EXHIBIT U – User Manual

FCC ID# NMEAVTS1000

DATA CRITICAL CORP.

AlarmView™
Users Guide Document

Precautionary Information

 Caution

Instructions - For continued safe use of this equipment, it is necessary that the listed instructions be followed. However, instructions listed in this manual in no way supersede established medical procedures concerning patient care.

Intended Use - The system is intended to monitor various patient-monitoring devices for alarm conditions, and responds by transmitting message data that includes text information from the patient.

Confirmation - When the system sends out a page, there is NO confirmation back that the intended pager has successfully received the page.

Maintenance - Failure on the part of the hospital or institution to maintain the equipment as outlined in this manual may cause pre-mature equipment failure.

Installation - The AlarmView System has been installed by qualified technicians. Modification of this installation may cause undue equipment failure.

Electromagnetic Interference - The AlarmView System may cause electromagnetic interference with devices operated in close proximity to the transmitter (refer to Appendix C).

System Components - Do not spill liquids on any of the AlarmView™ System components.

⚠ Warnings

Patient Monitoring - The most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment. Patient alarm conditions and notifications are primary functions of the patient monitoring system. It is imperative that the caregiver and/or monitoring floor technicians monitor patient alarm conditions. **The AlarmView System is not intended for use as the primary source for the patient alarm notification.**

Accidental Spills - In the event fluids are accidentally spilled in the equipment, take the equipment out of service and check for damage. Check operation after drying 24 hours later.

Antenna Placement - The transmitter unit with a transmitter antenna may interfere with computer equipment with electronic switchboards located close to the antenna. If the transmitter unit must be located close to these types of equipment, a remote antenna should be used.

Change of Performance - If the system fails to page users reliably, contact the hospital staff responsible for electromagnetic environment and Data Critical Corp. immediately. (Data Critical Corp. 24 hour support at 1-877-322-7828)

Electrical Shock - To reduce the risk of electrical shock, DO NOT remove cover (or back). Refer servicing to qualified personnel.

Environment - Data Critical Corporation does not assume responsibility for damage to the equipment caused by improperly vented cabinets, improper or faulty power, or insufficient wall strength to support equipment mounted on such walls.

Explosion Hazard - Do not use this equipment in the presence of flammable anesthetics, skin cleaning agents, and disinfectants. Great care must be exercised when the device is used in an oxygen-enriched atmosphere. The atmosphere is considered to be oxygen enriched when the room air contains more than 25% of oxygen or nitrous oxide.

Home Use - AlarmView™ System is not intended for home use.

Power - Convenience outlets and all others that may be used for the patient must be on the hospital emergency circuit so that they are energized at all times.

Site Surveys - Each institution is responsible for surveying existing equipment and ensuring no conflict exists when considering the introduction of additional radiating devices.

Transmission Bands - Each institution is responsible for maintaining continued surveillance of transmission bands being used in the facility to prevent co-occupation of bands and cross-band interference.

Indications for Use

This device is intended for use in real-time monitoring of routine patient status and alarm events on medical devices. It serves as a parallel, redundant mechanism to inform the clinical staff of patient events. It is intended to be a secondary means of annunciating and displaying patient alarm information to mobile healthcare providers.

AlarmView is limited to use by qualified medical professionals who have been trained on the use of the device. It is intended for use in hospital and hospital type environments and is not for home use.

AlarmView is intended to supplement and not to replace any part of the current device monitoring procedures.

AlarmView is not considered in and of itself to be diagnostic without skilled interpretation and does not replace physician's care.

AlarmView is currently validated for use with the N-$x9y$ and the N-3000 data protocols.

Please note that we have demonstrated compatibility with the data protocols that Nellcor Puritan Bennett has defined, not the individual monitors. However, for FDA reference, the chart below indicates all models using the protocol. Data Critical is compatible with all the listed monitors.

Protocol:	All Current Models:
N-$x9y$	N-290, N-295
N-3000	N-3000

For devices not listed in the above compatibility chart, a separation distance of 5.5 feet between the AlarmView Transmitter and other emitting devices should be observed.

For the devices listed on the above compatibility chart, the AlarmView Transmitter may be placed in either of the configurations described below:

- The AlarmView transmitter can be located remotely from the patient device (e.g. place the AlarmView Transmitter on the wall instead of the patient monitoring equipment).
- When placing the AlarmView Transmitter in close proximity to the patient monitoring equipment, place it as shown in the drawing below, using the velcro attachment provided:

Alarm Data

The alarm data that the AlarmView system echoes are listed in the following chart.

Alarm	Nx9y	N3000
SPO2 Upper Limit	X	X
SPO2 Lower Limit	X	X
PR Upper Limit	X	X
PR Lower Limit	X	X
No Pulse Motion	X	X
No Pulse No Motion	X	X
Sensor Disconnect	X	X
HR Upper Limit		X
HR Lower Limit		X
Asystole		X
ECG Lead Off		X
ECG Cable Off		X
ECG Operations Error		X
ECG Noise		X
RR Upper Limit		X
RR Lower Limit		X
Apnea		X
Respiration Lead Off		X
Respiration Cable Off		X
Respiration Ops Error		X
Respiration Noise		X
Low Monitor Battery	X	

It should be emphasized that this alarm data is passed to AlarmView via simple text strings. No interpretation of this information is made. Whatever the monitor passes AlarmView is what will be passed through and transmitted to the nurse.

Also, these alarm modes are determined by the protocols we are claiming compatibility with: N-x9y and N-3000.

Service and Technical Support

Direct all inquires to:
Data Critical Corporation
19820 North Creek Parkway
Suite 100
Bothell, WA 98011

For technical advice or information concerning any equipment in your AlarmView™ System, contact Technical Support. Call, toll free at 1-877-DCC-STAT (1-877-322-7828).

Conventions of this Manual

Two items that may help you as you work through the AlarmView User's Guide are the special notes and cautions that appear throughout this text. Individual icons identify these notes and cautions, and they alert you to special information.

The Caution icon alerts you to possible problems that you may encounter as you work through the AlarmView™ System programs. The possibility of losing data, for example, is information that could be mentioned in a caution.
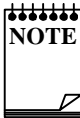
The Note icon alerts you to tips or hints that may make it easier for you to work within AlarmView System programs. These might include data entry tips, additional information about a window or field, or recommended procedures.

NOTE: Due to continuing product innovation, specifications in this manual are subject to change without notice.

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Windows™ CE is a registered trademark of Microsoft Corporation.

AlarmView™ System is registered trademark of Data Critical Corporation.

Introduction

AlarmView™ System Product Description

The AlarmView System is a secondary alarm notification system that transmits alarm data from Primary Patient Monitoring Equipment (PME) to pagers that are worn by caregivers.

- The AlarmView Pager - The AlarmView Pager is an off the shelf pager that is worn by caregivers responsible for individual patient care.

- The AlarmView Programmer - The AlarmView Programmer is an off the shelf Personal Digital Assistant (PDA) with Windows CE operating system and equipped with AlarmView programming software. The PDA needs to have an infrared (IR) port to communicate with the transmitter.

- The AlarmView Transmitter - The AlarmView Transmitter is connected to the Patient Monitoring Equipment (PME) (i.e., Nellcor Puritan Bennett Pulse Oximeter – NPB-290, NPB-295, NPB-3000) with an AlarmView cable that is connected to the PME's serial port.

