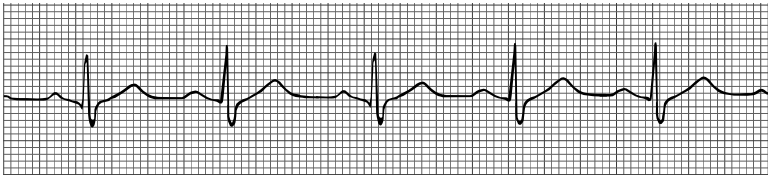


NEXAN

Instructions for Use



NEXAN[®] SYSTEM Nx-300

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Manual purpose and intended users

These instructions are intended for the Health Care Professional, as a guide to the use of the Nx-300 System including the Nexan Software -Nexoft (found in the Telemonitoring Station computer).

It is assumed that the user of the Telemonitoring Station and Nexoft is a Registered Medical Practitioner who has experience of using Windows Software on a PC.

The Patient is the user of the Nexi, Nexi-Clip, PDA, Base Station and Auxiliary Sensors.

A set of instructions, called 'Patient Guide' is intended to be left with the patient (to assist him/her with day-to-day-use)

A set of instructions called 'READ ME FIRST' is provided with each Nexi for patient application of Nexi and Nexi-Clip.

User assistance information

To obtain service contact Nexan Customer Support on 770-360-9090.

Availability of Clinical Study Data

Clinical Study data, obtained using the Nx-300, is available on request from Nexan Ltd.

Nexan Ltd, cautions the reader of this manual:

- This manual, wholly or partially, is subject to change without notice. Some features described in this manual may not be available with this Nexan system.
- All rights are reserved: No one is permitted to reproduce or duplicate, in any form, the whole or part of this manual without the permission of Nexan Ltd.
- Nexan assumes no responsibility for usage not in accordance with this manual resulting in illegal or improper use of the Nexan system.

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SECTION 1

Important information

General warnings & precautions

All users should read these Safety Instructions carefully and thoroughly before using the system. To ensure patient safety, all parts of the system must be used in accordance with the Instructions for Use as indicated by the warning triangle on the product labels. Particular attention should be made to **WARNINGS**, **CAUTIONS** and *Notes* identified within this document.

- **WARNING** statements identify occurrences that could result in personal injury.
- **CAUTION** statements identify conditions or practices that could result in damage to the equipment.
- *Note* statements disclose pertinent information.

Warnings

- THE BASE STATION MUST BE CONNECTED TO AN EARTHED (GROUNDED) POWER SUPPLY.
- THE NEXI® MUST NOT BE APPLIED TO BROKEN, DAMAGED OR IRRITATED SKIN.
- MONITORING OF PATIENTS WITH PHYSICAL OR MENTAL OR SENSORY IMPAIRMENT SHOULD ONLY BE UNDERTAKEN IF THE MEDICAL PRACTITIONER/PHYSICIAN CONSIDERS THEY CAN USE THE Nx-300 SYSTEM CORRECTLY AND THAT IT WILL NOT CAUSE UNDUE STRESS OR ANXIETY.
- THERE IS A POSSIBILITY OF DEGRADATION OF THE RESPIRATION SIGNAL IN PATIENTS WITH HIGH BODY MASS INDEX.
- REPLACE FUSES WITH CORRECT TYPE AND RATING; FOR PROTECTION AGAINST FIRE AND OTHER HAZARDS.
- IF USED IN HOSPITAL, THE BASE STATION UNIT MUST BE CONNECTED TO A HOSPITAL GRADE OUTLET.
- THE Nx-300 IS NOT FOR USE AS A CRITICAL CARE MONITORING SYSTEM.
- THE Nx-300 IS NOT AN APNOEA MONITOR.

Precautions

- Substitution of a component different from that supplied may result in measurement error.
- Only use the Nexan Supplied Charger or Base Station Unit (BSU) to re-charge the Personal Data Assistant (PDA).
- Do not use two systems close together since corruption of data may occur. The Nx-300 system should be used under the supervision of Registered Medical Practitioner.
- Patients must be advised to contact their Registered Medical Practitioner if they feel any deterioration in their condition whilst using the Nx-300 system.
- The Base Station, Auxiliary sensors and Telemonitoring Station (TMS) should be placed in locations where the cables are safely positioned and the units cannot harm anyone if the units fall.
- No part of the Nx-300 system should be allowed to come into contact with water or other fluids, substances which could cause combustion, flammable/explosive gases.
- Do not place any part of the system close to a source of heat (radiator etc.)
- The performance of the Nx-300 system cannot be guaranteed if tampered with in any way.
- Inspect the Base Station power cord periodically for fraying or other damage. Do not operate the equipment from mains power with a damaged power cord or plug.
- Ensure that air can circulate freely around the Base Station and that contaminants, e.g. talcum powder, are not allowed to ingress.

Glossary of symbols & terms

As used in instructions and on product labels:

<i>Auxiliary sensors</i>	An Nx-300 facility to use additional sensors directly connected to the Base Station.
<i>Download</i>	Data that is transferred from one location to another.
<i>Event</i>	Specific occasion(s) of patient response.
<i>Monitoring schedule</i>	A period of time during which patient monitoring is carried out.
<i>Trend Data</i>	Data from all the auxiliary sensor sessions which is viewed over an extended period of time.

Environment

Environmental conditions that affect use:

The Nx-300 system uses a radio frequency signal in the low power, unlicensed Bands of 869.7- 870MHz in Europe and 916-917MHz in the United States of America (Part of the 902-928 Band) to transfer system information from the Nexi-Clip to the PDA. It is possible that interference may occur between the Nx-300 and other radio equipment operating on the same frequencies. Due to the low power of the transmissions, the potential for interference is only likely if the two are close to each other.





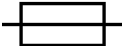


Before installing the Nx-300, it is recommended that the installation environment be checked for other radio devices that may be affected.

Examples of these environments are as follows:

- Domestic
- Social alarms
- Radio-controlled car security devices
- Hearing aids
- CB radios
- Panic alarms
- Television receivers
- Cordless telephones
- FM receivers

It is recommended that if any such equipment is identified, then it should be checked for correct operation while the Nx-300 is operating as close as possible to the equipment. Should any problems be observed we recommend the Nx-300 is switched off and Nexan Customer Support is contacted (see page 2 for contact details).

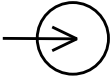
Symbols on Nx-300 system labelling

SYMBOL	TEXT DESCRIPTION
	ATTENTION , Consult Accompanying Documents
	Type BF Equipment. Type B equipment with an F-type applied part (patient isolation from electric shock) Used on Nexi.
	Type B Equipment. (patient isolation from electric shock). Used on Base Station
SN-	SERIAL NUMBER of device
	Direct Current
	Fuse 2x T2AH 250V (used on Base Station)
	Not for Re-use (Single Use Only) applies to Nexi (ISO7000/1051, BSEN980:1996)
	Use- by (Year-month) applies to Nexi

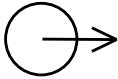
Symbols on Nx-300 system labelling (continued)

SYMBOL

TEXT DESCRIPTION



Input - used on Base Station. Intended only for connection to patients' phone.



Output- used on Base Station. Intended only for connection to patients' phone line.



Used on Base Station to connect any auxiliary sensor



AECG Type 1 equipments (all)



Base Station Power ON



Base Station Power OFF



PDA Power ON/Confirm action button (green)



R&TTE equipment Class 2 (Member States restrictions)
May apply to Nexi-Clip and Portable Data Assistant (PDA)

Intended use

'The Nx-300 system is an ambulatory patient monitoring system intended for use in the home or alternate care settings. The device stores and transmits ECG data, respiration data, systolic and diastolic blood pressure (non-invasive), and PEF and FEV1'

Contra-indications:

- THE Nx-300 MUST NOT BE USED ON CHILDREN UNDER 9 YEARS OLD.
- THE Nx-300 IS NOT CONSIDERED SUITABLE FOR USE ON PATIENTS WITH IMPLANTED DEFIBRILLATORS/PACEMAKERS.
- THE Nx-300 MUST NOT BE USED ON PATIENTS WITH KNOWN SENSITIVITY TO MEDICAL ADHESIVES.
- THE Nx-300 IS NOT FOR USE AS A CRITICAL CARE MONITORING SYSTEM.

SECTION 2

Overview of Nx-300 system

System description

Data from physiological measurements, taken by sensors on the chest and underarm (Nexi) is converted into radio signals and transmitted via a radio transmitter (Nexi-Clip attached to the Nexi) to a radio receiver in a Personal Data Assistant (PDA). The PDA also stores the data for the monitoring period and normally sits (docked) in a Base Station Unit (BSU) located in the patients's home. Whilst docked, the PDA transfers the data to the BSU. A TeleMonitoring Station (TMS) computer, located within a remote monitoring centre, interrogates and downloads the data from the Base Station via the patient's phone line. The TMS computer software is then used by the Registered Medical Practitioner to display and interpret the patient data.

The diagram below shows the complete Nx-300 system in operation.

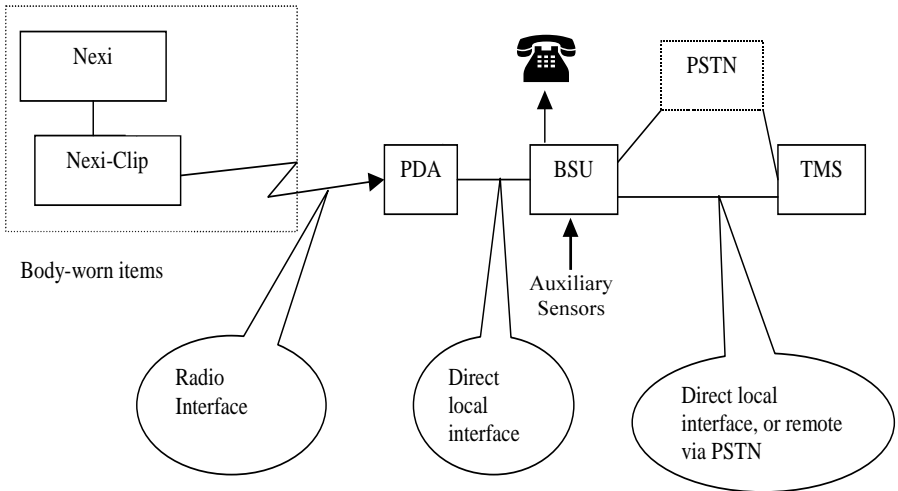


Figure 1. Nexan Nx-300 System

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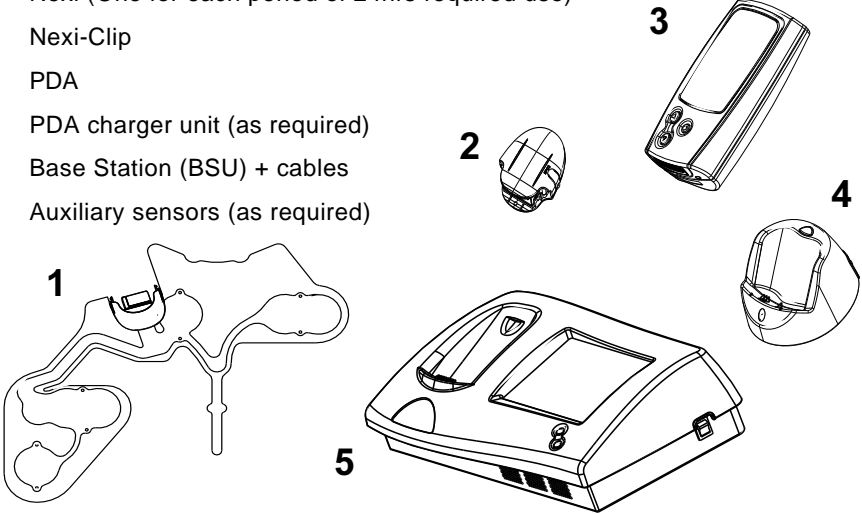
Description of parts:

