ARYTELL-D & ARYREC

3 channel digital holter Analyzer

Software Version 6.5

User Manual

Nasan Medical Electronics Pvt. Ltd.

Hope you don't require service at all.

But incase you require,

Please contact: 09371039255

For any working days 9.30a.m to 6 p.m

Dear customer,

We take this opportunity to thank you once again for your patronage. We reiterate our commitment to live up to the confidence you have shown in us. Our continued endeavor is to exceed your expectation by offering you products that have optimum features and reliable, high quality performance, backed by prompt technical support.

It is our pleasure to give you this user manual. Please study the same thoroughly before using the software.

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User manual for

ARYTELL-D

The complete Windows based 3-channel digital holter analyzer.

1. Introduction

Nasan Medicals has pioneered PC based medical equipments in India. We thank you for purchasing **ARYTELL- D**, 3-channel digital holter analyzer.

Intended use

It is intended to be used by doctors or trained clinicians to acquire, record and store 24 hours ECG of patients that have been connected to reveala recorder. ECG data of 3 channels for 24 hours is stored on the SD (Secure Digital) card. The holter is tied around the patient's waist for 24 hours only to record the ECG and mark the event. The data is then analysed on computer with Reveala software.It is intended to be used for Adult.

The system records and enables the classification, analysis, review and reports of electro-cardiogram, arrhythmic disorders.

Software features-

The **ARYTELL** software has following vital features -

- Store three channels ECG data of 24 hours.
- Download three channels ECG data from pen drive
- View disclosures of 1, 10, 20, 30 and 60 minutes.
- Selection of normal beat automatically or manually.
- Mark noise before classification.
- Reversing selected channel polarity.
- View the ECG data of all channels of all beats in selected template.
- Edit multiple templates at a time.
- Edit label of individual beat or multiple beats at a time.
- View trends of HR, detected arrhythmias, ST level of all channels.
- Mark RR Interval for the recalculation of heart rate and display of RR interval in milliseconds while marking the interval.
- View pages of max HR, min HR, longest pause, longest V-Tach, longest SV Tach,Longest ST episode, maximum delta ST as standard event pages.
- Edit Arrhythmia summary.
- Facility to print following reports:
  - Summary
  - Arrhythmia summary
  - Template summary
  - ST analysis
  - Arrhythmia disclosure

- One minute disclosure of any channel
- Full disclosure of 10, 20, 30 and 60 min of any channel
- Operator Selected Strip Report

- View medians in entire test and edit the fiducial points.
- View ECG data of selected event.
- Edit multiple or all arrhythmias in a group at a time
- Reanalyze test.
- Review previously analyzed patient.

2. Safety and Warning Information and Cleaning Instruction

Note: This product should be used by trained person ONLY.

1. Do not leave the battery in the recorder when it is not in use. Damage from corrosion could result.
2. Use of rechargeable batteries is not recommended.
3. It is recommended that trained medical personnel handle the application of electrodes.
4. Ask patient if he is allergic to any tape or other adhesives while application of electrodes
5. The patient should be instructed not to wear the recorder in the shower or bath.
6. The patient should be instructed to avoid close proximity to heavy electrical equipment or other sources of electromagnetic interference such as electric blankets, heating pads.

Cleaning Instruction

To clean the recorder:

1. Remove the battery from the recorder.

2. Dampen a soft cloth with a mild detergent and water mixture.
3. Clean the recorder, lead wires, and belt clip.
4. Remove any adhesives from the patient lead wires with an adhesive tape remover solution or swab with mild detergent.

Caution: 

Do not use alcohol or acetone to clean the lead wires as this can cause the wires to stiffen and the insulating plastic to crack. Do not immerse the recorder in water while bathing. Use of non-recommended solution for cleaning of the device may wipe off the information.

3. System requirements

Minimum Requirement of PC for **ARYTELL-D** system:

3.a Motherboard : Intel Pentium 5, 2.4GHzs onwards.

3.b RAM : 4 GB.

3.c USB : Two free USB port to connect holter.

3.d Monitor : 14" color monitor

3.e Hard disk : 500 GB.

3.f Display Settings : Resolution - 800 X 600

3.g Key board : with 101 keys.

3.h Mouse : one.

3.i Operating system : Windows 10 pro, 64bit

3.j1 OR 2 KVA Online UPS .

3.k Laser Printer desirable.

4. Configuring the System

4.a At the time of installation.

When the application is started for the first time, a dialog box as shown in Fig. 4.1 is displayed, which asks you to configure the system as per the requirement. It is necessary to configure the system before conducting a test. Configure your PC as per instruction given in the dialog box for the best results.

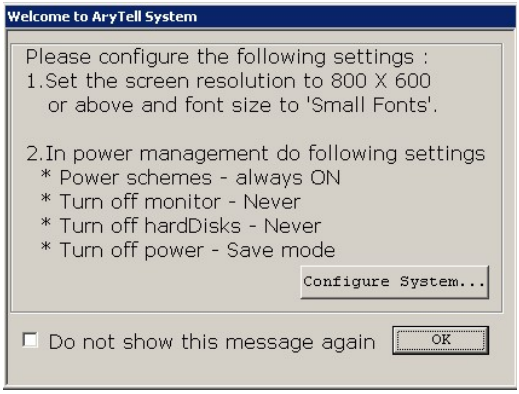


Fig: 4.1 - Installation dialog box.

- **For setting monitor resolution to 800 x 600 use the procedure given below:**
  1. Go to the Windows "**Start**" menu.
  2. Then select "**setting**" folder.
  3. Select "**Display**" option.

4. Select the required **Display resolution** from dropdown.

- **Use following procedure to set the printer**
  1. Control Panel\Hardware and Sound\Devices and Printers
  2. Set following properties for the printer
     - Portrait
     - Print quality to 'BEST'
     - Page size to 'A4'.

- Restart the PC and check that required setting are set.

4.b Through configure menu.

For configuring the ARYTELL-D software, go to **'Configure'** menu or press **'Configure System'** button on **'Welcome to ARYTELL system' dialog box,** Property Page named **'Configure'** will be displayed with the following tabs as in fig.4.2

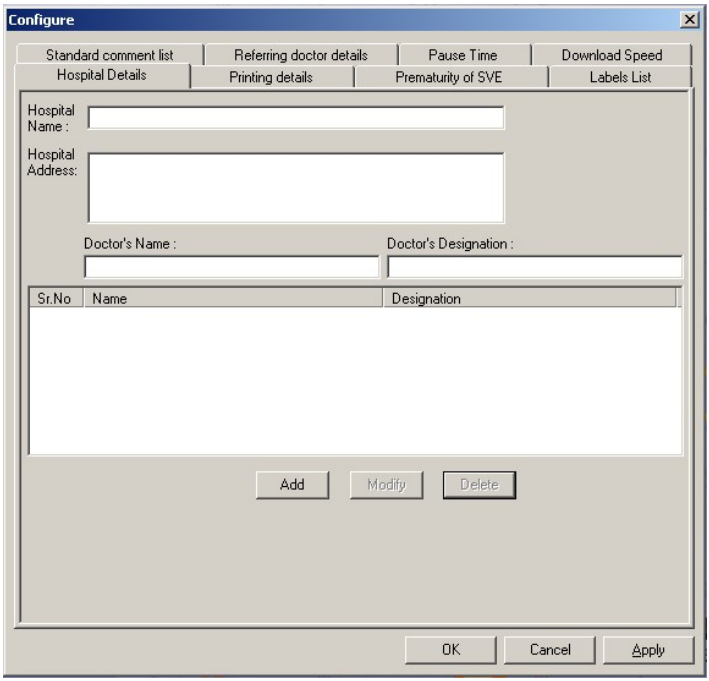


Fig: 4.2 Hospital details

4.b.1. Configure Hospital Details.

This option from the **'Configure'** menu provides facility of storing the list of doctors and the consultant doctors attached to your hospital. This list gets popped up in the Patient details entry dialog box, from where you can select the concerned doctor for the patient.

For entering the details, follow the steps below.

1. Select the '**Hospital Details** ' tab from the '**Configure**' Menu.
2. A window will appear on the screen as shown in fig. 4.2
3. Enter hospital name in the upper edit box.
4. Enter address of the hospital.

5. Enter the name and designation of a doctor you want to add to your list and click the '**Add**' button.
6. To delete any doctor from the list, select the corresponding Sr.No and click the 'Delete' button. The selected doctor will be deleted.
7. To change or modify any doctor's details double-click on Sr.No & click the '**Modify'** button.
8. After entering the entire information click on "**Apply**" button to save the contents in the list.
9. Press "**Cancel**", the information will not get saved.

4.b.2. Configure printing details.

To have the printouts of the required report with the pre-configured font, titles etc, click on '**Printing details'** tab of '**Configure'** menu. You can set following details as shown in Fig.4.3-

- Report title.
- Report title alignment (either center right or left of the page).
- Fonts for report title, hospital name, Patient details and Summary report.
- Grid type.
- Color or black and white printing.
- Administrative details with grey background.
- Print arrhythmia in different colour.
- Print bradycardia and tachycardia in different colour.

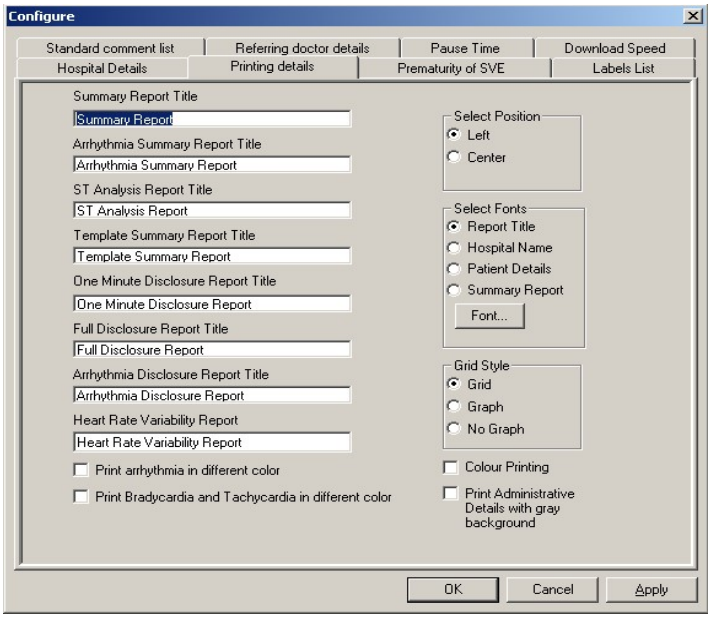


Fig: 4.3- Printing details

4.b.3. SVE maturity.

To configure % Prematurity of SVE, click on '**Prematurity of SVE'** tab of '**Configure'** menu. The following dialog box as in Fig.4.4 will be shown.

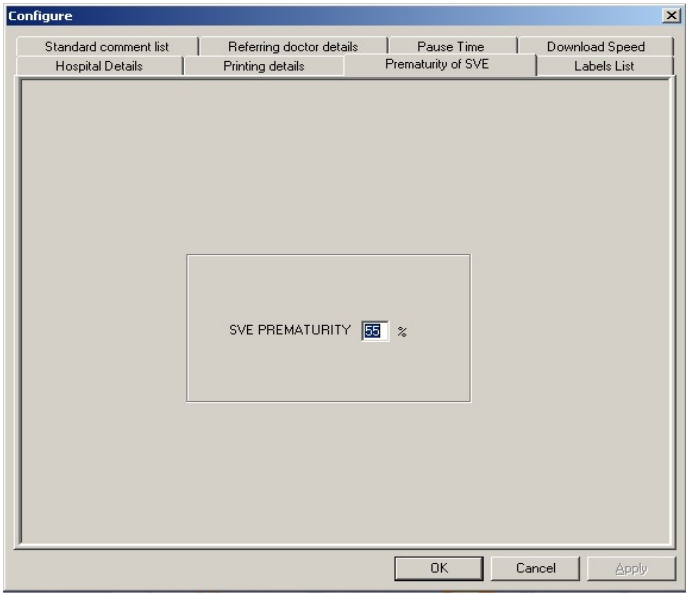


Fig: 4.4- Prematurity of SVE

Enter the required percentage and press "**OK**" or "**Apply**" button to save the changes and "**Cancel**" to exit without saving.

4.b.4. Edit labels list

To add new labels for arrhythmias, click on '**Labels list'** tab of '**Configure'** menu.

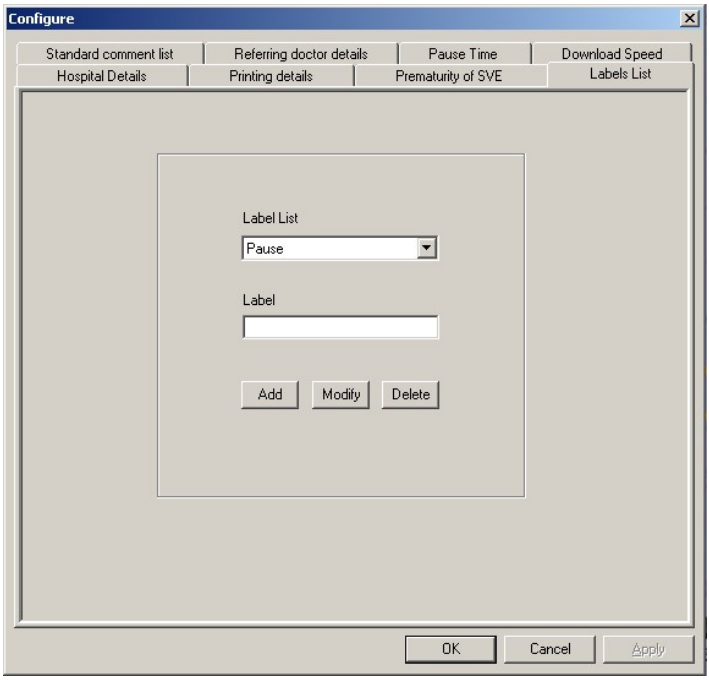


Fig: 4.5 Label editors

User can add a new label as well as modify or delete added labels. To add, delete or modify, click on the respective buttons. Some standard labels are present in the Label list, which cannot be modified. The standard labels are "Pause", "Trigeminy", "VE Pair", "ROnT", "SVEPair", "Bradycardia", "Bigeminy", "Isolated VE", "VTach", "SVE", "SVETach" and "Tachycardia". Press "**OK**" or "**Apply**" button to save the changes and "**Cancel**" to exit without saving.

4.b.5. Standard comments list

To configure standard comments to print in the reports, click on '**Standard comment list'** tab of '**Configure'** menu. Refer Fig 4.6

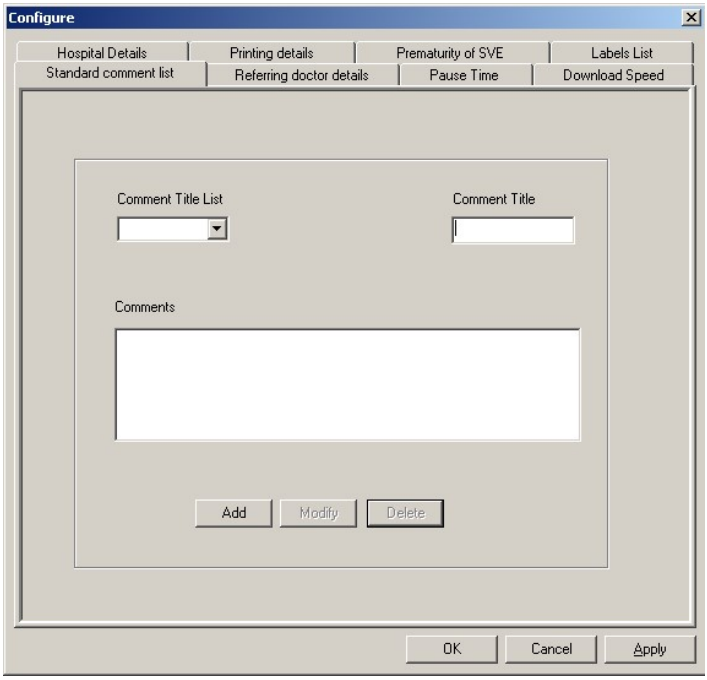


Fig: 4.6 Standard comments list.

To enter the comments, type the comment title in "**Comments title**" edit box, comments in the "**Comments**" edit box. Click "**Add"** to add the comment. To delete or modify the comments, select the required comment from the "**Comments title**" combo box, and click respective button on the "**Standard comments**" dialog box. Press "**OK**" or

"**Apply**" button to save the changes and "**Cancel**" to exit without saving.

4.b.6. Referring Doctor Details

This option from the **'Configure'** menu provides facility of storing the list of referring doctors. This list gets popped up in the Patient details dialog box, from where you can select the concerned referring doctor for the patient.

For entering the details, follow the steps.

1. Select the '**Referring doctor details** ' tab from the '**Configure**' Menu.
2. A window will appear on the screen as shown in fig. 4.7
3. Enter the reference doctor's name and designation you want to add to your list and click the '**Add**' button.
4. To delete any doctor from the list, select the corresponding Sr. No and click the '**Delete**' button. The selected doctor will be deleted.
5. To change or modify any doctor's details double-click on Sr. No & click the '**Modify'** button.
6. After entering all information click on "**Apply**" button to save the contents in the list.
7. Press "**Cancel**", the information will not get saved.

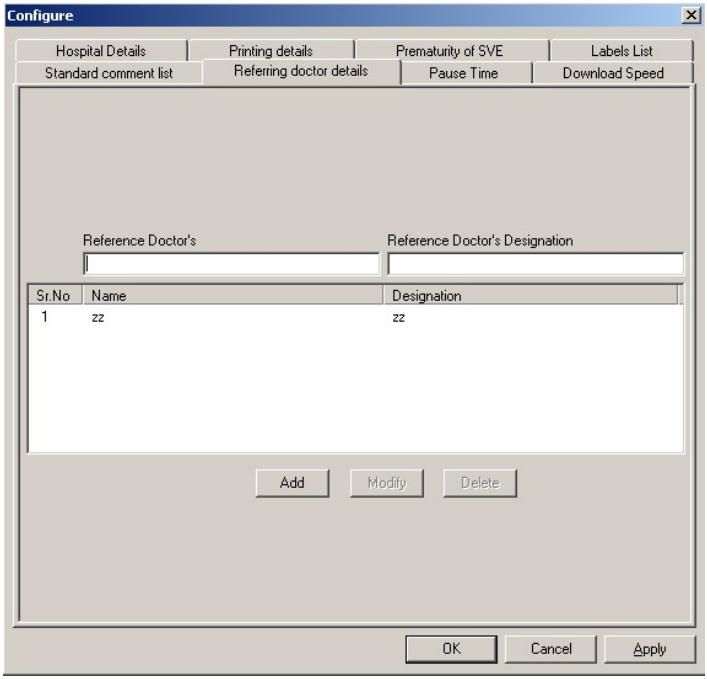


Fig: 4.7 Referring Doctor List.

4.b.7. Pause Time

To configure Pause Time, click on '**Pause Time'** tab of '**Configure'** menu. The following dialog box as in Fig.4.8 will be shown.

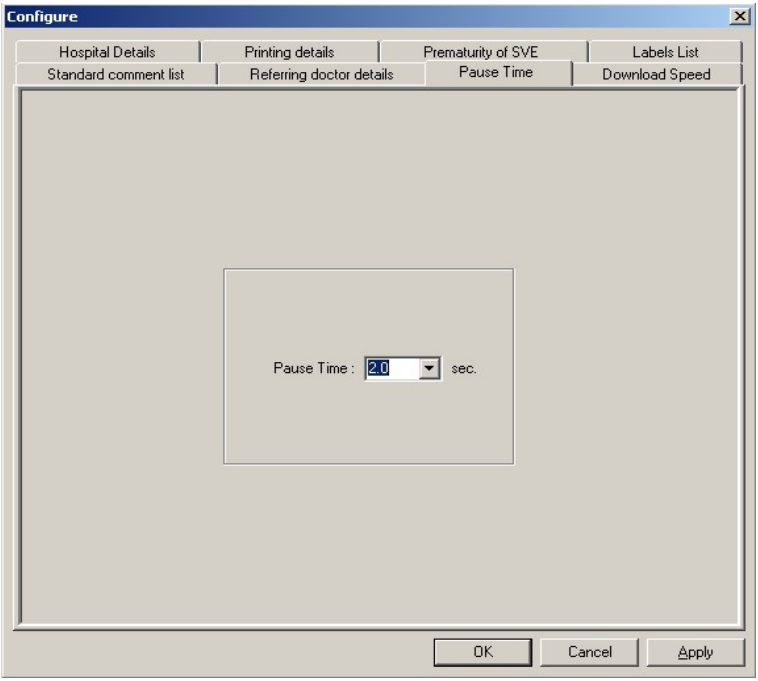


Fig: 4.8 Pause Time.

Check the list shows time settings as, 1 sec, 2 sec, 2.5 sec, 3 sec, 4 sec & 5 sec. Default setting is 2.0 sec.

Select the required Pause time from the available list and click **'OK'** or **'Apply'** button to save the time.

Click **'cancel'** to exit without saving.

4.b.8. Download Speed

To select download speed, click on **'Download Speed'** tab of '**Configure'** menu. The following dialog box as in Fig.4.9 will be shown.

