the professional
labeling software

# Patient Safety with Bar Code and RFID Labeling Identification

## White Paper

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Niceware® Healthcare
Patient Safety through Positive Identification.

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# Executive Summary

The healthcare industry has undergone a wide range of regulatory changes, patient safety challenges and third-party pressures to improve identifying patients, medications and procedures. The Food & Drug Administration (FDA) issued regulations providing FDA acceptance criteria for electronic signatures, data tracking, as well as patient and laboratory specimen identification.

To streamline, automate, and improve accuracy within the healthcare market, regulatory personnel turned to the automatic identification industry for help. Leveraging the wide range of benefits bar coding has brought to other industries, the healthcare industry quickly sought to implement and benefit from the universal bar code labeling tool.

This white paper illustrates how healthcare identification solutions provided by Niceware International enable healthcare providers to solve some of the most difficult identification and tracking problems. Niceware has developed a variety of solutions to improve automatic identification in the following areas:

- Positive Patient Identification with automated bar code and RFID wristband printing.

- Offline Patient Wristband Generation with data archiving for later file reconciliation with the parent database.

- Bedside Blood Collection and Identification with data scanning and verification off the patient's wristband and blood collection sample.

- Blood Bag Identification to design labels and applications that can comply with ISBT 128 bar code standard.

- Laboratory Specimen Identification to drive printer cassettes and slide printing systems to uniquely identify specimen in laboratories.

- HIS application integration through Health Level 7 (HL 7) global messaging compliance for patient identification, laboratory orders and more.

# Healthcare Identification Challenges

Thousands of patient deaths occur each year due to medication errors. Many organizations, such as professional societies, hospital networks, industry consortiums and patient safety groups, have pushed to use bar codes to improve medication administration safety. Healthcare service providers are required to improve methods of identifying patients, medications and procedures. These requirements offer many opportunities to use NiceLabel software in the healthcare market.

## FDA Regulation on the Healthcare Industry

In March 1997, the Food & Drug Administration (FDA) issued the final Part 11 regulations providing FDA acceptance criteria when under certain circumstances electronic records, electronic signatures, and handwritten signatures to electronic records are equivalent to paper records and handwritten signatures on paper (see NiceLabel white paper *Healthcare and Pharmaceutical Label Printing*). The FDA regulations, which aim to protect the public health, permit the widest possible use of electronic technology in the healthcare sector.

In March 2004, the FDA released its final rule requiring bar codes on drug and biological products. With improved bar code tracking, the FDA hopes to reduce the number of preventable medication errors and reduce the cost of healthcare.

The final rule applies to most drug manufacturers, re-packers, re-labelers, private label distributors and blood establishments. Starting in April 2004, medication covered by the rule have to include bar codes within 60 days of their approval; most previously approved medicines and all blood products will have to comply within two years.

## Issue of Bar Code Managed Patient Safety

Proper patient care is the top priority. An easy way to improve patient care is by ensuring that staff can easily identify patients before providing treatment. Wristbands with bar codes that symbolize the patient's medical record or patient visit number are a perfect way to ensure easy patient identification. Clearly imaged text, including patient name, DOB, medical record number, and other identifiers – such as printing a picture of the patient on the wristband – give caregivers the information they need in crisp print with a clear laminate to protect the image.

In addition, some hospitals have taken one step further and use bar codes to ensure that charges are captured accurately and promptly for all patients. Complete billing and accurate cost records – all captured through bar code scanning – have been a huge boon to hospitals that have taken advantage of the bar code technology.

However, finding a way to easily add bar codes to a healthcare provider's documentation can be a chore. In addition, placing the data where you want it on the wristband and chart labels have been the hardest part of implementing a new patient ID wristband.

When people ask about patient identification using bar code and RFID label printing technologies, they want to know the following:

- How to print bar code and RFID wristbands from the current HIS Software?

- How to continue patient identification and printing wristbands when the IT system is down and not functioning?

- How to identify patients and specimen at the bedside, far away from a desktop computer station?

- How to interface patient identification solutions with healthcare information systems from GE, Cerner, McKesson and others?

The overall challenge is to implement healthcare identification solutions that address the following:

- Provide high value while moderately priced.

- Provide easy connectivity to multiple healthcare information systems.

- Comply with global messaging standards in the healthcare industry (HL 7).

- Increase the confidence of patients and caregivers to correctly apply patient medication, procedures and treatment.