Nexi:	A disposable, multi-parameter adhesive sensor patch worn on the upper chest and underarm. Contains two batteries used to power both the Nexi and the Nexi-Clip when connected.
Nexi-Clip	A Radio Transmitter which Clips to the Nexi and contains a transmitter.
PDA:	A Receiver and storage Unit for data storage of data recieved by radio communications transferring that data to the Base Station when docked.
Base Station:	A Base Unit, located in the patient's home, for data storage, analysis and transfer of data to a Telemonitoring centre on request. Also permits connection of Auxiliary sensors such as Blood pressure and Spirometry devices for point-in-time measurements. The Unit also contains a call discriminator unit, which allows normal use of the patient's phone. The discriminator identifies the difference between incoming voice or data calls and routes the call appropriately.
TeleMonitoring Station (TMS):	A dedicated PC, located in the Telemonitoring Centre, running a Nexan software package.
Nexan Software:	A software package in the TMS for data interpretation and presentation of the data received from the Patient's Base Station. Nexan software is only for use by Healthcare Professional.
Auxiliary Sensors:	Auxiliary sensors connected to the Base Station for the recording of blood pressure, weight (option) and spirometry measurements.

Parts supplied

Parts supplied to patient

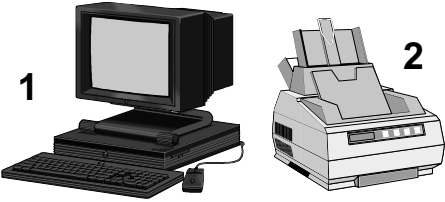
- 1 Nexi (One for each period of 24hrs required use)
- 2 Nexi-Clip
- 3 PDA
- 4 PDA charger unit (as required)
- 5 Base Station (BSU) + cables
Auxiliary sensors (as required)



NOTE: Not all parts may be supplied to all patients

Parts supplied to Health Care Professional (HCP)

- 1 TMS Personal Computer (containing installed Nexan Software)
- 2 Printer



NOTE: Not all parts may be supplied to all HCPs

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CAUTION: Do not store in a damp area. Dampness may affect the device and cause rust.

System setup and operation

Successful operation of the Nx-300 system depends on thorough patient instruction. Nexan recommends that you walk through the following steps with each patient, **using the PATIENT GUIDE as a reference**:-

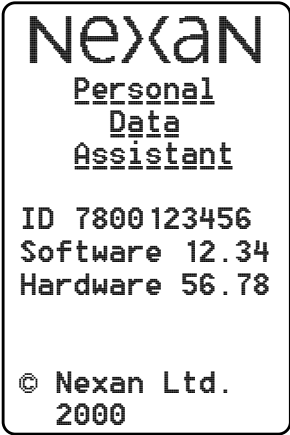
- Explain the equipment and procedures to the patient.
- Connecting and powering up the Base Station and PDA.
- Check the patient's telephone still works (incoming & outgoing calls).
- Applying the Nexi and Nexi-Clip using the READ ME FIRST guide supplied with each Nexi.
- Verifying operation of the equipment (check out).
- Explain the basic operation of the system and on line help screens.
- Patient tasks (e.g. take blood pressure) and display messages.
- What to do if the telephone line is busy?
- Discuss wearing the Nexi and Nexi-Clip day-to-day.
- Discuss the use of the PDA day-to-day.
- Taking auxiliary sensor measurements - if supplied.
- Explain where and how to call for help/assistance.
- Troubleshooting patient equipment.

SECTION 3

Setting up the PDA and Base Station

Configuring the PDA

To switch on the PDA, press and hold the green button. The screen will briefly display an information view showing the unique PDA identification number, plus its software and hardware revisions ⇨

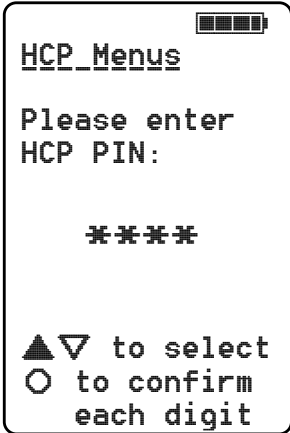


Accessing the HCP menu

When preparing the PDA for a new patient, a number of actions should be carried out, all of which require access to the HCP menus that are hidden from the patient. A pre-set PIN code is required to gain access to the HCP menus.

To access the HCP menus:

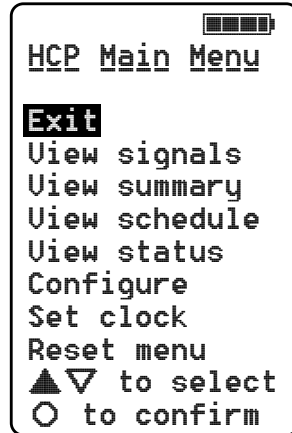
- 1 Press and hold the ▲ key to show this display ⇨
- 2 Press the ○ key to begin entering the PIN. The first * will be replaced with '0'.
- 3 Use the ▲ or ▼ keys to select the required PIN digit and press ○ to confirm when the number is correct.
- 4 Repeat step 3 until all four digits are entered.



Accessing the HCP menu (cont.)

When the correct PIN has been entered, the *HCP Main Menu* is displayed ⇨

Note: If the PIN is not known, then there is a second, fixed PIN, that will provide access. If required you can get this PIN by contacting Nexan.

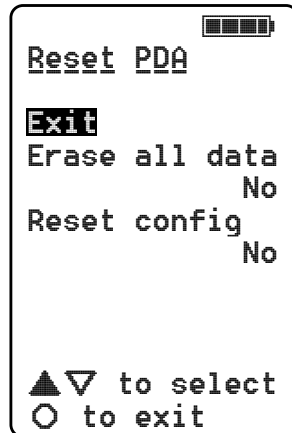


Clearing the memory

When you are preparing the PDA for a new patient, the first action must always be to ensure that the memory is completely free of residual data.

To clear the memory:





- 1 Enter the *HCP Menu*.
- 2 Press the ⏴ key until **Reset Menu** is highlighted. Press the ○ key to display the *Reset PDA* screen ⇨
- 3 Press the ⏴ key until **Erase all data** is highlighted and then press the ○ key. Press the ▲ or ▼ keys until the option states **Yes** and then press ○.
- 4 Press the ▲ key until **Exit** is highlighted and press the ○ key to execute the erase function and return to the *HCP Main Menu*.



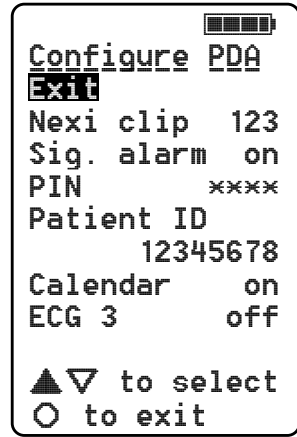
Configuring the PDA for a new Nexi-clip






When setting up a new installation, you must ensure that the PDA is configured to receive data from the specific Nexi-clip being used.

To register a new Nexi-clip with the PDA:

- 1 Enter the *HCP menu*.
- 2 Press the  key until **Configure** is highlighted. Press the  key to display the *Configure PDA* screen ⇨
- 3 Press the  key until **Nexi clip** is highlighted and press the  key to highlight the first number of the Nexi-clip code.

On the rear of the Nexi-clip to be used, locate the printed label. On the label note the three figure ID code - this is the code that must be entered into the PDA.



- 4 Press  or  to set the first digit of the Nexi-clip ID code and then press  to store this value and move to the next digit. Repeat this procedure with the remaining two ID digits.
- 5 When the last digit has been set, press the  key until **Exit** is highlighted and then press . The configured options are implemented as the screen is exited.

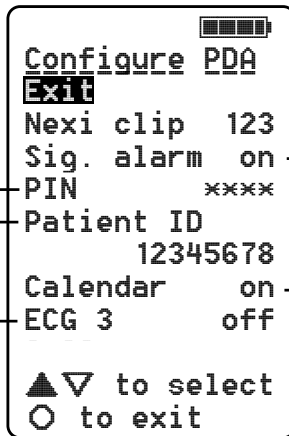
Other Configure PDA options

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Allows you to set a new PIN to gain access to the HCP menus (set to 0000 to disable the PIN)

An eight figure representation of the current Patient ID.

When ON, enables storage for optional ECG data from an external 'flying lead' attached to the Nexi.



When ON, sounds an alarm when the signal from the Nexi-clip becomes weak.

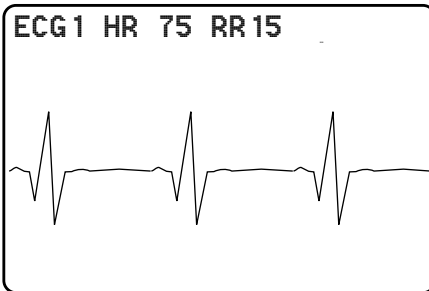
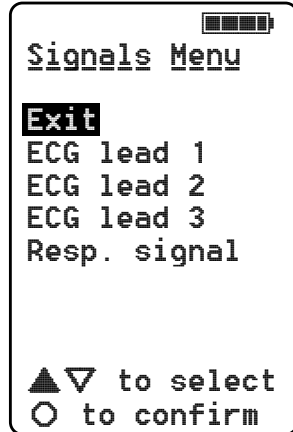
When ON, displays the date on the standby screen.