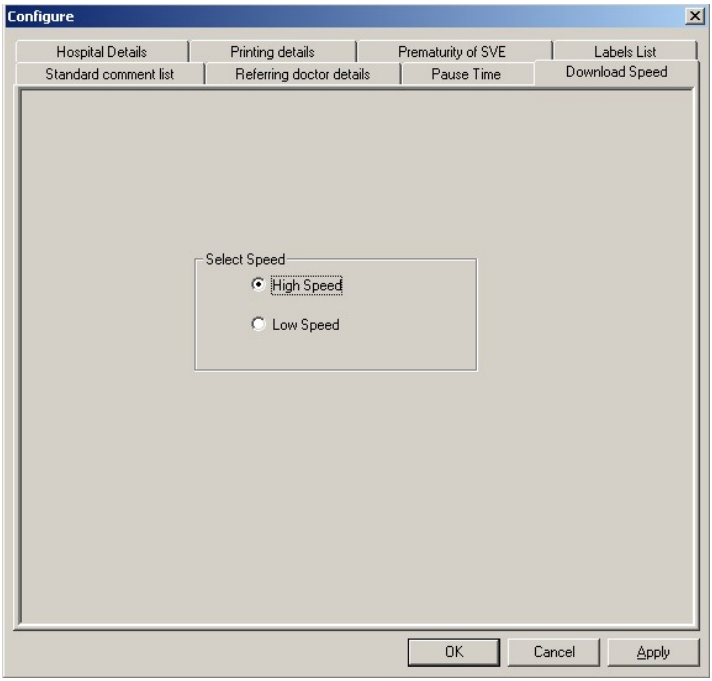


Fig: 4.9 Download Speed

Default download speed is 'High Speed'. If download error occurs then select 'Low speed' from the configure menu and click **'OK'** or **'Apply'** button to save the speed.

Click **'cancel'** to exit without saving.

5. Downloading the test

5.a Downloading data from unit.

Press "**Download**" button on the main screen or go to "**File**" and press "**Download"** option to download the data directly from unit. The patient details dialog box will appear on the screen as shown in the fig 5.1 below.

In this dialog box, patient name and age of the patient are compulsory fields. So it is indicated by '*' sign.

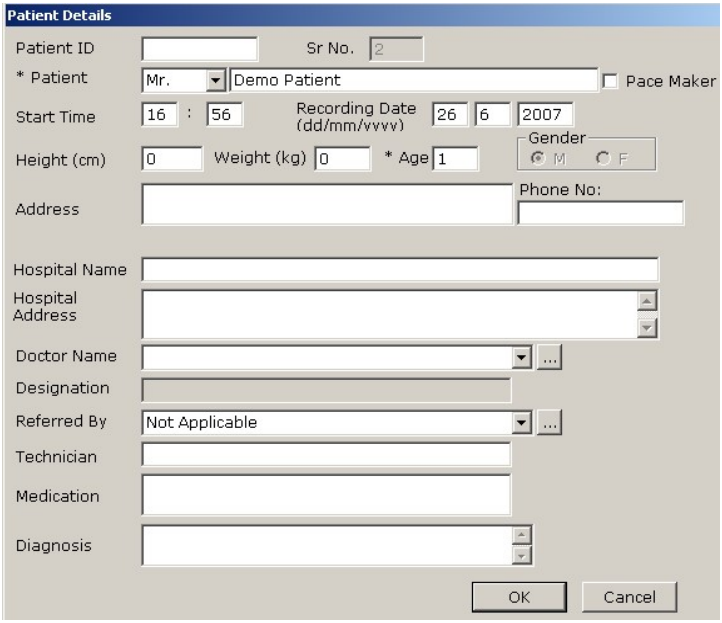


Fig: 5.1- Patient details.

Enter the patient details.

1. Above patient detail dialog box is displayed with patient prefix combo box adjacent to patient name edit box. As per selection in this combo box, the 'Male' or 'Female' radio button under gender is set accordingly.
2. To edit the doctor list, click '…' push button near Doctor Name edit box. 'Doctor Details' dialog box will be displayed with details as shown in fig 4.2. Edit the doctor list as per requirement and press OK button. The doctor list on the patient details dialog box will be updated accordingly.
3. To edit the referring doctor's list, click '…' push button near Referred By edit box. 'Doctor Details' dialog box will be displayed with details as shown in fig 4.7. Edit the doctor list as per requirement and press OK button. The 'Referred By' list on the patient details dialog box will be updated accordingly.

After entering the details press "**OK**" button.

A progress bar along with the message, "**Please Wait...**" will appear on the screen. After about 2 sec, following message box will be displayed.

Fig: 5.2

Press OK button.

After about 16 minutes data download will get complete following message box appears on the screen.

Fig: 5.3

Press "**OK**" button to view the downloaded data.

5.b Downloading data from pen drive

Press "**Download from Pen drive**" button on the main screen or go to "**File menu**" and press "**Download test from pen drive**" option to download the data saved in pen drive. Following dialog box will be displayed on the screen as shown below.

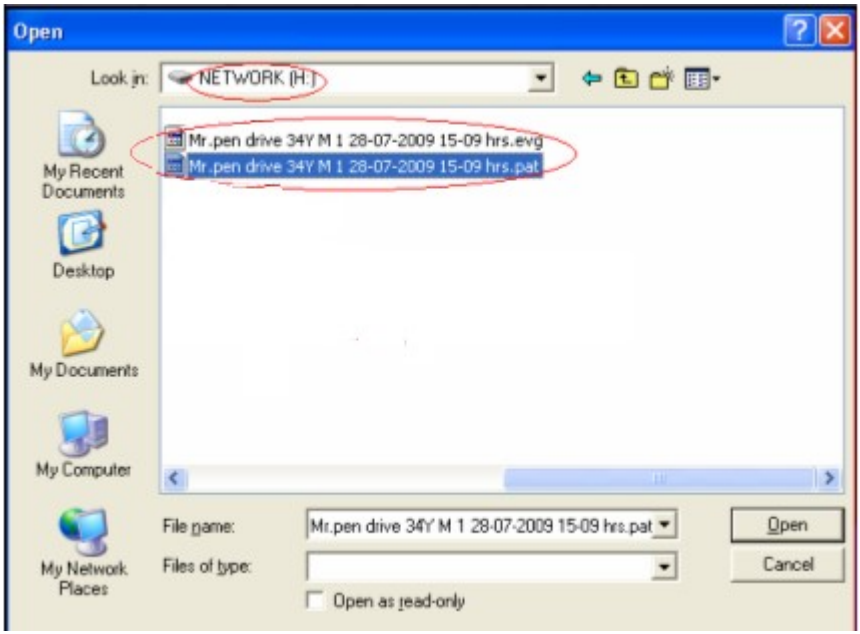


Fig: 5.4

Select pen drive location and select ".evg" or ".pat" any one file. Click 'open' button. The

"Patient details" dialog box will be displayed with previously entered patient information (Disabled) while coping data into Pen drive.

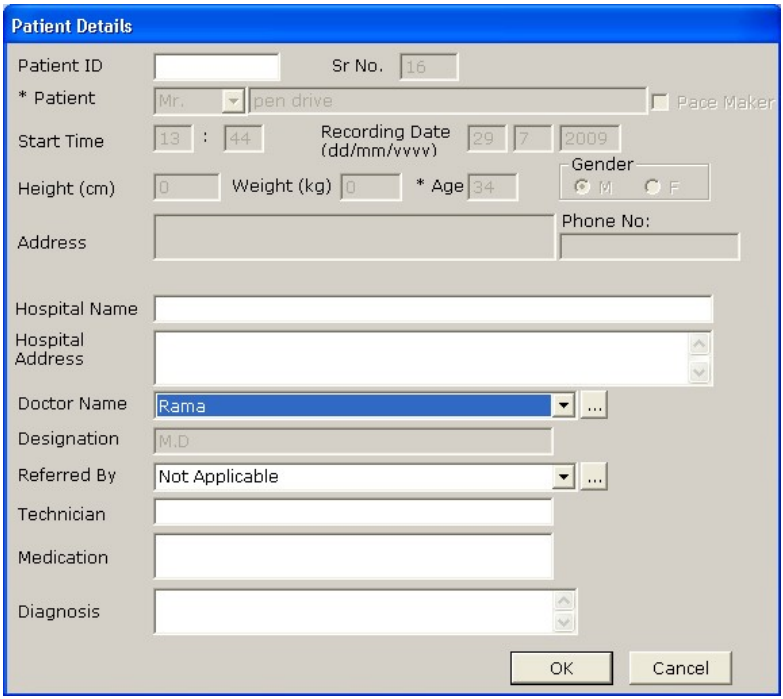


Fig: 5.5

After entering Hospital & Doctor details press "**OK**" button. Then data will be downloaded within 12 to 15 seconds and following message will be displayed on the screen.

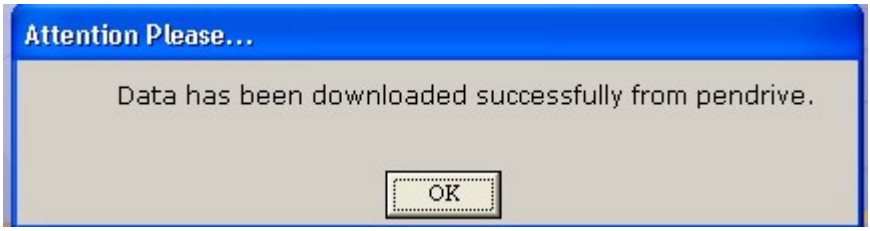


Fig: 5.6

Press "**OK**" button to view the downloaded data.

5.c Full disclosure

The Full disclosure screen as shown in Fig 5.8 will appear. By default 10 minutes data will be shown from the start time. This screen also contains a Menu bar as shown below,

Fig: 5.7- Menu bar.

The menu bar as shown in the Fig 5.7 contains following controls. A tool tip will be displayed as the mouse is moved on the controls or buttons. The start time of the Full Disclosure Page is displayed.

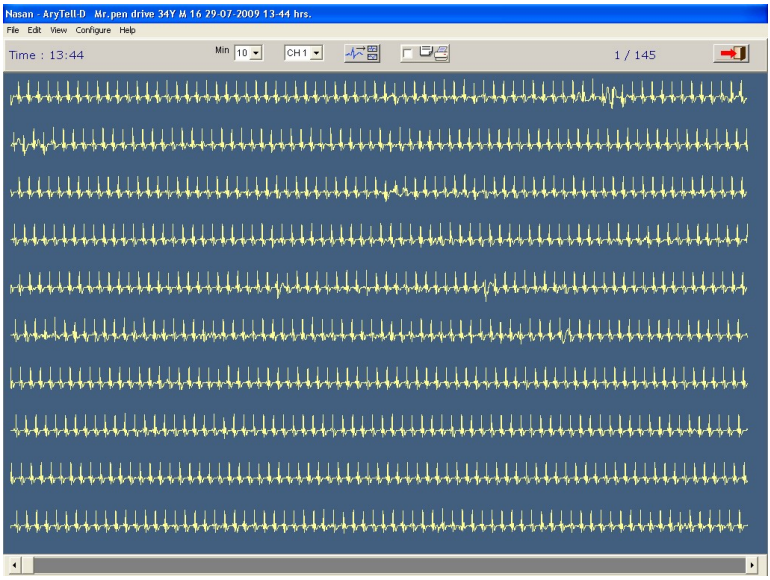
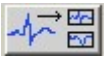


Fig: 5.8- Full disclosure screen.

5.c.1. Min: 

This drop down box is used to select the disclosure minutes to view the ECG data. Facility is provided to view the data of 10, 20, 30 and 60 min by selecting the minutes from the drop down.

5.c.2. Select channel: To view the ECG on any of the channels, select the channel from combo box. The ECG data of the selected channel will appear on the screen.

5.c.3.  **Start beat for classification:** To classify the data press the "**Start beat for classification**" button.

5.c.4.  **Mark page for printing:** To mark the page for the printing, click this check box. The checked page will be marked for printing.

5.c.5. Browse pages: A scroll bar control is provided at the bottom of the screen as shown in fig 5.8. Use the scrollbar to navigate in the backward and forward direction for viewing the ECG data. You can also use the left and right arrows on the keyboard for this functionality. The track bar on the scroll bar can be dragged in forward or backward direction to view a particular page directly.

5.c.6. Page number and total pages: The page number of currently displayed page along with the total number of pages in the entire test is displayed on the right hand corner of the menu bar as shown in the fig 5.7.

5.c.7. Exit: `**Exit'**

To exit from the test, press the button on the menu bar.

5.c.8. Zoom: As the mouse is moved on the full disclosure screen a '**Zoom In**' cursor is displayed on the ECG data. To zoom and view One Minute Disclosure of selected minute, click on required row. One-minute disclosure of that ECG data will be displayed on the screen as shown in the Fig. 5.8 below. Each line contains 10 second ECG data.

5.d One-minute disclosure.

Fig: 5.9- One-minute disclosure.

Note:

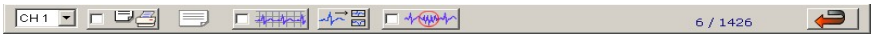
HR displayed on the one min page is HR stored at the end of one min page, i.e at 60 sec from page start time.

By pressing "bit count" button on one minute page software calculate HR, based on actual bit in that minute.

HR displayed on one minute page and HR calculation by "bit count" button on one minute page is different.

If QRS amplitude is small then the bit is not counted OR T wave is tall it is counted as bit for HR calculation.

One minute ECG data (normal ECG in light yellow color and arrhythmia detected ECG data in red color) is seen on the screen with a menu bar on the top of the screen. This screen contains a Menu bar as shown below.



5.d.1. Select channel: 

To view the ECG on any of the channels select the channel from combo box. The ECG data of the selected channel will appear on the screen.

5.d.2. Mark page for printing:  Click this check box to mark the current page for printing. The marked page will be available for printing.

5.d.3. Comments:  This button is enabled when the page is marked for printing. To enter the comments for the selected page, press the "**Comments**" button on the menu bar. The comments dialog box will appear on the screen as shown below in the Fig 5.10. The entered comments will be printed on the marked page.

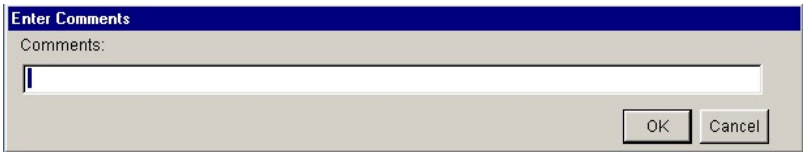


Fig: 5.10- Comments dialog box.

5.d.4. Grid ON / OFF:  When checked, one-minute disclosure screen will be display with grid as shown in the fig 5.11.

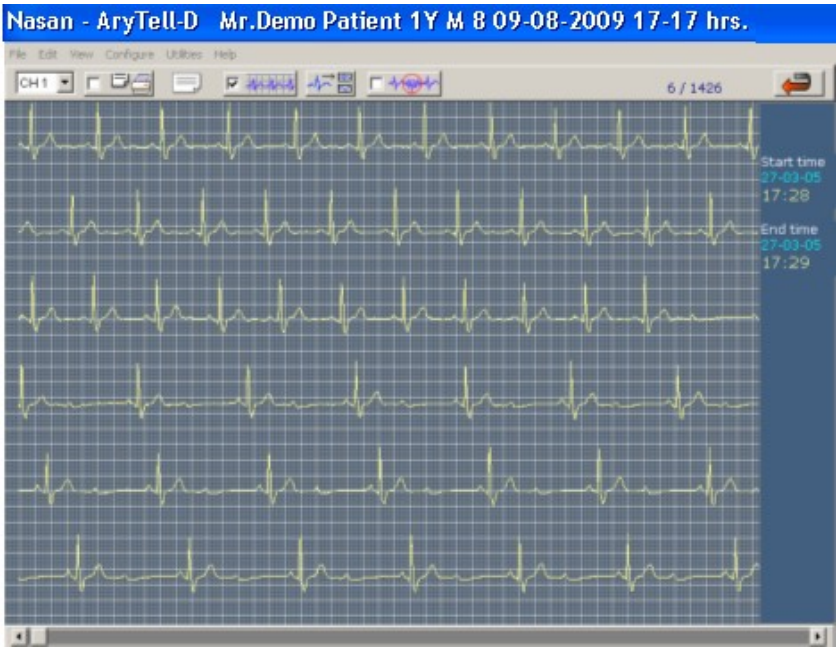
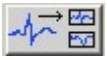


Fig: 5.11- One minute disclosure with grid

5.d.5. Select beat for classification:  To classify the data press the "**Select beat for classification**" button, the screen as shown in Fig 4.8 will be displayed.

5.d.6. Mark noise:  If some noise is observed on the recorded data, then one can mark it as noise before the classification starts. Click on this check box to mark the displayed one-minute as noise. This data will be excluded from all the calculations. To unmark the noise, just uncheck the check box.

5.d.7. Browse pages: A scroll bar control is provided at the bottom of this screen as shown in fig 5.11. Use the scrollbar to navigate in the backward and forward direction for viewing the ECG data. You can also use the left and right arrows on the keyboard for this functionality.

5.d.8.  **Back:** To go back to the Full Disclosure screen Press the '**Back'** button.

5.e Beat selection panel.

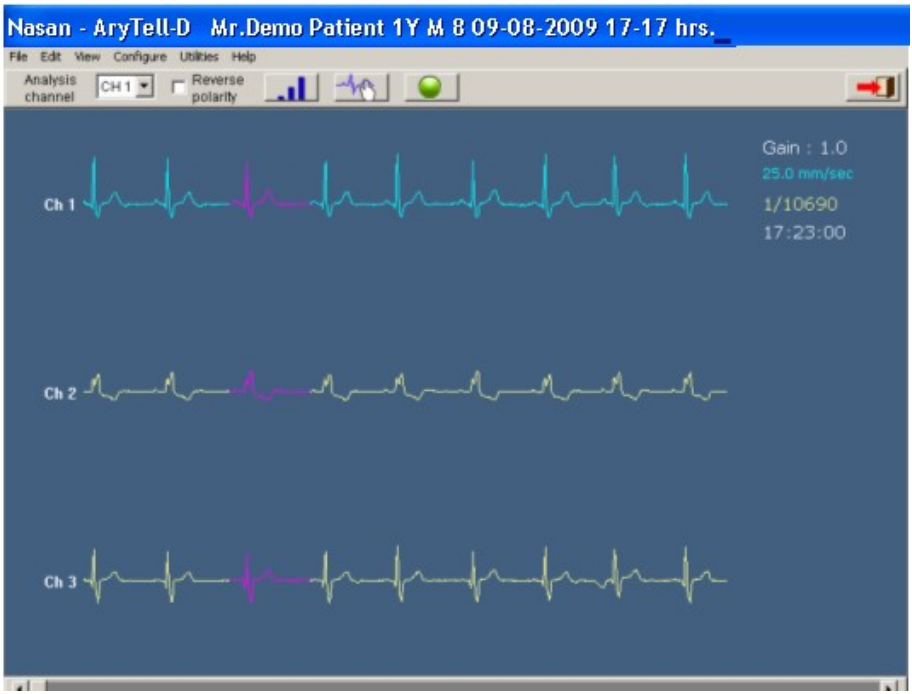


Fig: 5.12 Beat selection panel.

The data of 8 sec from the start of the test is seen on this screen. The first normal reference beat automatically detected is displayed in magenta color. This screen also contains a Menu bar as shown below.

5.e.1. To select channel for analysis: Select the required channel from the combo box.

5.e.2. To reverse the polarity: In case the electrodes are wrongly placed, then the ECG waveform is displayed in reverse direction. To change the polarity, check on the

reverse polarity check box. The waveform of the selected channel is displayed with polarity reversed as shown in fig 5.13.

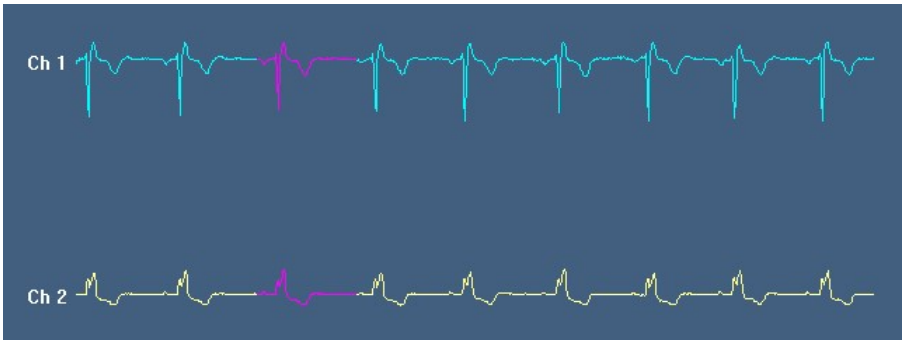


Fig: 5.13 Polarity of ch1 reversed.

5.e.3. To set the gain:  To set the gain of the ECG between 0.5, 1.0, 2.0 3.0, 4.0 and 5.0 press "**Gain**" button on the menu bar.

5.e.4. Select beat for classification manually: 
For manual selection of the reference beat press "**Select beat for classification manually**" button. A Vertical line cursor will appear on the screen. Click on the required beat, then that point will be marked as the start of the reference beat. Another vertical line cursor will be displayed. Fix the position of this cursor & that point will be marked as the end of the reference beat.

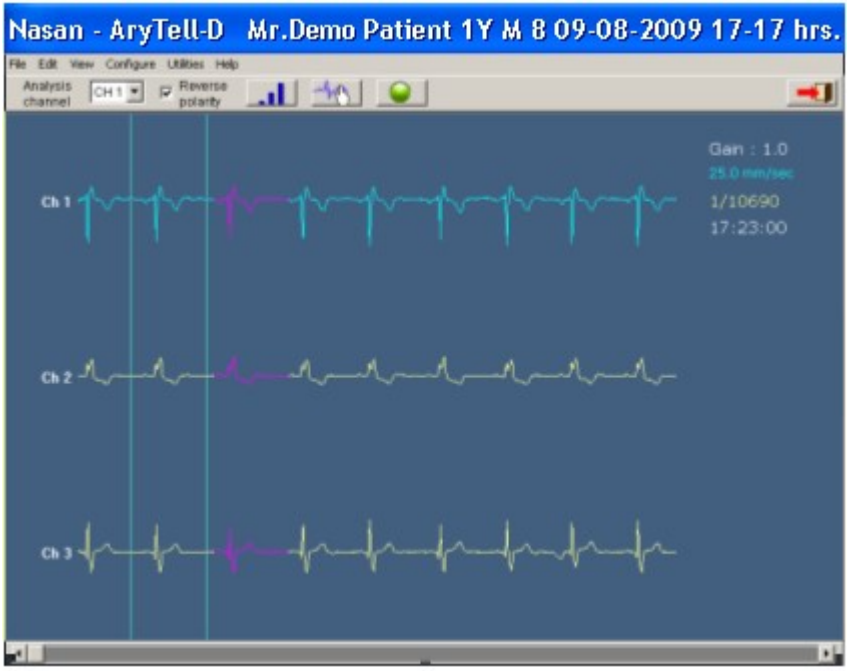


Fig: 5.14 Manual selection of beat.

