

## Version Notification – 3.0.2

*This section contains additions and changes that have been made in this version release of the print server.*



*This version supersedes the Version 2.21 and Version 3.0 releases of the HemaTrax Print Server and adds several new features. The Printer Independent Label Format (PILF) language makes its appearance in this release. PILF provides a powerful new label formatting capability that formerly was embedded in the print server and was inaccessible to the LIS developer.*

### **Match Unit with Recipient (NEW)**

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.

### **Patient Wrist Band (NEW)**

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.

### **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 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 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). Only worked for data structure 12 and 14 test codes in Version 3.0, but was 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.

*This maintenance release supersedes the Version 3.0 and Version 3.0.1 releases of the HemaTrax Print Server. What follows is the list of issues addressed by this release:*

### **Product Label Database**

(1) Extension of the ICCBBA label database to product code "E5650".

(2) Correction made to the volume line in all FROZEN RED BLOOD CELL products.

Formerly the volume line for this class of products read as follows:

From ? mL Whole Blood

now the volume line will read as follows:

? mL

(3) The testing statement for RECOVERED PLASMA products formerly read as follows: Negative by tests for HIV-1 antigen, antibodies to HIV, HBc and HCV and nonreactive for HBsAg and syphilis.

Now with all of these products the testing statement has been changed to:

Nonreactive for HBsAg and negative for anti-HCV and anti-HIV by FDA required tests.

(4) Formerly all product labels for products that included the attribute indicating "not for transfusion" displayed the cautionary statement:

"CAUTION: NOT FOR TRANSFUSION OR FURTHER MANUFACTURE"

printed beneath the product name. This statement has been changed to read:

"CAUTION: FOR LABORATORY RESEARCH USE ONLY".

(5) Formerly all Pooled Platelet products did not include the statement, "Number of units in pool \_\_\_\_\_", in the additional information portion of the product label. This HTServer.odt -8- Copyright © 2007 by Digi-Trax Services, Inc.

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statement has been added for all such products.

(6) Formerly, manufacturing caution statements used the word "NONINJECTABLE", this has been corrected to be "NON-INJECTABLE".

(7) Formerly, PLATELET-RICH PLASMA products, such as "E2774", were missing the

volume / anticoagulant line; that line is now included.

### **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 99999999

US License Number 9999

Where: "99999999" 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.

### **The Donation Type / Intended Use ("DnrTyp.txt") File**

The donation type information file "DnrTyp.txt" formerly did not list any text to appear at the bottom of the ABO-Rh label (quadrant 2) for the "R" and "r" donation type/intended use codes. This file has been corrected to specify that "FOR LABORATORY|RESEARCH USE ONLY" appear at the bottom of that quadrant.

*Note: The vertical bar character, "|", is used to indicate where the new line is to be inserted.*

### **Emergency Use Only**

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

### **External HT Client Files**

The ICCBBA product tables have included a few new attributes which had to be accounted for in the combination boxes used by the HTClient program. These attributes and the associated codes are obtained from external files which the patch will replace. SATO Printing Failure With CRC Enabled. A side effect of the introduction of the wristband printing functionality in Version 3.0 (Version 3.0.1) of the HemaTrax Printer

Server is that for the SATO America CL412e printer, using serial communications with cyclic redundancy checking (CRC) turned on, would not successfully print labels. This function has been corrected in the HemaTrax dynamically linked print engine library. ABO-Rh BIOHAZARD Label Format The zealous efforts to stay in sync with the U.S. Consensus Standards have once again bitten. Our software now follows the recent change in Appendix D of the U.S. Standards regarding the correct format of the biohazard and intended use text that print at the bottom of the ABO-Rh (quadrant 2) label. The errata issued on February 2008 indicates that the word "BIOHAZARD" is to no longer follow at the end of the intended use message separated by a comma. Now "BIOHAZARD" is to appear centered and above the intended use message. So a an autologous biohazard intended use text message will now appear as follows:

BIOHAZARD  
FOR AUTOLOGOUS  
USE ONLY

### **Split Unit Deglycerolized or Frozen RBC Product Label Format**

When a Deglycerolized Red Blood Cell product such as E4520 or a Frozen Red Blood Cell product such as E5079 is printed without being split the volume line prints as follows:

\_\_\_\_\_ mL

When either of these products was split the volume line was being printed as:

\_\_\_\_\_ mL from \_\_\_\_\_ mL

The reformatting logic in the new HemaTraxLIB.dll that installs with 10 DEC 2008 of the print server has been corrected to now product the following volume line format:

\_\_\_\_\_ mL

### **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.

### **Test Message Without a Test Code**

A test message can now be sent to the print server 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 digits 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

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