Viewing signals and data to check Nexi operation

The PDA allows you to view the ECG and/or respiratory waveforms being monitored by the Nexi patch and sent to the PDA by the Nexi-clip. This function is useful when checking that the patch has been correctly applied and that the Nexi-clip and PDA are communicating correctly.

To view raw data signals:

- 1 Apply the Nexi to the patient and attach the Nexi-clip in the usual manner.
- 2 Enter the *HCP Menu*.
- 3 Press the ∇ key until **View signals** is highlighted. Press the \bigcirc key to display the *Signals Menu* \Rightarrow
- 4 Press the ∇ or \blacktriangle keys until the required ECG or Resp. signal is highlighted. Press the \bigcirc key to display the chosen raw data display \Downarrow



The screen changes to a 'landscape' display and shows the current waveform, plus along the top: the current Heart Rate and Respiration Rate.



If no waveform or HR/RR values are displayed then there may be a communication problem or fault with the Nexi/Nexi-clip combination.

Note: If you do not see a good signal, refer to the Troubleshooting section at the rear of this guide.

- 5 Press the \bigcirc key to return to the *Signals Menu*.

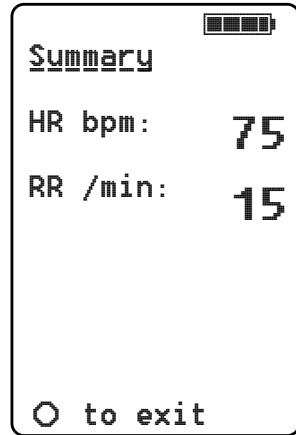
Additionally you can also view the incoming data simply as numeric values. This method is discussed next.

To view numeric signal values:

- 1 Apply the Nexi to the patient and attach the Nexi-clip in the usual manner.
- 2 Enter the HCP Menu.
- 3 Press the  key until **View summary** is highlighted. Press the  key to display the **Summary** screen ⇨

This screen shows incoming values for the Heart Rate and Respiration Rate.

If the values remain at ### then there may be a communication problem or fault with the Nexi patch/Nexi-clip combination.



To view the PDA Status screen:

- 1 Enter the HCP Menu.
- 2 Press the  key until **View status** is highlighted. Press the  key to display the **PDA Status** screen ⇩

The image shows a handheld device screen with a battery indicator at the top right. The screen displays "PDA Status" at the top. Below it, the following information is shown: "Id: 8700123456", "Nexi clip: 123", "Nexi clip OK", "Mem free %: 85", "Signal mV: 1234", "On at: 10:15 Oct 12", "Session: 123", "10:25 Oct 12", and "O to exit".

Callouts from the left side:

- The patient ID number. (points to Id: 8700123456)
- Indicates that signals are being received from the designated Nexi-clip. (points to Nexi clip OK)
- Indicates the strength of the signal from the Nexi-clip. 1000 or less indicates a weak signal that could result in data loss. 2000 or more indicates a strong signal. (points to Signal mV: 1234)

Callouts from the right side:

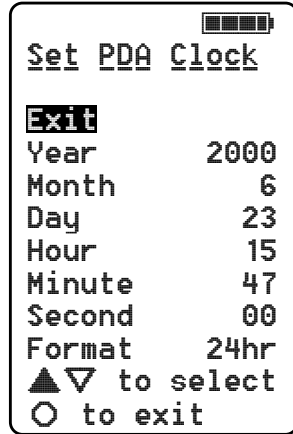
- Indicates the ID number for the current Nexi-clip. (points to Nexi clip: 123)
- Indicates how much data storage memory is free within the PDA. (points to Mem free %: 85)
- Indicates when the PDA was last switched on (points to On at: 10:15 Oct 12)
- Indicates the current patient session and when it commenced. (points to Session: 123 and 10:25 Oct 12)

Setting the PDA Clock and Calendar

The PDA has an internal clock and calendar against which the incoming data is monitored. It is important that the clock is set correctly when installing the system.

To set the clock and calendar:

- 1 Enter the *HCP Menu*.
- 2 Press the ∇ key until **Set clock** is highlighted. Press the \circ key to display the *Set PDA Clock* screen \Rightarrow
- 3 Press \blacktriangle or ∇ to highlight the required setting and then press \circ begin altering that setting.
- 4 Press \blacktriangle or ∇ to change the current setting and then press \circ when it is correct.
- 5 Repeat steps 3 and 4 until all time and date settings are correct and then press \blacktriangle or ∇ until **Exit** is highlighted. Press \circ to quit the screen and apply the changes made.



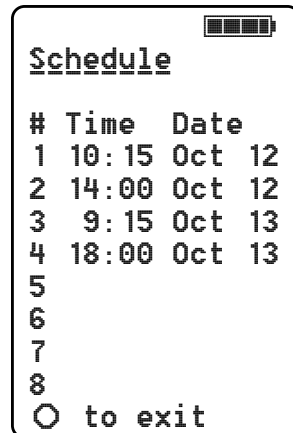
Viewing stored schedule information

If the Base Station and PDA have any scheduled extra measurements (blood pressure, spirometry or weight) programmed, then it is possible to view a summary of these on the PDA.

To view scheduled measurements:

- 1 Enter the *HCP Menu*.
- 2 Press the ∇ key until **View schedule** is highlighted. Press the \circ key to display the *Schedule* screen \Rightarrow

Note: This screen shows only the times and dates for the scheduled measurements. It does not differentiate between the different measurements, nor does it allow any editing of the entries.



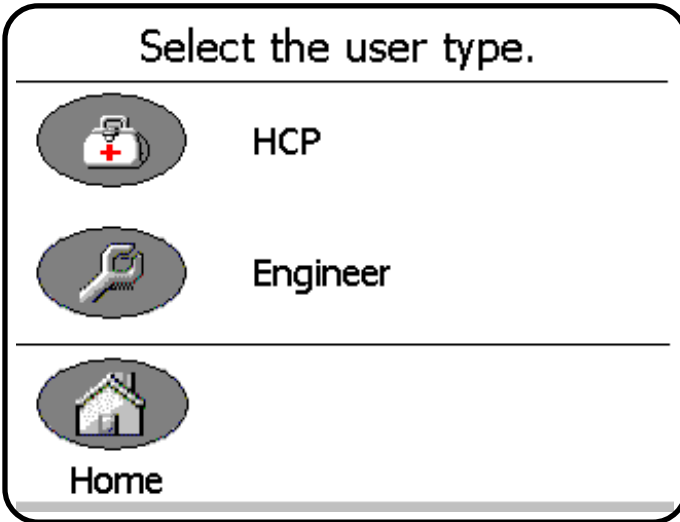
Configuring the Base Station

Accessing the HCP Menus

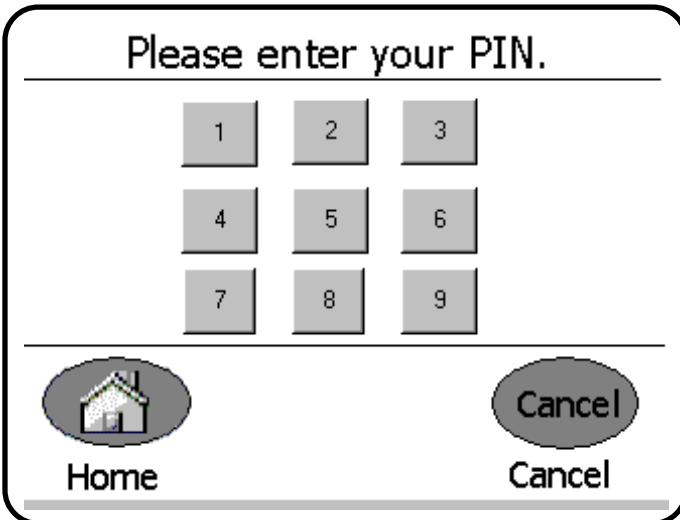
When the Base Station is switched on, it displays the patient home page. To configure the Base Station for a new patient it is necessary to access the HCP menus.

To access the HCP menus:

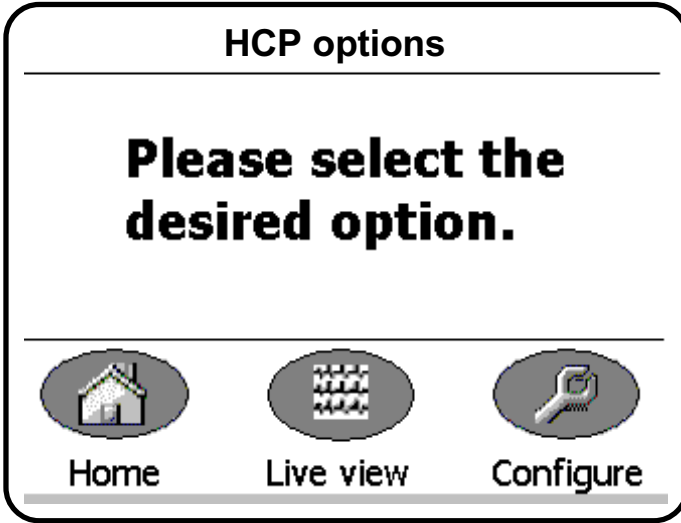
- 1 Press the 'smiley face' logo (in top right corner) until the following is displayed:



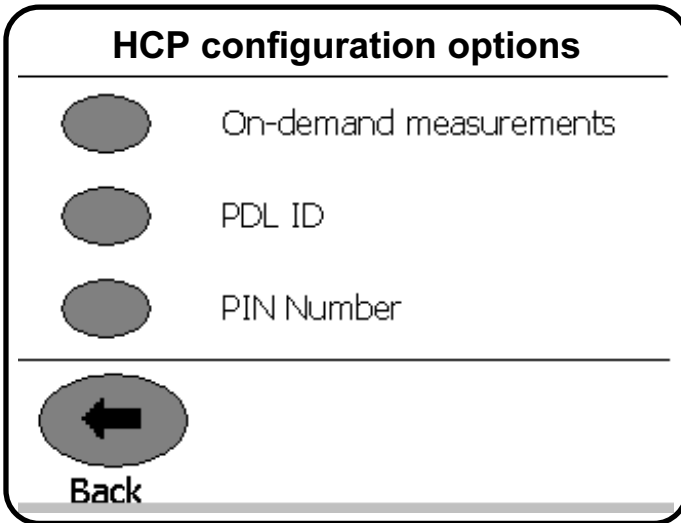
- 2 Press the **HCP** button to display:



- 3 Enter your four digit PIN code to display:



- 4 Press the **Configure** button to display:



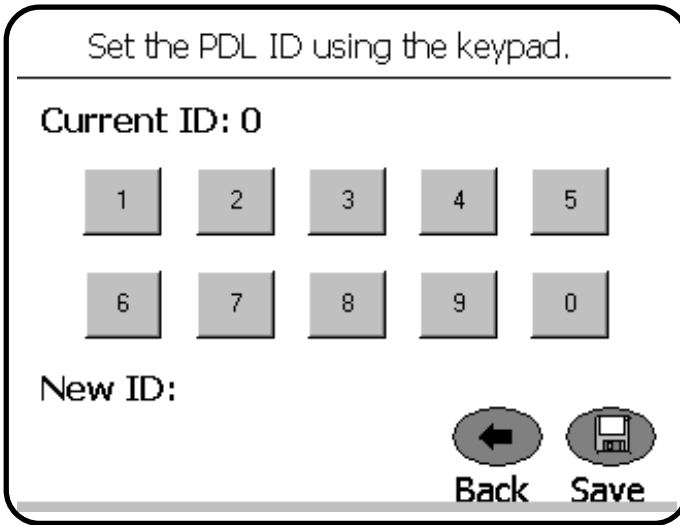
- 5 Select the required action that you wish to perform.