A message box is displayed after completing the marking of beat.

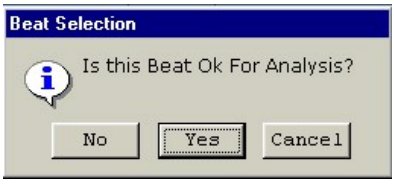


Fig: 5.15 Manual beat selection message.

If the beat selected is OK for analysis then press "**Yes**" button and if the beat selected for the analysis is not OK then Press "**No**" button and mark other beat for analysis. To cancel the process and continue with automatically selected beat, press "**Cancel**" button.

5.e.5. Browse page: A scroll bar control is provided at the bottom of this screen as shown in fig 4.8. Use the scrollbar to navigate in the backward and forward direction for viewing the ECG data. You can also use the left and right arrows on the keyboard for this functionality.

5.e.6. Start analysis:  After selecting the reference beat, press "**Start analysis**" button to start the classification process. The screen shown in Fig 5.15 will be displayed.

5.f Template classification.

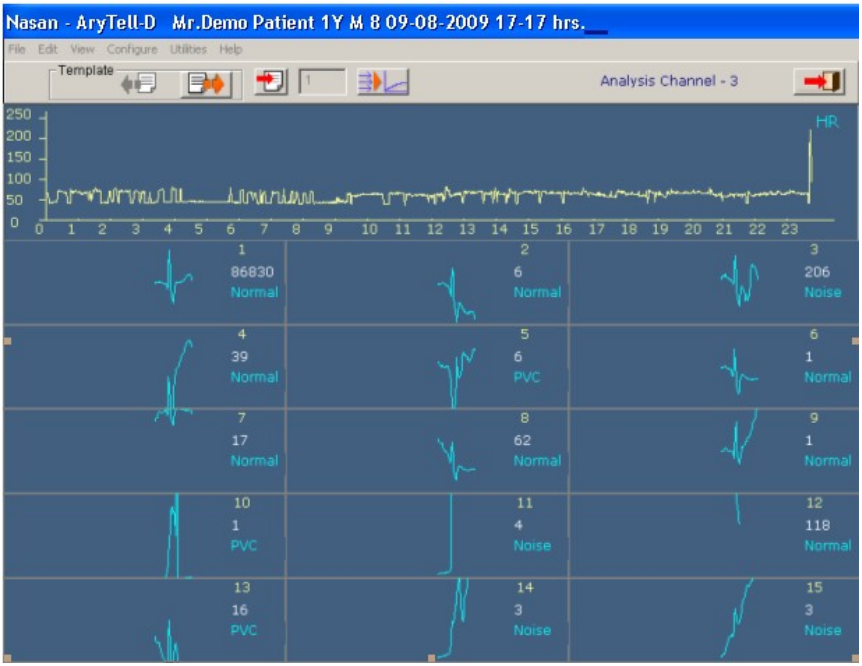


Fig: 5.16 Classification screen.

The screen shows the details mentioned below,

- Running heart rate trend as the beats are being classified.
- The templates identified from the classification of the ECG till that instance.
- Total 15 templates are seen on one screen. After viewing the particular template its color changes to magenta color.
- If the template number exceeds 15, new page is created and "**View next template page**" button and "**Page"** edit box are enabled.

5.f.1. To view next/ prev. template page: Press the 

"**View next / previous template page**" buttons on the tool bar or the left / right arrow keys on keyboard. The next or previous template page is displayed.

5.f.2. Display selected page: To go to particular template 

pages enter the page number in edit box, and press "**Display selected page**" button.

5.f.3. Analyze data and view trends: After the  classification is over "**Analyze and view trends**" button gets enabled. Click this button to analyse arrhythmias and to view trends.

5.f.4. To edit template type: The templates can be edited by right clicking on the respective template. A menu is displayed as shown in the fig 5.16a.

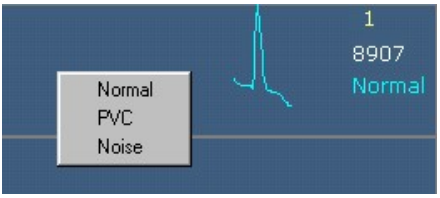


Fig: 5.16a Menu on right click.

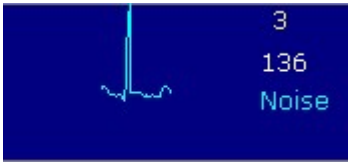


Fig: 5.16b

You can select any of the beat type from the list and the template is renamed with selected beat type. You can edit multiple templates at a time. For this press either the "Shift" or the "Ctrl" key on the keyboard and then click on the required templates with the "Shift" or "Ctrl" key pressed. The template/s selected for editing will be displayed in different background color as shown in Fig. 5.16b. After the selection is over, right-click and select the type to change from the menu displayed. All the selected templates will be renamed to the selected type.

5.f.5. To view beats in template: A hand reference cursor appears on the template. Left click the mouse on the template to view the beats in that particular template. The screen showing the ECG beats in that template is seen as shown in the following Fig 5.17.

5.g Template beats editor.

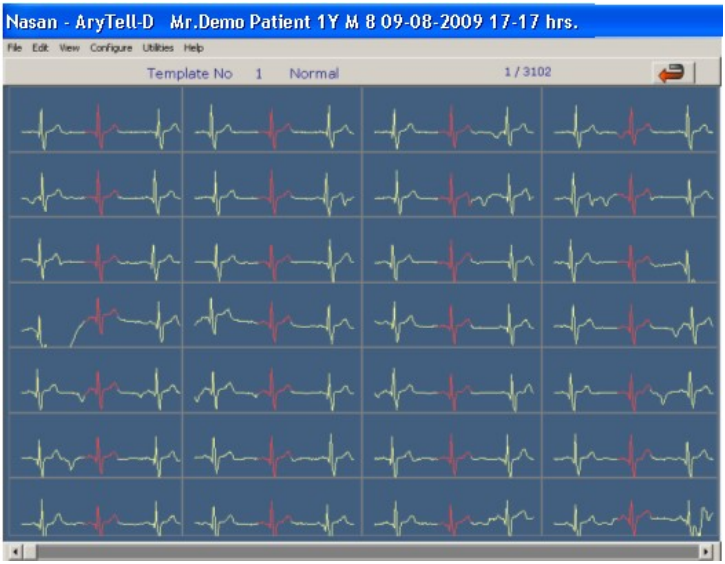


Fig: 5.17 Template beats screen.

5.g.1. Browse page: A scroll bar control is provided at the bottom of this screen as shown in fig 5.17. Use the scrollbar to navigate in the backward and forward direction for viewing the ECG data. You can also use the left and right arrows on the keyboard for this functionality.

5.g.2. To view **ECG** data of 8 sec of any beat for all channels, click on any of the required beat on the page. The screen as shown in Fig 5.18 is displayed.

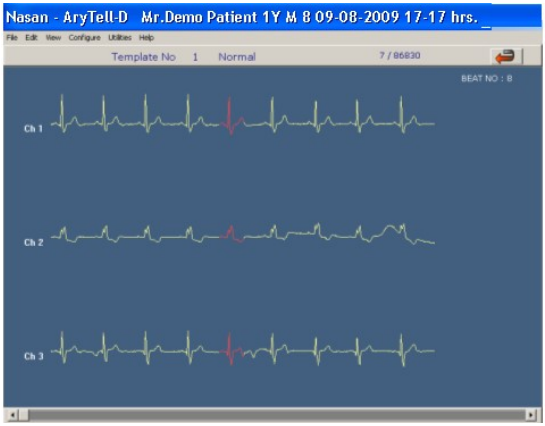


Fig: 5.18 Edit individual beat.

5.g.3. To change label of a beat: Right-click on the beat and select the new beat type. You can edit multiple beats in a template at a time. Press the "Shift" or the "Ctrl" keys and then click on the required beats. The selected beats will be displayed with different background color. After the selection is over, right-click and then select the required label from the menu displayed. All the beats will be renamed to the new label type.

5.g.4. Browse pages: A scroll bar control is provided at the bottom of this screen as shown in fig 5.18. Use the scrollbar to navigate in the backward and forward direction for viewing the ECG data. You can also use the left and right arrows on the keyboard for this functionality.

5.g.5.  **Back:** To go back to the classification screen / review screen, click on 'Back' button or press the "Esc" key on the keyboard.

6. Reviewing The Test

Click "**Review Test**" button on the main screen or go to "**File Menu**" and press "**Review Test**" option. File open dialog box is displayed as shown in Fig. 6.1

6.a Select patient from list

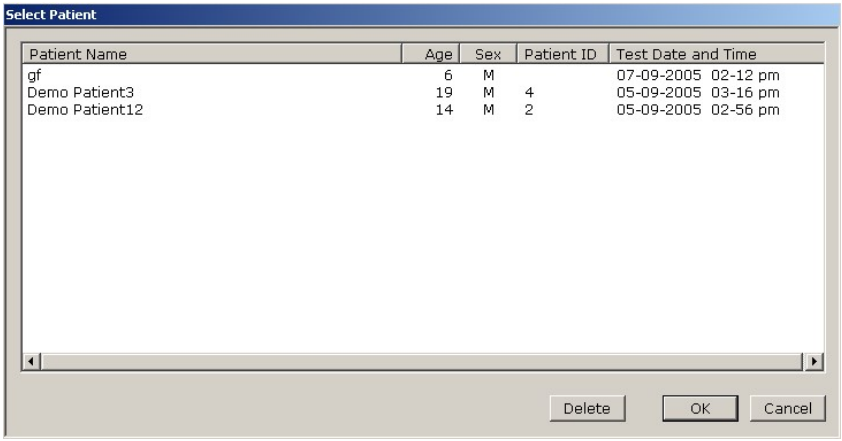


Fig: 6.1 – Select patient dialog box.

6.a.1. To sort the patient list according to a particular field, click on the respective tab. e.g.: - To sort the list according to age click on Age.

6.a.2. To delete a record, click on the required record and press "**Delete**" button. The record will be deleted with confirmation.

6.a.3. To select a patient for review click on the required record. To discontinue with the selection press "**Cancel**". To continue with the selection press "**OK**".

6.b Trends.

The screen as shown in Fig 6.2 shows the following information,

- Maximum heart rate
- Minimum heart rate
- Longest Pause
- Longest V-Tach
- Longest SV Tach
- Longest ST Episode
- Maximum Delta ST.
- There are total 12 trends that can be seen, 4 each on one page. These trends are as follows,
- Heart rate trend
- Ventricular ectopic trend (VE).
- V tach trend.
- Supra Ventricular ectopic trends (SVE).
- SVE tach trends.
- ST levels of all 3 channels.
- Bigeminy trend.
- Trigeminy trend.
- Bradycardia trend.
- Trachycardia trend.

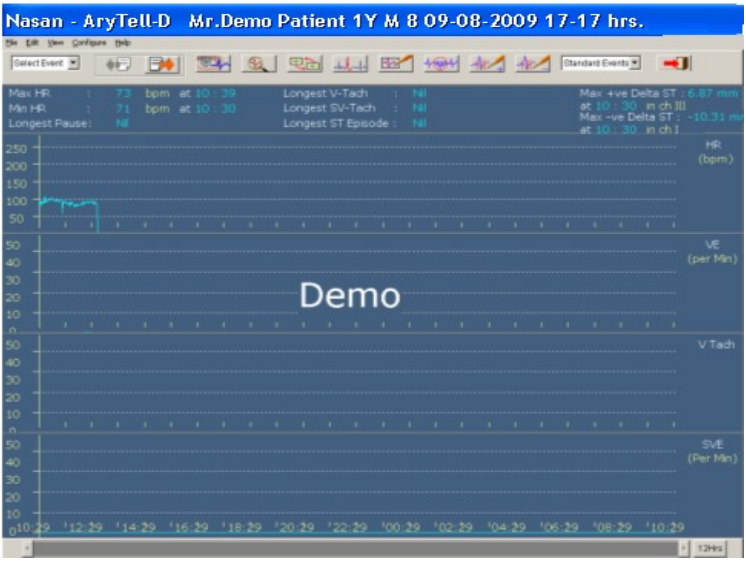


Fig: 6.2- Trends screen.

A tool bar as shown in fig. 6.3 is displayed on the top of the screen.

Fig: 6.3- Review tool bar.

6.b.1. View previous & next trend page: To go to next/ previous trend page use these buttons or press the left / right arrow keys on the keyboard.

6.b.2. View ECG:  To view the ECG of the particular minute, click "**View ECG**" button. After the button is pressed a cursor appears at the tip of the mouse. Place the cursor on the minute to be viewed and click the mouse left button. One-minute disclosure of selected minute will be seen on the screen as shown in the Fig 6.4.

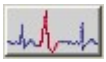
6.b.3. View medians:  To view medians click this button; the median screen will get displayed on the screen as shown in the Fig 6.5.

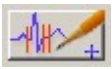
6.b.4. Select event: 

The patient marks the event when he is feeling uneasy. These events can be seen in the review. "**Select event**" drop down box contains the event marked by the patient. Select the event to be viewed from the drop down box and a One minute disclosure screen as shown in Fig 6.4 is displayed. The event is marked as a red vertical line on the ECG.

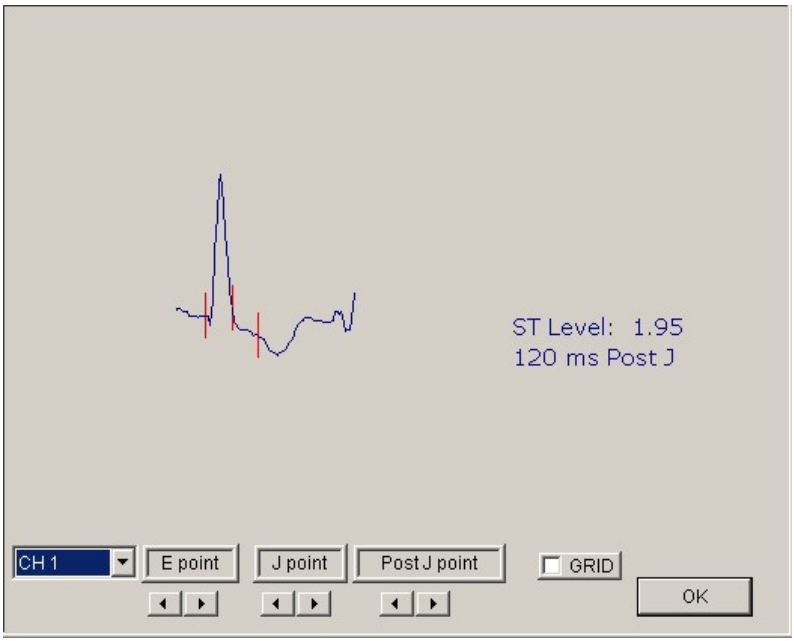
6.b.5. Reanalyze test:  If the analysis done is not satisfactory then you can analyse the test again. For that purpose press the "**Reanalyse test**" button. Full disclosure screen will be displayed as shown in Fig 6.5a. You can once again select the channel for classification and reanalyse the test.

6.b.6. Mark noise:  One can mark the noisy data in review too. For this on the trends screen, click on the "Mark noise" button. A vertical line cursor will appear on screen. Place the cursor at the start of required area and click. Then another vertical line cursor will appear. Place this cursor at the end of required area and click. All the calculations will be newly performed and the noisy area will be excluded from the calculations. The area marked as noise will appear in red on the trend. This facility is also available from one-minute disclosure screen.

6.b.7. View arrhythmia:  To view the 8-second disclosure of the arrhythmias found in the test after analysis, click "**View arrhythmia**" button. After clicking the button you can see the 8-second disclosure display as shown in the Fig 6.6.

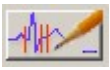
6.b.8. View and edit Max +ve Delta ST median: 

To view or edit the fiducial points of the Max +ve delta ST median, click on the "**View and edit Max +ve delta ST median**" button. The Zoom median screen will be displayed as shown below.

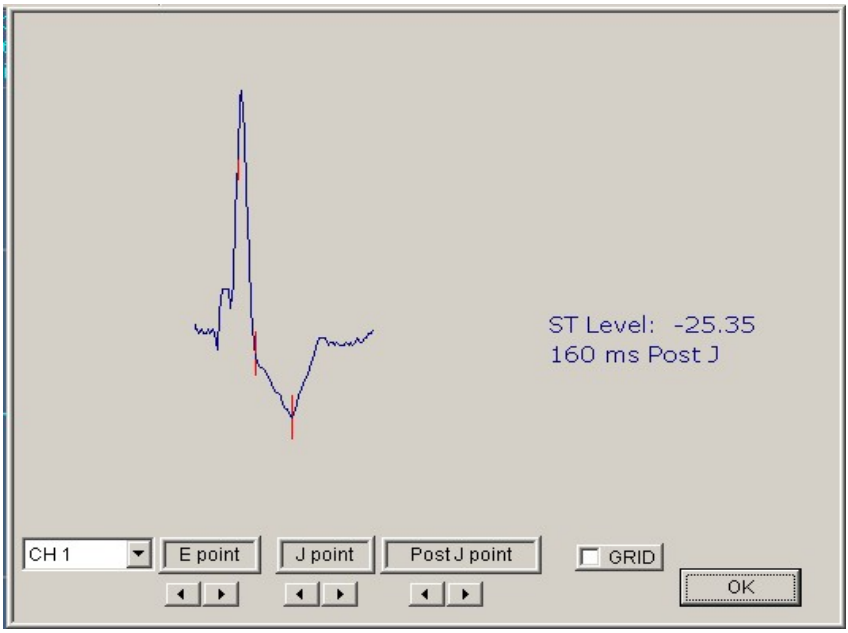


The fiducial points or the ST level of any required channel at the time instant (max delta ST timing) can be edited by selecting the channel.

6.b.9. View and edit Max -ve Delta ST median:



To view or edit the fiducial points of the **Max -ve** delta ST median, click on the "**View and edit Max -ve delta ST median**" button. The Zoom median screen will be displayed as shown below.



The fiducial points or the ST level of any required channel at the time instant (**Max -ve** delta ST timing) can be edited by selecting the channel.

6.b.10. Standard Events: To view standard events page directly, this combo box is provided. It contains following standard events:

- Max HR
- Min HR
- Longest ST
- Longest Pause
- Longest V Tach
- Longest SV Tach
- Max +ve delta ST 1
- Max +ve delta ST 2
- Max +ve delta ST 3
- Max -ve delta ST 1
- Max -ve delta ST 2
- Max -ve delta ST 3

Select the required event to view from the combo box and the corresponding event page will be displayed as shown in fig 6.4.

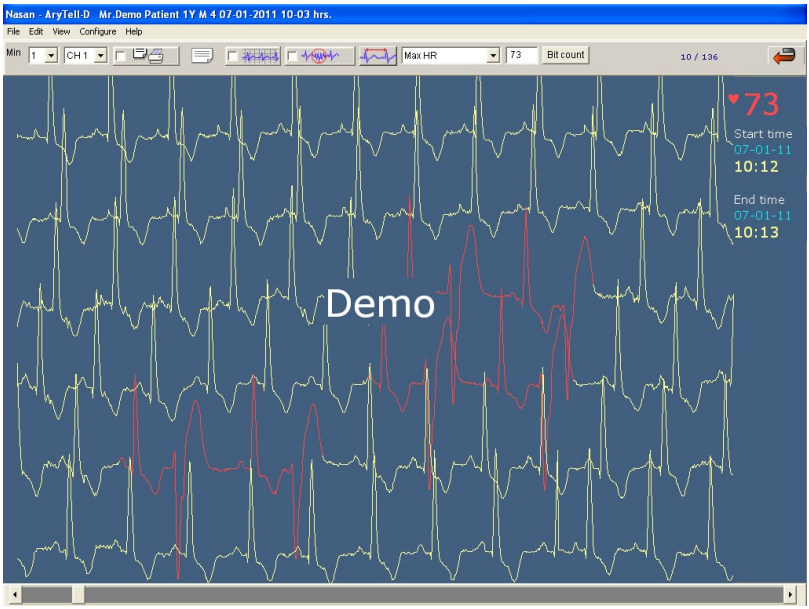


Fig 6.4 One-minute disclosure for Standard Event (Max HR)

6.c View ECG:

To view ECG of a particular instance, click the view ECG button on control panel and then place the cursor on the required time on the trend and click. Following screen is displayed with toolbar as shown in fig.

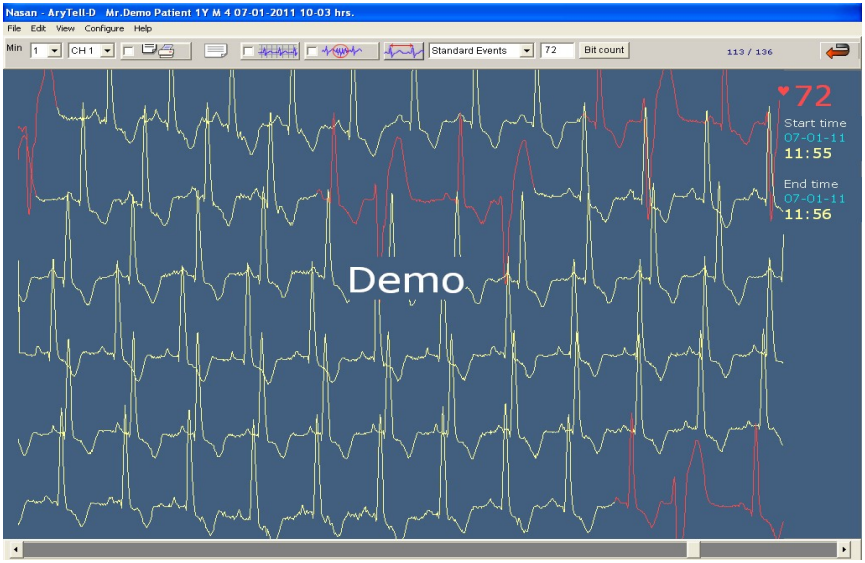
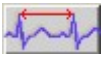


Fig: 6.5 One-minute disclosure

6.c.1. Minute selector: A drop down box is provided to select the minutes to view the data. The view minutes are available as 1 min, 10 min, 20 min, 30 min and 60 min.

