Document Number: INR-P-001
Title: INR Pro© Patient Anticoagulation Tracking System
Revision: A

A beginner's guide to using INR Pro© (www.inrpro.com) to manage patients on warfarin, within a clinic setting, with INR values being reviewed by qualified nurse and nurse practitioners.

Revision History	Release Date	Author	Changes
A	8/22/2007	B. Hurley	Added Admin and Support sections, and information on accessing the system for physicians, patients, and labs
--	8/1/2007	B. Hurley	Initial Release

1.0   Index

2.0   Prerequisites

Statistical Process Control (SPC) Training

3.0   Getting Started

To get started, obtain the website link, username and password from the clinic administrator. Each individual will have their own username and password. Enter the information on the main page, and click 'login". Remember to turn off any pop-up blocker settings in the web browser, since the system uses pop-up windows routinely.

There are two main areas of the website, the top links, and the bottom links. The top links contain the information needed to properly manage the daily activities of the clinic.

Need to contact: [1]   Overdue: [10]   Scheduled: [0]   Education: [1]   Renew: [2]   Set Limits: [2]

The bottom links contain links to general information and functions: searching for patients and medical contacts, admin settings, reports page, links page and feedback information. It will also display who is logged in, and what the current time is, according to the database. This should match your local time.

you are logged in as: **guest**
local time is: 10:29:27 AM
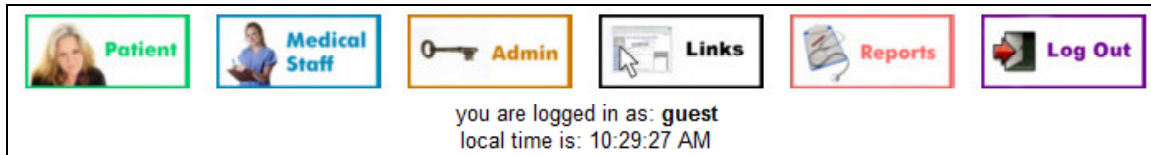
4.0   Add new patient

After clicking on the "Patient" button at the bottom of the page, there is a "add a new patient" link at the top. Click on the link, and fill out the form. Fields with a red asterisks (*) are required.

> 4.1   When the patient has been scheduled for the next testing date, enter that date at the top of the page. This patient will show up in the "Scheduled" link at the top of the page on that date, so the clinic can expect to receive results from them, or arrive in person for Point of Care testing.

> 4.2   The annual referral date is the date when the referring physician provided documentation that the patient should be seen by the clinic. Every 12 months, the patient's name will show up in the "Renew" section at the top of the page, until an updated document is received by the clinic, and the date is changed in the system.

> 4.3   In the admin section, the actual medical record number can be used for each patient, or a random number can be assigned to each patient from the system. If the medical record is being used, make certain to fill in this field. Refer to section 9.2.2

> 4.4   A recommended therapeutic range must be selected for each patient. If the range is not listed, a new range can be added in the admin section.

> 4.5   It is recommended that each patient take a knowledge test prior to any training, and some time after training has been provided (recommended that the post test not be given right away, to test for long term retention). The scores should be entered into these fields when obtained. After the patient has completed training on each section, fill in the training date in the field.

> 4.6   If a patient is no longer on warfarin, or is on vacation or at a vacation home, the patient can be listed as inactive. This will retain their information in the database, but not show up in the search criteria unless the red "X" box is selected.

> 4.7   Towards the bottom of the page, there are yes/no questions that are part of a Bleeding Risk Index (BRI). The results of the assessment will be displayed on the patient summary page upon completion. This information can be utilized to determine the risk for bleeding complications. The higher the score, the higher the risk for bleeding. The assessment will produce a rating of Low, Intermediate, or High.

> 4.8   If the patient is self-testing at home, then select "yes" and provide a password in the field below. The patient can use their Medical record number and the password to access their historical results, and enter their new results each

time they test. The results will show up in the "need to contact" section, so that the clinic can review them each time.