Setting the PDA (PDL) ID code

Each PDA carries a unique identification (PDA ID) code to ensure that recorded data can be traced back to a specific patient and their PDA. It is important that the Base Station is programmed with the correct ID number for the PDA in use.

To set the PDA ID code:

- 1 Enter the HCP/Nurse menu, choose **Configure** and then select the **PDL ID** option. The following screen will be displayed:



The unique 10-digit PDA ID code can be located in three ways:

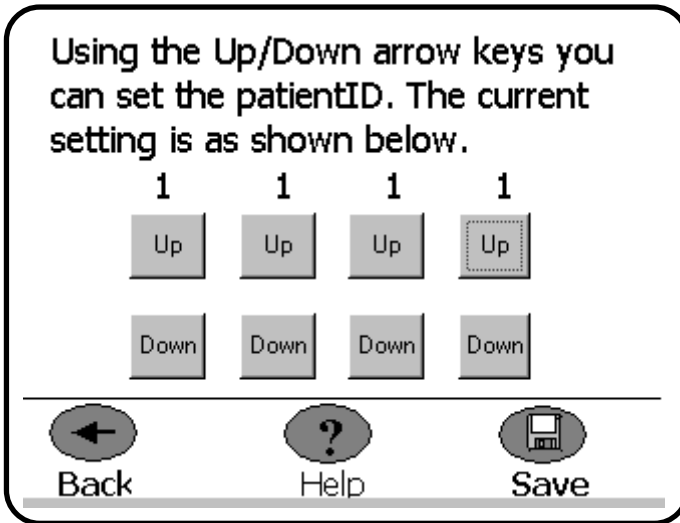
- It is printed on the label located on the base of the PDA,
 - It is displayed during the start-up screen of the PDA, and
 - It is displayed in the PDA Status screen that is mentioned earlier in this section.
- 2 Locate the 10-digit PDA ID code and enter it into the Base Station using the on-screen keypad.
 - 3 Press the **Save** button.

Setting the Patient ID code

In order to maintain a traceable link between recorded data and a particular patient, it is important that Base Station is programmed with the correct Patient ID code.

To set the Patient ID code:

- 1 Enter the HCP/Nurse menu, choose **Configure** and then select the **PatientID** option. The following screen will be displayed:



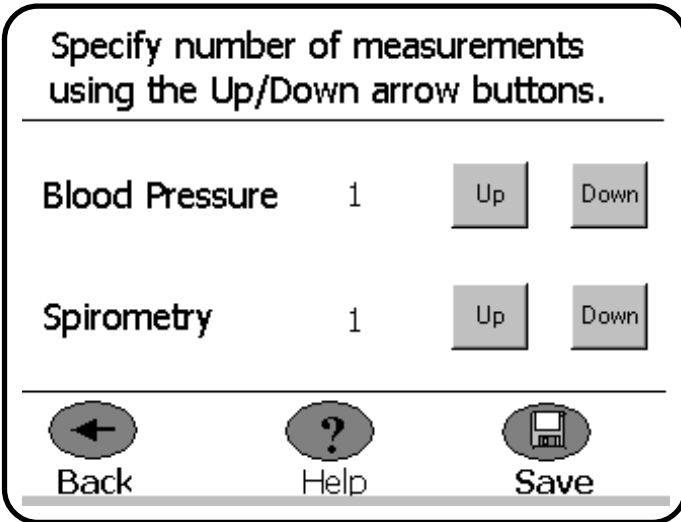
- 2 Use the on-screen **Up** and **Down** buttons to increment/decrement each of the four digits until the Patient ID code matches the number that has been designated for that patient.
- 3 Press the **Save** button to store the entered code and exit to the options screen.

Setting or editing the measurements schedule

Schedules for taking extra measurements (such as blood pressure, spirometry or weight) are generally set using the Nexoft software from the remote TeleMonitoring Station (or TMS). However, it is sometimes necessary, or more convenient, to set or edit these settings whilst on-site with the Base Station.

To increase or reduce the number of measurements:

- 1 Enter the HCP/Nurse menu, choose **Configure** and then select the **Schedule** option. The following screen will be displayed:



- 2 Use the on-screen **Up** and **Down** buttons to increment/decrement the quantity of Blood Pressure or Spirometry readings that are required.
- 3 Press the **Save** button to store the new scheduled measurements and exit to the options screen.

Note: The scheduled measurements that are set on the Base Station will take priority over any similar settings made at the remote TeleMonitoring Station. The next time that the TMS connects with the Base Station, the new settings will be uploaded and used to alter the TMS schedules.

SECTION 4

Setting up and using the TeleMonitoring Station

TeleMonitoring Station (TMS) overview

Data from the Base Station is transferred, via patient's telephone line, to a Telemonitoring Centre. Here the Registered Medical Practitioner has access to the Nexan software, called *Nexoft*, installed on a Nexan TMS computer.

Note: It is recommended that archiving of patient data is carried out both as a pre-use check between patient use of the Nx-300 system and periodically.

The Registered Medical Practitioner can control the use of the Nx-300 using the Nexoft program that enables the following features:

- Dial-up to a patient's home for downloading the monitoring schedule to the patient's Base Station.
- Dial-up to a patient's home to retrieve and view recorded and /or analysed data from the patient's Base Station.
- Scheduling the download times.
- Setting up or changing the schedule for blood pressure and/or, spirometry measurements; collectively known as auxiliary measurements.
- Management of a database of recorded data.

Setting up the TMS computer

Connecting the TMS

- 1 Unpack your TMS Computer following the instructions on the packaging.
- 2 Connect the monitor, keyboard and mouse using the colour-coded plugs then connect the mains power cables to the monitor and computer.
- 3 Next, using the modem cable provided, connect one end into the modem socket of the computer and the other end into your telephone line socket.
- 4 If required connect the computer to the supplied printer by following the printer manufacturer's instructions.

Switching on the TMS

PRECAUTIONS

It is recommended that you do not install non-Nexan software onto your TMS machine. Third-party applications may degrade the performance of the Nexan software or otherwise interfere with its operation.

In particular:

- 1 Do not use software that might use the modem(s) (e.g. browsing the Web).
- 2 Do not run software that may occupy the processor for extended periods (e.g. long scientific computations).
- 3 Be aware that the machine has a finite amount of disk space and any space used will not be available for storing patient data.
- 4 Be aware that running multiple applications will reduce the availability of main memory, and degrade performance.

Refer to the manufacturer's instructions; connect power and switch on your TMS Computer and monitor. After approximately one minute the Nexan software logon screen should appear.

Using Nexoft

Logging on

To use the Nexoft Software, you must first log on. Wait a few seconds after the screen in Figure 2 first appears then enter a username and a password. Click on the 'Log On' button.

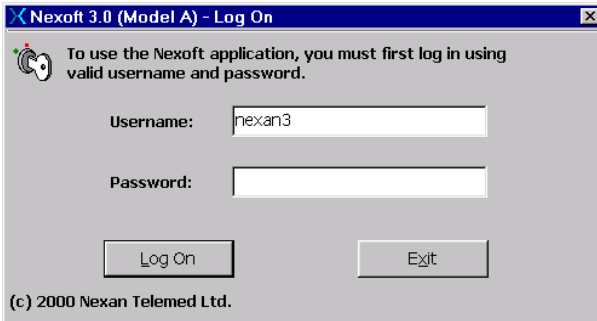


Figure 2: Logon Screen

NOTE 1: The screens displayed throughout this section assume that the system default configuration is being used.

NOTE 2: If your password has expired you will be prompted to enter and confirm a new one. Do not use 'common' passwords.

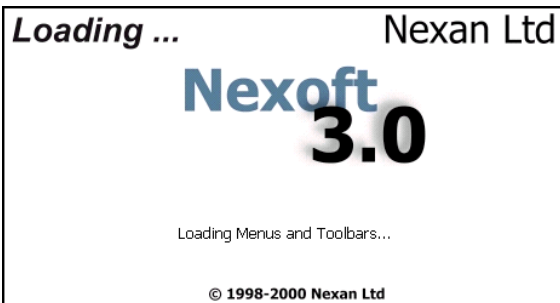


Figure 3: Splash Screen

The splash screen provides feedback while the application is loaded (since there can be 10-15 second delay loading all the screens).

The main application window appears with the *Search Patients* panel (note the tool bar and menus).

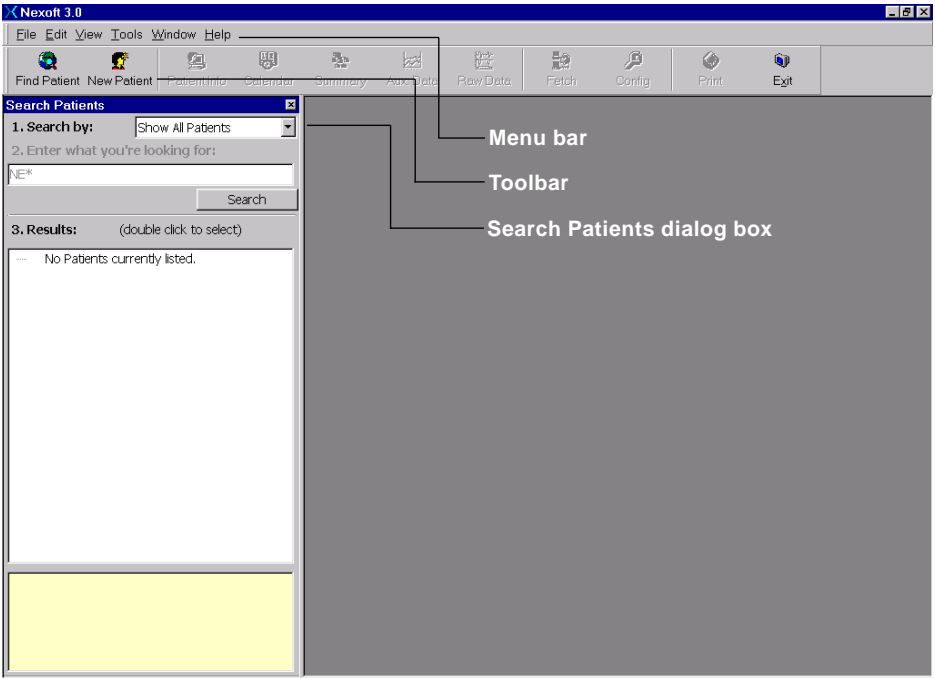


Figure 4: Nexoft main application window

You can ‘undock’ (move around) the Search Patients dialog box, the toolbar and the menu bar so that you can rearrange the screen to suit. Simply click and hold on the item to be moved and drag it to a new position.