6.c.2. Mark R-R interval:  If the HR is not correctly calculated, then the R-R intervals can be marked so that the HR is recalculated. For marking the R-R interval, press the '**Mark R-R interval**' button, a vertical line cursor will be displayed. Place the cursor on the R wave and click. A second vertical line cursor will be displayed. As this cursor is moved on the screen the value of R-R interval in milliseconds will be displayed on the screen. Place the cursor on successive R wave and click again. The HR for that page will be recalculated according to the marked R-R interval.

6.c.3. Standard Events: This control has the same functionality as described before.

6.c.4. Beatcount: 

"Bit count" button is added on One Minute Disclosure page to calculate HR automatically based on actual bit count in that minute.

6.c.5. Note: For functionality of other buttons refer description in 5.c.

6.d To Mark ECG Strip:

To mark ECG strip on full disclosure, select 1,10,20,30 or 60 minutes from the minute combo box. Right click on the screen.

Then **'Mark ECG'** menu will be displayed on the screen as shown in Fig **6.5 a.** Then click on **'Mark ECG'** menu, all the buttons except **'Back'** button on the tool bar will be disabled.

Place mouse cursor at the desired position over the waveform & press mouse left button to mark starting of the ECG strip & drag the mouse keeping left button pressed.

A rectangle will be drawn from the starting point to present mouse cursor position.

Now release the left button at the point where end of the ECG strip is to be marked. Duration of the strip being marked is displayed at the top centre in waveform window as shown in Fig **6.5 b.**

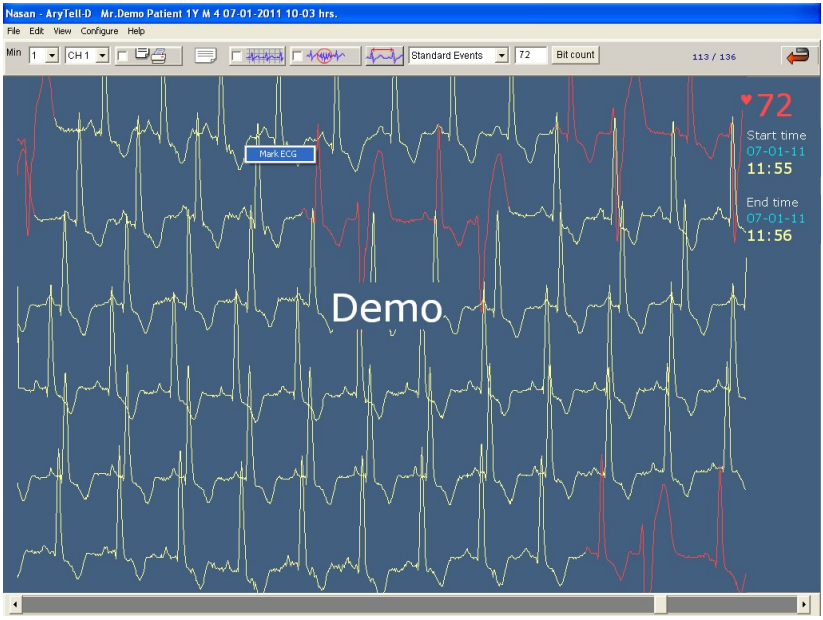


Fig : 6.5 a

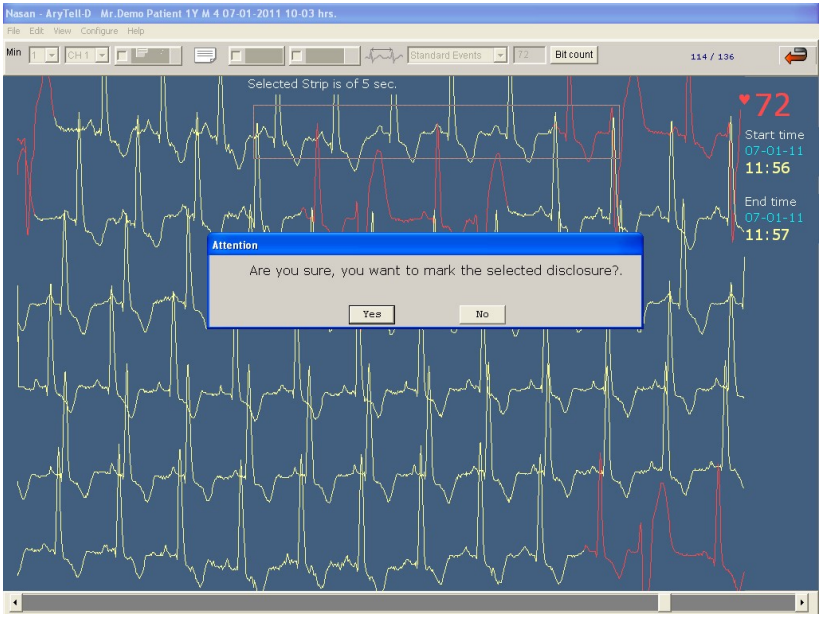

Nasan - AryTell-D Mr.Demo Patient 1Y M 4 07-01-2011 10-03 hrs.
File Edit View Configure Help
Min
Standard Events
Bit count
114 / 136
Selected Strip is of 5 sec.
72
Start time
07-01-11
11:56
End time
07-01-11
11:57
Attention
Are you sure, you want to mark the selected disclosure?.
Yes
No

Fig : 6.5 b

When the marked disclosure is within 1 minute range then Attention dialog box will appear on the screen as shown in Fig **6.5b.**

If **'Yes'** button is pressed then the rectangle is retained and will be drawn in Blue color and then the **'Enter Label'** editor box is displayed with **'OK'** button, as shown below**.**

If this page is marked for printing then the "**Operator Selected Strip Report**" of the selected page will be printed with the entered comments.

If **'NO'** button on Attention dialog box is pressed, the rectangle is erased.

If the marked ECG duration is more than one minute then following message box will appear on the screen.

All the buttons on tool bar are enabled when each mark strip cycle is over.

Maximum 5 strips can be marked on a page. If selected page has already 5 strips marked on it, then following message box will appear on the screen.

While scrolling through the disclosure the selected strips will be displayed every time when the page is displayed.

6.e View medians.

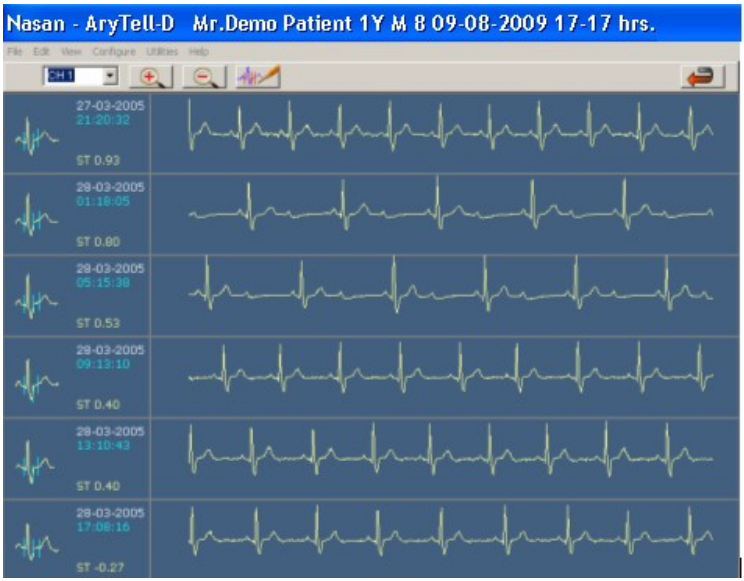
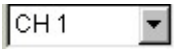


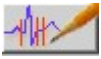
Fig: 6.6 Medians screen

6.e.1. Zoom  **in**: In this screen the whole test is divided in six equal parts and a median is drawn of that particular time group. 8 seconds ECG data from start of that time group is seen in front of that median. You can further zoom in the time group by pressing the "**Zoom In**" button. After clicking this button a hand reference cursor is available. Click the time group you want to zoom in. The time group, which is been clicked, is further divided into six equal parts and corresponding medians are calculated. The corresponding 8 seconds ECG data is also seen in front of the median.

6.e.2. Zoom out:  Use "**Zoom Out"** button to move in reverse direction.

6.e.3. Select Channel: 

To view medians of required channel, select channel from combo box. Medians and ECG of selected channel are displayed.

6.e.4. Edit fiducial points:  In case the ST levels have been wrongly calculated due to improper detection of the fiducial points, there is a facility to edit the fiducial points and thus correct the ST levels. To edit the fiducial points follow these steps given below:

a. Click on the button
b. A hand cursor will be seen.
c. Click on the median, whose fiducial points are to be edited. An enlarged form of the selected median is displayed in a dialog box as shown in the fig.6.7 below:

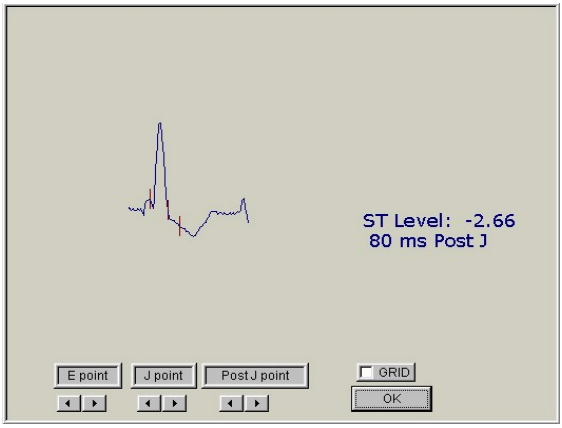


Fig. 6.7: Zoom median.

d. Click on the left / right arrows below the required fiducial point to move that point to the

required position. The ST Level displayed on this screen is updated online. After the changes are done, press the "**OK**" button. All the ST levels within that duration will be recalculated.

6.e.5. Back:  To go back to trend screen press "**Back**" button.

6.f Arrhythmia disclosure.

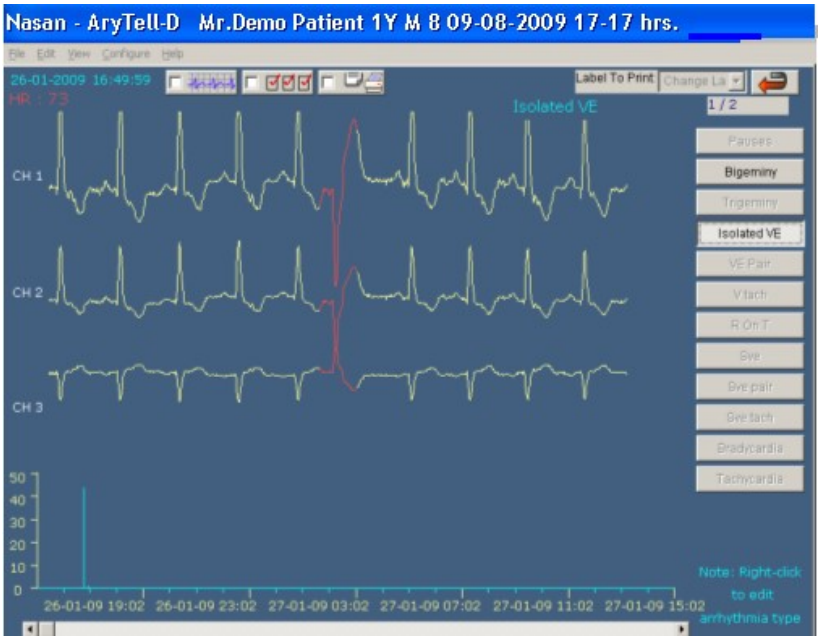


Fig: 6.8- Arrhythmia disclosure screen.

This screen contains the following,

6.f.1. 8 sec ECG data of all channels with the respective arrhythmia along with the heart rate value.

6.f.2. Arrhythmia buttons to view all the arrhythmias in the test. If a particular arrhythmia is not detected, then that button will be disabled.

6.f.3. If Pause is detected in the test, pause time will be displayed on upper right side of the screen as shown in Fig 6.8.

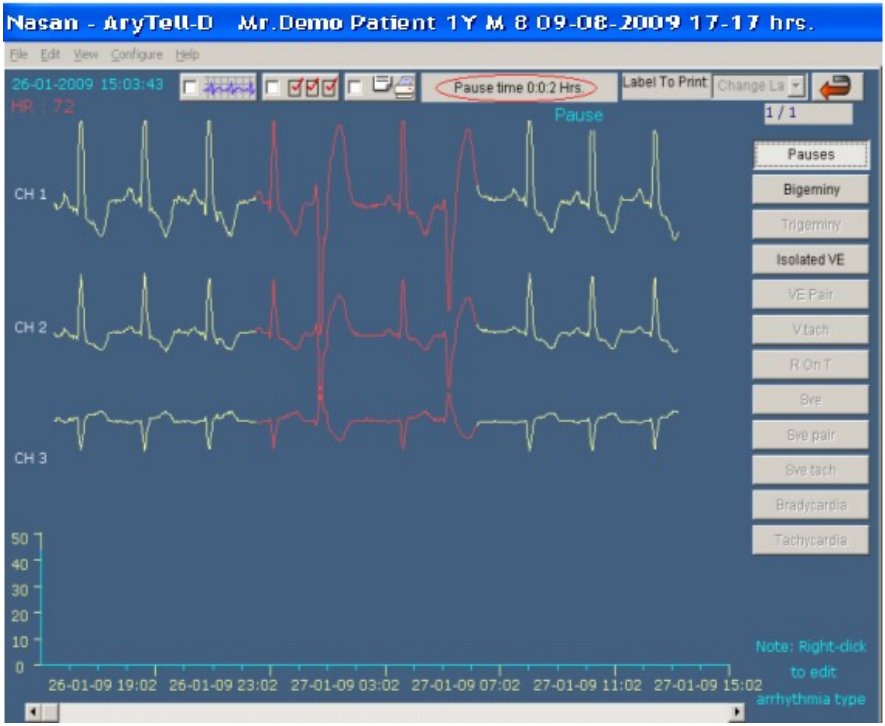


Fig 6.9

6.f.4. Selected arrhythmia trend at the bottom of the screen.

6.f.5. Browse page: A scroll bar control is provided at the bottom of this screen as shown in fig 6.9. Use the scrollbar to navigate in the backward and forward direction for viewing all arrhythmias of the selected type, in the entire test. You can also use the left and right arrows on the keyboard for this functionality.

6.f.6. Mark page for printing:  This button is use to mark the page for printing.

6.f.7.Label to print: To change the label of the arrhythmia

to the user configured arrhythmia type, this combo box is used. This option is enabled only if the page is marked for printing. This option is visible only if there are user-configured labels. If the label of the arrhythmia is changed, "*" will be printed in front of the label.

If the current displayed arrhythmia type is to be changed to either another arrhythmia type or normal or noise then, right-click on the arrhythmia. A list of standard arrhythmia types along with normal and noise will be displayed on the screen as shown in fig 6.9.

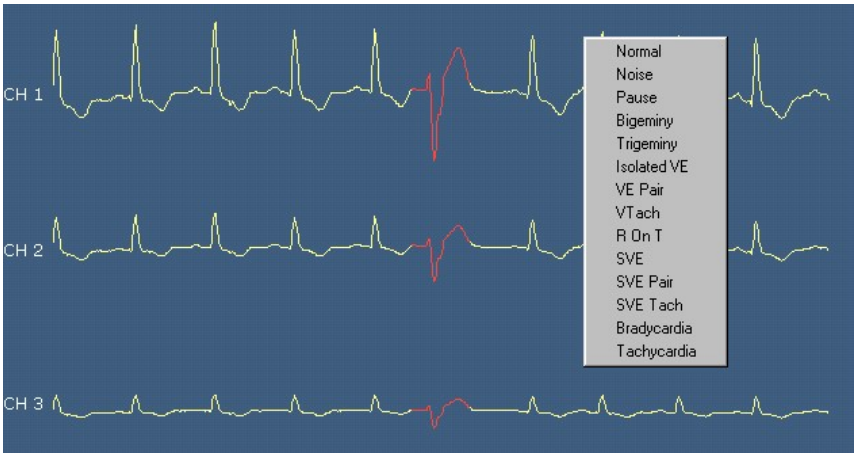


Fig. 6.10: Editing arrhythmia type.

Select the type to be changed to. The current displayed arrhythmia type will be renamed to the new type. Multiple arrhythmias in a group can be selected for editing by keeping the "Shift" or "Ctrl" key pressed while selecting the arrhythmia with mouse click. The selected arrhythmias for editing are displayed with a different background color.

6.f.8. Select all:  When checked, all the arrhythmias of current type are selected for editing. With this option you can edit the arrhythmia type of all the arrhythmias in a group at a time.

6.c.6. Back:  To go back to the trends screen. ESC key on the keyboard has the same functionality.

7. Menu Options

7.a.1 Edit Menu

7.a.2 Patient details: To edit the patient details, select "**Patient details**" from "**Edit**" menu.

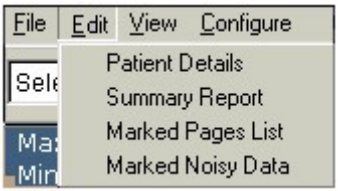


Fig: 7.1 - Edit menu.

The patient details entry screen as shown in the Fig 7.1 is displayed. You can edit patient information and save the changes by pressing "**OK**" button.

7.a.3 Summary report:

For editing the summary reports select "**Summary report**" option from "**Edit**" menu. The summary report will be displayed on the screen as show in the Fig 7.2.

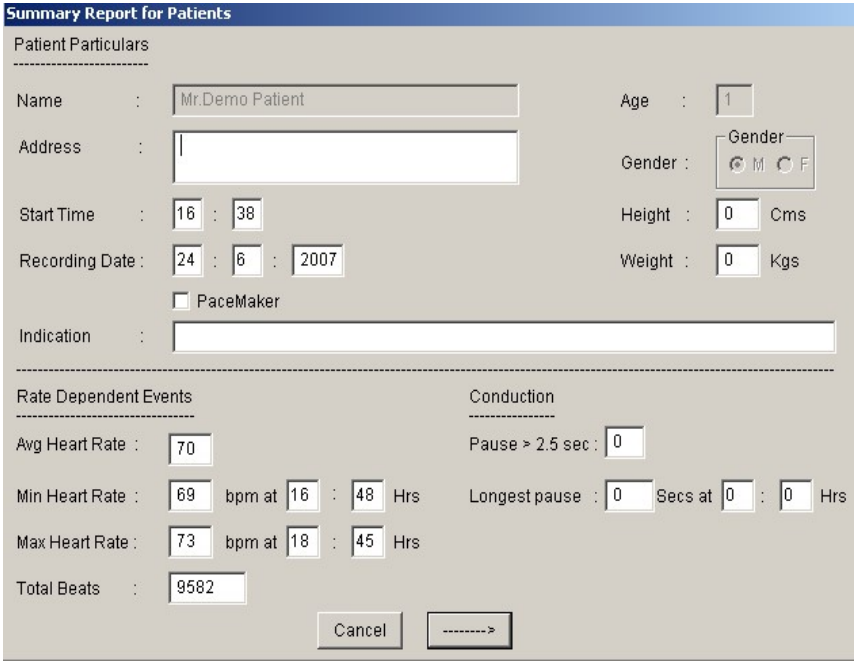


Fig: 7.2 - Summary report (Part 1).

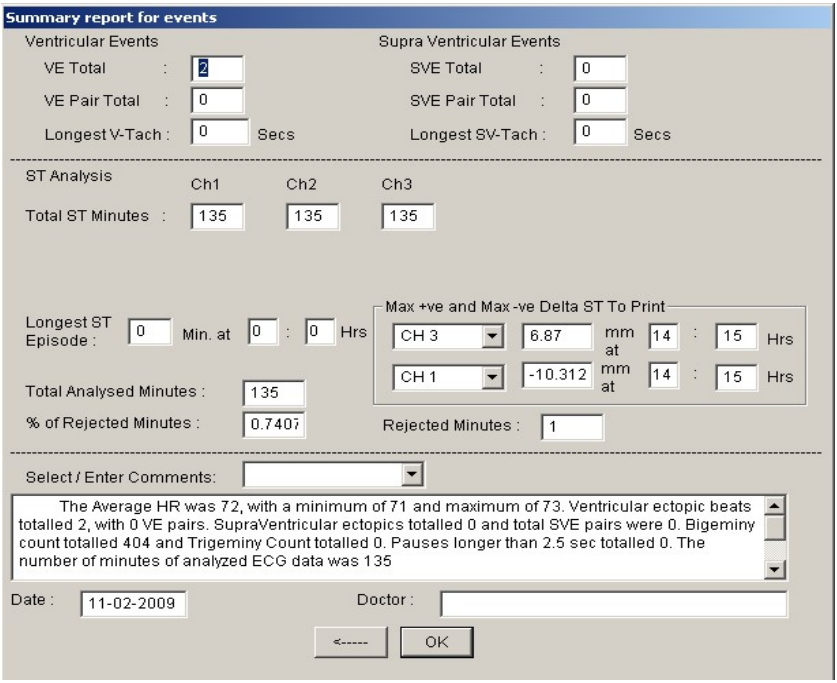


Fig: 7.3 - Summary report (Part 2).

It contains the summary of the test. You can modify or make changes in the report if required. To print max +ve and –ve delta ST of required channel, select the channel from combo box. The selected channel's max +ve and –ve delta ST details are displayed in comment edit box. The Doctor can enter his

comments or insert the standard comments from the comments dialog box. Press ok to save changes.
If entered comment length was more than assigned length in summary report then following message box will be displayed.

7.a.4 Marked pages list: To view the marked page list select "**Marked pages list**" from "**Edit**" menu. The dialog box as shown in the Fig 7.4 is displayed.