AlarmView System Diagram
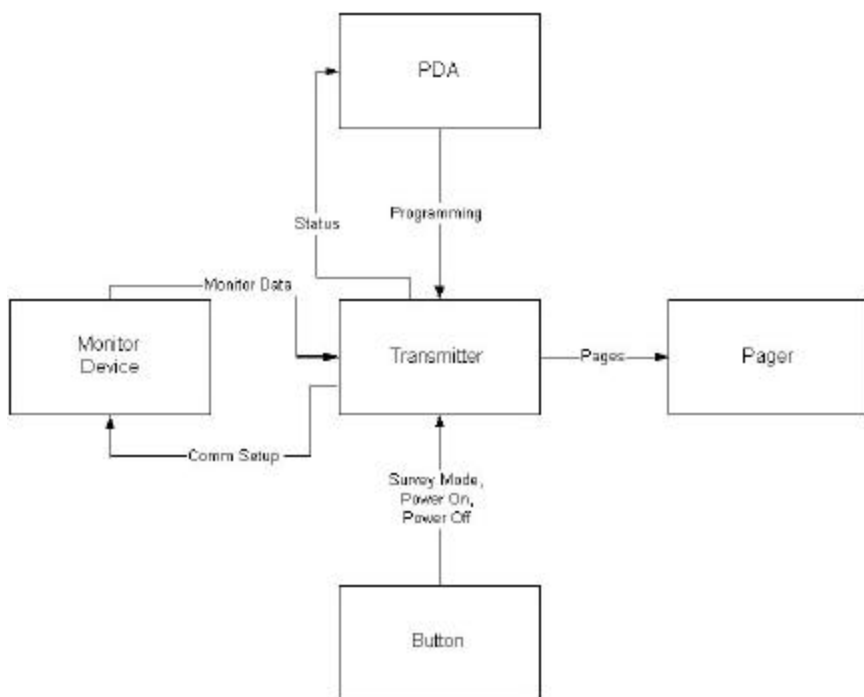
AlarmView™ System

System Components

Transmitter

The transmitter is Data Critical Corporation's proprietary RF transmitter operating in the UHF band (450-466MHz). It has an a BNC connector for the antenna needed for the RF transmissions, an IR port used for setup, a button for power on/off and certain user initiated transmissions, and an RJ-45 connector for connection with the Patient Monitoring Equipment.

<Insert AlarmView Transmitter Device Unit image here>

Pager

The pager is a 4 by 20 character text based, off the shelf pager operating in the UHF band (450-466MHz), and able to receive POCSAG encoded pages.

<Insert AlarmView Paging Device Unit image here>

PDA (Personal Digital Assistant) Programmer

The PDA programmer is an off the shelf Personal Digital Assistant with Windows CE operating system and equipped with AlarmView programming software. The PDA programmer includes an IR port for communications with the transmitter. At least one PDA running Windows CE with AlarmView software is needed to be used for user programming of the transmitters.

<Insert PDA image here>

Monitoring Device Types

The AlarmView software is currently configured to be compatible with Nellcor Puritan Bennett Pulse Oximeters N-290, N-295, or N-3000.

<Add photo of NPB? >

Getting Started

Before turning on the transmitter, ensure that the antenna is attached to the transmitter. The antenna is attached to the transmitter via a BNC connector found on the back of the transmitter (directly behind the LED). The power cable is attached on the back of the transmitter to the far right. The unit can now be turned on by pressing the button on the top of the transmitter.

<Insert AlarmView Transmitter Device Unit image with arrow pointing to button here>

Survey Mode

The Survey Mode is a mode in which frequent periodic pages are sent from the transmitter to the assigned pager(s). To begin the Survey Mode, turn on the transmitter, as described above. The transmitter should not be attached to any patient monitoring equipment as this point. The LED on the front of the transmitter will be ORANGE to indicate that the transmitter is attempting to establish communications with the patient monitoring equipment. Press the button on the top of the transmitter, and hold the button down for approximately 5 seconds. A numbered "Survey Page" will be sent. Every 15 seconds, another "Survey Page" will be sent. This will continue until one hundred pages have been sent. To stop the survey mode before one hundred pages have been sent, press the button on the top of the transmitter, and hold the button down for approximately 5 seconds.

Pages sent during the Survey Mode will have a line of data, which will indicate that the Survey Mode is in process.

Pages sent during the Survey Mode will contain the following data:

Bed Number
Transmission Number (in sequence)

<Insert photo>

Programming Mode

The Programming Mode is the mode in which the PDA is used to change or view the current setup (i.e. the bed number and the pager cap codes) of the transmitter. To program the transmitter, the transmitter must be trying to establish communications with the patient monitoring equipment (the LED is ORANGE), or have established communications with the patient monitoring equipment (the LED is GREEN).

The Editor Program

Turn the PDA "ON". The first screen of the PDA will appear and will resemble the screen below.
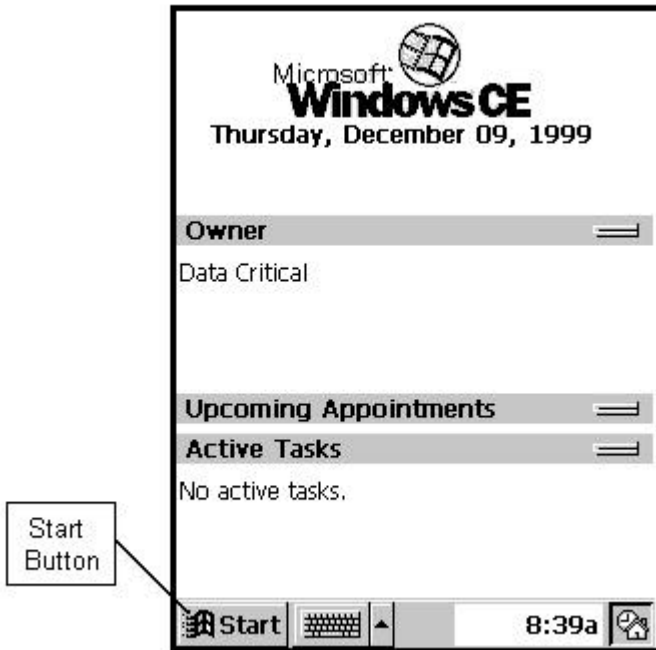
Select the Windows Start menu button.

From the Windows Start menu, select the "AV System Manager" program.

The AlarmView System Manager main screen will appear as shown below.

Exit Button

About Button

AlarmView
System Manager
(c) Data Critical 2000

Programming Button

Editor Button

Keyboard Icon

Start Button

Start

12/21/99
2:56p
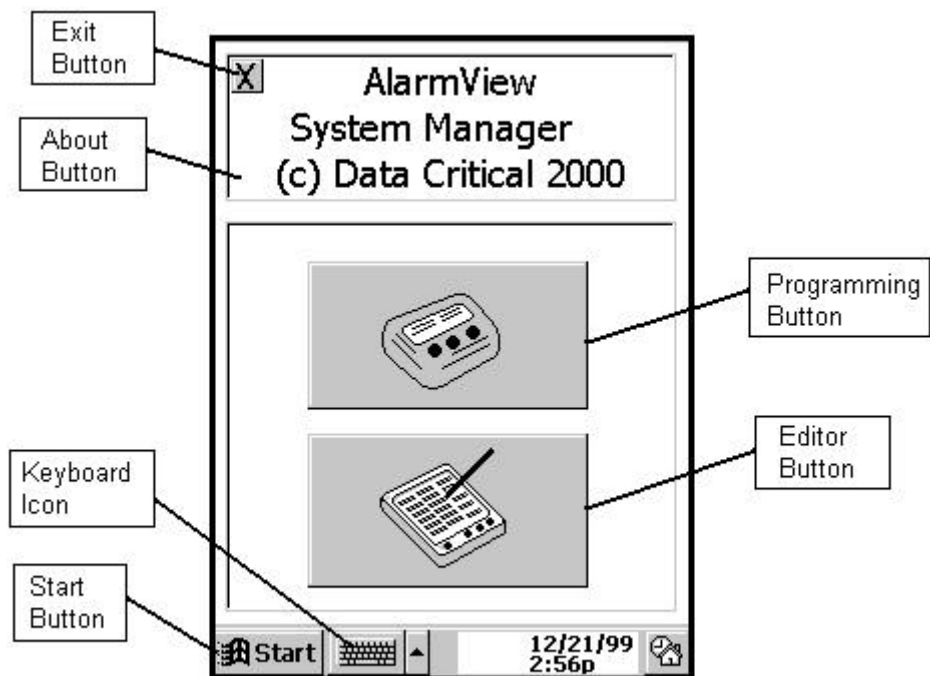
Tap the About button for information about the System Manager software.
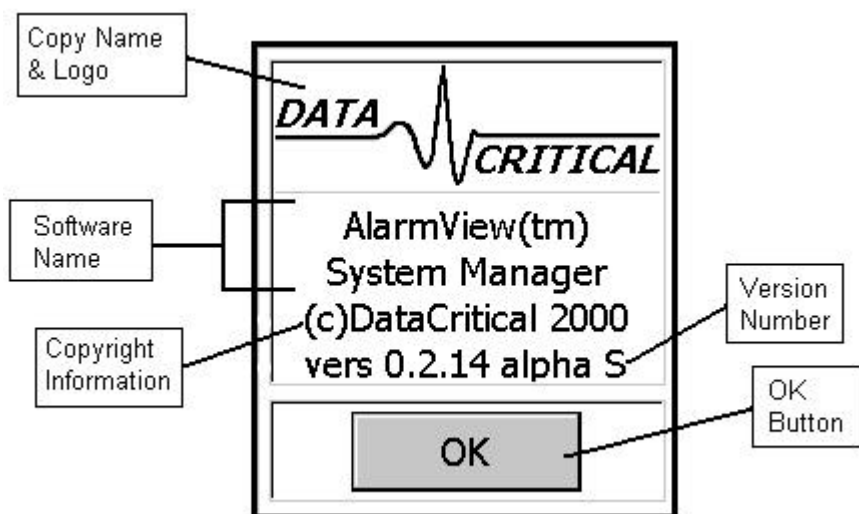
Tap the OK Button to return from this dialog box.