The items within the toolbar and menu bar can also be customized using the Configuration option within the Tools menu (or click the Config button on the toolbar).

Patient Records

Nexoft allows you to add new patients or view the records of existing patients.

To add a new patient:

- Click the **New Patient** button on the toolbar, or
- Select the *File* menu and then click the *New Patient* option.

The Patient information dialog will be displayed:

The screenshot shows the 'Nexoft 3.0 - Patient Information' dialog box. The header bar is green and contains the text 'Monitoring started 13/09/00' and a button labeled 'Add New Patient'. The dialog is divided into four main sections:

- Patient Identification:** Contains fields for Patient Name, Patient Initials, Patient Number, and Study Code.
- Nexsystem Identification:** Contains fields for Patient System ID (with '0000' entered) and Patient Phone No.
- Study/HCP Details:** Contains fields for Physician/HCP, HCP/Study Centre, and Monitoring Start Date (with '13/09/00' entered).
- Additional Patient Details:** Contains fields for Date of Birth (with '13/09/00' entered) and Gender (with a dropdown menu).

At the bottom of the dialog are two buttons: 'Save New Patient' and 'Cancel'.

Figure 5: Entering new information using the Patient Information dialog

The Patient Information dialog is divided into four main areas:

- *Patient Identification* - including the patient's name, number and study code,
- *Nexsystem Identification* - including the ID (must be 4 characters) of the patient's Nx-300 system and the phone number on which the patient can be contacted,
- *Study/HCP Details* - including the name of the patient's physician or Health Care Professional, the hospital/health care center name and the start date,
- *Additional Patient Details* - including the date of birth and the gender of the patient.

When all necessary information has been entered, click the **Save New Patient** button.

The new data is then displayed in the *Patient Information* screen shown overleaf.

When new patient information has been entered (as discussed on the previous page) the new data is presented for review in the following screen.

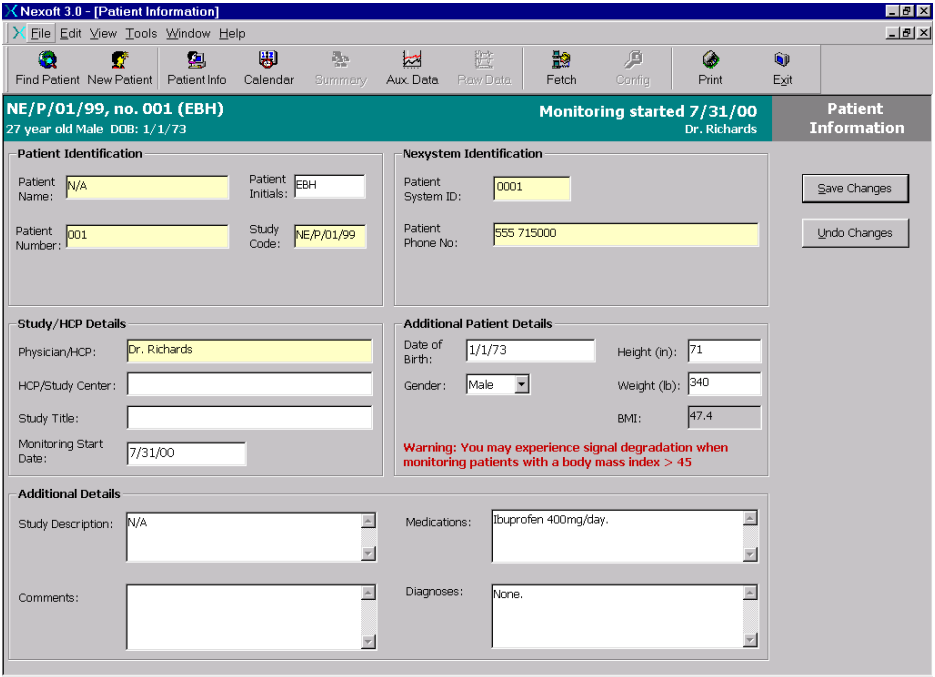


Figure 6: Patient Information screen showing the entered information

This screen allows further data to be added to the patient information in the following areas:

- *Additional Patient Details* - Patient Height and Weight. From this information a Body Mass Index (BMI) is automatically calculated (A warning will be displayed if the calculated BMI figure is greater than 45).
- *Additional Details* - Study Description, Comments, Medications and Diagnoses.

When changes are made to this screen, remember to click the **Save Changes** button in order to update the patient record.

To locate existing patient records:

- 1 If the Search Patients dialog is not already displayed:
 - Click the **Find Patient** button on the toolbar, or
 - Select the *File* menu and then click the *Find Patient* option.

The Search Patients dialog allows you to *Show All Patients* or to search the database using various criteria:

- Patient Name
- Patient Initials
- Patient Study Code
- Patient Number
- HCP/Physician
- All Patient Notes (search on any patient details)

- 2 Click on the *Search by:* drop down list to select the required search criteria.

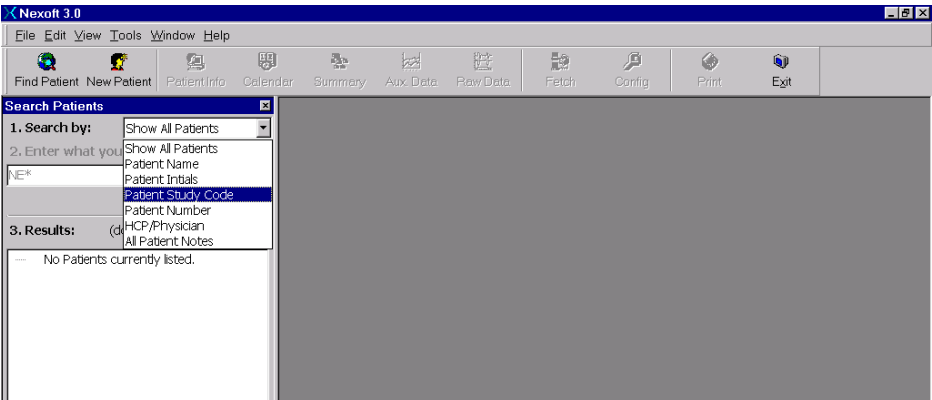


Figure 7: Search Patient dialog showing the database search criteria

- 3 Now enter additional search information into the text box labelled 2. *Enter what you're looking for:*

- 4 Click the **Search** button to interrogate the database.

The patient details that match your search criteria will be displayed in the *Results* section.

- 5 **To view a summary for a patient:** Click on the patient entry in the list - the summary is displayed in the yellow box below.

To view a complete patient record: Double-click on the patient entry in the list - the complete patient record is displayed in a new window.

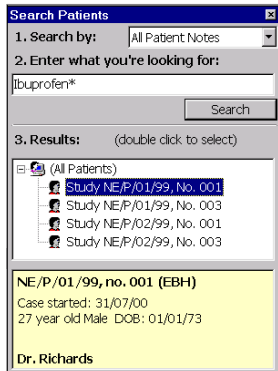


Figure 8: Search results

Using the Calendar function to set a download schedule

Once a new patient has been added, or an existing patient located, the next step is to organise a download schedule. This defines the dates and times when the TeleMonitoring Station (TMS) will dial the Base Station (installed at the patient's premises) in order to download the recorded data.

To set a download schedule:

- 1 Display the record page for the required patient (see 'To locate existing patient records').
- 2 Click the **Calendar** button on the toolbar. A calendar screen will be displayed:

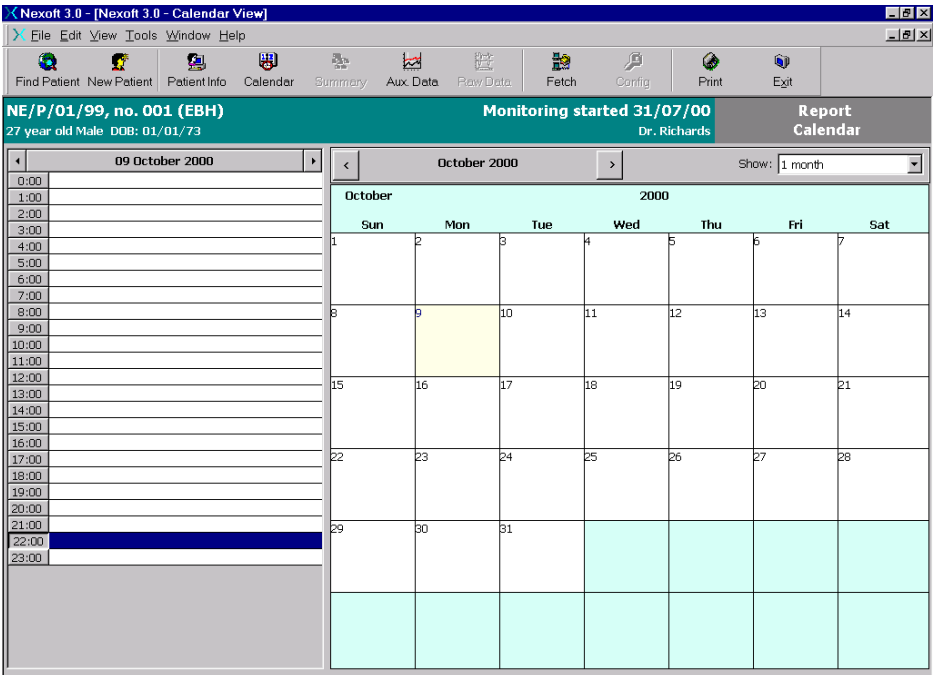
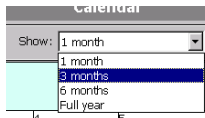
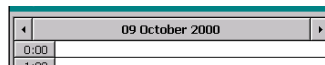


Figure 9: One month calendar view

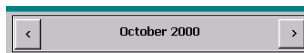
- 3 Optionally, use the *Show:* drop down list to select an alternative calendar view.