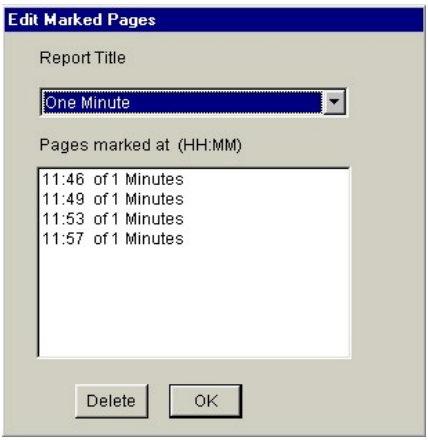


Fig: 7.4 - Marked pages list.

Select the report title from the list; all marked pages of selected report are displayed. If the user wants to delete any

of the marked pages, select the time of the page you want to delete and press the "**Delete**" button.

7.a.5 Marked noisy data: To delete the marked noisy data, select "**Marked noisy data**" from "**Edit**" menu. The dialog box as shown in the Fig 7.5 is displayed.

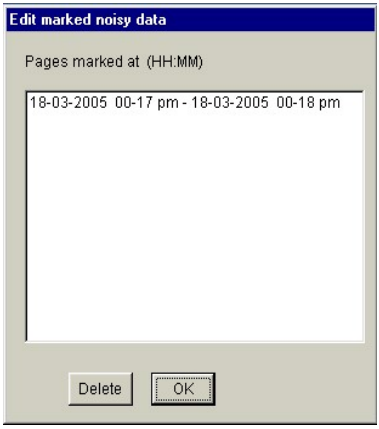


Fig. 7.5: Edit marked noisy data.

If the user wants to delete any of the marked noisy periods in review, select the required period from the list and press the "**Delete**" button. The deleted noisy period will be unmarked and all the calculations will be performed again.

7.b Printing the reports:

To print the reports, select "**Print**" option from "**File**" menu. A dialog box as shown in the 7.6 will be displayed.

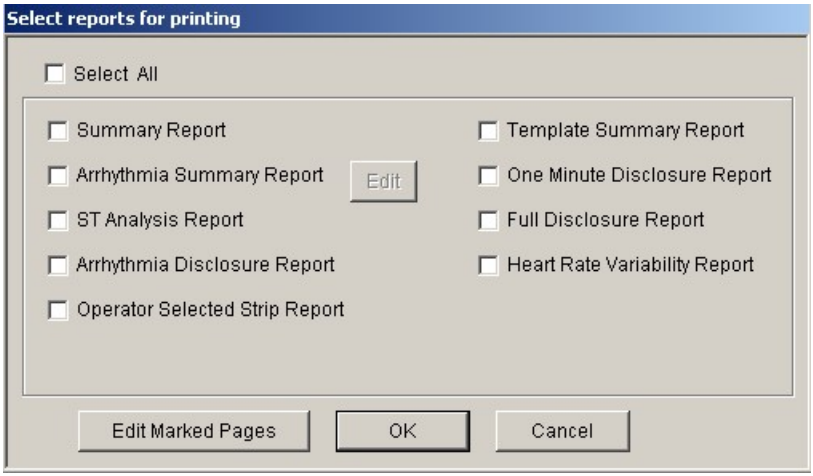
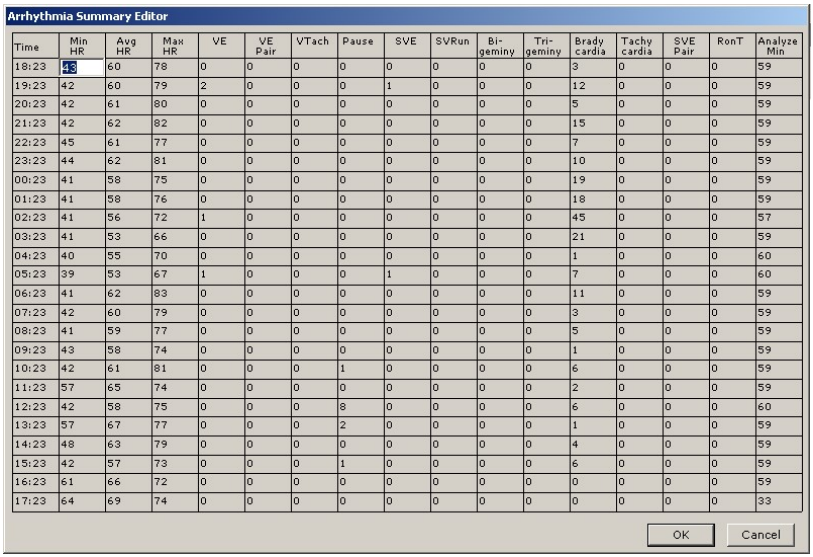


Fig: 7.6 - Select report for printing.

The functionality on the dialog box is as explained below:

Select all: When this option is checked, all the reports are selected for printing. If pages are not marked for any of the disclosures report, then those reports are not selected for printing.

7.b.1 Edit: The edit option is for editing the values in arrhythmia summary report. When clicked on this option a dialog box as shown in fig 7.7 is displayed.



Time	Min HR	Avg HR	Max HR	VE	VE Pair	VTach	Pause	SVE	SVRun	Bi-geminy	Tri-geminy	Brady cardia	Tachy cardia	SVE Pair	RonT	Analyze Min
18:23	43	60	78	0	0	0	0	0	0	0	0	3	0	0	0	59
19:23	42	60	79	2	0	0	0	1	0	0	0	12	0	0	0	59
20:23	42	61	80	0	0	0	0	0	0	0	0	5	0	0	0	59
21:23	42	62	82	0	0	0	0	0	0	0	0	15	0	0	0	59
22:23	45	61	77	0	0	0	0	0	0	0	0	7	0	0	0	59
23:23	44	62	81	0	0	0	0	0	0	0	0	10	0	0	0	59
00:23	41	58	75	0	0	0	0	0	0	0	0	19	0	0	0	59
01:23	41	58	76	0	0	0	0	0	0	0	0	18	0	0	0	59
02:23	41	56	72	1	0	0	0	0	0	0	0	45	0	0	0	57
03:23	41	53	66	0	0	0	0	0	0	0	0	21	0	0	0	59
04:23	40	55	70	0	0	0	0	0	0	0	0	1	0	0	0	60
05:23	39	53	67	1	0	0	0	1	0	0	0	7	0	0	0	60
06:23	41	62	83	0	0	0	0	0	0	0	0	11	0	0	0	59
07:23	42	60	79	0	0	0	0	0	0	0	0	3	0	0	0	59
08:23	41	59	77	0	0	0	0	0	0	0	0	5	0	0	0	59
09:23	43	58	74	0	0	0	0	0	0	0	0	1	0	0	0	59
10:23	42	61	81	0	0	0	1	0	0	0	0	6	0	0	0	59
11:23	57	65	74	0	0	0	0	0	0	0	0	2	0	0	0	59
12:23	42	58	75	0	0	0	8	0	0	0	0	6	0	0	0	60
13:23	57	67	77	0	0	0	2	0	0	0	0	1	0	0	0	59
14:23	48	63	79	0	0	0	0	0	0	0	0	4	0	0	0	59
15:23	42	57	73	0	0	0	1	0	0	0	0	6	0	0	0	59
16:23	61	66	72	0	0	0	0	0	0	0	0	0	0	0	0	59
17:23	64	69	74	0	0	0	0	0	0	0	0	0	0	0	0	33

Fig. 7.7: Arrhythmia summary editor.

To edit any of the value, click on the required cell. The selected cell value can be edited. Press the "OK" button to save the changes. These edited values will be printed in the report. This button is enabled only if the report is selected for printing.

7.b.2 Edit marked pages: This has the functionality same as that explained in section 7.a.3.

7.c Copy file for backup.

To copy the data of patient being reviewed for backup, click on the "Save test for backup" option from File menu. This option is enabled only if a test is opened for review. Refer fig 7.8

Fig. 7.8: Save test for backup.

When this option is selected a dialog box to select the location for backup is displayed as shown in fig. 7.9.

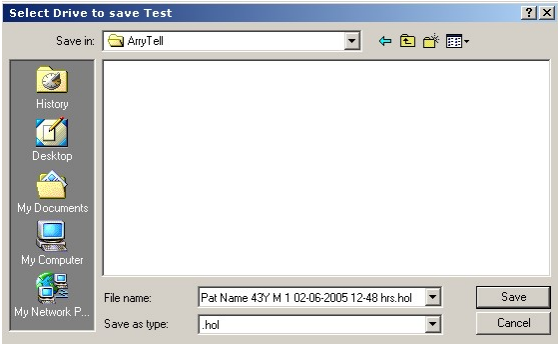


Fig. 7.9: Select drive to save test.

Select the location of your choice and press "Save" button. The current test, which is being reviewed, will be saved on the selected location.

7.d Review saved test.

To review the test that is stored in some other location for backup select the "Review saved test" option from File menu.

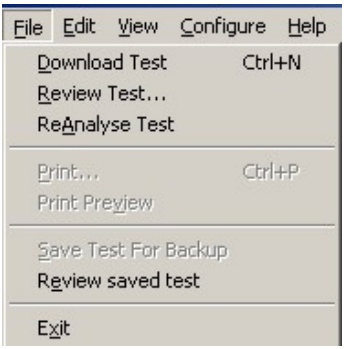


Fig. 7.10: Review saved test.

When this option is selected, a dialog box to open the file for review is displayed as shown in fig. 7.11.

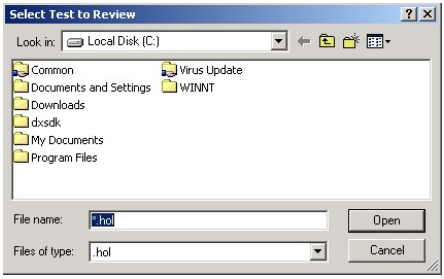


Fig. 7.11: Select test to Review.

Select the file from the required location and press "Open" button. The file will be available for review.

7.e View HRV Report

To view the HRV report selects the "HRV report" option from the View menu.

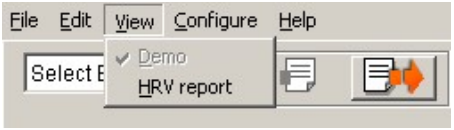
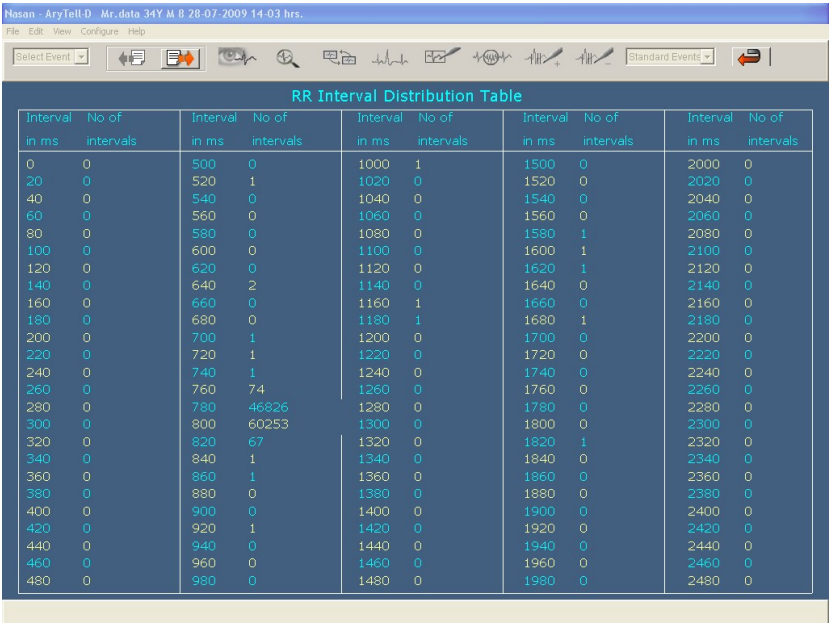


Fig. 7.12: View HRV report.

The "RR interval distribution table will be displayed as shown in the fig. 7.13



Interval in ms	No of intervals	Interval in ms	No of intervals	Interval in ms	No of intervals	Interval in ms	No of intervals	Interval in ms	No of intervals
0	0	500	0	1000	1	1500	0	2000	0
20	0	520	1	1020	0	1520	0	2020	0
40	0	540	0	1040	0	1540	0	2040	0
60	0	560	0	1060	0	1560	0	2060	0
80	0	580	0	1080	0	1580	1	2080	0
100	0	600	0	1100	0	1600	1	2100	0
120	0	620	0	1120	0	1620	1	2120	0
140	0	640	2	1140	0	1640	0	2140	0
160	0	660	0	1160	1	1660	0	2160	0
180	0	680	0	1180	1	1680	1	2180	0
200	0	700	1	1200	0	1700	0	2200	0
220	0	720	1	1220	0	1720	0	2220	0
240	0	740	1	1240	0	1740	0	2240	0
260	0	760	74	1260	0	1760	0	2260	0
280	0	780	46826	1280	0	1780	0	2280	0
300	0	800	60253	1300	0	1800	0	2300	0
320	0	820	67	1320	0	1820	1	2320	0
340	0	840	1	1340	0	1840	0	2340	0
360	0	860	1	1360	0	1860	0	2360	0
380	0	880	0	1380	0	1880	0	2380	0
400	0	900	0	1400	0	1900	0	2400	0
420	0	920	1	1420	0	1920	0	2420	0
440	0	940	0	1440	0	1940	0	2440	0
460	0	960	0	1460	0	1960	0	2460	0
480	0	980	0	1480	0	1980	0	2480	0

Fig. 7.13: RR interval distribution table.

Press the "**view Next Trend Page**" button then the RR interval distribution histogram will be displayed as shown in the fig. 7.14.

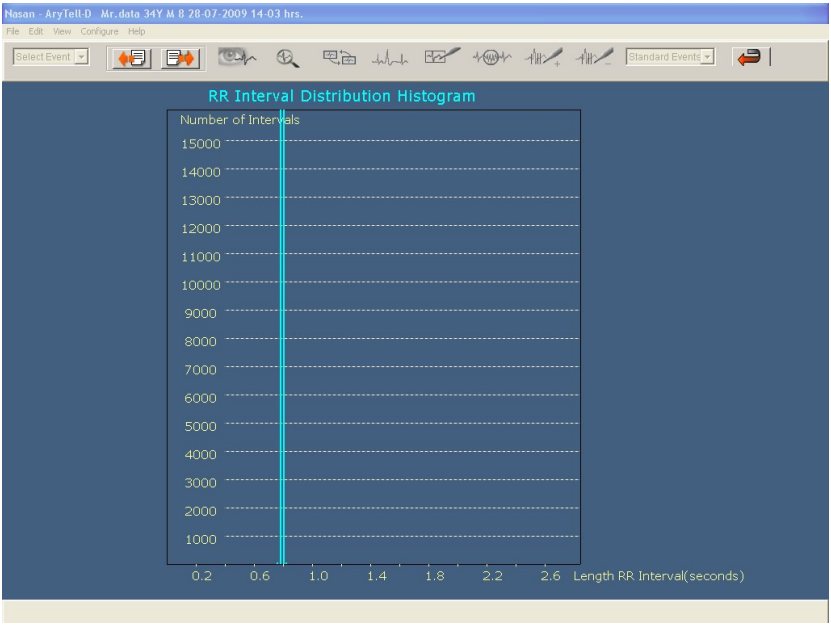


Fig. 7.14: RR interval distribution histogram.

Press the "**view Next Trend Page**" button then the Heart Rate Variability Indices table will be displayed as shown in the fig. 7.15.

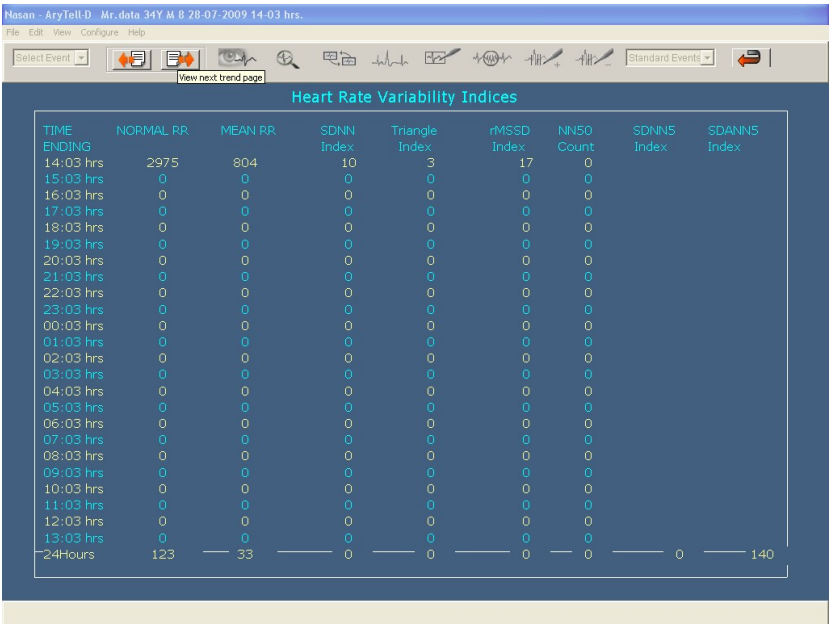


Fig. 7.15: Heart Rate Variability Indices Table.

Press the "**view Next Trend Page**" button then the Poincare Graph and the Normal RR histogram will be displayed as shown in the fig. 7.16.

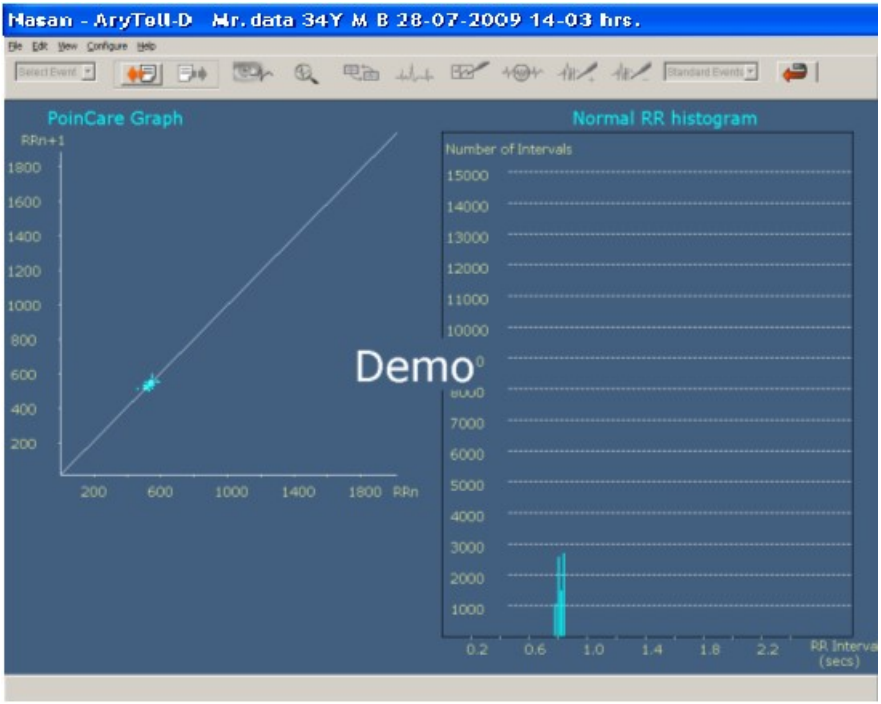


Fig. 7.16: Poincare Graph and Normal

8. Unit initialization/Installation

First install Arytell-D software. Refer Reveala USB driver installation procedure from Utility folder in CD,OR Refer 'Driver installation' in manual if drivers are not installed.

NOTE: Kindly do not forget to download the data before connecting the holter unit to new patient.

NOTE: Check Slide switch position while recording or downloading the data, for recording it should be at REC side, for downloading it should be at USB side, OFF position when not in Use

NOTE : Use new battery (Duracell MN1500 or equivalent, Alkaline batteries of AA size) for every new test.

Following are the steps for initializing ARYREC unit and recording patient test:

1. Initially make sure that ARYRAC unit is switch off.

2. Use 2 AA size Duracell for ARYRAC. Insert batteries in batteries compartment as per polarity indicated and put the battery cover.
3. Prepare the patient and connect patient cable to patient as shown in 'Fig 8.1 Electrodes placement'.
4. Select "Rec" mode by using the slide switch.
5. The green (Recording status) LED on front will glow. Buzzer will sound.
6. Press "Start key". Buzzer will give beep sound. Memory Full (Red) LED will glow and previously stored data will start erasing. At that time Green LED will remain glow.
7. After about 5 to10 sec, buzzer will give beep sound and recording will start. This will be indicated by blinking of Recording status (Green) LED and Memory Full (Red) LED will become off.
8. Press 'Event Mark' key, the patient marks the event when he is feeling uneasy. These events can be seen in the review. "**Select event**" drop down box contains the event marked by the patient. Select the event to be viewed from the drop down box. The event is marked as a red vertical line on the ECG.
9. After 24 hrs. Of recording, Buzzer will give two beeps. Recording status (Green) LED will stop blinking. Memory Full (Red) LED will glow continuously indicating recording is over.

10. Keep the slide switch at OFF position when recording and downloading of data is complete.
11. When any one of the lead from patient body get displaced the 'LEADS OFF' LED will glow with buzzer sound, check lead cable for any loose connection and press Event button on the unit.

INDICATIONS:

1. '**Batt Low' (YELLOW):** When this is indicated, battery should be replaced.

Note: Use new battery (Duracell MN1500 or equivalent, Alkaline batteries of AA size) for every new test.

2. **Leads Off (RED):** When this is indicated, meaning one or more than one leads are displaced from the patient's body.
3. **Recoding status (GREEN):** This LED will start blinking when recording start and when data is getting download.
4. **Memory Full (RED):** This LED will glow continuously indicating that data download is complete and previously stored data will start erasing

Steps for Data downloading through unit:

1. Remove batteries from the unit.
2. Connect download cable to PC and Holter unit.
3. Select USB mode by using the slide switch.
4. Recording Status (Green) LED will glow continuously.
5. Run ARYTELL-D software.
6. Connect hardware lock to USB port of PC.
7. Select download option.

8. Do not execute other program during downloading the data.
9. If download error occurs, following dialog box will display.

