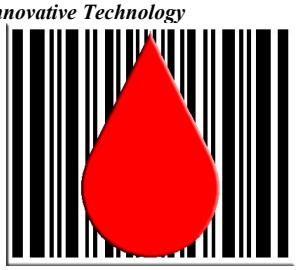
DIGITRAX CORPORATION

Improving Health and Science Through Innovative Technology

HemaTrax Standalone

Version 6.2.1 Release Notes



Information regarding changes made in this release of the HemaTrax Standalone blood labeling application.

Divided Units

Releases prior to Version 6.2.1 erroneously displayed an unknown volume line, " _____ mL" immediately below the product attribute lines for some products which did not require it when those products were indicated as divided (split). The program logic has been modified to correct the displayed label information text. When printing product labels (2" x 2") that were divided and there were several unknown values initially requested, subsequent requests to print the same product resulted in the number of unknowns requested to not include the first unknown originally requested. The program logic has been modified to correct this error.

Product Label Database

Product label databases prior to the Version 6.2.1 did not define "Red Blood Cells" with "Plasma Added" as "Reconstituted Red Blood Cells". The database now properly identifies these products. The "Hematocrit _____" line shown in the ICCBBA examples is considered optional and is not included by default in the HemaTrax product label definition. This additional line can be added manually to the database records via the Maintenance - Product Label functionality. The values
for the Plasma ABO-Rh and anticoagulant must be manually written on the label after it is printed for the time being.

Product label databases prior to the Version 6.2.1 release often included the product name in the prompts for volumes being requested just before the label was to be printed. The product name no longer appears in the entry prompts as it was suggested that the use of the product name was confusing when split units were being labeled. Now "Original draw volume in mLs" or "Unit volume in mLs" will be used in the volume entry prompts.

The latest ICCBBA product label definition tables were used in the latest release. Now there are label definitions for all products up to and including ICCBBA product code E5998.

Granulocyte and Granulocyte/Platelets Search
It was reported that when a search was made for Granulocyte products that a list of Granuloctye/Platelet products was produced. Searches for Granulocyte/Platelet products listed Granulocyte products. This error was traced to the external file, "CompDef.txt", which lists the component class (product) names and supplies the search codes for each component class.

The code for Granulocytes and the code for Granulocyte/Platelets was determined to be transposed. This has been corrected in the file accompanying this release.

ABO-Rh Label
The DnrTyp.txt file has been corrected in this release to include the text "FOR LABORATORY RESEARCH USE ONLY" at the bottom of the quadrant when ever the donation type code "R" or "r" is selected for this label quadrant. See "Appendix D Donation Type" on page 76, Table 7 of the US Industry Consensus Standard (Version 2.0.0, November 2005) for more information.

BIOHAZARD
All labels that include the biohazard symbol no longer print the word "BIOHAZARDOUS" or "BIOHAZARD" centered and immediately below the biohazard graphic. Now the word "BIOHAZARD" is appended with a leading comma and space to the end of the intended use text that normally appears at the bottom of the ABO-Rh label quadrant. See "Appendix D Donation Type" in the US Consensus Standards document for details.

Note: The use of the word "BIOHAZARDOUS" in the US Consensus Standard document is in error, it should read as "BIOHAZARD". Facility, Facility/Product, Full Face and Time & Date/Test Labels The facility name and licensee name fields may now contain up to one hundred characters each. If the name length exceeds fifty characters the name will automatically wrap to a second line. Wrapping to a second line can be forced at any point by including the vertical bar character (|) in the name field text.

Product Label Database
This release ships with an extended product label database. Details regarding the impact of these changes follow:

Expanded Product Code Range
With this release label designs for ICCBBA product codes in the range from E0001 to E5998 are included in the HemaTrax product label database.

ICCBBA Product Description Text Adopted
The full ICCBBA product description is now used in place of the HemaTrax text description formerly used. This means that for some U.S. products such as Source Plasma for example, the description will appear as Apheresis PLASMA For Further Manufacture. Other such products include Source Leukocytes and Recovered Plasma.

Product Label Database Corrections
Several product codes have had their label verbiage corrected to comply with FDA labeling requirements.

Eliminated the Use of Period Punctuation Characters in Label Text
The use of the period character "." to terminate text or for abbreviations has been eliminated in the latest release of the database that ships with this version of the standalone.

Elimination of the Use of the Degree Symbol
The use of the degree symbol, "°", in the storage temperature text on the label has been eliminated.

Correction to RBC„ Low Volume Anticoagulant Adjusted Products
Previously in the HemaTrax product label database a low volume Red Blood Cell product with an adjusted anticoagulant volume had additional information text that wasn't exactly correct. For example the text for product code E5253 read as follows:

Approx. _____ mL plus _____ mL CPD
Store at 1 to 6°C.
The HemaTrax product label database has been corrected to now contain the following:
_____ mL from _____ mL Whole Blood
containing approx _____ mL CPD
Store at 1 to 6 C

HemaTrax Print Engine
An updated version of the print engine library (HemaTraxLIB.dll, Version 09036.1428) has been introduced to support new label formatting logic. Details of these changes follow:

Donation Identification Number Font Size Change
The FDA has requested and the ATAG voted to no longer display the six digit sequence number portion of the DIN in a larger point size than the rest of the interpretation line appearing below the DIN bar code. The feeling is that the entire number is important and that emphasis shouldn't be placed on any fraction of the number. This change has been implemented in this release.

Product Name Typeface Point Size Reduction
The font point size of the product name has been reduced slightly. Of course this reduces the size of all text that must match the height of the product name. This change has been made to compensate for space constraint issues raised by the need to match manufacturing caution statement text height to the product name text height.