5.0   Adding a new patient visit

A new visit should be initiated when a patient comes to the clinic for training or on-site Point of Care testing, or the clinic receives INR results from a patient (via a lab printout, or self-testing submission).

   5.1   When the INR results are received manually (fax, phone call, or hardcopy printout), click on the "scheduled" link at the top, and find the patient's name. Click on the patient name to bring up the patient information screen. Click on the link at the top titled "Add visit information". You can also search for the patient using the button at the bottom of the page called "Patient". When you find the patient's name, you can click on the "new visit" link, shown to the right of the patient's name.

      5.1.1   If the results are automatically submitted into the system by the lab, or by the patient (self-testing), then the patient's name will be listed under the "Need to Contact" link, and a new visit will not need to be initiated. Skip ahead to paragraph 5.6

   5.2   The program will default to the type of visit and test process established in the administration section. The three choices are "Point of Care", "Self-testing", or "Outside Laboratory". If the current visit differs from the established default, then click on the correct testing process to the right of the default, to display the appropriate list of questions.

   The major difference between the three: the "Outside Laboratory" results will ask for the actual time of day for certain steps in the process, so the cycle time can be properly managed between the labs, clinic and the patient. Visits that are "Point of Care" will not show up on the "need to contact" list, since it is assumed that the patient was contacted during the testing.

   5.3   The "Reason for contact/visit" is a required field, and must be chosen from the dropdown list. A description of each visit is explained below

   • "Scheduled Visits" - the majority of visits, these are INR results that the clinic was expecting to see.
   • "Onsite Training" – no INR results were taken, the patient came in for education or training
   • "Telephone Contact" – patient calls into the clinic to ask a question about their therapy, ask about medication changes, refill requests, or anytime when there are no INR results. If a patient is calling back to discuss a recent INR value, then it should be documented within that specific visit details.

- "Major/Minor Bleeding" – patient was not planning on getting and INR test, but due to bleeding symptoms, the patient or physician decided to get another reading to make sure their INR is acceptable.
- "Prior Training" – patient received training from another facility on a prior date
- "Prior Visit" – patient received INR results prior to using the current clinic

5.4   If the patient received an INR test, then the INR value should be entered into the appropriate field, and the patient's name will show up in the "need to contact" section of the system, until the patient is contacted and date/time is entered into the system.

5.5   Although there are no additional questions shown, the evaluation is only halfway complete. Click the submit button to proceed to the next step

5.6   For every new visit, the patient's INR history and charts will be displayed on a separate window. The newest INR value will be displayed for comparison to historical values. The chart should be reviewed prior to any decision making on dosage changes or patient compliance to the therapy. SPC Training can aid in proper interpretation of the control chart.

5.7   After reviewing the charts, close the chart window (optional), and select the "Complete visit information" link. This will display the remaining visit questions which require input from the patient.

5.8   The field "Patient comments about results" is an open text field, which should detail comments received from the patient, after they were told of their INR value. These comments can also be used when completing the CAT Score assessment at the bottom of the page. There is no limit to the amount of information that can be entered into this field.

5.9   If the INR reading was greater than 5, or higher or lower than normal readings, and required a physician to review the results, then the physician name should be selected from the dropdown menu. If no physician was needed, then the field should be left blank.

5.10   The "Instructions given to patient" is another unlimited text field. This should be a summary of the instructions that were provided to the patient, prior to their next visit date.

5.11   The remaining fields should be completed if possible. If the INR field is left blank, then the system will treat the visit as non-critical, and will not appear in the "need to contact" link at the top.

5.12   If the patient's INR reading was too high or too low, then the main reason for the difference should be determined from the dropdown menu, based upon the CAT score at the bottom of the page, and the patient's comments and recollection of recent events. If the reading was acceptable or not deemed abnormal, then the field should be left blank.

5.13   The CAT score is an assessment of the patient's compliance to their therapy. The lower the score, the more the patient is compliant to following the diet and dosing recommendations. When talking to the patient, ask each question and provide the drop down list for them to decide how to answer, without giving them the scoring points. A high score will also help identify when a dosing change should probably not be made, since the patient's INR value may be due to non-compliance instead of the wrong dosage amount.