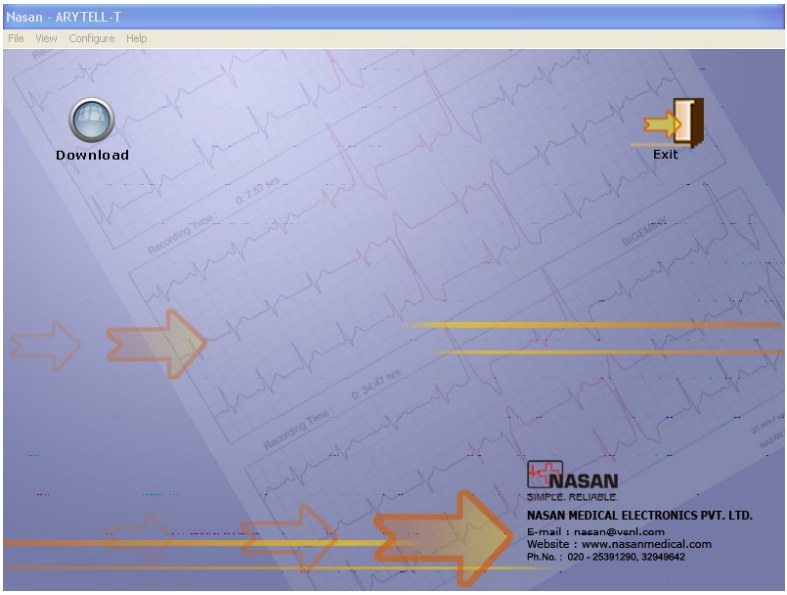
Fig. 8.1

Click on **'Ok'** button. Default download speed will be **'High Speed'** so select **'Low Speed'** from the **'Configure'** menu and click 'Apply' and 'OK' button. Again select download option.

10. Enter patient details and press OK.
11. After about 2 sec, "Aryrec unit found" message will be displayed. Press OK.
12. Recording status (Green LED) will start blinking, indicating data is getting download.
13. After about 10 to 15 minutes data download will get complete if low speed option is selected.
14. "Data has been downloaded successfully" message will appear on PC screen. Buzzer will sound two beeps. Recording Status (Green) LED will stop blinking, it will become off. Memory Full (Red) LED will glow continuously indicating data download is over.

Steps for Data downloading into pen drive:

1. Remove batteries from the unit.
2. Connect download cable between USB port of PC and Holter unit.
3. Connect Pen drive to another USB port of PC.
4. Select USB mode by using the slide switch.
5. (Recording status) (Green) LED will glow continuously.
6. Run ARYTELL-T software. Idle screen will be displayed as shown below.



Select download option. Patient details dialog box will be displayed as shown below.

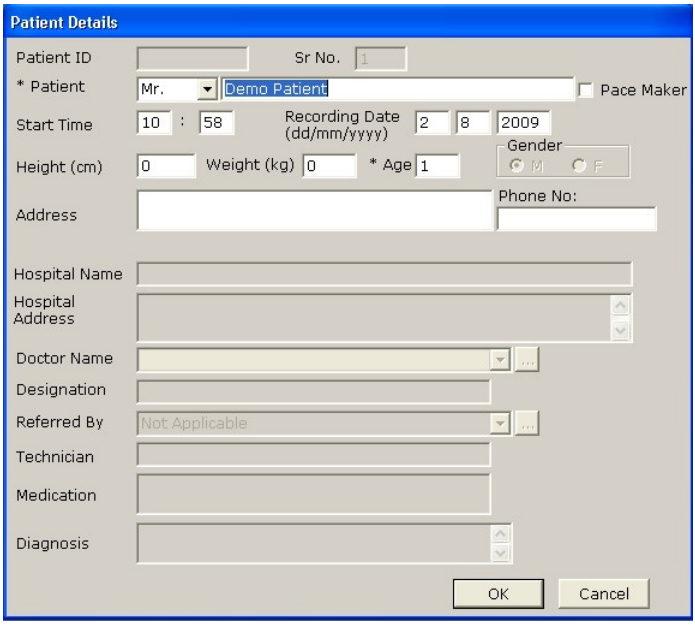


Fig-1

Enter the patient details. Hospital details and doctor details are disabled.

After entering the details press "**OK**" button. 'Save as' dialog box as shown in fig-2 will be displayed. Select the location of pen drive and click on 'save' button.

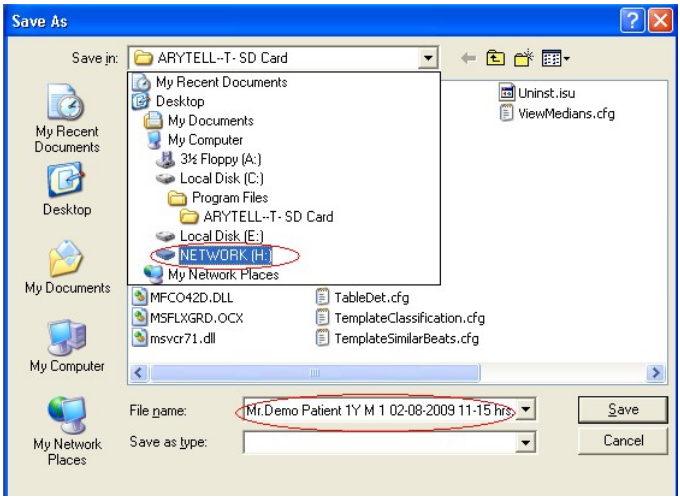
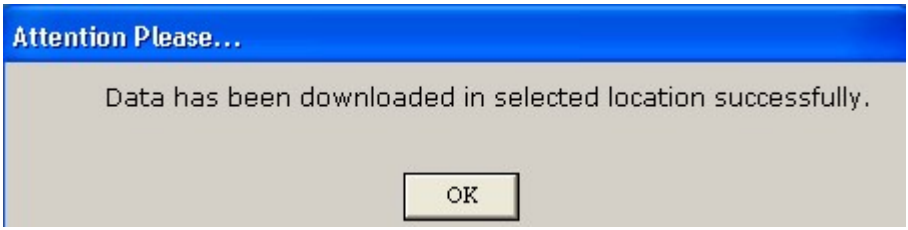


Fig-2

A progress bar along with the message, "**Please Wait...**" will appear on the screen.

After about 2 sec, following message box will be displayed.

After 5 to 7 min. data will be downloaded in Pen drive/ or at selected location and following message will be displayed.

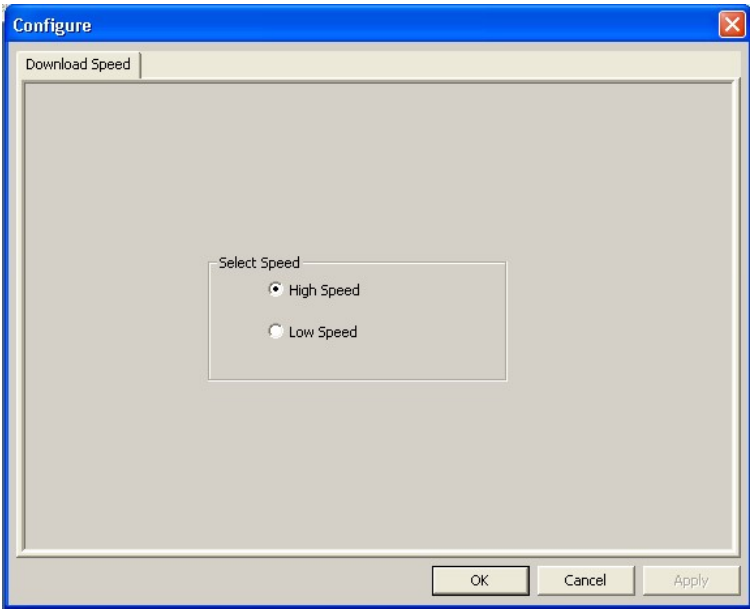


Click ok button. Idle screen will be displayed.

If download error occurs, following dialog box will display.

Fig. A

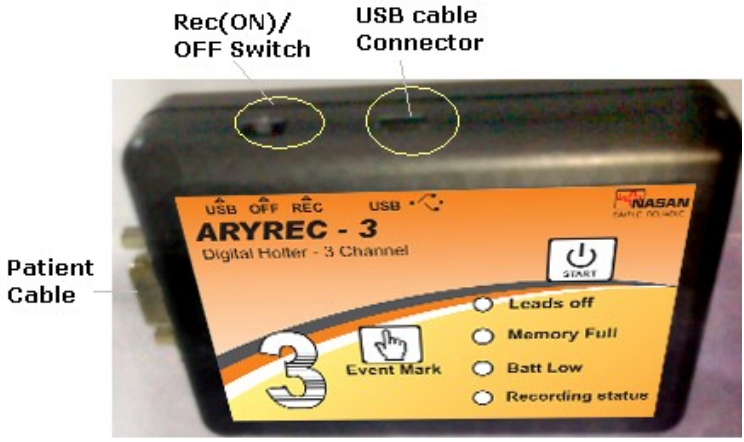
Click on **'Ok'** button. Default download speed will be **'High Speed'** so select **'Low Speed'** from the **'Configure'** menu as shown below and click 'Apply' and 'OK' button.



Again select download option and repeat download procedure.

7. Click ‘Ok’ button and exit from ARYTELL-T software.
8. Switch OFF the unit.

Aryrec 3 with keyboard unit photo-

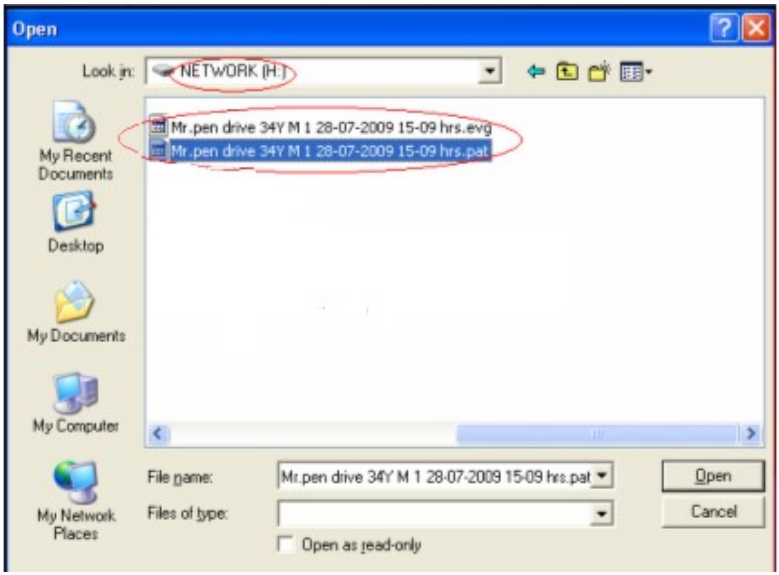


USB Data Cable

Patient Cable:

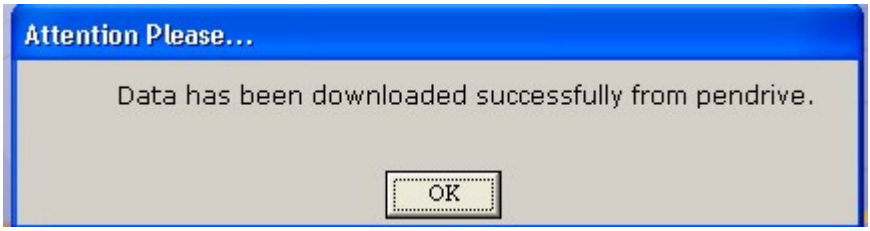
Steps for Data downloading from pen drive:

9. Connect Pen drive to PC.
10. Now connect hardware lock to PC.
11. Run ARYTELL-D software.
12. Select 'Download from Pen drive' option.
13. A dialog box as shown below will be displayed then select the connected pen drive location.



14. Select ".evg" or ".pat" any one file. Click on 'open' button.
15. Patient details dialog box as shown in fig.4.5 will be displayed. Enter the doctor details & hospital details and click 'Ok' button.

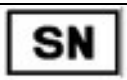
16. After 12 to 15 seconds following message will be displayed and data will be downloaded from Pen drive.



17. Click 'ok' button to view downloaded

9. Appendix A

a. SYMBOL Description

Symbol	Description
 CAUTIONS:	Cautions indicate conditions which may damage or malfunction of the device.
WARNINGS:	Warnings indicate a potential harmful condition that can possibly lead to injury or death.
Note:	Note: Alert the user to pertinent fact and conditions.
Mfg .Lic.No	Manufacturing license number
	Manufacturer symbol,
	Medical Device
	Type CF applied part
	Serial number
	Keep dry

	Dispose of in accordance with the requirements of your state
	Instruction for use
	Medical device that has not been subjected to a sterilization process.

b. Patient preparation.

- Proper patient preparation is the most important factor in obtaining proper results from a system. If electrodes are applied to improperly prepared skin site then this may result in excessive base line shift and severe artifact while obtaining an ECG.

- Apply some jelly to the electrode site and thoroughly rub the site with gauze till it becomes slightly red. This removes the horny non-conducting layer of the epidermis enabling a good electric contact with the body fluids.

- Remove all the traces of jelly by wiping the abraded site with warm dry cloth and completely dry up the site with dry towel. The skin must be clean, dry and completely free of jelly for the electrodes to remain well in position till the end of ECG acquisition.

- Take an electrode and peel it of from its plastic backing. Finger contact with the adhesive should be minimized and

jell in the foam pad should not be disturbed. If the jell has dried out then discard the electrode.

- Apply the electrode to the prepared site and run your fingers around the foam pad smoothing it from the center out. Repeat this procedure for all sites.

NOTE-

We recommend the use of good quality disposable electrode (With one time usage only).

No assurance of quality result can be given if reusable electrodes are used.

c. Electrodes placement:

Right **left**

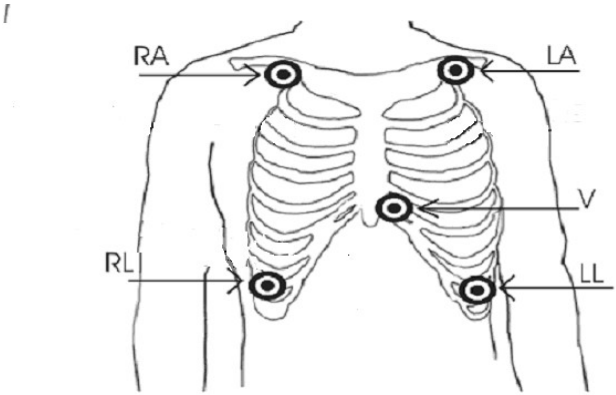
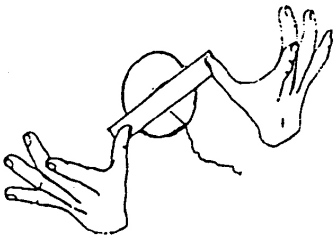


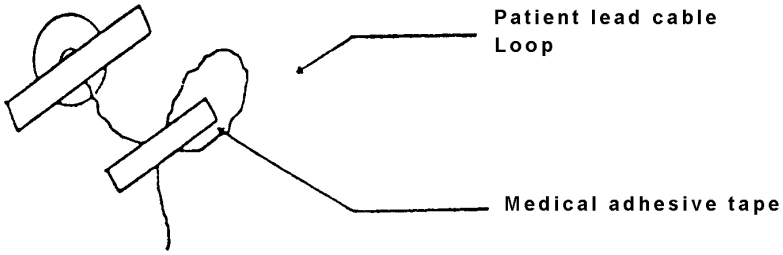
Fig: 8.1 Electrodes Placement.

Place electrode one by one on selected sites. Press the electrodes from inside to outside covering entire electrode area.

Take care that gelled pad is in firm contact with the skin surface. Place patient lead on all electrodes as per colour code.

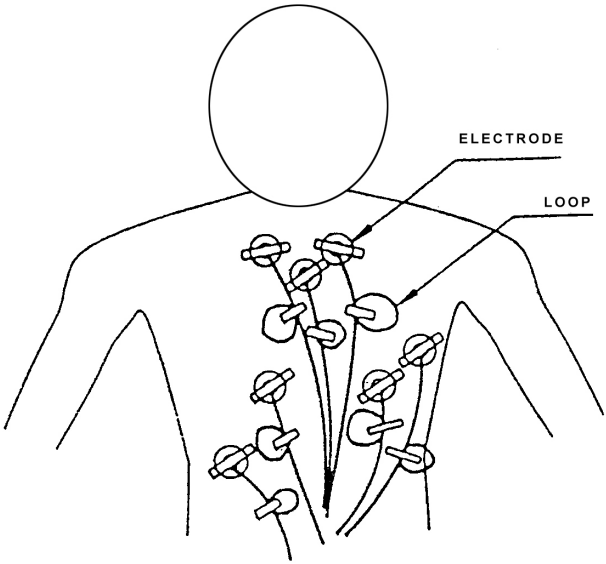
Apply Medical adhesive tape (dressing tape/ bandage tape) across the electrode.





Form loop of patient cable and apply Medical Adhesive tape (dressing tape/ Bandage tape) to avoid stress on electrodes during usage.

Use of vest (stretchable, antistatic) is advisable to avoid patient leads getting detached from electrodes.


ELECTRODE
LOOP

d. Specifications

1. Environmental

Operating Temp : -5 to +50 ºC

Operating & Storage Humidity : 0 to 95 % non-condensing

2. Dimension and Weight

Dimension : 104 X 74 X 25 mm (LXBXH)

Weight : 180 gm with battery

3. Power supply

Battery : Duracell MN1500 or equivalent, Alkaline batteries of AA size

Back up time : 24hrs

4. Performance

Language : English

PC interface : USB

Storage medium : In built SD card

Data Download rate : USB @ 3MBPS

Visual Indications : Through LED for Bat Low, Memory Full, Recording, Leads Off

Audio indications : Beep Buzzer-
Record start & end
: Alarm Buzzer -
Leads off
Switch : keys- Start,
Event mark
Slide switch-
USB (download)/OFF/ ON (Rec)

5. Acquisition

Frequency response : 0.5 Hz to 35 Hz
Filter : DSP
Input impedance : 10 M ohm
Time constant : > 1.6 sec
A/D conversion : 8 bit
Noise : < 20μV_{p-p}
Leakage current : < 10 µA
Gain : 5, 10 & 20
mm/mV selectable.
CMRR : > 120 dB
Accuracy : +/- 1 bit
Sampling Frequency : 100 samples per
second simultaneous
Data acquisition : Simultaneous
recording of 3 channels for 24hrs

Printouts : Printing of marked report with grid On/off facility,

Print colour reports.

Detailed features

1. Download

a. Facility to download 3 lead ECG data recorded in SD card @100 samples/ second to PC using data down load cable.
b. Arytell-D software is used to download three channels ECG data from pen drive
c. Arytell-T software is used to store three channels ECG data of 24 hours in to pen drive.

2. Full disclosure

a. Default display of 10 min disclosure of Ch 1 in 3 Channel
b. Configurable Disclosure time of 10, 20, 30, 60 Min.
c. Selection of any of the channels for disclosure.
d. Editable page start time for full disclosure.
e. Facility to view next / previous ECG page for the selected disclosure time with Left-Right arrow keys with horizontal scroll bar

f. Mark page for printing
g. Facility to zoom selected minute ECG.

3. One minute disclosure

a. Selection of any of the channels for disclosure
b. View next / previous 1 min. ECG page with Left-Right arrow keys or horizontal scroll bar
c. Mark page for printing.
d. Facility to enter comments (up to 70 chars).
e. Grid or Graph on / off.
f. Mark noise facility (before and after classification).
g. Select start beat and channel for classification.
h. Mark noise

4. Start beat and channel selection for analysis

a. Display of 8 sec ECG data in 3-channel model for all channels.
b. Detection of Normal beat automatically / manually. Automatically selected beat displayed in red color
c. Selection of any of the channels for analysis.
d. Gain Increment / Decrement
e. View next / previous 8 sec ECG data for 3 channels with Left-Right arrow keys or horizontal scroll bar
f. Facility to invert channel

5. Classification

a. Display of continuous Heart rate trend during Classification
b. Facility to view 15 templates at a time

c. View next / previous 15 templates with Left-Right arrow keys or horizontal scroll bar
d. Facility to rename the selected template
e. Edit templates during Classification
f. Analyze data to detect arrhythmias and display trends

6. Edit Template

a. Facility to display 28 similar beats in a template at a time on the screen.
b. View 8 sec of 3 channel data of all beats one at a time in selected template.
c. Facility to edit Labels of selected beats in template
d. View next / previous 28 beats with Left-Right arrow keys or horizontal scroll bar

7. Review Screens

a. Facility to select patient from patient list.
b. Review screen displays 24 hour trends of following parameters
    i. HR
    ii. VE
    iii. V-Tach
    iv. SVE
    v. SVE-Tach
    vi. ST Levels of 3 channels
    vii. Bigeminy
    viii. Trigeminy
    ix. Bradycardia
    x. Tachycardia
c. Following parameters are displayed on review screen
    i. Min HR bpm with time.
    ii. Max HR bpm with time.

iii. Longest Pause duration with time.
iv. Longest Vtach duration with time.
v. Longest SVTach duration with time.
vi. Longest STEpisode duration with time.
vii. Max Delta ST (+/-) in mm for channel with time.

d. View one minute disclosure of selected events
e. View one minute disclosure of standard events
f. View medians and edit fiducial points
g. View Arrhythmias
h. View ECG of any minute
i. View following HRV reports
   i. RR interval distribution table
   ii. RR interval distribution histogram
   iii. Heart rate variability indices
   iv. PoinCare graph
   v. Normal RR histogram

8. Review mode utilities

a. Editable marked page list.
b. Unmark the marked noisy data in review.
c. Editable patient details
d. Editable summary report
e. Editable arrhythmia summary report
f. Select reports for printing
g. Save & retrieve saved test from backup

9. Reports

a. Facility to navigate through pages, zoom-in and out in a page in Print preview

b. Arrhythmia disclosure report
    i. 8 sec of ECG strip of all channels with arrhythmia in center and in different color (if selected).
    ii. Arrhythmia label
c. Arrhythmia summary report
    i. 24 hrs details at the interval of 1 hr. of Min HR, Max HR, Avg HR, VE, VE Pair, Vtach, Pause, R On T, SVE, SVE Pair, SV Run, Bigeminy, Trigeminy, Bradycardia, Tachycardia, Total analyzed minutes
    ii. Trends for 24 hrs of HR, VE/Min, VTACH, SVE/Min, SVRun, Bigeminy, Trigeminy, Bradycardia, Tachycardia, Pauses, VE Pair
d. One minute disclosure report
    i. 1 min ECG data of the given Channel No starting from Report date and time with arrhythmia in different color (if selected and if exists) along with event marks (if selected and if exists).
e. Full disclosure report
    i. 10, 20, 30, 60 minute disclosure
    ii. 10 / 20 / 30 / 60 min ECG data of the given Channel.
    iii. Arrhythmia printed in different color if selected
    iv. Event marks is selected.
f. Template summary report
    i. Template label
    ii. 2 sec ECG data of each template with total number of

templates and total number of beats in template

g. ST-Analysis report
    i. ST reference beats of all channels with E, J and Post J points
    ii. Following information about ST levels
        1. Total ischemic time
        2. Number of episodes between 1 – 2 min, 2 – 5 min, Above 5 min
        3. Severity in mm between 1.0 – 1.9, 2.0 – 2.9, Above 3.0
    iii. Trends of ST levels of all channels for 24 hrs
h. Summary report
i. HRV report
    i. Normal RR interval distribution table
    ii. Normal RR interval distribution histogram
    iii. HR variability table
    iv. PoinCare Graph

10.Settings

a. Hospital details
b. Referring Doctor list
c. Printing details configuration
d. Prematurity of SVE
e. Arrhythmia labels
f. Standard comments
g. Pause time
h. Download speed

*Due to our continuous product improvement programme, features can be enhanced.

e. **Supplies and Accessories: List of Accessories**

NOTE: Do not store any consumables after its expiry date.