Now tap the Editor Button on the Main Screen. The following warning
will appear.

INCORRECT ENTRIES
MAY IMPAIR THE
ALARMVIEW SYSTEM
CONTINUE ??

Yes Button -
OK to continue

YES

NO

No Button -
Do not continue
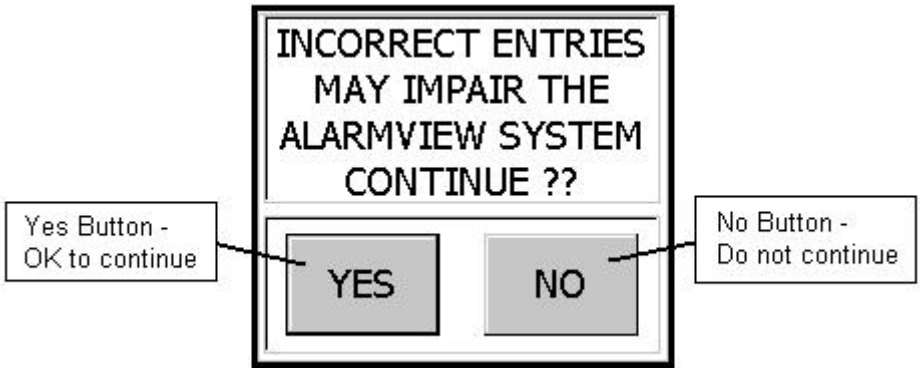
Pressing the "No Button" will return the user to the AlarmView System
Manager main screen. Pressing the "Yes Button" will launch the
"AlarmView Editor" program. This is the program used to setup which
bed number and cap codes are present in the system. It can be
reconfigured when pagers are sent back to the factory, or new pagers
are obtained.

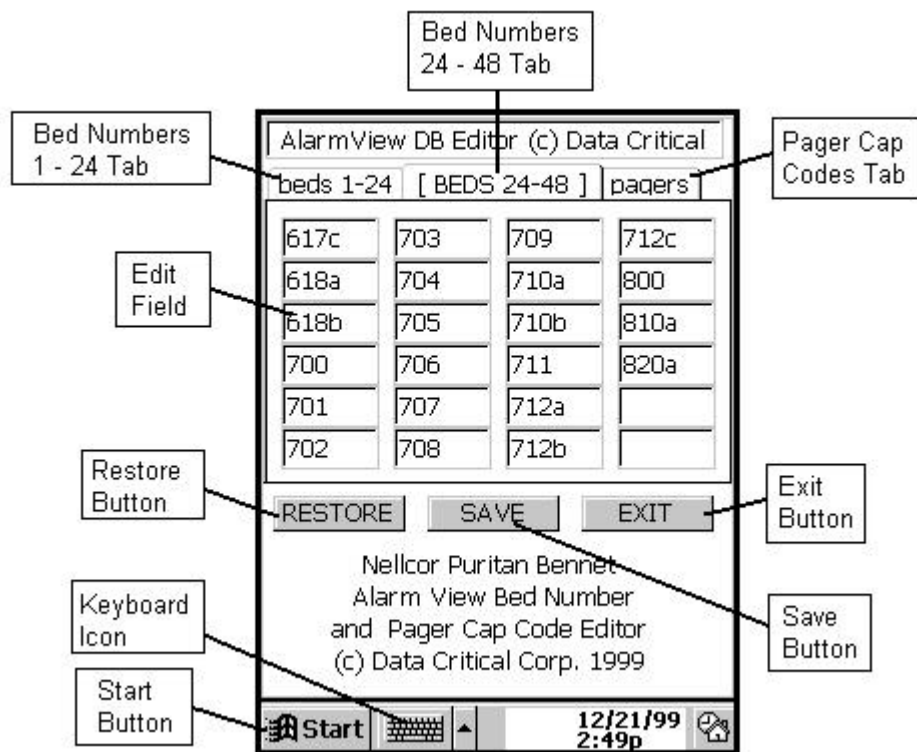To configure the bed numbers available in the system, tap the Bed Numbers 1 - 24 tab or the Bed Numbers 24 – 48 tab. The first tab lists the first 24 bed numbers available to the system. The second tab lists the last 24 bed numbers available to the system. It is not necessary to fill in all 48 slots.

Below is the Bed Numbers 1 – 24 screen.

Bed Numbers
24 - 48 Tab

Bed Numbers
1 - 24 Tab

Pager Cap
Codes Tab

Edit
Field

Restore
Button

Exit
Button

Keyboard

Save
Button

Keyboard
Icon

AlarmView DB Editor (c) Data Critical

[BEDS 1-24] beds 24-48 pagers

601a	603	609	615c
601b	604	610	616a
601c	605	611	616b
602a	606	612	616c
602b	607	614	617a
602c	608	615a	617b

RESTORE   SAVE   EXIT

Esc 1 2 3 4 5 6 7 8 9 0 - = ←
Tab q w e r t y u i o p [ ]
CAP a s d f g h j k l ; '
Shift z x c v b n m , . / ↵
Ctl áü ` \   ↓ ↑ ← →

Start ⌨ ▲   12/21/99
                  2:48p

Below is the Bed Numbers 24 – 48 screen. Note that the "active" tab is displayed in all caps.

Bed Numbers
24 - 48 Tab

Bed Numbers
1 - 24 Tab

Pager Cap
Codes Tab

Edit
Field

Restore
Button

Exit
Button

Keyboard
Icon

Save
Button

Start
Button

AlarmView DB Editor (c) Data Critical

beds 1-24   [BEDS 24-48] pagers

617c	703	709	712c
618a	704	710a	800
618b	705	710b	810a
700	706	711	820a
701	707	712a	
702	708	712b	

RESTORE   SAVE   EXIT

Nellcor Puritan Bennet
Alarm View Bed Number
and Pager Cap Code Editor
(c) Data Critical Corp. 1999
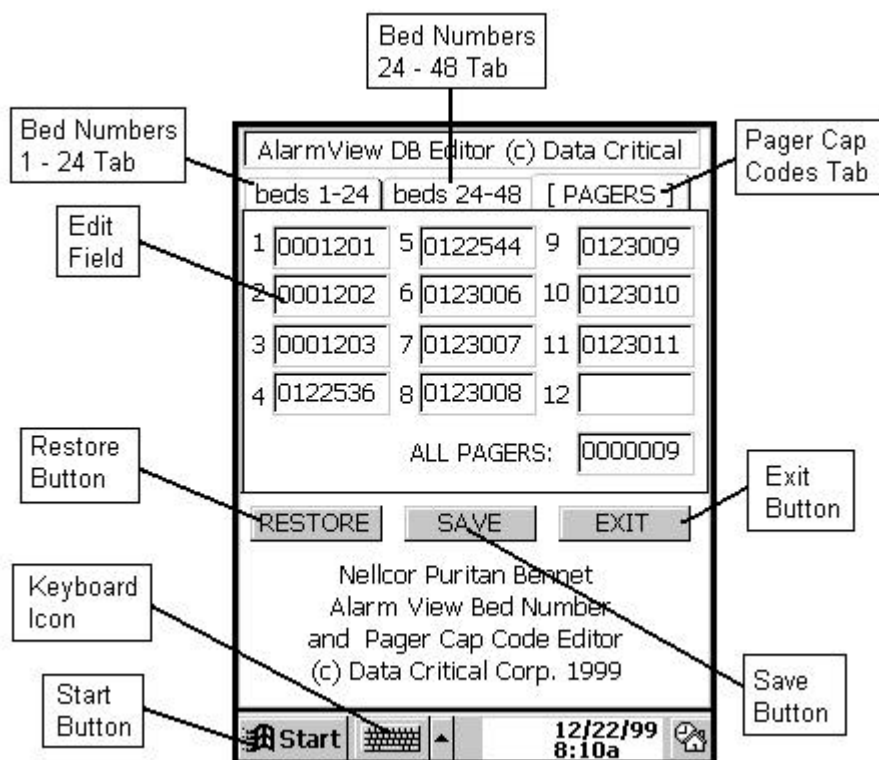
Start ⌨ ▲   12/21/99
2:49p