# Healthcare Identification Solutions

Niceware International offers identification solutions to the healthcare market that are easy to deploy without complicated programming changes. NiceLabel Print Center, Pocket NiceLabel and NiceWatch Enterprise provide solutions to address the following:

- **Integrated Patient Identification** with NiceWatch Enterprise

- **Offline Patient Wristband Generation** with NiceLabel Print Center and NiceForm

- **Bedside Blood Collection and Identification** with NiceWatch Enterprise and Pocket NiceLabel

- **Blood Bag Identification** with NiceLabel Print Center and NiceLabel Pro

- **Laboratory Specimen Identification** with NiceLabel Print Center and NiceForm

- **Health Level 7 (HL 7) Compliance** with NiceWatch Enterprise–HL7 Edition

## Integrated Patient Identification Solution

Niceware offers a server based software tool, NiceWatch Enterprise, which can be used to capture structured text from any Healthcare Information System (HIS) or Laboratory Information System (LIS) Application and generates a bar code label print job for printing patient wristbands, chart labels or admitting forms. The NiceWatch Enterprise tool can operate from an HL7 compliant output to extract data, set target label templates and printers to execute the print functions in seconds. HL7 is a global messaging standard for healthcare applications and providers. The messaging interface enables healthcare,

insurance and supplier institutions and disparate software applications to communicate with each other in a common language.

The NiceWatch Enterprise tool reduces the development and maintenance costs associated with modification of HIS application output. Future changes to two dimensional bar codes or RFID smart tags can be implemented in seconds.
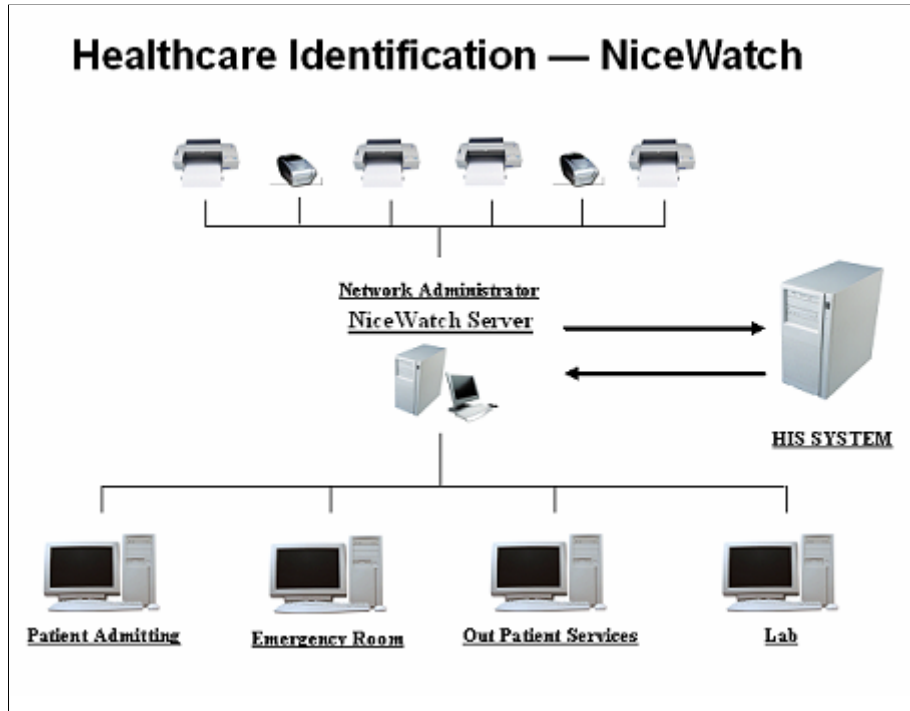


*Figure 1: Label Printing through NiceWatch Enterprise*

To fully comply with HL7 global messaging standards, use the NiceWatch Enterprise–HL7 edition that can communicate with HL7 v2.5 compliant software applications. NiceWatch Enterprise-HL7 comes with new functionality to address the management of outgoing HL7 messages and a new filter for parsing incoming HL7 messages.

NiceWatch Enterprise also provide IT personal management tools for central logging of print jobs, central management of printers and advanced alerting for fast problem solving.

NiceWatch Enterprise comes with one license of NiceLabel Pro. You can easily customize wristband design with the NiceLabel Pro desktop design tool.


## Benefits for Healthcare Providers

Deploying NiceWatch Enterprise, healthcare providers can print a wristband without custom programming from any Healthcare Information System (HIS)/ Laboratory Information System (LIS) provider. Current output can be easily parsed or mapped to print information on a wristband. NiceWatch can monitor multiple events with special action for every trigger event. Data can be easily extracted from non-structural data sources and

transferred to the variable fields on the label. Output results can be incorporated into text, bar codes, graphics and RF smart tags.