Sr. No.	Material Name	Qty.	
1.	Patient Cable 5 Lead	1	Detachable
2.	Pencil Alkaline Duracell make, AA size	2	Detachable
3.	USB cable B type mini to A type,M to M,1.5 meter length	1	Detachable
4.	Manual	1	-
5.	carrying bag	1	Detachable
6.	Holter unit	1	-

f. Maintenance

Material name	Recommended frequency	Maintenance details reference
Holter Machine	weekly	Refer Point 3 Cleaning Instruction
Reusable Patient cable	After each patient use	Refer Point 3 Cleaning Instruction

g. Environmental protection

❖ Disposal of the Equipment:

Prior to disposal, remove the batteries. Then dispose of the device and supplies in accordance with your state regulations.

NOTE:

Disposal of the product: The product described in this user manual must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

h. Servicing Information

Service life of machine is 7 years.

Warning:

Authorized personnel should only open this device as there are no user serviceable parts inside.

For servicing contact an authorized NASAN Medical Electronics Pvt. Ltd. Service Engineer.

Contact us:

All INDIA SERVICE (Mobile) : 09371039255

Email address : service@nasanmedical.com

Website : www.nasanmedical.com

Appendix B

a. Defragmentation:

Defragmentation of the hard disk is a recommended job to do at least once in 3/4 months. This is because as the number of test conducted get increased doctors stats deleting the tests.

The tests are stored randomly on the hard disk. This creates delay to open any of the applications. By Defragmentation of the hard disk all the files are arranged in sequence. Thus helps in making PC faster.

Following steps can do this,

- Click '**Start'** button.
- Go to '**Program'** then '**Accessories'.**
- Go to '**System Tool'.**
- Select '**Disk Defragmentation'.**

After selecting the Defragmentation option it ask for the drive to select. Select the drive as per your requirement and click the '**OK'** button of that screen. As soon as the button is click Defragmentation starts and the dialog box as seen in the fig 10.1 below will appear on the screen.

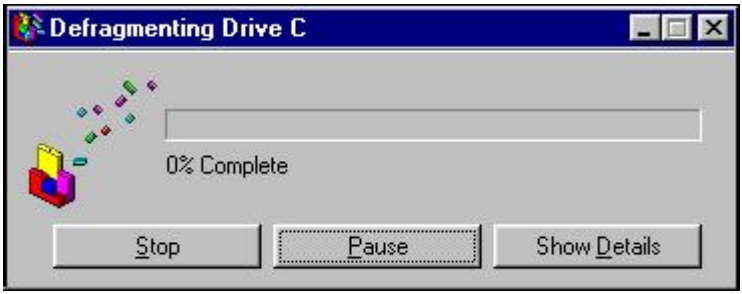


Fig: 10.1 - Defragmentation.

This will take several hours to complete as per the data stored in the Hard disk.

NOTE: - Please do not carry on any application when the Defragmentation is in process.

b. Software Installation:

NOTE:
Software link on NASAN website is https://nasanmedical.com/download-centre.html
Whenever you download the software from NASAN website, ensure that WINZIP software is installed on customer PC.
After downloading the software from NASAN website, it is in zipped folder then unzip (For unzip WINZIP software is required) it, then install the software

To install the ARYTELL Software in PC, follow the steps mentioned below:

- Open the folder '**Arytell D'** and double click the '**disk1'** icon as shown below

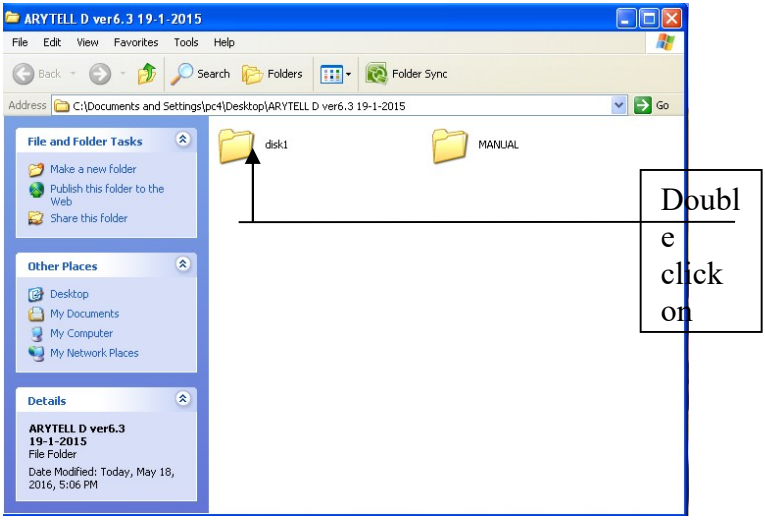
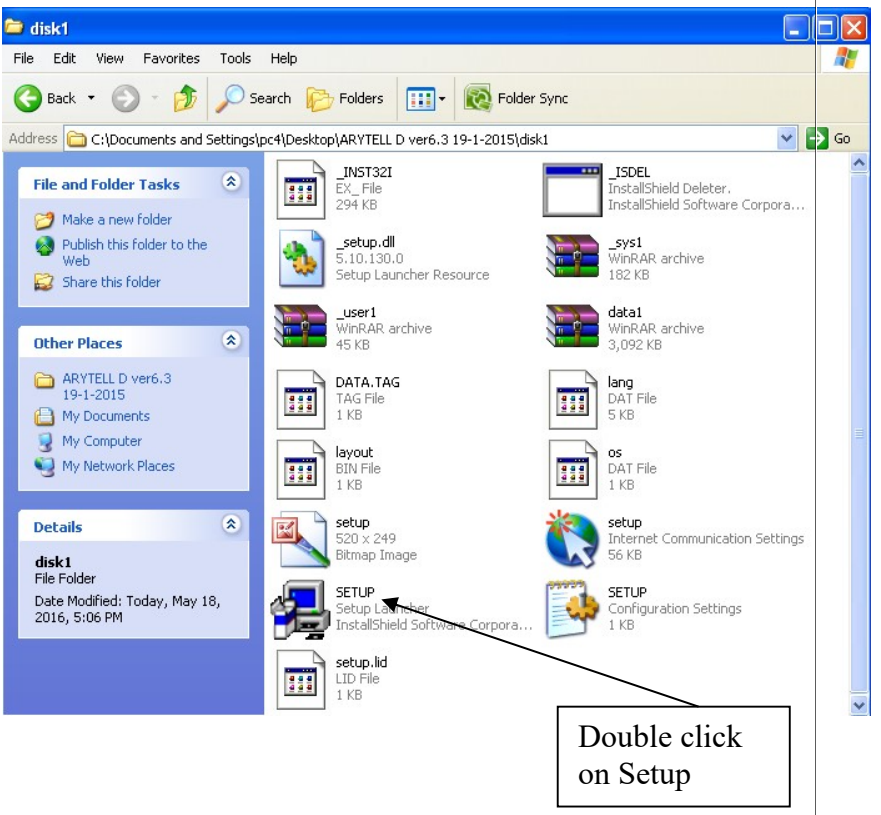


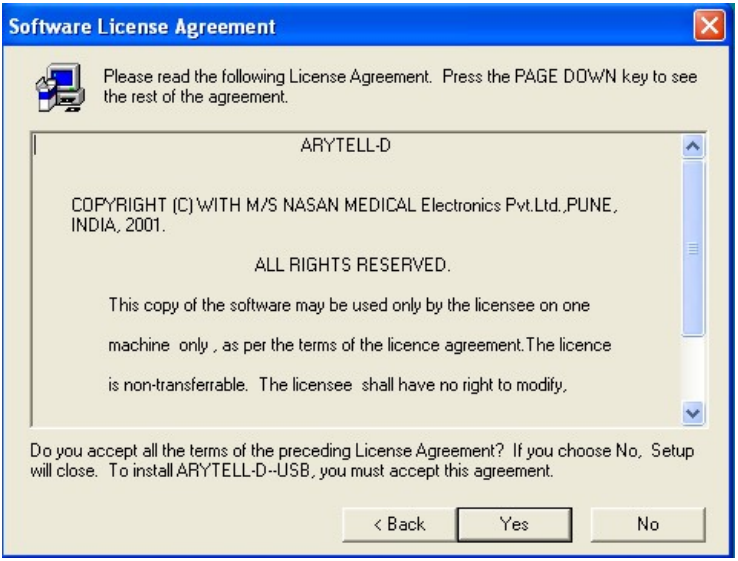
Fig 10.2: Installation setup.

- Run '**Setup.exe**' (Setup icon) and follow the installation steps.

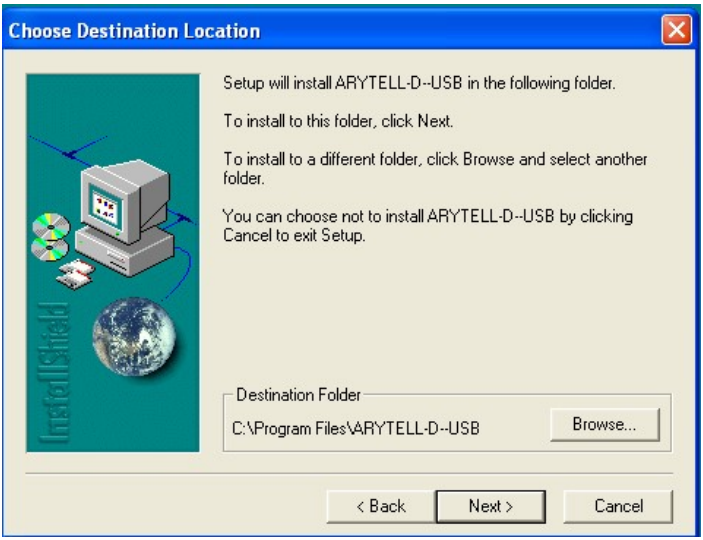


- Click 'Next'

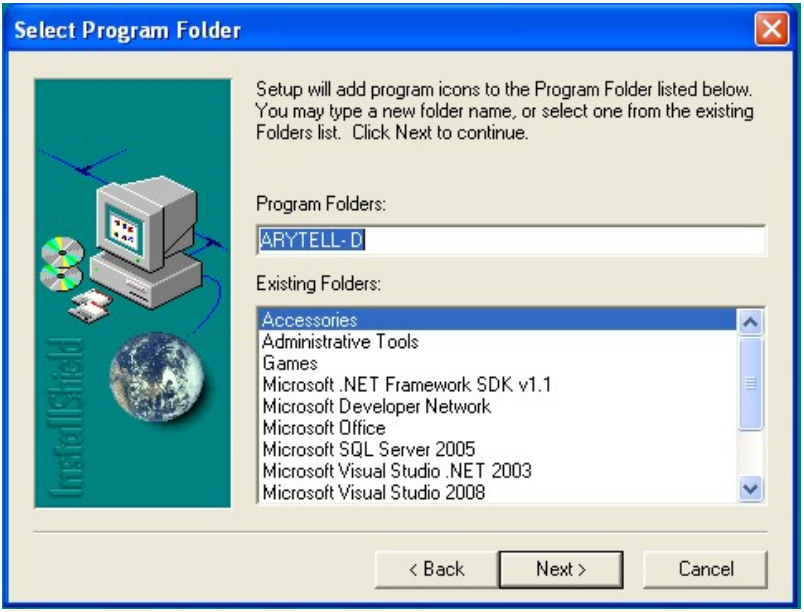
- Click 'Yes'



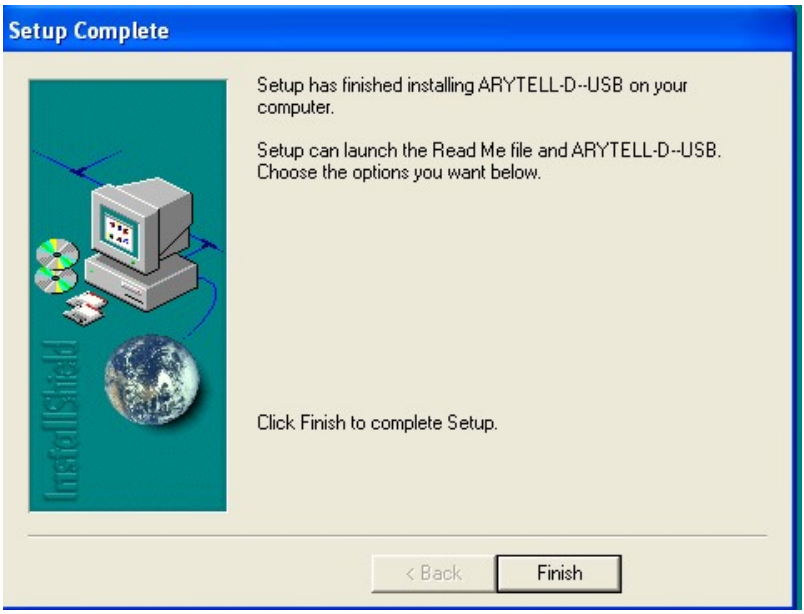
- Click 'Next'


Choose Destination Location
Setup will install ARYTELL-D--USB in the following folder.
To install to this folder, click Next.
To install to a different folder, click Browse and select another folder.
You can choose not to install ARYTELL-D--USB by clicking Cancel to exit Setup.
Destination Folder
C:\Program Files\ARYTELL-D--USB
Browse...
< Back
Next >
Cancel
InstallShield

- Click 'Next'


Select Program Folder
Setup will add program icons to the Program Folder listed below. You may type a new folder name, or select one from the existing Folders list. Click Next to continue.
Program Folders:
ARYTELL-D
Existing Folders:
Accessories
Administrative Tools
Games
Microsoft .NET Framework SDK v1.1
Microsoft Developer Network
Microsoft Office
Microsoft SQL Server 2005
Microsoft Visual Studio .NET 2003
Microsoft Visual Studio 2008
< Back
Next >
Cancel
InstallShield

- Click ‘Finish’



- A shortcut is created on the desktop

- Double click on the icon on the desktop to run the software of Arytell D

10.c Driver Installation:

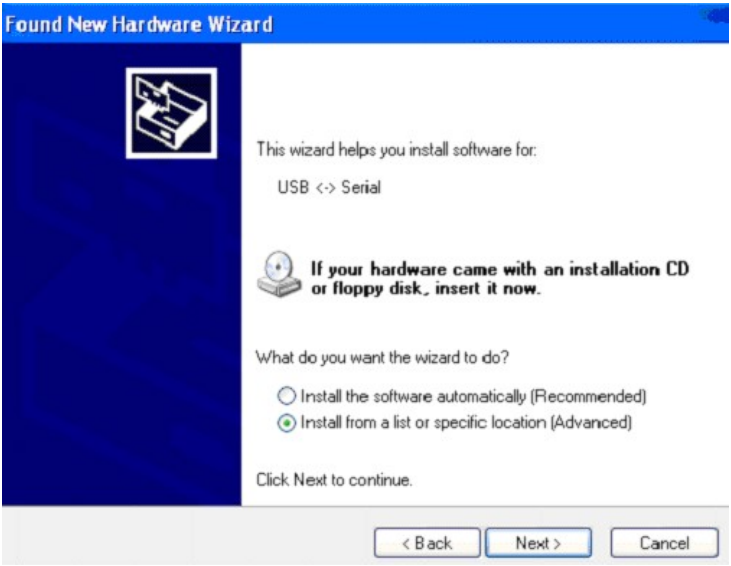
Procedure To install CDM drivers for an FTDI device under Windows XP(Driver Installation for Windows XP)

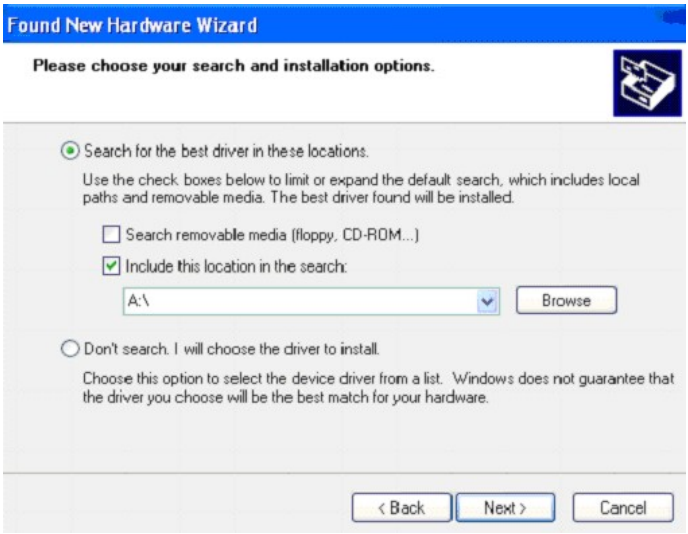
- Initially install Arytell –D software on your PC or LAPTOP.
- Connect the Arytell-D unit to USB Port of LAPTOP or PC.
- Power ON LED on the unit will glow.
- Following message will be displayed at the bottom right side corner on the

  PC screen.

- The following dialog box will be displayed on the screen.
- Follow the instruction on wizard to continue the installation


Found New Hardware Wizard
Welcome to the Found New Hardware Wizard
Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission).
Read our privacy policy
Can Windows connect to Windows Update to search for software?
Yes, this time only
Yes, now and every time I connect a device
No, not this time
Click Next to continue.
< Back
Next >
Cancel

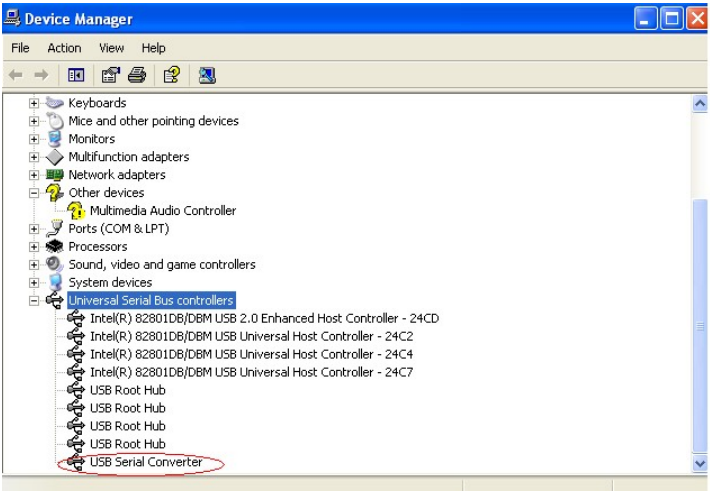

Found New Hardware Wizard
This wizard helps you install software for:
USB <-> Serial
If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel



- Click the Browse button and give the FTDI driver path **\Utility\FTDI driver for all OS OR** copy **FTDI driver for all OS to desktop or any drive** to install it on PC OR Laptop.
- Click NEXT button.

- By examining the **device manager** located in **control panel** then select the **Hardware** tab and click **device manager**. The device appears as a

"USB serial converter" as shown below. Thus driver installation is complete.



- Double click on Arytell D (latest version software) icon on the desktop. The acquisition screen will be displayed.

10.d Procedure To install CDM drivers for an FTDI device under Windows 7(

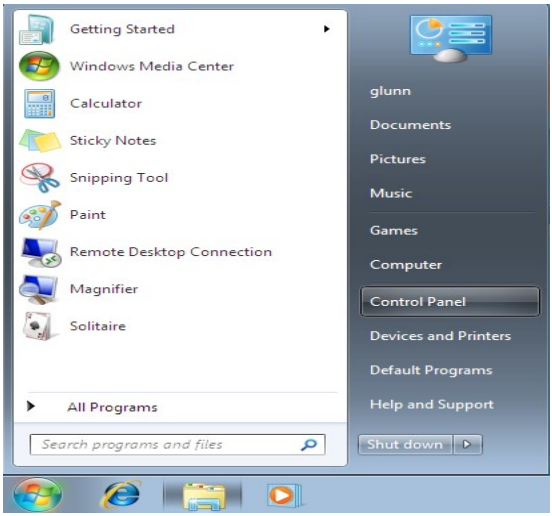
Driver Installation for Windows 7)

(Before Installing CDM drivers for an FTDI device under Windows 7, first check that win7 is 32 bit OR 64 bit{Right click to 'My computer' icon on desktop and select 'properties'} so it is easy to give path(FTDI driver) of particular folder.)