Bed Numbers can be added and deleted from this list. Click on a bed number to edit. Using the stylus, tap the backspace key on the keyboard to delete the bed number to be edited (or highlight the entire bed number as shown below), and using the numbers and letters on the key board, type in the new bed number. Tap the "Save" button on completion, or the "Exit" button to exit the Editor Program.
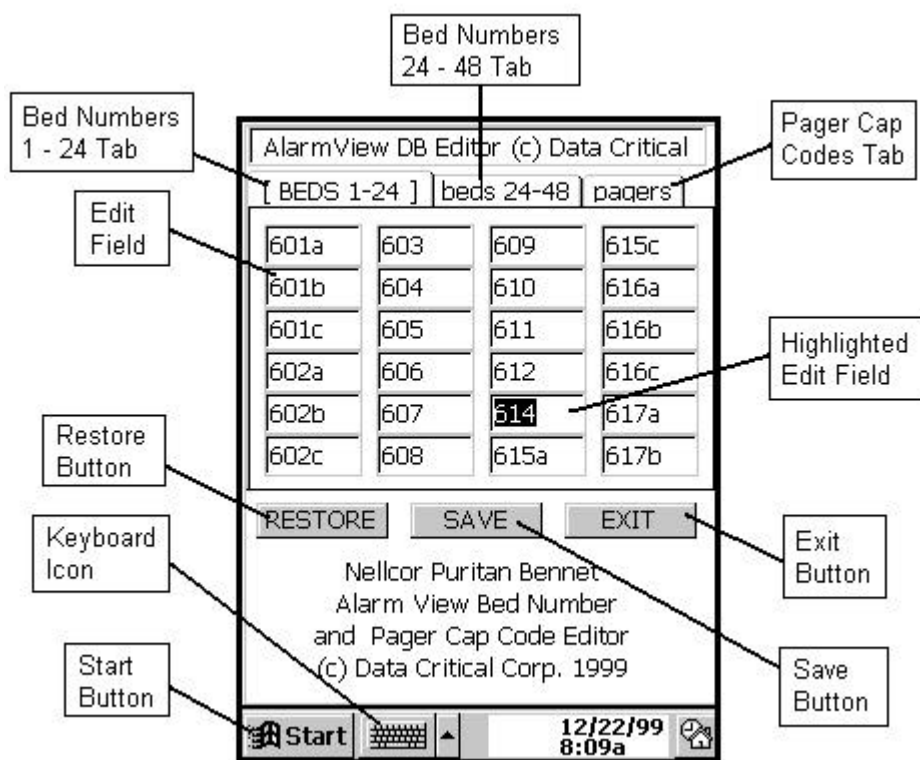
Bed Numbers
24 - 48 Tab

Bed Numbers
1 - 24 Tab

Pager Cap
Codes Tab

Edit
Field

AlarmView DB Editor (c) Data Critical

[BEDS 1-24] | beds 24-48 | pagers

601a	603	609	615c
601b	604	610	616a
601c	605	611	616b
602a	606	612	616c
602b	607	614	617a
602c	608	615a	617b

Highlighted
Edit Field

Restore
Button

RESTORE | SAVE | EXIT

Nellcor Puritan Bennet
Alarm View Bed Number
and Pager Cap Code Editor
(c) Data Critical Corp. 1999

Exit
Button

Keyboard
Icon

Start
Button

Save
Button

Start | ▦ | ▲ | 12/22/99 8:09a | ⌂

If the key board is not visible, tap the keyboard icon to display the keyboard. If an additional bed number is desired, a bed number can be added to any blank space on page one or two of the bed number listing. Simply tap the cursor in the blank space and begin typing the new bed number.

To edit the pager numbers, tap the "Pagers" tab on the upper right of the screen. The "AlarmView Editor" Screen Pagers page will appear.

Bed Numbers
24 - 48 Tab

Bed Numbers
1 - 24 Tab

Pager Cap
Codes Tab

Edit
Field

AlarmView DB Editor (c) Data Critical

beds 1-24 | beds 24-48 | [PAGERS]

1	0001201	5	0122544	9	0123009
2	0001202	6	0123006	10	0123010
3	0001203	7	0123007	11	0123011
4	0122536	8	0123008	12	

ALL PAGERS: 0000009

Restore
Button

RESTORE   SAVE   EXIT

Exit
Button

Keyboard
Icon

Nellcor Puritan Bennet
Alarm View Bed Number
and Pager Cap Code Editor
(c) Data Critical Corp. 1999

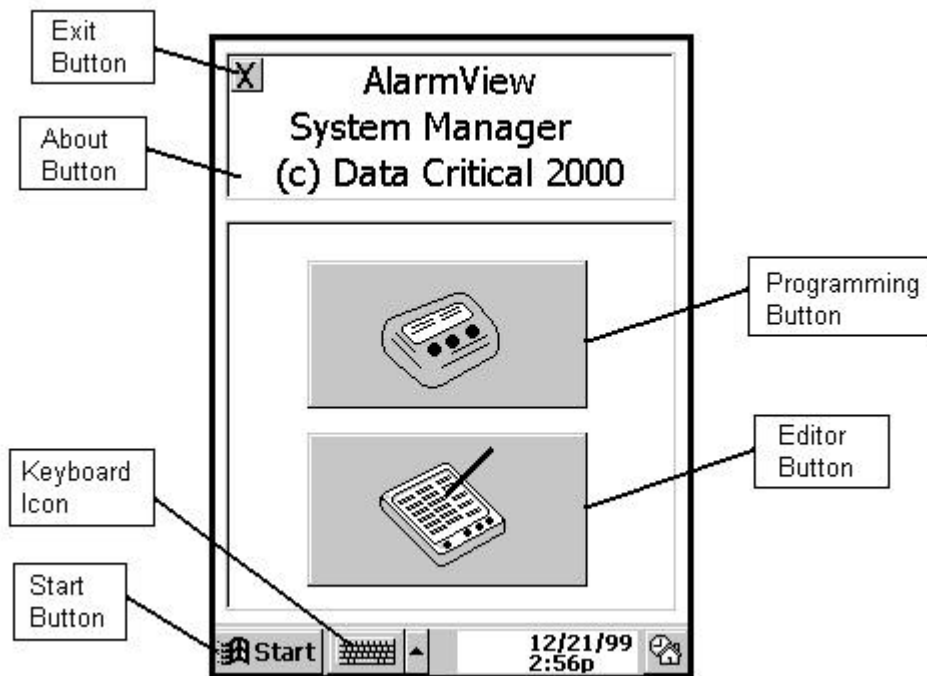Save
Button

Start
Button

Start   12/22/99
8:10a

Pager Cap Codes can be added and deleted from this list. Click on a cap code number to edit. Using the stylus, tap the backspace key on the keyboard to delete the cap code number to be edited (or highlight the entire cap code number), and using the numbers and letters on the key board, type in the new cap code number. Tap the "Save" button on completion, or the "Exit" button to exit the Editor Program.

If the key board is not visible, tap the keyboard icon to display the keyboard. If an additional bed number is desired, a bed number can be added to any blank space on page one or two of the bed number listing. Simply tap the cursor in the blank space and begin typing the new bed number.

Note that the global cap code value can not be changed by the user.
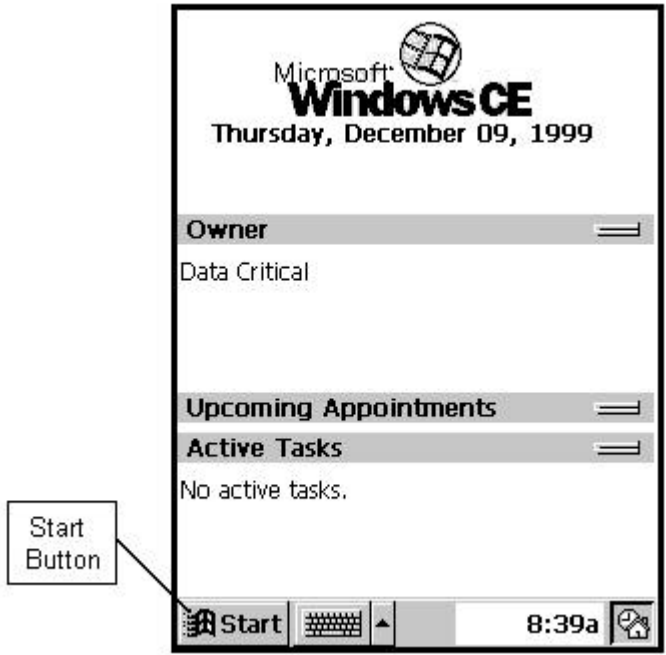
To restore values to the state they were in before editing began, tap the Restore Button on any of the pages before pressing the Save Button. Once the Save Button has been pressed, however, the original values are not restored.