6.0   Add new medical contact

If anyone from one of the groups below is not listed in the system, click on the "medical staff" button at the bottom of the page. At the top of the search page for the medical staff, select the appropriate link.

6.1   Physician: list primary care physicians (PCP) and any physicians involved in the warfarin management process (cardiologists, reviewing physicians, etc). Listing an email address allows email notifications to be sent to the physician when their patient is seen or reviewed by the clinic.

6.2   Pharmacy: list any pharmacies where the patient obtains their warfarin

6.3   Lab: list any labs that provide blood draw and INR results for any patient

6.4   Medical Group: used to group physicians together, so reports can be run across the group, not just the individual physician.

Information about accessing the website (each group has different functions and access privileges) can be found in each group's summary page.

7.0   Daily Management of Patients

The top of the page will display the same management information on every screen. Next to each category is a number, which is the number of patients that fall into that category. The goal is to keep all the numbers at zero at the end of each day (listed from left to right in order of importance).

7.1   Need to Contact - for clinics that do not use Point of Care testing (in-house finger stick with instant results), this category will track patients that have their INR results in the system, but have not be contacted by the clinic to discuss their INR reading.

7.2   Overdue - patients who were scheduled to get tested on a prior date, but their INR results have not been entered into the system, or the patient has not been tested.

7.3   Scheduled - patients who were scheduled to get tested today. If they do not get tested today, they will move into the "overdue" section on the following day.

7.4   Education - patients who have not completed all of their training

7.5   Renew - patients who are overdue for their annual paperwork from their referring physician, authorizing the clinic to handle the management of the patient while on warfarin.

7.6   Set Limits - once a patient has at least 20 INR readings in the system, they will be listed in the header section under "Set Limits".

      7.6.1   After clicking on this link, a list of patients, from most INR readings to least, will appear on the popup screen. These patients do not have assigned control limit values, and should be evaluated to determine if limits are appropriate. Starting at the top, click on the patient name, and view the INR chart. The summary INR report will calculate the limits automatically. In many cases, the LCL (lower control limit), CL (center line) and UCL (upper control limit) will be appropriate for the patient.

      7.6.2   The following issues can make the calculated limits inappropriate:

      I.   INR readings that are trending upward or downward, or showing out of control data points (outside calculated control limits).

           a.   If there is an upward or downward trend or outlier identified within the last 5 readings, then the patient's INR readings may not be stable enough to establish limits. Outlier readings may be flagged (if there is an assignable cause or reason for the excessively high or low reading).

      II.   Over 75% of the INR readings are from a prior clinic or facility

           a.   It is important to consider the differences between the current clinic and the patient's prior clinic, as well as the patient's diet and dosage, before setting the control limits.

      III.   Percent of time/visits in therapeutic range less than 50%

           a.   If a patient has struggled to stay within therapeutic range, there is typically more than one reason that causes these readings to be unpredictable. If a patient is inconsistent with diet, alcohol, and dosage taking, then the fluctuation in readings may be

      IV.   Recent dosage changes within the last 5 INR readings

           a.   Dose changes can impact the INR readings in the future, and may make the current control limits invalid, especially large dose changes that have taken place recently.

7.6.3   If control limit calculations are appropriate, then go to the "Edit Patient" screen, scroll to the bottom, and type in the values for the Upper Control Limit, Lower Control Limit, and Center Line. If the limits are not set for a patient, then they will continue to be calculated every time the INR summary report is viewed, and will change with every new INR value. The lower control cannot be less than zero.

7.6.4   INR Pro defaults to using 3 standard deviation control limits, which calculates limits, based upon the data in the system, so that approximately 99.7% of the patient's INR readings will fall within. The default can be changed to 2 standard deviations in the Admin section. This would reduce the percentage to approximately 95% of the INR readings. Refer to section 9.2.3.