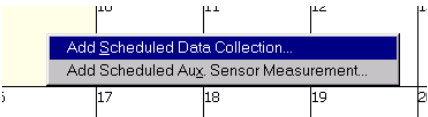
To change the current day:
Click the smaller arrow buttons above the hourly view.



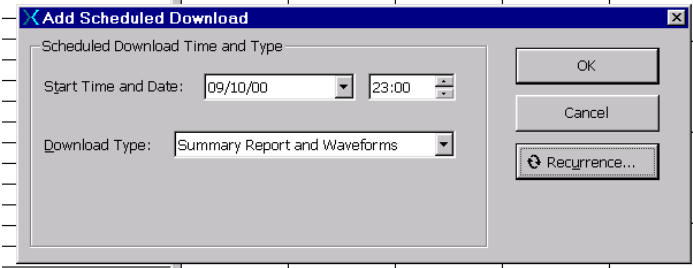
To change the current month:
Click the larger arrow buttons above the day by day view.



4 Right-click on the first required data collection day and then left-click on the *Add Scheduled Data Collection* option to display the *Add Scheduled Download* dialog.



5 Enter the required *Start Time and Date*. Next, select the required *Download Type* from the following options:

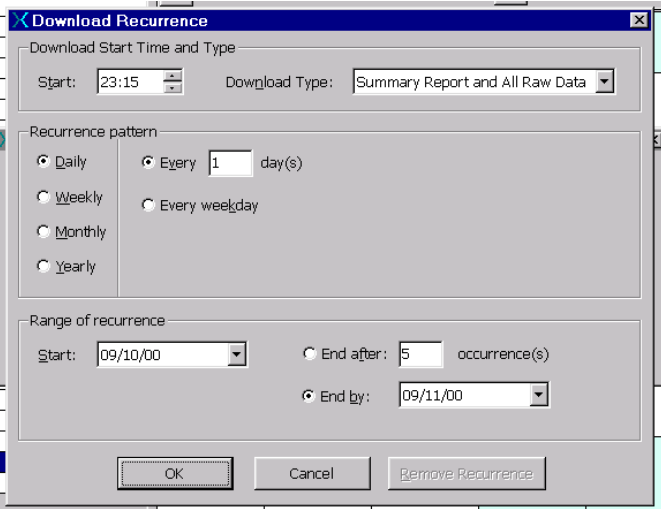


- Summary Report Only,
- Summary Report and Waveforms, or
- Summary Report and All Raw Data

6 If only a single download is required, click the **OK** button.

If a series of data downloads are required, click the **Recurrence...** button to display the *Download Recurrence* dialog:

7 Set the required *Recurrence pattern* by selecting a *Daily*, *Weekly*, *Monthly* or *Yearly* base interval as appropriate.



8 In the *Range of recurrence* section, set either the *End after:* or the *End by:* options as required.

9 When all details of the download schedule have been entered, click the **OK** button. The *Add Scheduled Download* dialog will now be visible again, click its **OK** button to apply the changes.

The download schedule will be summarised in the previously selected calendar view as shown on the next page.

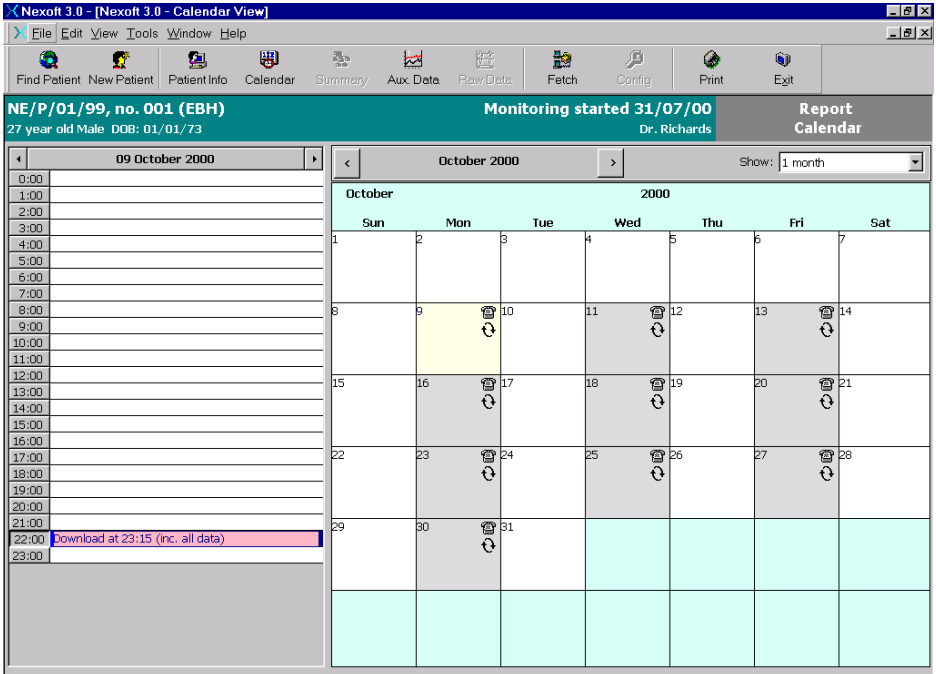


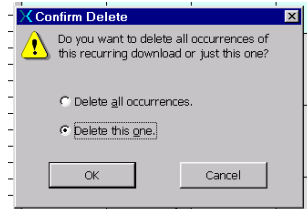
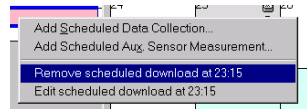
Figure 10: Calendar view showing summary of scheduled downloads

To edit or delete a download schedule:

- 1 Display the record page for the required patient (see 'To locate existing patient records').
- 2 Click the **Calendar** button on the toolbar. A calendar screen will be displayed.
- 3 Right-click on the appropriate data collection day and then left-click on either:

- *Edit scheduled download...* option to display an editable summary of the selected download settings,
- *Remove scheduled download...* option to display the *Confirm Delete* dialog:

Select either the *Delete all occurrences* or the *Delete this one* option as appropriate and click the **OK** button.



Initiating an immediate download

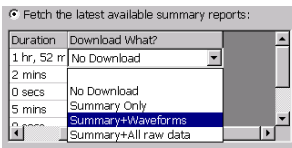
The system provides an option to make an immediate connection to the Base Station in order to download data (in addition to, or instead of any programmed download schedule)

To initiate an immediate download:

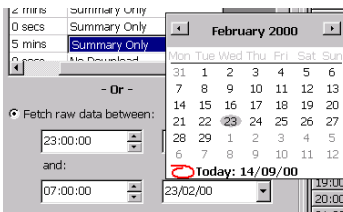
- 1 Display the record page for the required patient (see 'To locate existing patient records').
- 2 Click the **Fetch** button on the toolbar. The *Download Data* dialog will be displayed:
- 3 Click the **Connect** button to open a connection between the TMS and the selected Base Station.

Once connected, the *Download Data* dialog provides a number of options:

- The *Fetch the latest available summary reports* option allows you to select which of the reports (that are stored in the Base Unit) should be downloaded and in what form:



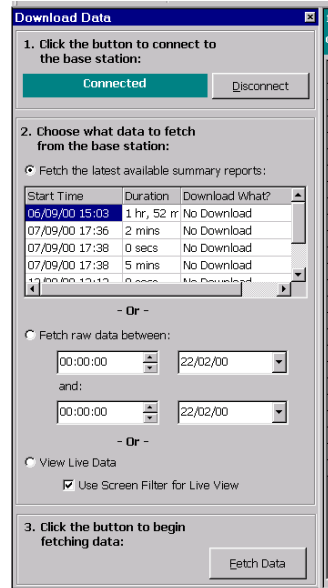
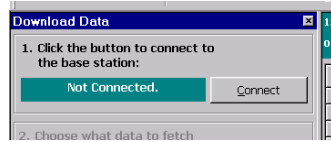
- The *Fetch raw data between* option allows you to download stored data from monitoring sessions defined by date and time limits:



- The *View Live Data* option allows you to view real time data as it is collected by the Base Unit.



- 4 When all required options have been set, click the **Fetch Data** button to begin the download. A dialog provides an indication of progress. Once complete, you will be prompted to refresh the patient - click **Yes**.



*Note: Click **Stop Download** if you need to quit the download.*

Viewing Downloaded Data

Once data has been downloaded for a particular user you can view various aspects of the information in a graphical form.

To view raw data on screen:

- 1 Display the record page for the required patient (see 'To locate existing patient records').
- 2 Click the **Raw Data** button on the toolbar. A *Raw Data View* dialog will be displayed with one or more channels enabled:

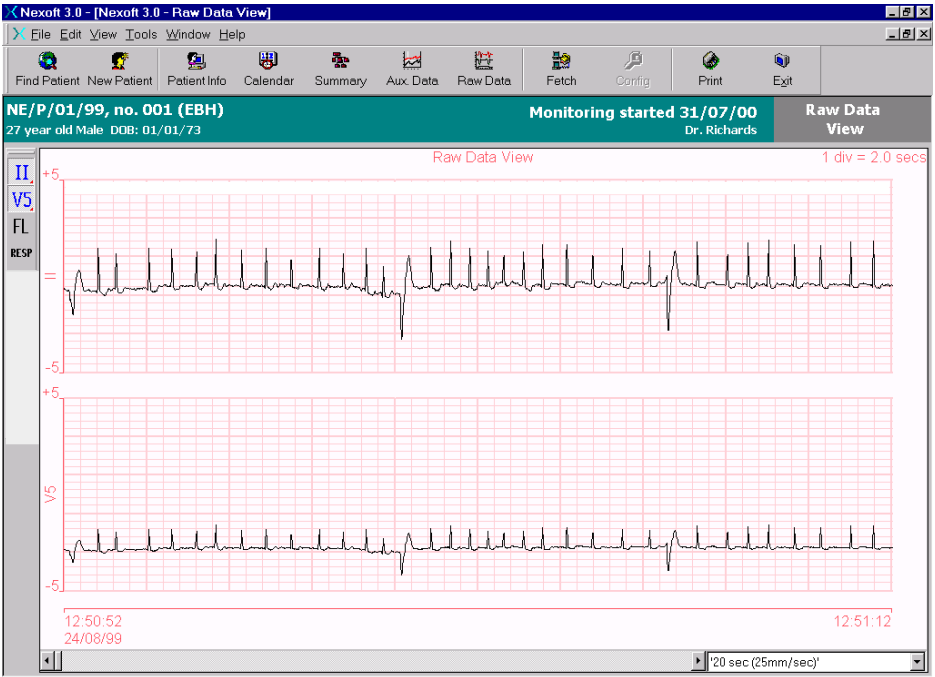


Figure 11: Raw data view with two channels enabled

To alter the viewed data:

Channels

The channels to be displayed are controlled by the toolbar buttons shown on the left hand edge of the screen. The channels are as follows:

- **II** - ECG waveform from position modified lead 2 (II) of the Nexi.
- **V5** - ECG waveform from position modified lead V5 of the Nexi.
- **FL** - Optional 'floating' sensor connected independently to the Nexi-Clip.
- **RESP** - Respiration signal from the Nexi respiration impedance sensor.
- **Filter ON/OFF** - When enabled, this baseline filter compensates for changes in the overall voltage levels measured by the ECG and flying lead sensors.