When the "Editor Program" is exited, the Main Screen is again displayed.
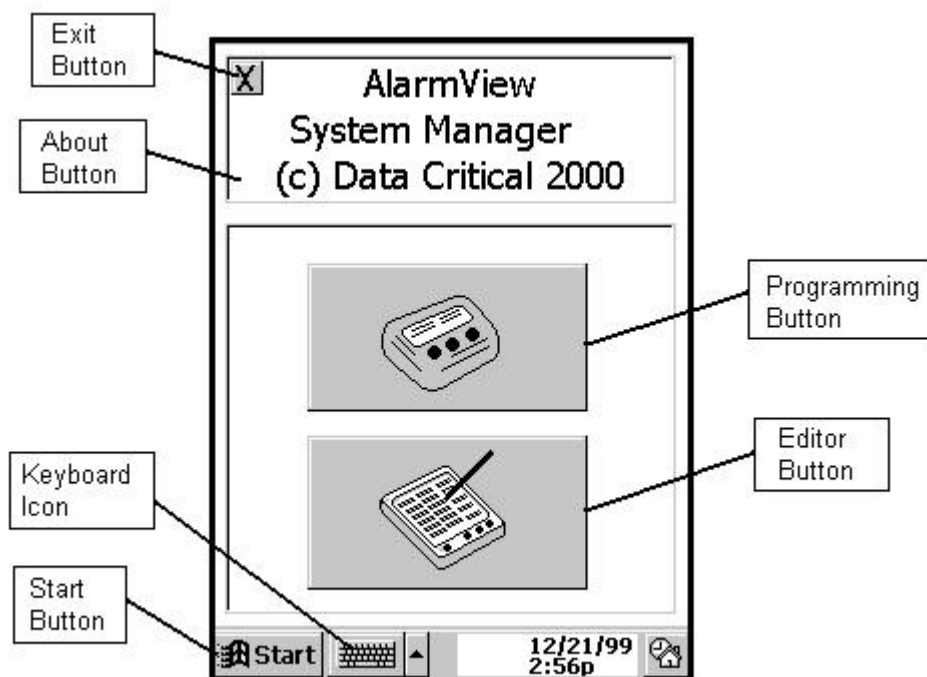
Exit
Button

About
Button

**AlarmView
System Manager
(c) Data Critical 2000**

Programming
Button

Editor
Button

Keyboard
Icon

Start
Button

Start | 12/21/99 2:56p

The Configuration Program

If the main PDA screen is displayed, tap Windows Start menu button.

Microsoft
Windows CE
Thursday, December 09, 1999

Owner	
Data Critical

Upcoming Appointments
**Active Tasks**
No active tasks.

Start Button

Start | 8:39a

From the Windows Start menu, select the "AV System Manager program.

The AlarmView System Manager main screen will appear as shown below.

Exit Button

About Button

Programming Button

Editor Button

Keyboard Icon

Start Button

AlarmView
System Manager
(c) Data Critical 2000

Start   12/21/99 2:56p

To launch the Configuration Program, tap the Programming button. The "Configuration Program" Main Screen will appear. This program is used to change the transmitter's setup of bed numbers, cap codes, alarm severity, and reminder page interval. It also displays information that can not be modified by the user. This information includes: monitor identifier (N3000, N295, N290), transmitter number, hardware version, software version, protocol version, authorize identification, paging frequency, and paging baud rate. This program can be used at shift change, or whenever there is a need to change/view the current transmitter configuration.
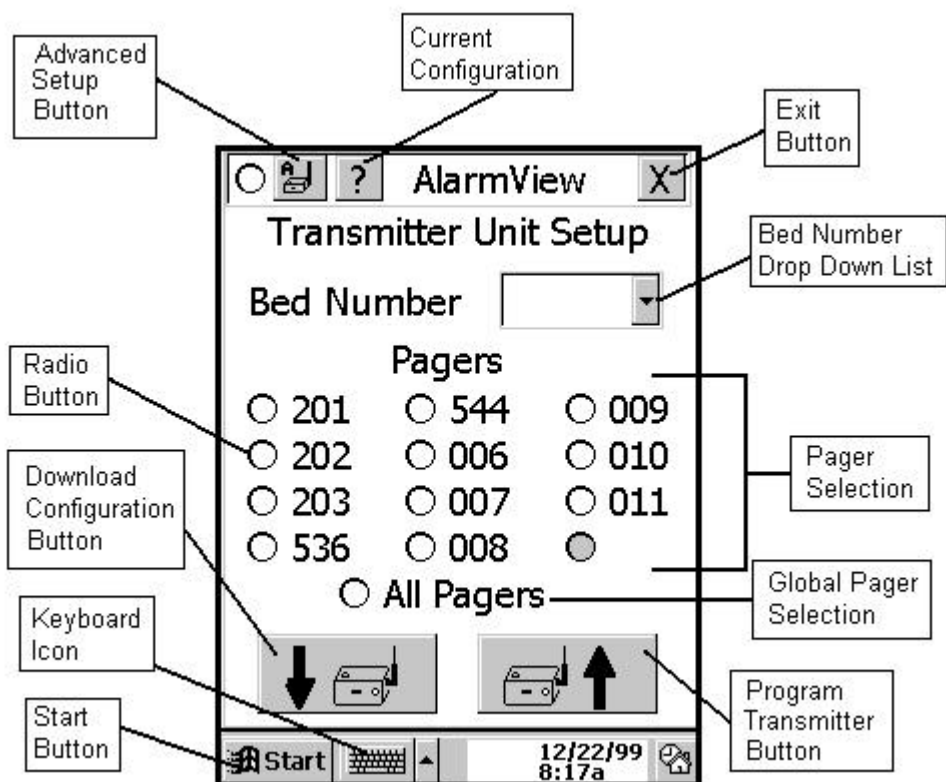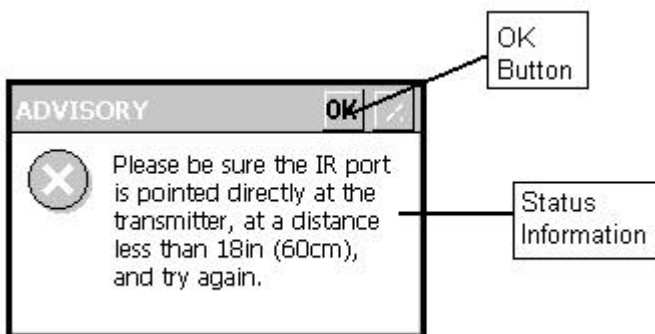
To obtain the current configuration programmed into the transmitter, tap the "Download Configuration Button". When this button is tapped, the PDA attempts to establish communications with the transmitter. If the IR port could not be accessed, the following dialog box will be displayed.
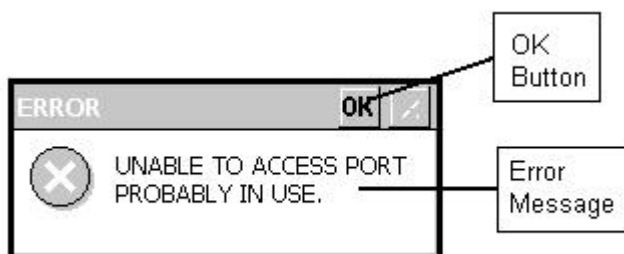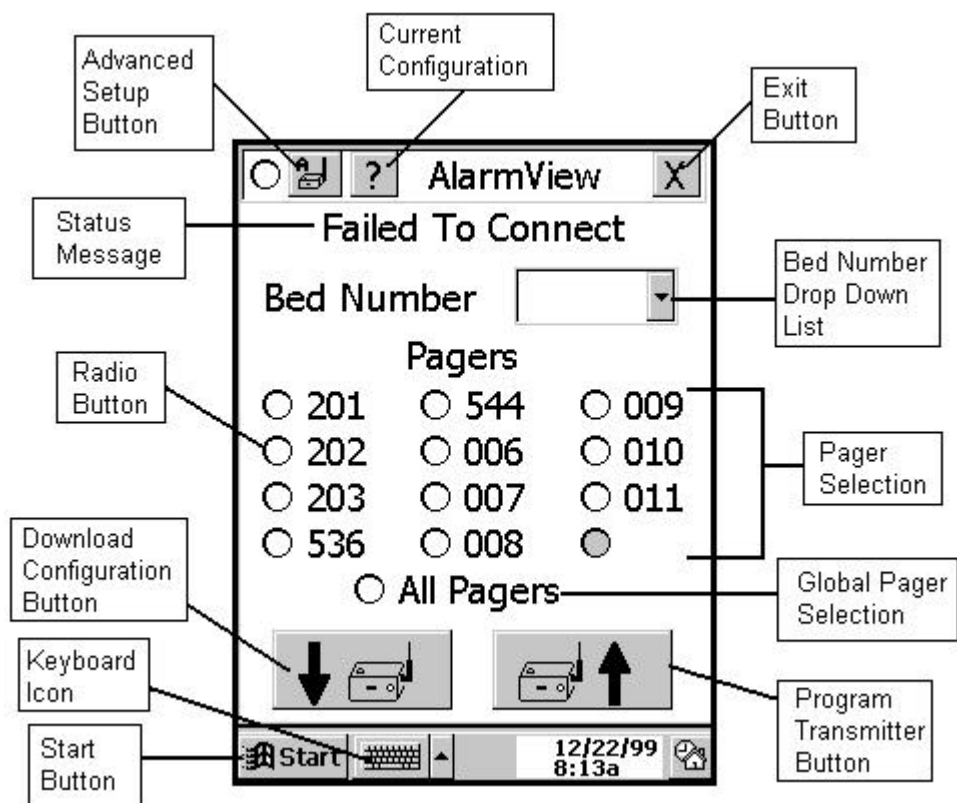