Despite the rich functionality of NiceWatch Enterprise, deployment is done in a quick and easy manner without requiring extensive knowledge or training.

# Offline Patient Wristband Generation

NiceLabel Print Center with NiceForm creates a customized application with personalized data entry screens. NiceForm is perfect for healthcare providers who need offline or downtime stand-alone applications to generate patient wristbands, chart labels or admitting forms.

Regardless of a scheduled or unscheduled downtime, healthcare providers must be able to admit patients. For this reason, NiceLabel Print Center offers two modules for stand-alone or offline generation of patient wristbands. The NiceForm and NicePrint modules are available within NiceLabel Print Center and provide either a standard or custom interface for patient care providers to enter data and generate a patient wrist band. NiceForm captures all entered data and archives it to a database or file that can be



*Figure 2: NiceForm Data Entry Interface*

reconciled with the parent database at a later time. This feature is available within both on-line and off-line applications.

## Benefits for Healthcare Providers

A NiceForm custom interface is easy to create, deploy and use. Caregivers use a simple and predefined user interface that simplifies data input and reduces errors in data processing and wristband printing. Training to use NiceForm takes only minutes. The NiceForm application can be used for both online and offline printing of wristband, chart labels and admitting forms.

# Bedside Blood Collection and Identification

NiceLabel Suite with **Pocket NiceLabel** in conjunction with a Symbol® Technologies Windows mobile computer and Zebra® Technologies portable printer enables data scanning and verification off the patient's wristband and blood collection sample. Phlebotomists use this solution at the patient bedside to obtain verification data from the patient's wristband and the lab's procedure request form. A simple confirmation of the scanned information for the procedure initiates the printing of a specimen identification label from a small desktop or portable label printer connected through serial cable, IR, Bluetooth or TCP/IP 802.11.

The Pocket NiceLabel tool is a mobile printing component which is used to simplify the connectivity between the Symbol and Zebra devices. Pocket NiceForm is ideal for the creation of a bedside labeling application because it is a rapid development tool for the creation of custom mobile printing applications. A personalized application can be created which will enable the care giver to print specimen labels as a byproduct of scanning or verifying patient data.
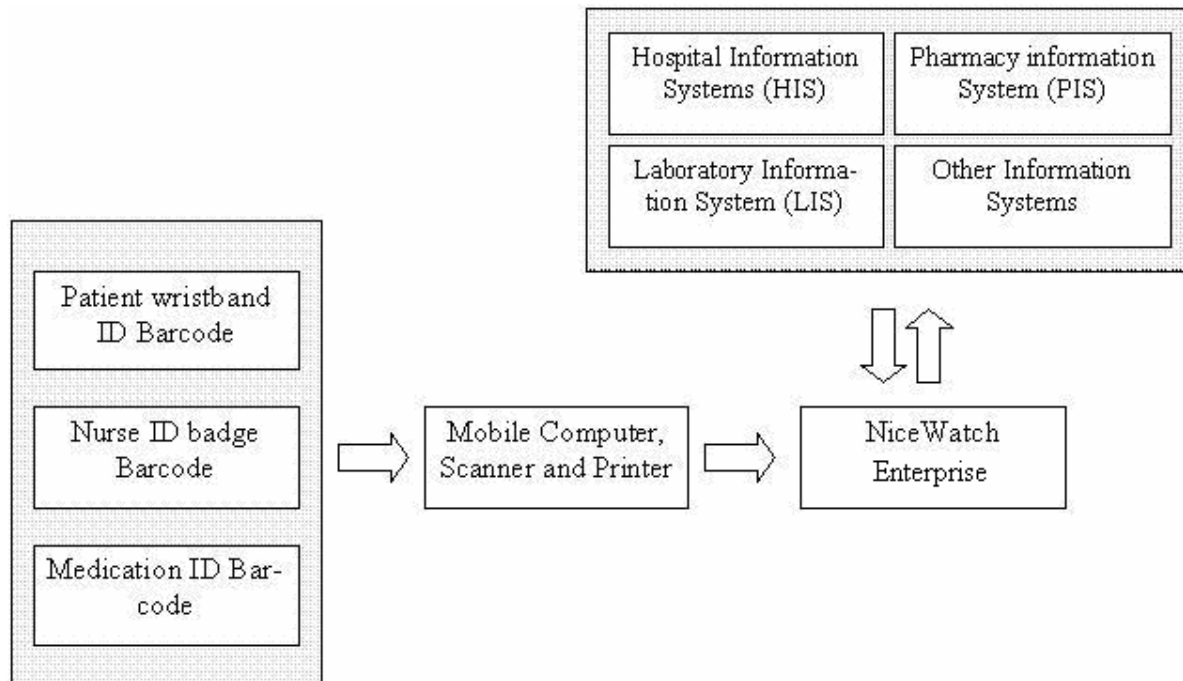


