HemaTrax Print Server 3.0.1 Release Notes

NEW

Match Unit with Recipient

The "MUR" label request message is a new label printing capability which allows HemaTrax to produce the label described in the Technical Bulletin 8 document available from the ICCBBA web site. This label is used to match a unit being pulled from inventory to the intended recipient information label.

NEW

Patient Wrist Band

The "PWB" label request message is a new label printing capability which allows the HemaTrax Print Server to produce a wrist band label. See the Technical Bulletin 8 document available from the ICCBBA web site for more information about the wrist band. A PILF structured format file must exist in the "FORMAT" directory in order to take advantage of this capability. No format file had been developed when the product release was made. The formats can be created with a standard ASCII text editor using the PILF commands covered at the back of this manual.

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.

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 E5607 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 print server.

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 6.0) 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 recently 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) the 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 any thing 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). Only worked for data structure 12 and 14 test codes in Version 3.0, but is now extended in Version 3.0.1 to structure 10 test codes as well.
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.

Print Server Settings
The panel to allow an alternate source of data files and settings from another server has been removed. This feature has not worked properly since the Version 2.0 release when the HemaTrax Print Server became a Windows service. Work will be done to make this a viable option in a future release.

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.