Tap the OK button to close this dialog box and return to the Configuration Program main screen.

If the IR port could be accessed, but communications could not be established between the PDA and the transmitter, the following error dialog box will be displayed:
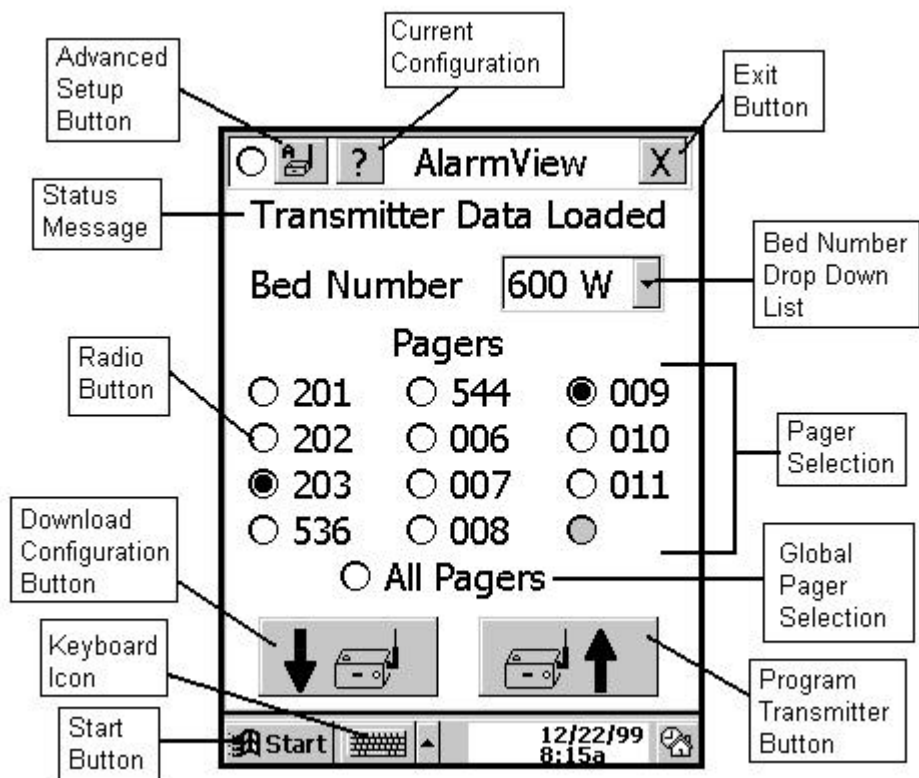
When "OK" is tapped on this dialog box, the Configuration Program main screen will be displayed with a status message informing the user of a "Failed to Connect" status.

Advanced Setup Button

Current Configuration

Exit Button

Status Message

Bed Number Drop Down List

Radio Button

Pager Selection

Download Configuration Button

Global Pager Selection

Keyboard Icon

Start Button

Program Transmitter Button

AlarmView

Failed To Connect

Bed Number

Pagers

○ 201   ○ 544   ○ 009
○ 202   ○ 006   ○ 010
○ 203   ○ 007   ○ 011
○ 536   ○ 008   ●

○ All Pagers

Start   12/22/99 8:13a

At this point, simply point the PDA at the transmitter, and tap the "Download Configuration Button" again. While the transmitter is being queried, the Configuration Program main screen will be displayed with a status message informing the user of a "Loading Data" status. The PDA will be in this state for less than 2 seconds.
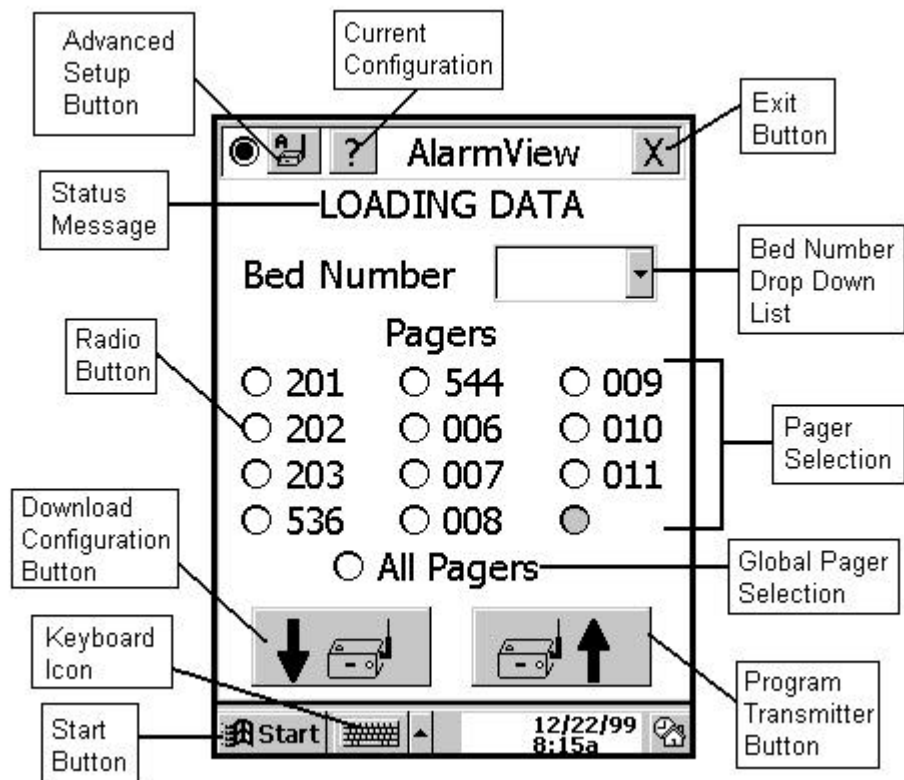
When the transmitter has been successfully queried, the Configuration program main screen will be displayed with a status message informing the user of a "Transmitter Data Loaded" status.

Advanced Setup Button

Current Configuration

Exit Button

Status Message

Bed Number Drop Down List

Radio Button

Pager Selection

Download Configuration Button

Global Pager Selection

Keyboard Icon

Program Transmitter Button

Start Button

AlarmView

Transmitter Data Loaded

Bed Number 600 W

Pagers

○ 201   ○ 544   ● 009
○ 202   ○ 006   ○ 010
● 203   ○ 007   ○ 011
○ 536   ○ 008   ○

○ All Pagers

Start 12/22/99 8:15a

At this point, if the displayed data is correct, no changes need be made, and the user is done. Exit the Configuration Program by tapping the "X" in the upper right corner of the screen.

If the data needs to be changed, the Patient Bed Number can be selected by tapping on the bed number drop down list, and highlighting the desired bed number.