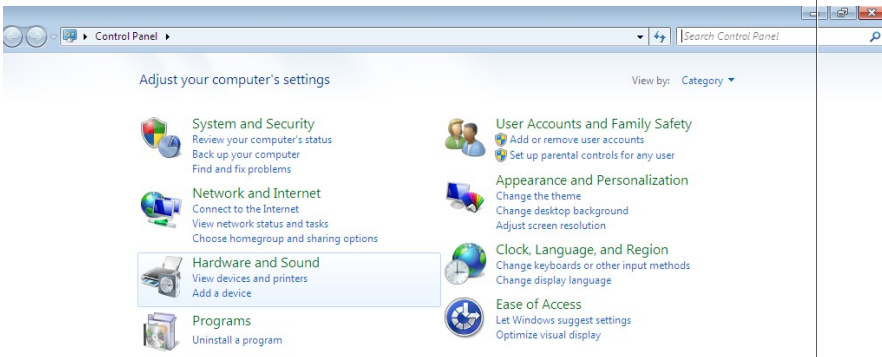
To install CDM drivers for an FTDI device under Windows 7, follow the instructions below:

Connect the device to a spare USB port on your PC.

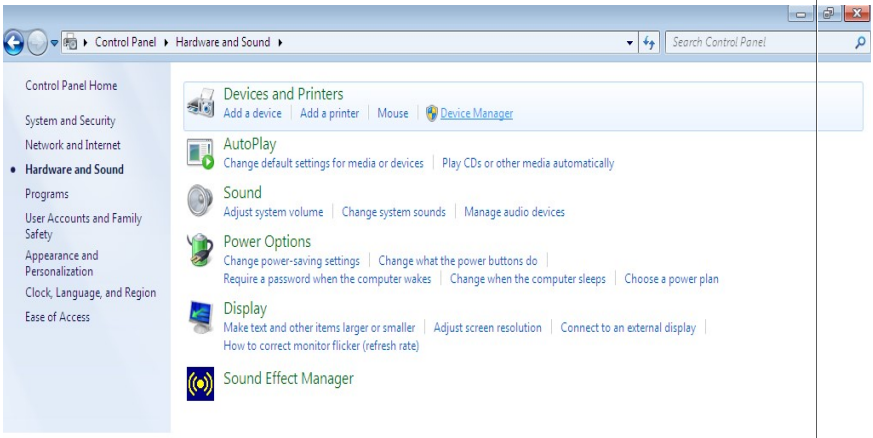
Press the Windows start button to bring up the start menu and select "Control Panel".



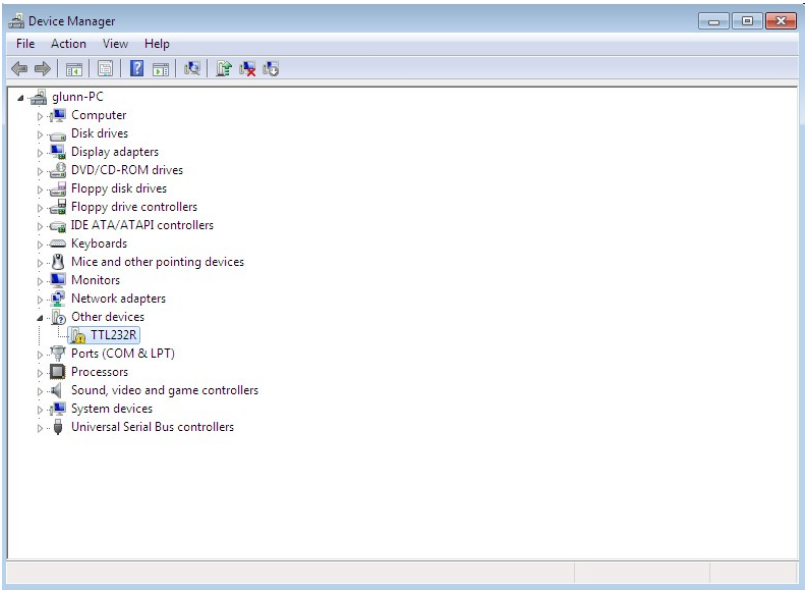
From the Control Panel window select Hardware and Sound



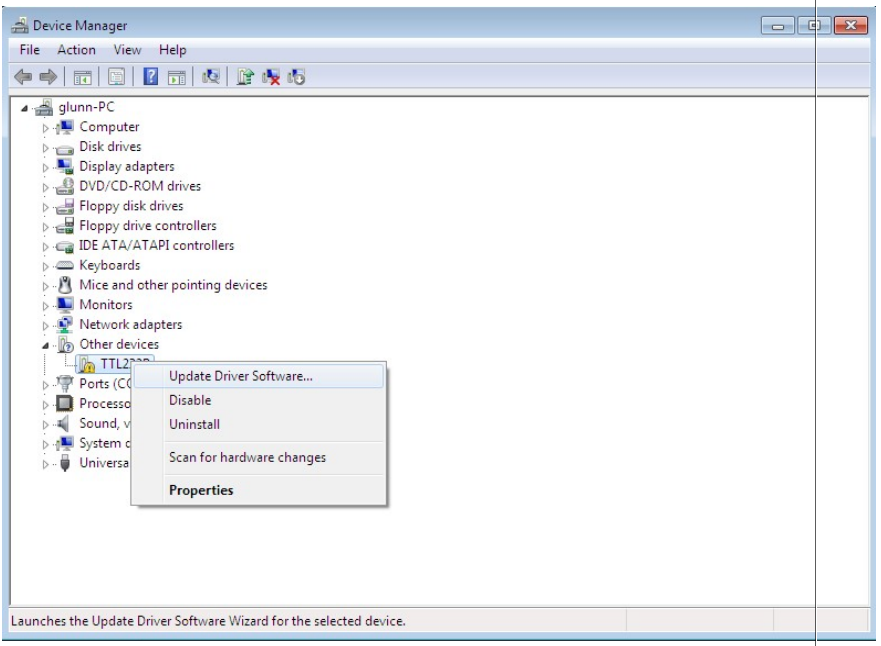
At the next screen select Device Manager:



In the Device Manager window there will be a device under Other Devices with a yellow warning symbol to indicate a problem i.e no driver installed. The text next to this device will depend on the device attached.
For example the device was a TTL232R device.

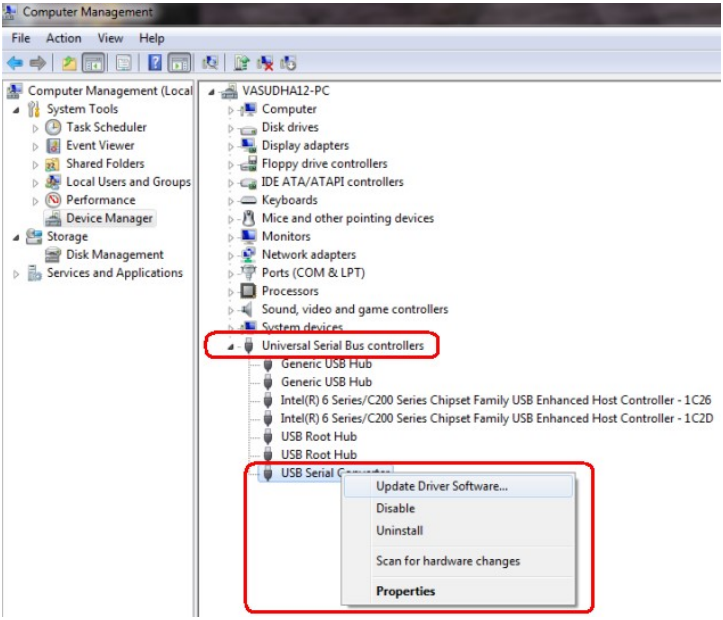


Right click on the other device (TTL232R in this example) to bring up a menu as shown below.

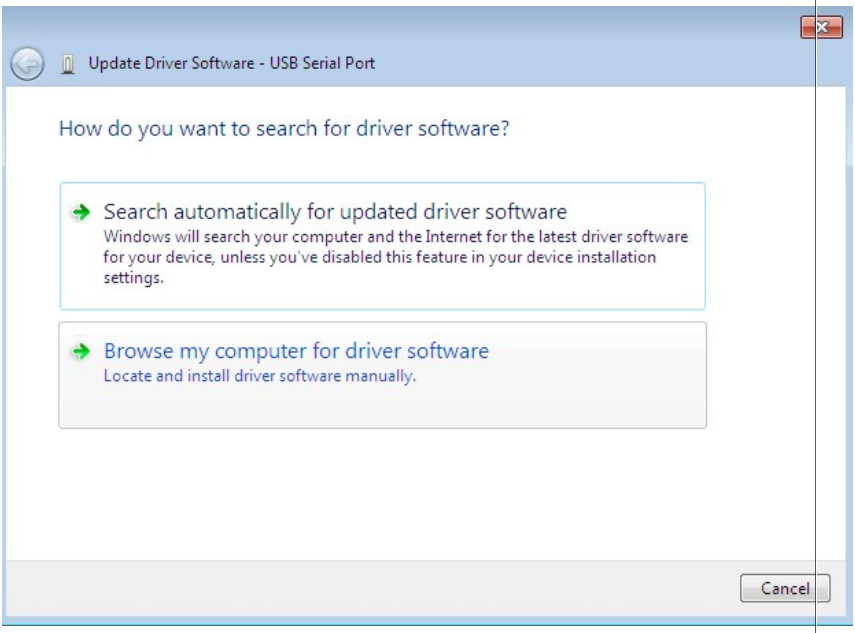


OR

From "universal bus serial bus controllers" select USB serial controller Right click on the other device to bring up a menu as shown below.

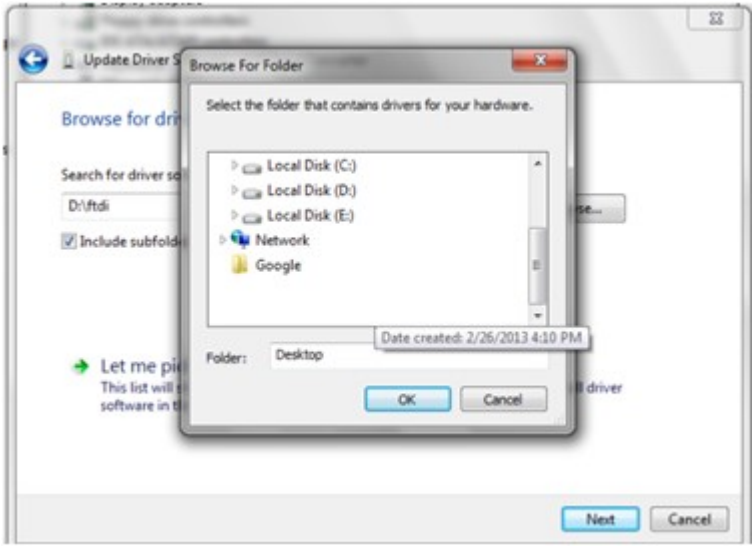


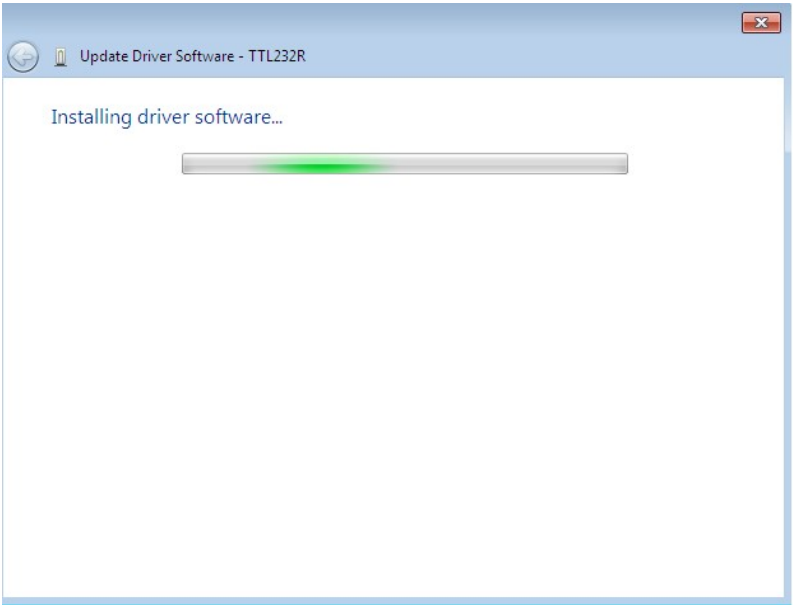
From the displayed menu select “Update Driver Software…”
This then displays the option for an automatic search or a manual search.
Select the second option to browse manually.



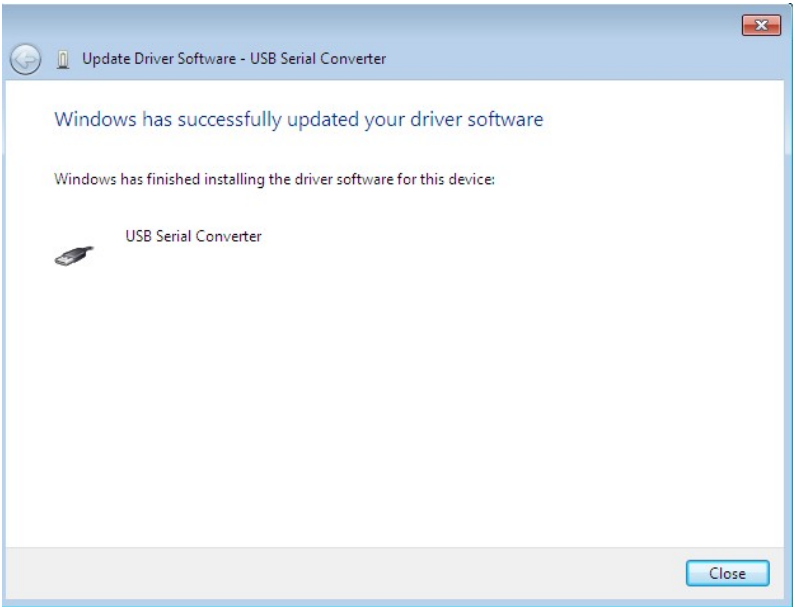
In the address box put the exact location (For FTDI driver- win7-64 bit OR For FTDI driver- win7-32 bit) of where the drivers have been saved to. This may be on a CD or in a folder on the PC. The drivers could have been saved anywhere of the users choosing.

After entering the address select “NEXT” to start the installation.


Update Driver S
Browse for dri
Search for driver so
D:\ftdi
Include subfolde
Let me pi
This list will
software in t
Browse For Folder
Select the folder that contains drivers for your hardware.
Local Disk (C:)
Local Disk (D:)
Local Disk (E:)
Network
Google
Date created: 2/26/2013 4:10 PM
Folder:
Desktop
OK
Cancel
driver
Next
Cancel



When the installation has finished a completion screen is displayed.

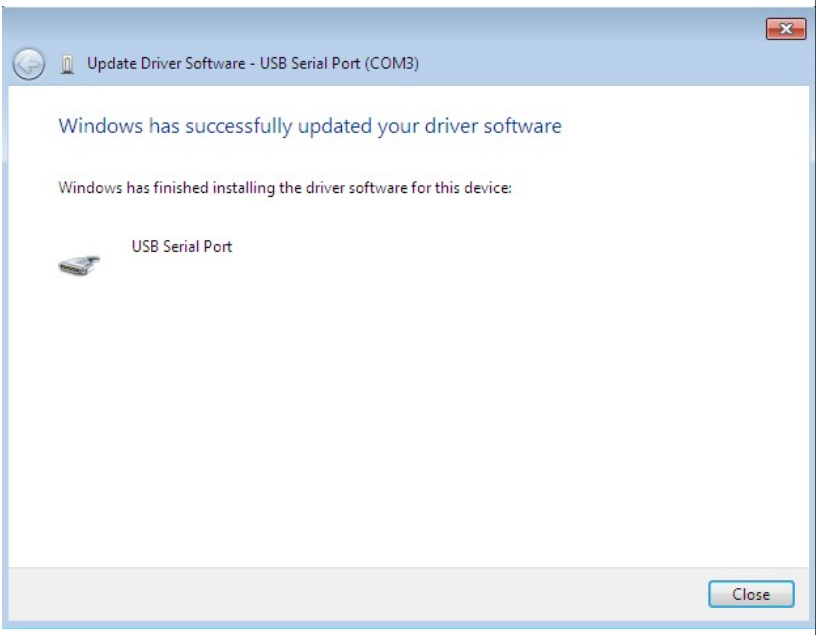


Press Close to close this window and go back to the Device Manager Window.

The Device Manager will still show a device under Other Devices but in addition to this there is a new entry under Universal Serial Bus Controllers indicated in the screenshot above as the USB Serial Converter. This indicates the bus layer of the driver is installed. Installing the Virtual Com Port layer of the driver is almost a repeat of the last few steps.

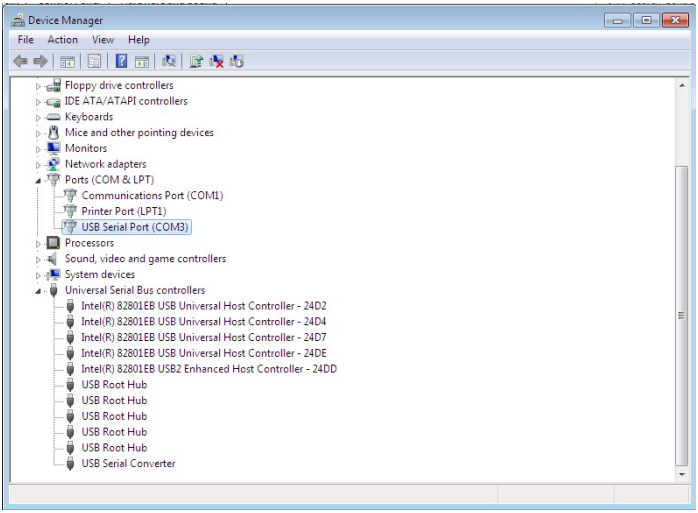
Right click on the other device and repeat above procedure

When the installation is finished a completion screen is displayed.



Note this screen also displays the COM port assigned to the device.

Press Close to close this window and go back to the Device Manager Window.



The above screen shot displays a correct installation. The device is now ready to use on COM3.
NOTE: Not all devices will install to COM3. The COM port allocation is determined by the installation wizard on the basis of the next free com port as designated in the PC registry.

Uninstalling FTDI Devices:

Devices can be removed using the Device Manager by simply right-clicking on the mouse and selecting "Uninstall". This will delete the associated registry entries for that device only. Windows 7 provides an automatic method to delete driver files via a check box to "Delete the driver software for this device" on the uninstall dialog box.

This stage is done twice.

Once for the device under Ports (COM & LPT) and once for the device under Universal Serial Bus Controllers

10.e Troubleshooting:

Sr	Problem / Question	Possible Solutions
1	In Holter S/W, the Grid is for how many seconds, How many squares make one second.	The grid interval on printout and on the screen is 1cm 2.5 cm makes one second.
2	H.R. of 65 bpm should not be labeled as bradychardia and H.R above 100 pm should be labeled as tachycardia.	Arrhythmia page contains 8 sec ECG data of all channels; HR displayed on arrhythmia page is HR of end of page. Time displayed is arrhythmia page start time. Detected arrhythmia is displayed in red color and can be reviewed from one minute page. Go to template page sort or check the NOISE, PVC and ECG template and analyze it again then view Arrhythmia page. In holter software on arrhythmia page HR displayed is for the ECG of 1minute where this arrhythmia is detected and shown on arrhythmia page.
3	If the analysis done is not satisfactory then following problem may occur- "When you go to 'MAX' or 'MIN' HR page, supposing the HR displayed is 185. The HR of 185 does not conform to the actual HR on that page as per the ECG data displayed. If you press 'BitCount', the HR changes to 141".	For that purpose press the "Reanalyze test" button On beat selection panel select such channel for analysis which is having amplitude 1cm or more. Check ECG amplitude of each channel by pressing select channel button Use gain button on beat selection panel page to increase the amplitude of selected channel ;After selecting the

		reference beat, press "**Start analysis**" button to start the classification process By pressing "bit count" button on one minute page software calculate HR, based on actual bit in that minute. HR displayed on one minute page and HR calculation by "bit count" button on one minute page is different.
4	The RR interval calculator is grossly wrong very often and varies a lot resulting in different rates being calculated when checked multiple times for the same interval. In View ECG when heart rate is calculated by RR interval tool and by grid it is grossly different.	'**Mark R-R interval**' button-Use one minute page to Mark R-R interval. Calculated HR will be displayed on one min page. Grid on screen is calculated from screen resolution and screen dimension and Grid on paper is calculated from printer resolution and paper dimension. While printing select paper size as A4. In our holter software screen size is fixed and nowadays monitor size is changing so do not compare the 'No. of Boxes' between two 'R' waves on paper and on screen.
5	Noise detection is very poor and heart rates are given for pages with lot of noise – this causes a lot of error in analysis.	After downloading data, Mark the noisy minute in zoom mode and analyze the data. Noisy minute will be excluded from analysis.
6	There is no explanation for the ECG trace being red coloured, blue coloured	On printout Red colour ECG trace for arrhythmia and blue colour for ECG trace and on-screen lemon yellow colour for ECG and red colour for arrhythmia.
7	Cannot take a printout	First Click the check box on one

	with Grid from the Holter S/W. We have chosen Grid etc, in configuration. Do we need to have a color cartridge also to print the grid?	minute page to mark the current page for printing. The marked page will be available for printing. Go to Configure-Printing details—Select grid style, as per selection report will be printed. We do not require color cartridge to print the grid. But for color printout color cartridge is required.
8	When we take a print of the 'one minute' data on the graph paper, the printout come is portrait orientation. Is it possible to take a print in the Landscape orientation as the data is seen on the Laptop/computer screen?	It is not possible to take a print in the Landscape orientation as the data is seen on the Laptop/computer screen.
	Due to a damaged software CD, users can download the software from the website as an alternative.	Visit the official website WWW.nasanmedical.com, If the download fails, check your internet connection ,Use Service information page for contact.