation Identification Number. An example is shown in Figure 1.

Non-numeric Format
Text or a symbol representing “ff” may be preferable. For example:

- Where “ff” is “03", printing the phrase “Container 3” on the label may be more useful to the person handling the unit;
- Where “ff” is “07”, printing an icon showing a small test tube may be preferable.

Figure 1

Table 1 *ISBT 128* Specified Values for Donation Identification Number Flag Characters, "ff"

Value of "ff"	Meaning
00	Flag not used; null value
01	Container 1 of a set
02	Container 2 of a set
03	Container 3 of a set
04	Container 4 of a set
05	Second (or repeated) "demand-printed" label
06	Pilot tube label
07	Test tube label
08	Donor record label
09	Sample tube for NAT testing
10	Sample for bacterial testing
11-14	Reserved for future assignment
15-19	Container 5 through 9 of a set
20-59	Reserved for assignment and use at national or facility level; therefore the interpretation of "ff" values 20-59 may differ. They should always be interpreted with this in mind.
60-96	ISO 7064 modulo 37,2 check character on the preceding thirteen (13) data characters, "αppppyynnnnnn," including the Collection Facility Identification Code, year and the unit serial number. Value is assigned as 60 + (modulo 37,2 checksum)
97-99	Reserved for future assignment

Scandinavian Use of Flag Characters for Process Control

In this technical bulletin the Scandinavian use of the flag characters for process control is described. This system uses a combination of the flag characters allocated by ICCBBA, Inc and flag characters defined in Scandinavia, *see* Table 2.

The process control is partly dependent on an amendment to the international label. At

the bottom of the main label there is a smaller label (100 mm x 25 mm (4" x 1")) with the Donation Identification Number and the Product Code data structures (*see* Figure 2). These two data structures codes uniquely identify the product worldwide. The label can be torn off and placed in the patient's records. Although the Donation Identification Number on this smaller label is identical to the Donation Identification Number in the upper left quadrant, the flag characters are different and therefore it is possible to discriminate between the two identical Donation Identification Numbers.

The flags characters are used to discriminate between *identical donations numbers* that are in *different places* and thereby *control critical points* during processing.

Examples of critical points that can be controlled by this system are:
- labeling at collection;
- labeling after separation;
- labeling after change of product code;
  - same container (*eg*, irradiation, thawing);
  - new container (*eg*, filtration, washing);
- pooling;
- dividing and splitting;
- distribution or issuing of component.

Table 2 Scandinavian Specified Values for Donation Identification Number Flag Characters, "ff"

Location	Flag characters	Container
Donor documentation	08	
Upper left quadrant	01 and 31	Container 1
	02 and 32	Container 2
	03 and 33	Container 3
	04 and 34	Container 4
	etc	
Label for the patient's records	41 and 51	Container 1
	42 and 52	Container 2
	43 and 53	Container 3
	44 and 54	Container 4
	etc	
Record following the unit	46	

Figure 2

Hyperlinks given below will access images from www.iccbba.org web site when this document is viewed on-line

Process Control of Labeling at Collection [images]

The base label of an *ISBT 128*-labeled blood container has two *ISBT 128* bar codes: The Manufacturer's Identity and Container Information data structure (lower left quadrant) and the Lot Number data structure (lower right quadrant). The data structure for the former is

=) b q q w w w w w w w

"=)"	is the data identifier;
"b"	is the container number in the set;
"qq "	is the manufacturer's Identification Code;
"wwwwwww"	is the manufacturer's catalog number.

When Donation Identification Numbers for the different containers have different flag characters, it is possible after collection and labeling to read on each container first the bar code Donation Identification Number data structure and then the bar code of the Manufacturer's Identity and Container Information data structure. The computer can then compare the flag characters of the Donation Identification Number and the container number in the Manufacturer's Identity and Container Information bar code and alarm if the two bar codes are discordant. The correct placing of the Donation Identification Numbers is pivotal for process control further down the production line as described below.

When this registration takes place after the collection it is also possible to make certain that an identical Donation Identification Number is on the donation record, any pilot tubes, the tube for bacterial testing and the tube for NAT testing. Newer mixers provided by several companies are able to collect these data during the collection procedure and therefore the process control described above can take place just beside the donor. This saves time and may even make control checks by a second staff person unnecessary.

Process Control of Labeling after Separation and Testing [images]

After the whole blood collection has been separated and tested the flag characters make it possible to control the critical final labeling of the blood component provided:

- the computer system has information on the product manufactured;
- the computer system has information on the results of the testing and blood group control procedures;
- what is missing for the final *ISBT 128* label is printed on-line (on-demand);
- that a second identical Donation Identification Number with different flag characters is printed on an attached label for the patient's records.

In practice, this can be done by the following series of events:

1. Donation Identification Number read in upper left quadrant (for example flag characters 02);
2. On-line (on-demand) label printed automatically;
3. Label placed on container;
4. Donation Identification Number read again in upper left quadrant;
5. Donation Identification Number read on label for patient's records (flag characters 42)
6. If Donation Identification Number or flag characters are incorrect (*eg*, if the Donation Identification Number is read from the same place twice) the computer alarms.
7. Product Code read (to make certain that the computer's information regarding the product is identical to that on the label).

Process Control for Change of Product Code (component stays in same container) [images]

After the final label has been attached to the component it may be necessary to change the Product Code even though the component stays in the same container, for example, after irradiation or thawing.