A maximum of two pagers can be selected by clicking the radio button next to the desired pager number.

To change/view alarm severity selection or reminder page intervals, tap the Advanced Setup Button on the upper left of the screen. If no data has been previously downloaded, the PDA will attempt to establish communications with the transmitter. When the data is downloaded, the following screen will appear.
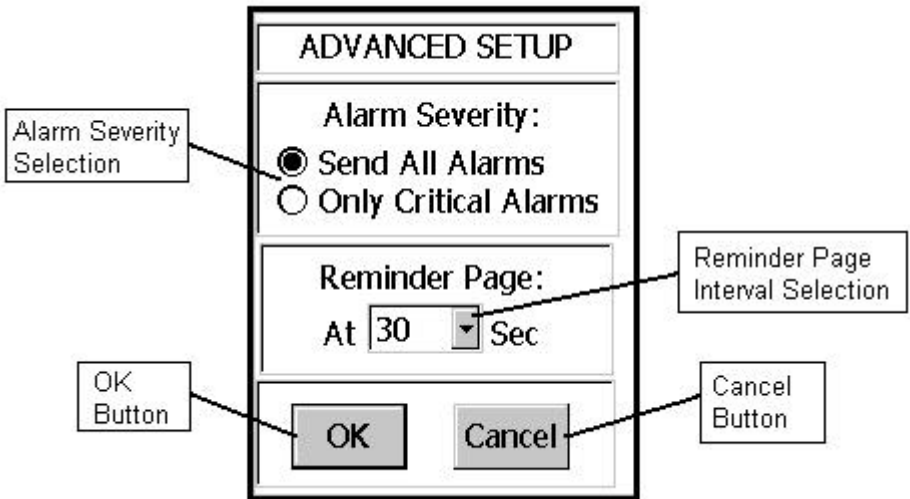
Alarm Severity selections:
Send All Alarms indicates that all alarms will be sent to the pagers regardless of the severity of the alarms.
Only Critical Alarms indicates that only critical (high prioirty and medium priority) alarms will be sent to the pagers.

Reminder interval indicates the time interval at which reminders will be sent after the original alarm has not been silenced.

Tap the OK button when all changes have been made.

To view transmitter data that can not be modified by the user, tap the Current Configuration Button on the upper left of the screen. If no data has been previously downloaded, the PDA will attempt to establish communications with the transmitter. When the data is downloaded, the following screen will appear.
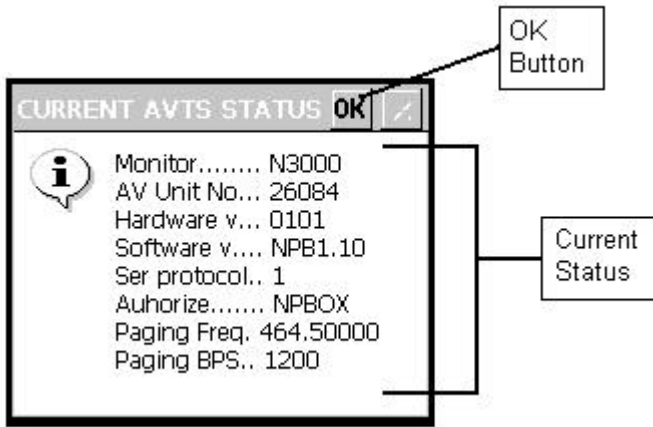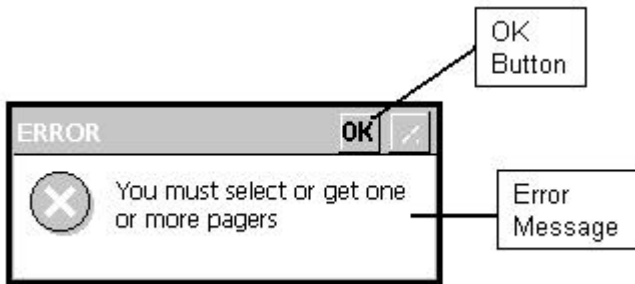

Tap the "Program Transmitter" button to program the transmitter with the newly selected values.

If no bed number was selected before the "Program" button was tapped, the following error dialog box will appear.
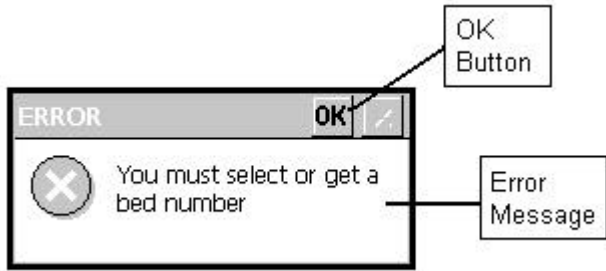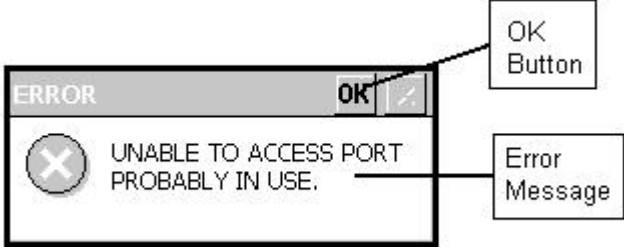

If no cap code was selected before the "Program" button was tapped, the following error dialog box will appear.
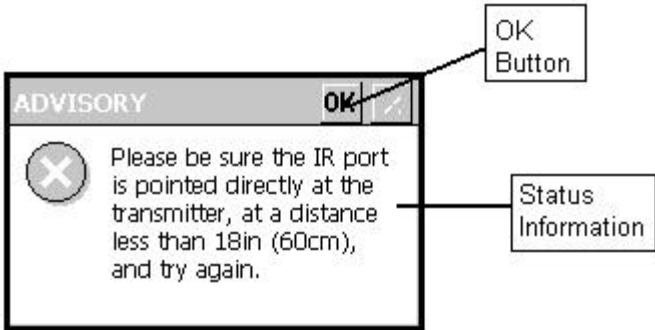

Exit both of the above dialog boxes by tapping the OK Button. After the above error conditions are rectified, tap the "Program Transmitter" button again. When this button is tapped, the PDA attempts to establish communications with the transmitter.

If the IR port could not be accessed, the following dialog box will be displayed.

OK
Button

ERROR   **OK**

UNABLE TO ACCESS PORT
PROBABLY IN USE.

Error
Message

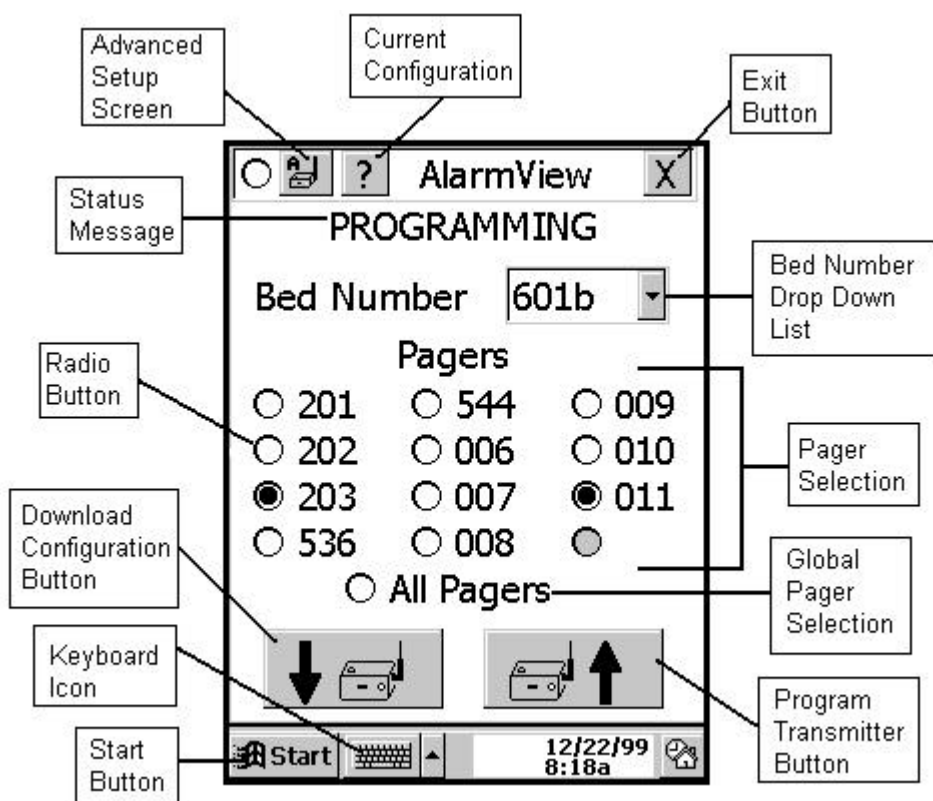Tap the OK button to close this dialog box and return to the Configuration Program main screen.