Manufacturing Caution and Product Name Text Height Matched
Formerly the text, such as "CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY" was printed in a slightly shorter text height than the product name. This has been corrected. by reducing the height of the product name text as indicated in the paragraph immediately above. If the cautionary text were to have been increased to match the product name text height, then this would have caused label space problems for certain products.

Therapeutic Donation
Certain logic changes have been introduced to handle printing of required text on the product label when a therapeutic donation is made as follows:

All Therapeutic Donations
All therapeutic blood donation product labels will include a space at the bottom of the label for the donor's disease diagnosis. See page 56, Figure 25 of the US Industry Consensus Standard (Version 2.0.0, November 2005) for more information about this label format.

Therapeutic Exchange Plasma
When the donation type is "T", the product is an apheresis plasma for further manufacture and the label compliance authority is the FDA, the product will automatically be displayed on the label as "THERAPEUTIC EXCHANGE PLASMA". See page 56, Figure 25 of the US Industry Consensus Standard (Version 2.0.0, November 2005) for more information about this label format.

Recovered Plasma Section 351 Public Health Service Act Text Added
The text, "Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act" has been added to the information printed for recovered plasma products. Note: This information is now printed in the fourth quadrant (area typically displaying expiration date & time and special test results).

Recovered and Source Plasma FDA Text Moved
Certain FDA required text that formerly was printed at the bottom of quadrant three (product label) has been moved to quadrant four for all recovered and source plasma products. See pages 54 and 55, Figure 24 of the US Industry Consensus Standard (Version 2.0.0, November 2005) for illustrations of these formats. So, when one of these products is printed on a printer loaded with 2"x2" (single quadrant) labels, the printer will issue two labels, a product label and a second label to be placed in quadrant four (date and time) that displays the testing and the Section 351 text if it is applicable.

Special Test Results
Certain changes have been made to support newly adopted code schemes in label quadrant four. These changes are as follows:

CMV Negative "1aaaa" Parsing Removed
The HemaTrax Print Server no longer enforces the "1aaaa" code restriction in the five

character test result code. Now anything may be encoded in the five character code passed. ICCBBA/ATAG have settled on the use of the "N0008" five character code to indicate a CMV Negative tested unit.

Two Line Test Interpretation Lines
The HemaTrax Print Server now supports two line test result interpretation lines as illustrated On page 56, Figure 26 of the US Industry Consensus Standard (Version 2.0.0, November 2005).

FDA Required Text in the Full Face Label First Quadrant Changed
Formerly the FDA required text shown immediately below was printed for all transfusable/injectable products:

PROPERLY IDENTIFY INTENDED RECIPIENT
See Circular of information for indications,
contraindications, cautions and methods of infusion.
This product may transmit infectious agents.
Rx ONLY

The print engine has been modified to print this text as follows:

Properly Identify Intended Recipient
See Circular of Information for indications,
contraindications, cautions and methods of infusion.
This product may transmit infectious agents.
Rx Only

In the event that the first four lines of this text must be changed, the library that opens operations will look in its resident directory for a text file named "PIIRSeeCircular.txt" which it will use as a source of alternative content. It will center this text automatically within the label window as is done currently. The "Rx Only" text is still supplied under program control when necessary.

Registration and License Number Format
The print engine was inserting the text "Registration # " before the facility registration number and inserting "License # " before any occurrence of a license number following the facility name and address in either or both quadrants 1 and 4. In cases where vertical space became too cramped the print engine would also concatenate the two lines on one line.

The registration number and license number text will now read as:
FDA Registration Number 9999999
US License Number 9999

Where: "9999999" and "9999" are the facility's registration and license numbers that would be inserted respectively. The lines are no longer concatenated as a smaller character height has now been used.

Product Label Format
Some product codes were identified that when divided caused the additional information text to run off the bottom of the product label quadrant. Font height and line spacing adjustments have been made to address this issue. Since the product name line was included in this font height reduction, the font heights related to the "VOLUNTEER DONOR" or "PAID DONOR" line and the intended use text that may appear at the bottom of the ABO-Rh label (quadrant 2) have also been matched accordingly.

Added New "HO" POOLED ABO (Rh unspecified) Code
A new ABO-Rh code to specify "POOLED ABO" with the Rhesus factor unspecified has been added for all ISBT labels.

Alternative Rhesus Factor text lines
In some countries outside of the United States they require the text on the Rh factor line of the ABO labels to be slightly different. This release accommodates differences in what is printed.

Emergency Use Only
The ABO-Rh label for this donation type now provides space for manual entry of "Patient" and "Hospital" information.

Test Message Without a Test Code
A test message that requires to have the text "DONOR UNTESTED" printed can now be selected without an accompanying test code. One instance where this might be desirable is with an autologous unit that is be be marked "DONOR UNTESTED".

Use of Build Numbers Instead of Version Numbers
All HemaTrax software will use a build number in place of version numbers. The HemaTrax build number encodes the date and time of the software build using the following scheme:
yyjjj.hhmm

where:
yy the last two figits of the year of the build (00 to 99)
jjj the three digit Julian day of the year (001 to 357)
hh the two digit hour of the build (24 hour clock) (00 to 23)
mm the two digit minute of hour of the build (00 to 59)
HTServer

Product Searches May Hang

It was reported that for some specific product searches that the search activity would not return a list and that the program would become unresponsive. This problem was traced to an error in the Digi-Trax Indexed Sequential Access Method (DTiSAM) library. The error specifically was in a function that is used to find records based on a duplicate file key. This function has been repaired in this release.