8.0   Adding a prior visit

To add the INR results from history, using another system or using the patient's medical records, click on the patient name, go to the visit history link, then select the link titled "add visit from prior date". All that is required from prior visits is the date, INR value, and whether the visit was performed by the current clinic, or another clinic. Reports can be run comparing the prior (Prior Visit) and current clinic (Scheduled Visit) in the reports section of the website. If the historical data is contained in an existing database, contact Healthcare System Solutions for information on how to upload the data into the new system.

9.0   Administration Settings

The administration section is only available for users with specific access to this section. The admin button on the bottom of the page will display for most users, to allow everyone to change passwords, but the list of users and the "edit system settings" link will only show for the admin users.

Change Password for 'guest'
Edit System Settings

Add a new user

Username: [   ]   Category: [▼]   search for contacts >>>

There are **3** results found in the system

Username	Password	Category	
guest	guest	Admin	delete
readonly	readonly	Read Only	delete
viewonly	viewonly	View Charts Only	delete

Showing records 1 to 3

9.1   Setting up system users

The first screen shows the list of current users in the system. Typing a name in the username field, or selecting a category, will filter the list of users.

The following categories are available in the system.

- **Admin** – full functionality and access to the system
- **Standard** – full functionality, but cannot access system settings, or modify users
- **Read Only** – can view patients and information in system, but cannot make any changes
- **View Charts Only** – can only access the INR chart report, when provided via email.

Select the appropriate level when adding a new user (using the link near the top of the admin page), or making changes to an existing user. It is recommended that each user receive their own login, so changes, historical information, and activity within the site can be tracked back to a single person.

9.2   Edit System Settings

Click the link on the top of the admin page to access the following options.

9.2.1   Default Patient Testing Setup – There are three options for patient testing. Select the most common option that the clinic will encounter. This will be set as the default, although the other options can be selected for any patient on any visit.
- Outside Laboratory – results received from outside lab or area, patient does not know results until contacted by clinic
- Point of Care – patient is on-site for testing, and results are reviewed before patient leaves
- Patient Self Testing – results received from patient via phone call

9.2.2   Medical Record Number – select whether to use the actual patient's medical record number, or a default number assigned by the system.

9.2.3   Patient INR - Control Chart Out of Control Rules – select the type of tests to be checked on the patient INR control chart.

- Control Limit Calculations – select two or three standard deviations. These limits can be overwritten for each patient. Refer to section 7.6

The following tests check for data shifts too close to the control limits, even though they do not exceed the control limits. Select "On/Off" to identify these on the chart.

- 4 out of 5 data points outside of 1 std dev limits (same side)
- 2 out of 3 data points outside of 2 std dev limits (same side)

The following tests check for data trends too close to the control limits, even though they may not exceed the control limits. Select on/off to identify these on the chart, and the quantity of data points that will trigger the condition.

- Trends – Number of consecutive points to denote a trend
- Runs - Number of consecutive points above or below centerline

9.2.4 Patient Cycle Time Dashboard

For those performing non-Point of Care testing, the cycle times are important to monitor. The red/yellow/green range for the cycle times can be established in this section. Estimates should be made when initially starting to track these times, but over time, real data should be analyzed to define the true acceptable color ranges. In the cycle time report, the average results will be calculated as an average and a median value, since cycle time data is often better represented as a median value. The user should also select either hours or minutes, depending on which value is a better measurement for the process.

> * Calculate cycle time data by: **hours** (current setting)
> ◉ Hours   ○ Minutes

The following cycle times are tracked and reported in the system. A description of each is listed below the screen shot.

Zones for Cycle Time Dashboards (all zones start at zero)