To switch a channel on or off: Click the button representing that channel.

The raw data view window and the channel toolbar can both be 'undocked' and rearranged to suit:

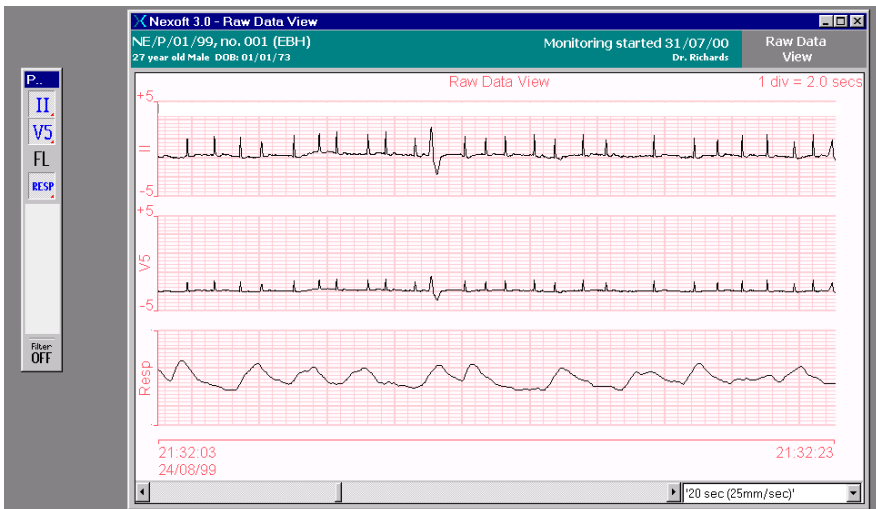


Figure 12: Raw data view and channel toolbar undocked

Printing Information

The system allows you to print various types of information, such as patient details, raw data graphs, etc.

To print patient information:

- 1 Display the record page for the required patient (see 'To locate existing patient records').
- 2 Click the **Print** button on the toolbar. A print preview screen will be displayed:

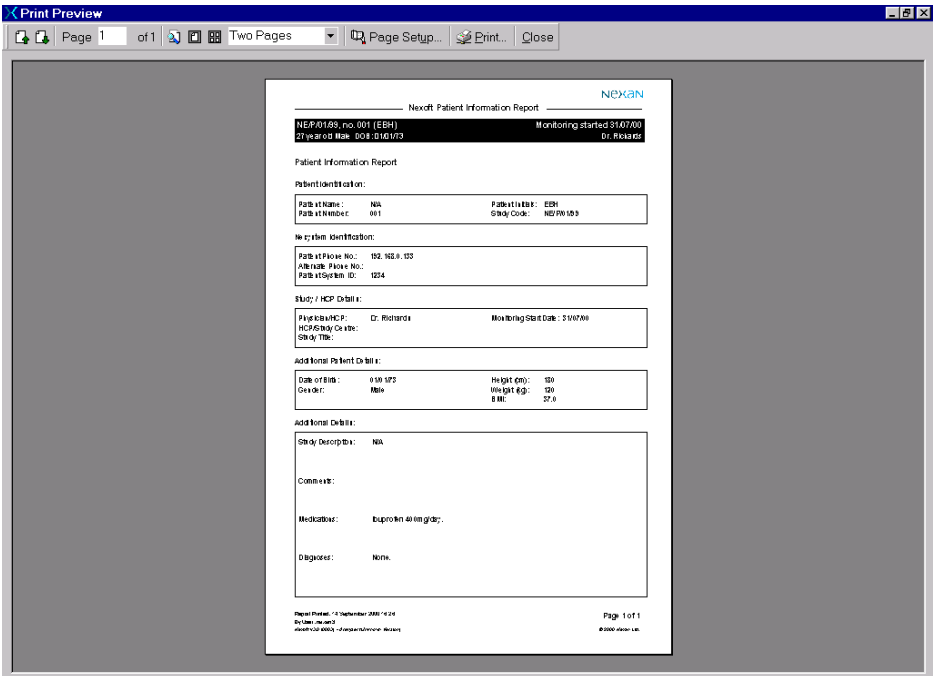


Figure 13: Print preview showing patient information

- 3 Ensure that the printer is switched on and ready to receive, then click the **Print** button on the preview toolbar.

To print raw data channels:

- 1 Display the required raw data view (see 'To view raw data on screen').
- 2 Click the **Print** button on the toolbar. A print preview screen will be displayed:

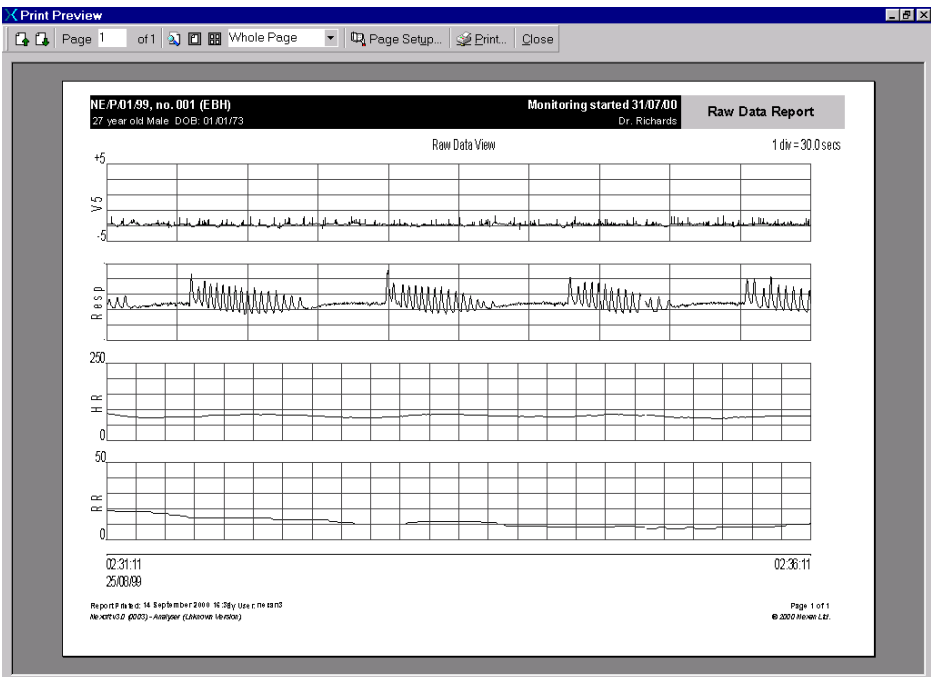


Figure 14: Print preview showing raw data

- 3 Ensure that the printer is switched on and ready to receive, then click the **Print** button on the preview toolbar.

On-line help

The Nexoft system incorporates an extensive on-line help system.

To access on-line help:

- 1 Select the *Help* menu (or press F1) and then click either:
 - *Contents* - to display the help system table of contents,
 - *Index* - to view the index listing, or
 - *Search* - if you wish to enter a keyword and have the help system locate related topics.

The help screen will be displayed with either the Contents, Index or Search tab selected on the left-hand side depending on which option was selected.

- 2 Choose the required item from the Contents/Index list or enter your keyword to perform a search.

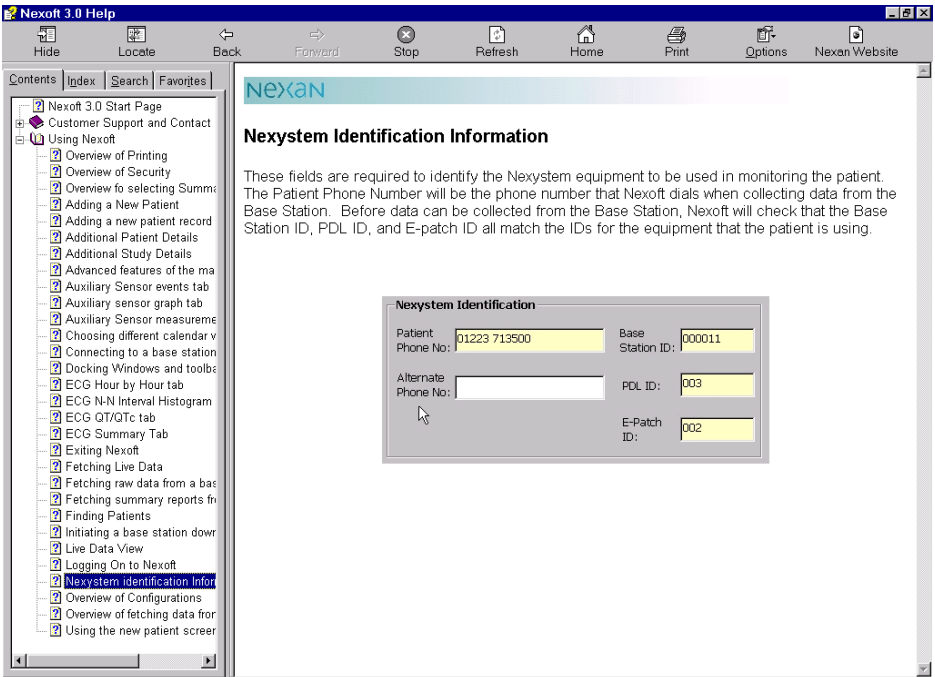



Figure 15: Help screen showing the Contents listing on the left-hand side

*Note: The help system is web-enabled so that you can transfer directly to the Nexan website for further details. Click the **Nexan Website** button on the help toolbar.*

Shutting down the TMS

CAUTION: If you exit Nexoft or shut down the computer, scheduled downloads will not occur.