*Figure 3: Bedside Blood Collection and Identification*

## Benefits for Healthcare Providers

The Pocket NiceLabel solution provides flexibility for specimen verification wherever the patient is located at the healthcare facility. There is no need to move the patient in order to draw blood samples, verify and print specimen labels. Caregivers are ensured that specimens are properly identified and results are for the correct patient. The Bedside Specimen Identification with Pocket NiceLabel reduces the need to re-draw blood samples because of unlabeled or incorrectly labeled specimen, eliminates the need to re-write

sample information on labels and ensures that time-sensitive samples are evaluated in a timely manner. Patients are assured that their specimen are correctly labeled and reported test results are their own, resulting in accurate diagnosis and treatment.

# Blood Bag Identification

NiceLabel Print Center with the NiceLabel Pro label designer enables you to design blood bag labels that include unique check digit algorithms required by the International Society for Blood Transfusion (ISBT). Using NiceLabel Pro, you can design labels and applications that comply with the ISBT 128 labeling standard in addition to supporting the ABC Codabar symbol that is commonly used in blood bag identification.
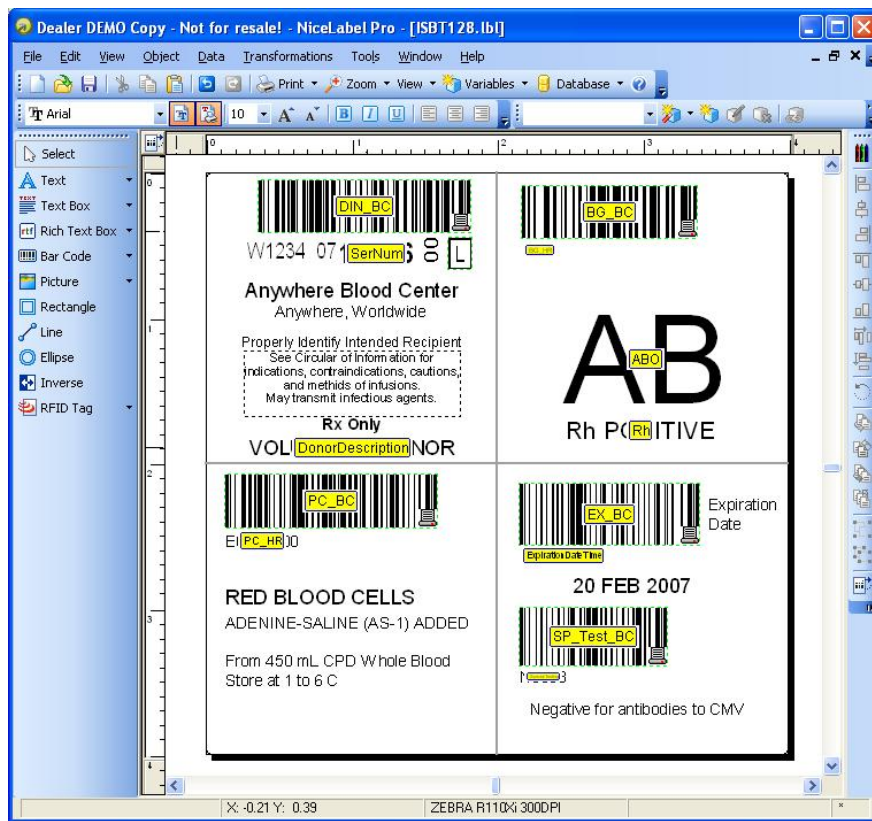


*Figure 4: NiceLabel Pro ISBT 128 Bar Code Blood Bag Label*

## Benefits for Healthcare Providers

NiceLabel Pro is a full-featured software for any kind of professional bar code and RFID label design and printing. NiceLabel Pro includes complete database support, user and document security and the widest barcode symbol support available today. The wide range of features and options make this software edition a powerful but easy-to-use tool for any labeling requirement.