In practice, this can be done by the following series of events:

1. Donation Identification Number read on label for patient's records (for example, flag characters 42);
2. Product Code read on label for patient's records (these two steps can be done in a single scan (read) if concatenation is used);
3. New Product code chosen;
4. On-line (on-demand) label printed automatically;
5. Label placed on container;

6. Donation Identification Number read in upper left quadrant again (flag characters 02);
7. Donation Identification Number read on label for patient's records (flag characters 52)
8. If Donation Identification Number or flag characters are incorrect (*eg*, if the Donation Identification Number is read from same place twice or if the flag characters are unchanged) the computer alarms;
9. Product Code read (to make certain that the computer's information about the product is identical to that on the label).

Process Control for Change of Product Code (component moved to a new container) [images]

After the final label has been attached to the component it may be necessary to change the product code during the production of the component in a new same container, for example, for leukodepletion or washing.

In practice this can be done by the following series of events:

1. Donation Identification Number read on label for patient's records (for example flag characters 42);
2. Product Code read on label for patient's records (these two steps can be done in a single scan (read) if concatenation is used);
3. New Product Code chosen;
4. On-line (on-demand) label (whole label and label for patient's records) printed automatically;
5. Label placed on new container;
6. Donation Identification Number read on label for patient's records on original container (flag characters 42);
7. Product Code read on label for patient's records on original container (these two steps can be done in a single scan (read) if concatenation is used);
8. Donation Identification Number read on label for patient's records on new container (flag characters 42);
9. Product Code read on label for patient's records on new container (to make certain that the computer's information on the Product Code is identical to that on the label) (these two steps can be done in a single scan (read) if concatenation is used);

10. If Donation Identification Number or flag characters are incorrect (*eg*, if the Donation Identification Number is read from the same place twice or if the flag characters are unchanged) the computer alarms.

***Important*: steps 5 to 9 must be performed before the two containers are disconnected.**

Process Control in Pooling [images]

Pooling may be performed in the original container of one of the components or in a new container. A new Donation Identification (batch) Number may be required by national legislation; in some countries one of the original Donation Identification Numbers may be used for the pool. I n both cases traceability of all included components and correct labeling are of paramount importance.

In practice the control of this process can be done as follows:

1. Registration of new component's Donation Identification (batch) Number and Product Code;
2. Registration of old component's Donation Identification Numbers (for example, flag characters 01);
3. On-line (in-demand) label (whole label and label for patient's records) printed automatically;
4. Donation Identification Number (for example, flag characters 41) and Product Code read from label for the patient's records on the new label. Can be done in a single scan (read) if concatenation is used;
5. Donation Identification Numbers (and Product Codes, if available) read from old containers;
6. If Donation Identification Number or flag characters are incorrect (*eg*, if the Donation Identification Number is read from the same place twice or if the flag characters are unchanged) the computer alarms.

***Important*: steps 4 to 6 must be performed before the containers are disconnected.**

Process Control for Dividing and Splitting Units [images]

Dividing and splitting of a product necessitates a change in the 7th and/or the 8th character of the *ISBT 128* Product Code. Traceability of all divisions and splits and correct labeling are important.

In practice the control of the division/split process can be done as follows:

1. Registration of component to be divided or split: Donation Identification Number (for example, flag digits 52) and Product Code read on the label for the patient's records.
2. Number of wanted division or splits is entered into the computer, which automatically creates the needed new Product Codes.
3. On-line labels (whole label and label for patient's records, one for each division or split, each with a different Product Code) printed automatically
4. Donation Identification Number (for example, flag characters 52) and Product Code read from label for the patient's records on the original container. This can be done in a single scan if the concatenation is used.
5. Donation Identification Number (for example, flag characters 42) and Product Code read from the divided or split container(s). This can be done in a single scan if the concatenation is used.
6. If Donation Identification Number or flag characters are incorrect (for example if the Donation Identification Number is read from the same place twice or if the flag characters are unchanged) the computer alarms.

***Important*: steps 4 to 6 must be performed before the containers are disconnected.**

Process Control in Shipping [images]

When shipping, the Donation Identification Number and the Product Code on the label for the patient's records can be read in a single scan and used to create a delivery note. This feature can also be used for billing and inventory control.

Process Control in Issuing

Control of issuing of blood components from the hospital's transfusions service to the wards is critical. The practice used in connection with an electronic cross match is described, but the process control can also be adjusted to a system using serological cross matching.

Control of this critical point can be achieved as follows:

1. The necessary requirements for an electronic cross match are fulfilled;
2. The patient's identification number is scanned;
3. Unit(s) is (are) ordered in the computer system;
4. The computer chooses appropriate unit(s);
5. A transfusion record for each unit is printed;

6. Unit(s) obtained from stock;
7. Donation Identification Number (flag characters 46) and Product Code scanned from transfusion record;
8. Donation Identification Number (flag characters different from 46) and Product Code scanned from label for patient's record;
9. If Donation Identification Number or flag characters incorrect (for example if the Donation Identification Numbers or Product Codes are different or the Donation Identification Number is read from the same place twice) the computer alarms.

Does it work?

The described system for process control has now been implemented in several facilities in Scandinavia beginning in 2000. In practice, process control of labeling does not result in a substantial increase in work load. Staff has welcomed the concept. Mislabeling has been a much rarer event. Most importantly, documentation of all labeling events, including registration of staff and time, has become possible.