You must save settings to see zones updated

Cycle Time	Green (hours)	Yellow (hours)	Red (hours)
#1 - Average Time to enter results into database after obtained from lab	0 - 2	2 - 4	4 - 15
#2 - Average Time to notify patients after entered into database	0 - 3	3 - 6	6 - 18
#3 - Average Time to notify patients after results obtained from lab	0 - 4	4 - 8	8 - 21
#4 - Average Time to notify patients after results faxed from lab	0 - 5	5 - 10	10 - 24
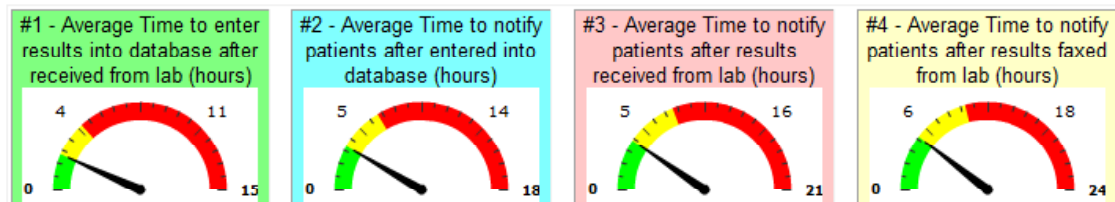
- #1: Average Time to enter results into database after obtained from lab

Simplified, this is how long it takes the lab to process the blood and submit the information to the clinic, and for the clinic to get the test results entered into the system. If the lab blood draw time is listed on the data sheet, enter it into the system for each visit. Once the INR results are entered into the system, the difference between when the time the submit button is clicked, and the time shown on the lab data sheet is calculated.

- #2: Average Time to notify patients after entered into database

Simplified, this is the response time of the clinic for getting back to the patient, once the clinic sees the patient's results. After communicating the results and any dose changes to the patient, enter the current date and time into the system. The time calculated is based upon when the INR results were first entered into the system.

- #3: Average Time to notify patients after results obtained from lab

Simplified, this is how the patient has to wait until their results are completed, before they are notified of the results. The system uses the lab blood draw time, and the time when the patient was contacted about their results to compute this time. Consider this the total patient cycle time. The goal of the clinic should be to minimize this time.

- #4: Average Time to notify patients after results faxed from lab

Simplified, this is the time it takes the clinic to contact the patient, after they receive the fax from the lab. It uses the lab faxed time, and the date/time when the patient was contacted.

9.2.5 Benchmark Line for Time in Therapeutic Range (% INR in Range) – to compare Time in Therapeutic Range metrics to a known baseline, enter the values for each of the three recommended calculation methods. These will be displayed in the reports section when the Time in Therapeutic Range report is generated.

Benchmark Line for Time in Therapeutic Range (% INR in Range)

Rosendaal Method	60	%
Traditional - % of Visits in Range	65	%
Cross-Section Method	70	%

9.2.6 INR Recommended Therapeutic Ranges – there will be default therapeutic ranges, but in some cases, new ranges are needed.

INR Recommended Therapeutic Ranges

Group Code	Low	Goal	High
A	2	2.5	3
B	2.5	3	3.5
C	3	3.5	4
D	1.8	2.15	2.5
E	2.2	3.2	2.7

Add the name of the group (E in the example above), and the high, middle and low range, then click the "Update System Settings" button.

9.2.7 System Time Zone Settings – adjust time zone to correspond with current time for the main location of the clinic.

10.0 Support

If any errors or problems are encountered, there are three ways to contact Healthcare System Solutions any time, day or night. Options below are listed in order of preference.

10.1 Email: (help@inrpro.com)

The preferred method is via email. Send details of problem (such as error messages observed, when it happened, and how long it has been occurring) in an email to help@inrpro.com, with subject "Problem with INR Pro". Support staff will instantly be notified via text message to their cell phones of any emails sent to that address. Typical response time is 5-15 minutes.

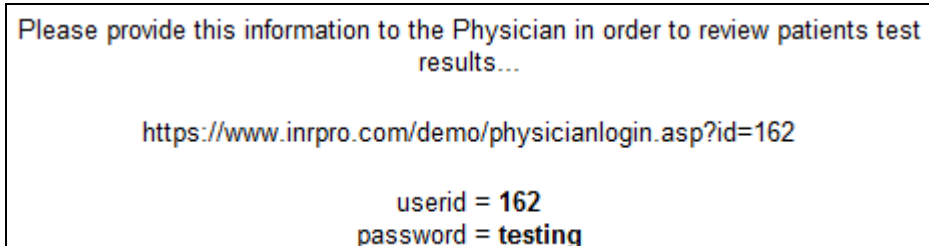10.2   Website: http://www.inrpro.com/contact.asp

Fill out the form online, which will send an email to help@inrpro.com, and will instantly notify support staff.