# Laboratory Specimen (Histology) Identification

NiceLabel Print Center with NiceForm can also be used for very specific identification applications in laboratory environments. For example, NiceForm is used to drive histology cassettes and slide printing systems to uniquely identify specimen in laboratories.

Leica Microsystems Inc., a manufacturer of high precision microscopic vision and identification systems for histology applications in laboratory environments, contacted Niceware to develop an application to enable their printers to output slides and cassettes. Clinical and research healthcare facilities use the Leica printing system to identify individual and groups of tissue samples for testing. Niceware developed a custom application using the NiceForm module with built-in features and Visual Basic Scripting that allows certain operator input from the lab technician and pulls data from a database before sending a job for slide and cassette identification to the Leica printer. The application included multiple forms that allowed clinical and research labs to use the unique features that are required for tissue testing. Currently, every Leica printer is shipped with a NiceLabel Suite license and the custom specimen labeling application for NiceForm.

The combination of the **NiceWatch Enterprise** and the **NiceForm** tools can also be used as the basis for very specific identification applications. NiceForm has been used to develop the application for driving the identification of specimens in the laboratory. When the Laboratory Information System (LIS) is incapable to output the required bar code, NiceWatch can add a bar code to any specimen requisition form.

GE Healthcare has written a native message interface into select Centricity® products that enables centricity to trigger an automated print to the Leica or Sakura histology printers. This technique can also be utilized for a printer that has a Windows® Printer Driver and is connected to the network.

## Benefits for Laboratories

NiceLabel Print Center with NiceForm is a fast development tool for organizations looking to simplify technology used by their staff. The NiceForm solution for laboratory specimen identification is an affordable system that provides exceptional value. You can easily deploy, maintain and upgrade this solution without using any external services for custom application development.

NiceWatch Enterprise links different IT systems to communicate with each other so that healthcare providers can print bar code and RFID smart labels from their LIS. In addition, the NiceWatch Enterprise-HL7 edition provides a messaging solution that complies with the HL7 global messaging standard.

# Health Level 7 Compliance with NiceWatch Enterprise–HL7 Edition

NiceWatch Enterprise-HL 7 edition is a healthcare focused product from Niceware. The NiceWatch Enterprise-HL7 edition enables HIS application integration to meet global messaging compliance for patient identification. The messaging interface enables healthcare, insurance and supplier institutions and software applications to communicate with each other in a common language. Using HL 7 messaging compliance enables hospitals to simplify patient admittance, patient identification, patient exit administration, laboratory orders and more.

NiceWatch Enterprise-HL7 edition reads incoming data with the filter called "HL7 Analysis". The filter saves the parsed data into variables for the future use within the NiceWatch Server module. Outgoing data is sent through an action in NiceWatch Enterprise-HL7 edition called "Outbound HL7 Message". The action sends data through a TCP/IP protocol to a selected host and port. Also possible on a TCP/IP trigger is an option to send an HL7 acknowledgement message through the same socket connection where the inbound message came in.  In cases where a TCP/IP socket interface is not used, NiceWatch Enterprise-HL7 edition will be able to accept an inbound HL7 Message through a File Trigger that monitors a file folder for an HL7 message "dropped" by another healthcare application.  In addition, an outbound HL7 message and acknowledgement can be sent by 'dropping' these messages as a text file into a local or shared folder for the host application to process.

NiceWatch Enterprise-HL7 edition manages the printer network. The client stations are managed by the hospital's Healthcare Information System (HIS), Laboratory Information System (LIS) or Pharmacy Information System (PIS). The two sub-systems (printer network and client stations) are integrated together through bi-directional HL7 messaging between NiceWatch Enterprise-HL7 edition and the healthcare application.


## HL7 Standards

The HL7 standard has two main releases. The version 2.5 release is a linear, delimited data structured file that uses headers in the beginning of each segment to clearly separate the segments.  The version 3 release of the standard is an XML data structured file. This release fixes the limitations of the version 2 standard by allowing stronger type declaration of the fields and offering a more standardized structure of the result file that is sent in a message.