- 1 In the main Nexoft window, click the **Exit** button. The Nexoft window will close, leaving the standard Windows desktop.
- 2 Click the Windows **Start** button.
- 3 Choose the **Shut Down** option and, in the dialog that appears, check that the *Shut down the computer?* option is selected.
- 4 Click the **Yes** button. After a short while the screen will display the message *It is now safe to turn off your computer.*
- 4 On the front panel of the TMS Computer, press the button marked  to set the computer to standby. If required, switch off the computer at the mains supply.

SECTION 5

General Information

Technical Description

System comprising:

- a) The on-body equipment, comprising the Nexi and the Nexi-Clip processing electronics. The Nexi is a disposable element, containing ECG electrodes, bioelectric impedance electrodes for respiration measurement, and a connector for an additional ECG electrode. It is a disposable item, designed to be worn for up to 24 hours. The Nexi-Clip takes measurements via the electrodes, and transmits them to the Portable Data Assistant (PDA.) The Nexi-Clip is non-disposable, and is detachable from the Nexi.
- b) The PDA which stores up to 24 hours worth of data received from the on-body equipment.
- c) The Base Station Unit (BSU) which stores up to 14 days worth of data received from the PDA.
- d) The Tele-Monitoring Station (TMS) which is used to interrogate the BSU, and to interpret and display the data.

Nexan Ltd will make available on request circuit diagrams, component parts lists, descriptions, calibration instructions or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.

Technical Specifications

General

Nexi	Two lead ECG sensors providing a modified Lead II view and modified CM5. Respiration impedance waveform. Optional 3rd flying lead with ECG electrode.
Nexi-Clip	Contains: PCB Europe- Radio TX UHF 868 MHz US- Radio TX UHF 916.5 MHz
PDA:	Contains: PCB, Storage device (memory card) EU- Radio RX operating in unlicensed Band of 869.7-870MHz US- Radio RX operating in UHF Band 916-917MHz * Displayed respiration by impedance: Range: 1 - 72 * Breaths Per Minute Accuracy: ± 2 Breaths Per Minute * Displayed two lead ECG sensors * Heart rate range: 30-250 Beats Per Minute * Heart rate accuracy: ± 3 Beats Per Minute
* The values displayed are only for 'Hook-up' signal checks by the HCP.	
BaseStation	Computer Mother Board with Pentium Processor and Hard Disk storage device, Call discriminator, LCD Touchscreen.
PDA Desktop charger unit	Contains: PCB
TMS Computer	700MHz Pentium III Computer with DVD Drive, backup tape drive, modem.
Printer	HP Deskjet 840C. See manufacturer's instructions for details.

Power requirements

- Nexi-Clip and Nexi:** Shared 3V requires 2 x 1.5V alkaline AAA cells. (fitted during manufacture to the Nexi -Not user replaceable)
- PDA:** 3.6V 1600mAh Re-chargeable Lithium Ion Cell. (No User Access) Recharge using only the following Nexan supplied charger units:
- a. Nx-300 Base Station Unit (PDA docking slot)
 - b. Nx-300 PDA Desktop Charger Unit
- PDA Desktop charger** Requires 7.5VDC 1A . Use only (Model No.JOD-48-09) supplied by Nexan for use with the with the Nx-300 system.
- Base Station** Requires 100-240V 50-60Hz~ Power consumption 2A-1A. Two UL approved fuses rated T2AH (250V).
- Omron ® IC Blood Pressure monitor:** 6V requires 4 x AA LR6 1.5V Alkaline batteries.
- Micro Plus Spirometer** 9V requires 1 x PP3 9V dry cell battery.
- TMS Computer** UK requires 220-240V 50/60Hz~
US Requires 110-120V 60Hz~
- TMS Printer (Option)** UK requires 220-240V 50/60Hz~
US Requires 110-120V 60Hz~

Transport and Storage conditions

CAUTION: These devices may not meet their performance criteria if stored outside the ranges stated below.

Nexi and Nexi-Clip

Temperature*	-20 to + 65°C
Humidity*	5 to 90% non-condensing
Ambient pressure*	700 to 1060 mbar

Base Station Unit

Temperature*	-20 to +65°C
Humidity*	5 to 90% non-condensing
Ambient pressure*	700 to 1060 mbar

*Set by EC38 as per 'Stationary Equipment'.

PDA and PDA Desktop Charger

Temperature*	-20 to +65°C
Humidity*	5 to 90% non-condensing
Ambient pressure*	700 to 1060 mbar

*Set by EC38 as per 'Stationary Equipment'.

Operating Conditions

CAUTION: These devices may not meet their performance criteria if stored outside the ranges stated below.

Base Station Unit, PDA and PDA Desktop Charger

Temperature	+10 to +40°C
Humidity	30 to 75% non-condensing
Ambient pressure	700 to 1060 mbar

Nexi

Temperature	+10 to +40°C
Humidity	30 to 75% non-condensing
Ambient pressure	700 to 1060 mbar

Nexi-Clip

Temperature	+10 to +40°C
Humidity	30 to 75% non-condensing
Ambient pressure	700 to 1060 mbar

Cleaning, Maintenance, Storage and Calibration

It is intended that maintenance is carried out between patient use by a suitably trained person. It is not intended that the patient will carry out any maintenance or repair (including Base Station fuse replacement) and there are no patient replaceable parts. If a fault occurs when using the system, first read the Trouble shooting guide. If the fault is still present then contact Customer Support as detailed in Page 2. If Customer Support request the return of a part of the system, it should be returned in its original packaging.

Maintenance of Base Station, PDA and Nexi-Clip

WARNING: REMOVE MAINS POWER FROM THE BASE STATION BEFORE CLEANING.

WARNING: DO NOT ALLOW THE CLEANING SOLUTION OR WATER TO RUN INTO CREVICES OR OPENINGS.

The Base Station, PDA and Nexi-Clip can be wiped with a nearly-dry cloth containing warm water and detergent. Thoroughly wipe off any excess residual cleaning solution from the Nx-300 system and allow to dry.

While cleaning the Base Station, PDA and Nexi-Clip, they should be checked for unusual wear or possible damage from an accident.

Re calibration of the Base Station, PDA and Nexi-Clip are not required.

Power Cables

WARNING: DO NOT OPERATE THE EQUIPMENT FROM MAINS POWER WITH A DAMAGED POWER CORD OR PLUG.

The Base Station mains power supply cable supplied is intended to be used only with the Nextation and should not be used for any other electrical equipment.

Disconnect the power cable from mains power before inspecting the power cord periodically for fraying or other damage, and replace as needed.

Replacing the Base Station fuses

The Base Station contains two fuses that can easily be replaced by service personnel if necessary.

CAUTION: Replace each fuse only with the specified type - as indicated on the Base Station label adjacent to the fuse holder.

Note: Both fuses should be replaced at the same time, even if only one fuse is found to be unserviceable due to an over current situation. The other fuse may have become stressed and could become unreliable.

To replace the Base Station fuses:

- 1 Unplug the power cord from the ac mains supply outlet then unplug the removable cord from the ac mains inlet of the Base Station.
- 2 Locate the fuse holder, which protrudes from below the mains inlet socket of the Base Station.
- 3 Using a flat bladed screwdriver, depress the centre tab, then carefully withdraw the fuse holder.
- 4 Replace both fuses with the specified type.
- 5 Refit the fuse holder.

Regulatory Markings

Federal Communications Commission (FCC) Compliance and Advisory Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions for use, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/television technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation.

FCC ID: PCPNX-300

CAUTION: Changes or modifications not expressly approved in writing by Nexan Ltd may void the user's authority to operate this equipment..

Warranty

Nexan Ltd. warrants to the original purchaser that the Nx-300 (Product), provided in the sales packaging, is free from defects in material and workmanship, under normal installation and use, according to the following terms and conditions:

- 1 The warranty for the 'Product' extends for ninety (90) days from the date of purchase by the customer.
- 2 The warranty for the installed/supplied software extends for ninety (90) days from the date of purchase by the customer.
- 3 Nexan Ltd shall be under no liability in respect of any defect arising from fair wear and tear, wilful damage, negligence, abnormal working conditions, failure to follow Nexan Ltd's Instructions (whether conveyed orally or in writing), misuse, improper installation or alteration or repair of the Products without Nexan Ltd's approval.
- 4 The above warranty does not extend to parts, materials or equipment not manufactured by Nexan Ltd, in respect of which the Customer shall only be entitled to the benefit of any such warranty or guarantee as is given by the manufacturer to Nexan Ltd.
- 5 Subject as expressly provided here, all warranties, conditions or other items implied by statute or common law are excluded to the fullest extent permitted by law.
- 6 Any claim by the Customer which is based on any defect in material or workmanship of the products shall be notified to Nexan Ltd immediately after discovery of the defect. If the Customer does not notify Nexan Ltd accordingly, the Customer shall not be entitled to reject the products and Nexan Ltd shall have no liability to the Customer.
- 7 Where any valid claim in respect of any of the Products which is based on any defect in the materials or workmanship of the Products is notified to Nexan Ltd, Nexan Ltd shall be entitled to replace with new or refurbished replacement items or repair (at Nexan Ltd's sole discretion, either at the customers premises or at Nexan Ltd's premises in the UK) the Products (or part in question) but Nexan Ltd shall have no further liability to the Customer. Repaired, refurbished or replacement 'Product' is warranted for the balance of the warranty period.
- 8 Nexan Ltd shall not be liable to the Customer by reason of any representation, or implied warranty, condition or other term, or any duty at common law, or for any consequential loss or damage (whether for loss of profit or otherwise), costs, expenses or other claims for consequential compensation whatsoever arising out of or in connection with any act or omission of Nexan Ltd relating to the manufacture or supply of the Products or use by the Customer.

Troubleshooting guide

Base Station green lamp not lit when Base Station power switch is set to On.

Base Station may not be plugged into wall socket. Ensure that the power lead is plugged into wall socket and it is switched on.

PDA ECG trace shows poor signals.

If no trace is seen:

- check the Nexi-Clip is transmitting satisfactorily - see Signal mV option on PDA Status screen. If no radio signal is present, check the Nexi-Clip is correctly clipped together.
- check the Nexi-Clip Id is correctly configured.
- if no trace is seen on ECG3, check ECG3 is enabled.
- if still no trace, check for Nexi battery failure by trying another clip.

If a noisy trace is seen:

- check Nexi is properly attached to patient. Pay special attention to skin preparation before application.

If there are gaps in the trace:

- this indicates poor radio reception, possibly due to local radio interference. Try to identify and remove the source of interference.
- move PDA closer to patient.

If a flat-line is seen:

- if seen on ECG3, the flying lead may not be properly connected to the Nexi;
- may indicate a faulty connection within the Nexi-Clip - try another.