10.3   Phone: 1-800-628-9841

Voice mail messages can be left at the following phone number. Support staff will instantly be notified via text message to their cell phones of any voice mail messages left at that number. Typical response time is 15-30 minutes.

11.0   Physician Access

11.1   To allow physicians to access the system, a website link and password must be provided to them. To view this information, click on the "Medical Staff" button at the bottom of the page. Search and click the physician name from the list, and scroll to the bottom of the form to view the details. Each physician will have their own id number. The password can be changed by the system adminstrators.

Please provide this information to the Physician in order to review patients test results...

https://www.inrpro.com/demo/physicianlogin.asp?id=162

userid = **162**
password = **testing**

11.2   Physicians will only have access to patients within their medical group. They will be able to view details of each patient, but will not have access to edit or change any information. They can click on the "feedback" button at the bottom to send comments or changes back to the clinic administrator.

you are logged in as: **162**
local time is: 10:50:51 PM

12.0   Patient Access

12.1   Patients can have access to the system using their medical record number (or system id number). Administrators should train the patient on how to access the site before providing the login information and website URL.

12.2   To access the patient information, click on the patient's name, then select the "edit patient information" link. At the bottom of the page, there will be a section about patient self-testing.

12.3   Patients can access the website, whether they do self-testing or not. Access to the site allows them to enter their own results if applicable. Each patient must be assigned a password. The patient email address is optional, and is not currently utilized in the patient access portion of the system.
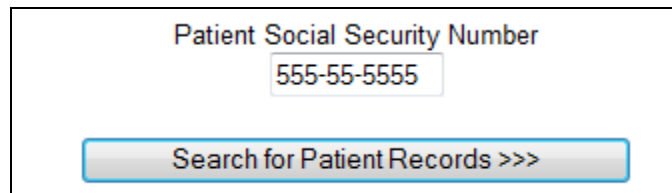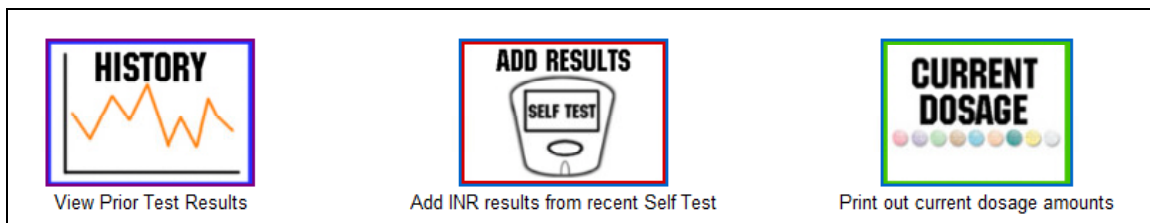

12.4   Patients can view their historical INR results (view only access), can add their INR results from self-testing (if applicable), and can view and printout their current dosage amounts.

13.0   Laboratory Access

13.1   See section 11.1 for information on providing access to labs. Labs should be trained on the system prior to using it. After results are entered, the patient names will show up in the "need to contact" section at the top of the webpage.

13.2   Labs only have access to enter patient results into the system. They cannot view or access any information from the system. The only common identifier between the patient and the lab is the patient's social security number.

13.3   Once the SSN is entered, the patient's name will be displayed, and the INR results can be entered into the system. If the name is incorrect, a link is provided next to the name to select a new SSN.

Modify/Insert patient visit information below :

Patient Details:

Patient Name : **Jon Doe**   (wrong patient or SSN?)

SS Number: 555555555

Date/Time when test performed?. 8/19/2007   (mm/dd/yyyy)   11 ▼ : 20 ▼   PM ▼

INR :

Protime :

Blood Pressure: /

Pulse:

Patient Observations or Comments Made During Testing:

Add Test Results >>>