Currently, NiceWatch Enterprise-HL7 edition only supports the HL7 standard version 2.5. According to Niceware research data, over 90% of the HL7 compliant applications available today support only version 2.5 of the HL7 standard. It is likely that it will take five years or more to convert many of the current version 2.5 deployments to version 3.x XML standard compliance. NiceWatch Enterprise-HL7 edition will comply with the version 3 of the HL7 standard in the near future. To use the powerful HL7 messaging compliance with NiceWatch Enterprise–HL7 edition, current HL7 version 3 customers use

the XML filter in the NiceWatch Server module to parse and map incoming XML messages.
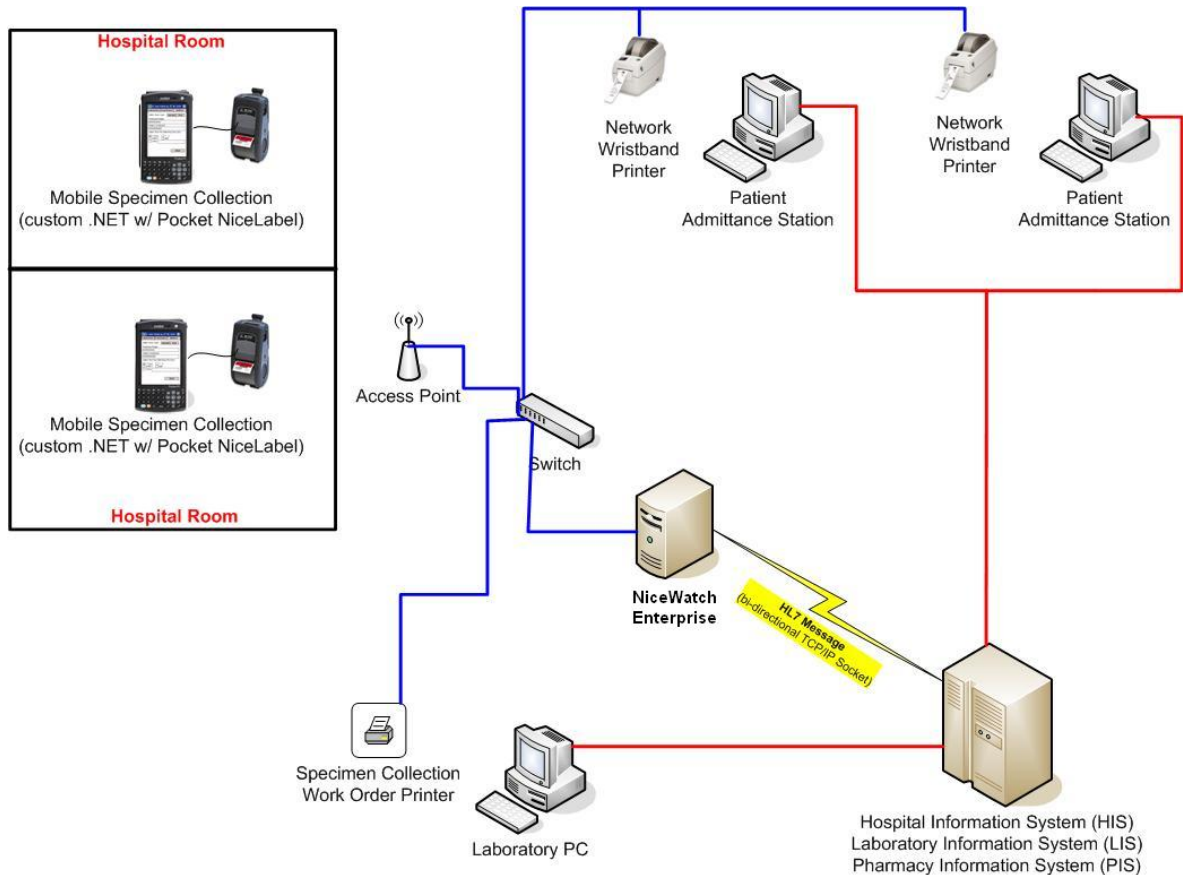


*Figure 5: NiceWatch Enterprise-HL7 Messaging*

## Benefits for Healthcare Providers

NiceWatch Enterprise-HL7 edition provides HL7 compliant global messaging for healthcare providers and all healthcare identification solutions. In addition, NiceWatch Enterprise-HL7 enables centralized print and messaging management through a web-based interface as well as wristband, charts and admittance form printing to any printer on the network. NiceWatch Enterprise-HL7 edition also provides a very reasonably priced HL7 messaging server that works well inside or outside of patient identification applications.

# Niceware Healthcare ID – Product Overview

Niceware Healthcare identification solutions include the NiceLabel Print Center software package for 5, 10, 20 or 50 concurrent users that comes with the Enterprise Print Manager, NiceLabel Pro, NiceForm and Pocket NiceLabel modules; the NiceWatch Enterprise-HL7 edition that comes with the NiceWatch Enterprise-HL7 and Enterprise Print Manager modules; support contract for one (1) year; and professional services for NiceWatch middleware setup and custom programming for Pocket NiceLabel.

## NiceLabel Print Center

NiceLabel Print Center is the premier label printing solution for both desktop and mobile label printing. NiceLabel Print Center offers a wide range of bar code and RFID smart label printing options for desktop and mobile printing applications. The NiceLabel Print Center software offers the following modules (among others):

- **Enterprise Print Manager (EPM):** Enterprise-level module for remote printer, print queue, event and alert management. The EPM provides central information regarding printer status, print job management, print queues, common messaging and alarming (*alerts*). The EPM manages the printing process centrally while label design and printing occurs locally on the client computers hosting NiceLabel Print Center.

- **NiceLabel Pro**: Full-featured label design and printing software that you use to create and print label (.LBL) files with your desktop computer. Includes all integration features from NiceLabel Pro edition plus export option to SAP/R3.

- **NiceForm:** A front-end labeling application generator for desktop and mobile label printing environments. NiceForm provides operators a simple and pre-defined label printing interface that simplifies data input and reduces errors in data processing and label printing. Pocket NiceForm is the front-end label application for mobile label printing and included in Pocket NiceLabel.

- **Pocket NiceLabel:** A mobile client that executes the label and form designs that were created on a desktop PC.

### Healthcare ID Solutions with NiceLabel Print Center

Integrated Patient Identification, Offline Patient Wristband Generation, Blood Bag Identification, Laboratory Specimen Identification

**NiceLabel Products:**

- NiceLabel Print Center edition for 5, 10, 20, 50 or unlimited concurrent users

- 1-year support contract for NiceLabel Print Center

- Niceware Professional Service for one module only (NiceForm)

**Model Price:** $6,000.00 for five (5) concurrent user licenses.

> **Note:** Combination of NiceForm and NiceWatch application will require two Niceware Professional Services and add to the total solution price.

# NiceLabel Print Center with Pocket NiceLabel

NiceLabel Print Center comes with the Pocket NiceLabel module that enables you to integrate label printing functionality into your custom application for Windows CE mobile devices. Pocket NiceLabel is a mobile client that executes the label and form designs that were created on a desktop PC. NiceLabel Print Center comes with one (1) Client Access License (CAL) for one mobile device. You must purchase one (1) license for each additional Windows CE/ mobile device that you will be using for mobile label printing. Each additional Pocket NiceLabel Client Access License costs $30.00 USD (bundled for 5, 10, 20 and 50 devices).

### Healthcare ID Solutions with Pocket NiceLabel

Positive Patient Identification and Verification, Bedside Blood Collection and Identification

**NiceLabel Products:**

- NiceLabel Print Center edition for 5, 10, 20, 50 or unlimited concurrent users
- Pocket NiceLabel Client Access License for 5, 10, 20, 50 or unlimited mobile devices
- 1-year support contract for NiceLabel Print Center
- Niceware Professional Service for one module only (mobile application development, NiceForm or NiceWatch)

**Model Price:** $6,500.00 for five (5) concurrent NiceLabel Print Center user licenses, five (5) Pocket NiceLabel client access licenses and one (1) Professional Service.

> **Note:** Combination of mobile application development, NiceForm and NiceWatch application will require three Niceware Professional Services and add to the total solution price. More licenses for NiceLabel Print Center or Pocket NiceLabel computer clients will increase the total price for the solution.

# NiceWatch Enterprise-HL7 Edition

NiceWatch Enterprise is a centralized label printing middleware software that integrates printing of wristband, charts and admittance form into Healthcare Information System (HIS), Laboratory Information System (LIS), Pharmacy Information System (PIS) applications and others.

NiceWatch Enterprise-HL7 edition includes the following modules:

- **NiceWatch Enterprise-HL7 Edition:** Remote administration to view list of triggers, start and stop triggers; centralized logging of executed actions and multi-threaded label printing execution to ensure fast and stable operation in heavy-load environments.NiceWatch Enterprise functionality plus HL7 messaging compliance through incoming data filter for HL7 analysis and outbound HL7 messaging options.

- **Enterprise Print Manager (EPM):** Enterprise-level labeling solution that manages central print and event log information of printed labels, executed NiceWatch actions, etc. The EPM provides central information regarding printer status, print job management, print queues, common messaging and alarming (*alerts*). The EPM manages the printing process centrally while label design and printing occurs locally on the client computers hosting NiceLabel Print Center.

- **Licensing Server:** To activate, view, upgrade existing NiceLabel licenses from a centralized user interface.

## Healthcare ID Solutions with NiceWatch Enterprise–HL7 Edition

Integrated Patient Identification, Patient Wristband Generation, Laboratory Specimen Identification

**NiceLabel Products:**

- NiceWatch Enterprise-HL7 edition license for one server

- 1-year support contract for NiceWatch Enterprise-HL7 edition

- Niceware Professional Service for NiceWatch Enterprise setup

**Model Price:** $12,000.00 for one (1) NiceWatch Enterprise-HL7 licenses, one (1) NiceLabel Pro Design license, one (1) Support Contract, and one (1) Professional Service.

## Healthcare ID Solutions with NiceWatch Enterprise–HL7: Pocket NiceLabel

Bedside Specimen or Blood Collection Identification

**NiceLabel Products:**

- NiceWatch Enterprise-HL7 license for one server

- 1-year support contract for NiceWatch Enterprise-HL7 edition

- Pocket NiceLabel Client Access License for 5, 10, 20, 50 or unlimited mobile devices

- Niceware Professional Service for two parts: mobile application development and NiceWatch Enterprise setup

**Model Price:** $15,000.00 for one (1) NiceWatch Enterprise-HL7 licenses, five (5) Pocket NiceLabel client access licenses and two (2) Professional Services.

**Note:** Combination of mobile application development, NiceForm and NiceWatch application will require three Niceware Professional Services and add to the total solution price. More licenses for NiceLabel Print Center or Pocket NiceLabel computer clients will increase the total price for the solution.

# References of Completed Healthcare Projects

Geisinger Health Systems

New Hanover Medical Center

University Kentucky Medical Center

Portage Health Systems

St. Nicholas Hospital

Duke University Hospital

Mountain View Hospital

HOAG Memorial Hospital

Henry Ford Kingswood Hospital

Marquette Memorial Hospital

American Medical Systems

City of Hope Medical

JFK Medical Center

Vista Victory Memorial Hospital

Children's Hospital

Mayo Clinic

Dunn Memorial Hospital

Parkview Memorial Hospital

Centennial Medical Center

Horizon Medical Center

Winnipeg Hospital Authority

# Frequently Asked Questions

This section discusses questions and answers regarding Niceware Healthcare Identification implementations. For additional information, please contact Niceware International.

**How is the application installed?**
The software is sent to the network administrator on a CD-ROM. The software installation instructions are included along with registration information. The network administrator will contact Niceware Technical Support to facilitate the complete implementation. Depending on the complexity of the installation, the whole process should take two hours.

**What needs to be completed by the health care provider prior to the installation?**
Complete the Requirements Document and provide it, along with the purchase order, to your sales representative. In addition, provide a sample output from the desired transaction. Email the sample output to Niceware International or save it to a disk or CD-ROM that you provide with the order. Please reference your account name to ensure proper routing of the file.

**How do I generate the sample data file from my system?**
An Information Systems staff person will typically be capable of generating and saving the sample data file. If you have any difficulty, you may need to contact the HIS/LIS vendor to determine the required steps.

**What if I want to create a custom form or label with this software?**
Niceware International's fee to create custom label formats is $100 per hour with a minimum billing of three hours. You may contact Niceware directly with your request. Niceware will provide a development and implementation schedule for each request.

**What do I do if I have a problem with my system?**
If you have a problem with the wristband or label media, contact your sales representative. If you have a question or concern about the system, either email support@nicewareintl.com or send a fax to 414-476-7955 with your question. If you have a support contract, you may also call Niceware Technical Support at 414-476-6408. Niceware's average response time is four hours.

**What testing is done before the product "goes live"?**
NiceWatch Enterprise will run in the development mode to validate accuracy of output. This test process will last up to 48 hours. At any point in that timeframe, the application can be switched over to a live environment.

**What is the warranty on the software? What about upgrades, bug fixes and product**

**updates?**

NiceLabel Software comes with a 30-day warranty. You can refer any problem or question during that period to Niceware International. At the time you purchase the software, make sure to ask for the annual Support Contract that will begin (if purchased) immediately after the 30-day warranty period.

# Conclusion

Niceware International offers patient safety and identification solutions to the healthcare market that are easy to deploy, affordable and fully compliant with current bar code and RFID labeling requirements. Niceware Healthcare provides high value and low maintenance software solutions to meet patient safety goals for patient identification established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

For more information about Niceware Healthcare and patient safety solutions, please contact Niceware International directly.

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