If the IR port could be accessed, but communications could not be established between the PDA and the transmitter, the following error dialog box will be displayed:

OK
Button

ADVISORY   **OK**

Please be sure the IR port
is pointed directly at the
transmitter, at a distance
less than 18in (60cm),
and try again.

Status
Information

When "OK" is tapped on this dialog box, the Configuration Program main screen will be displayed with a status message informing the user of a "Failed to Connect" status.

Advanced Setup Button

Current Configuration

Exit Button

Status Message

Bed Number Drop Down List

Radio Button

Pager Selection

Download Configuration Button

Global Pager Selection

Keyboard Icon

Start Button

Program Transmitter Button

AlarmView

Failed To Connect

Bed Number

Pagers

○ 201   ○ 544   ○ 009
○ 202   ○ 006   ○ 010
○ 203   ○ 007   ○ 011
○ 536   ○ 008   ●
○ All Pagers

Start   12/22/99   8:13a
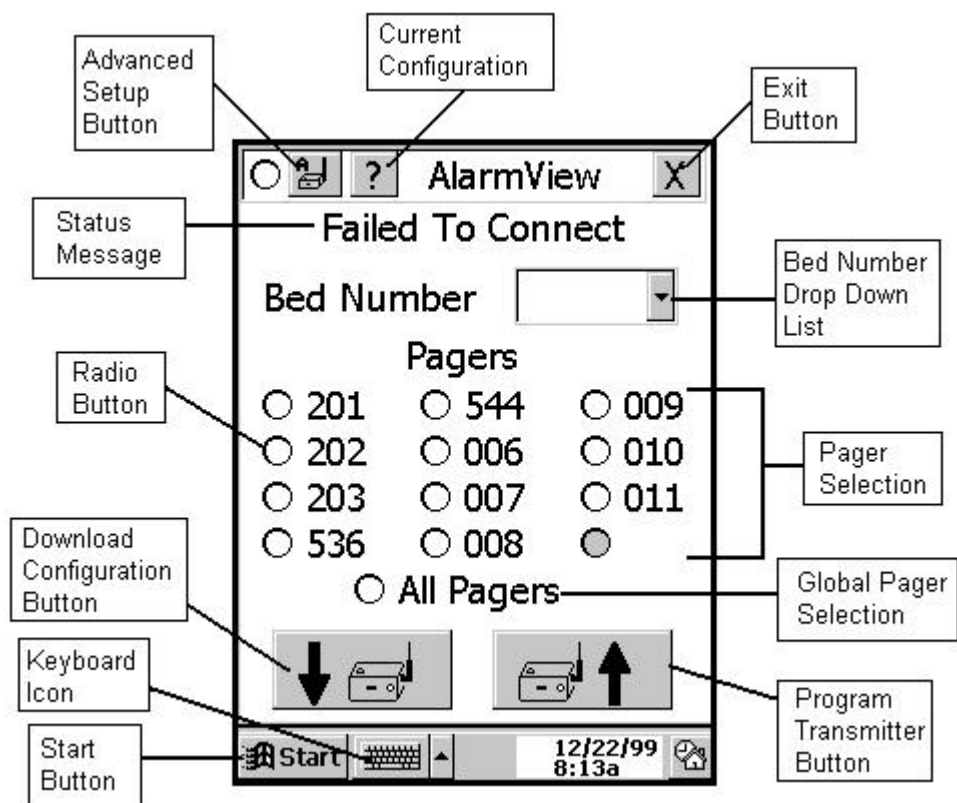
At this point, simply point the PDA at the transmitter, and tap the "Program Transmitter Button" again. While the transmitter is being queried, the Configuration Program main screen will be displayed with a status message informing the user of a "Programming" status. The PDA will be in this state for less than 2 seconds.

Advanced Setup Screen

Current Configuration

Exit Button

Status Message

Bed Number Drop Down List

Radio Button

Pager Selection

Download Configuration Button

Global Pager Selection

Keyboard Icon

Program Transmitter Button

Start Button

AlarmView

PROGRAMMING

Bed Number 601b

Pagers

○ 201   ○ 544   ○ 009
○ 202   ○ 006   ○ 010
● 203   ○ 007   ● 011
○ 536   ○ 008   ○

○ All Pagers

Start   12/22/99 8:18a

When the transmitter is successfully programmed, the Configuration Program main screen will be displayed with a status message informing the user of a "Programming Successful" status.

Advanced Setup Screen

Current Configuration

Exit Button

Status Message

Bed Number Drop Down List

Radio Button

Download Configuration Button

Pager Selection

Global Pager Selection

Keyboard Icon

Start Button

Program Transmitter Button

○ 📇 ? AlarmView X

Programming Successful

Bed Number 601b ▾

Pagers

○ 201   ○ 544   ○ 009
○ 202   ○ 006   ○ 010
◉ 203   ○ 007   ◉ 011
○ 536   ○ 008   ○

○ All Pagers

🔀 Start ⌨ ▲   📟 12/22/99 08:19a 🏠
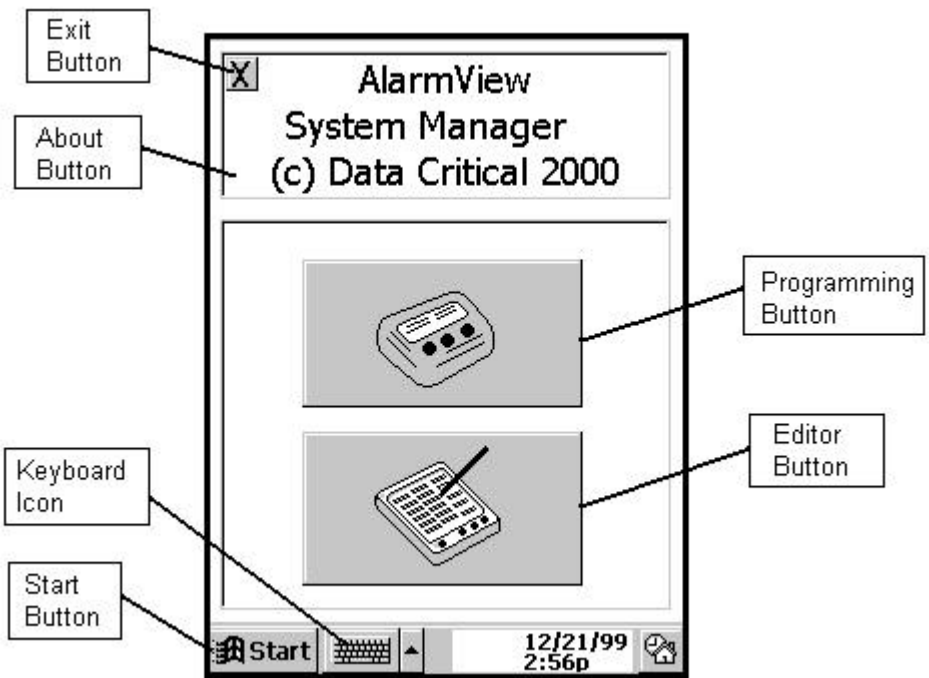
A "Programming Successful" page will also be sent to the newly selected pagers, displaying the newly selected bed number.

<Insert photo and or screen shot here>

Exit the "Configuration" program by tapping the "X" in the upper right corner of the screen.

When the Configuration Program has been exited, the System Manager Program main screen will be displayed as shown:

Exit this program by tapping the Exit Button in the upper left of the screen.

Communicating With Patient Monitoring Equipment

Turn on the transmitter, as described above. Attach the serial cable to the RJ-45 port. Attach the other end of the cable to the patient monitoring equipment. The transmitter will automatically detect the monitor (assuming it is an N-3000, N-295, or N-290). Once communications have been established with the patient monitoring equipment, a page will be sent to the pager indicating this, and the LED will turn GREEN.

The communications established page will have the following data:

Bed: xxxxx
Comms OK

<Insert photo and or screen shot here>

From that point, all alarms at the patient monitoring equipment will be sent to the pager(s), as assigned by the PDA (as described above).

Turn on the transmitter, as described above, and establish communications with the patient monitoring equipment (the LED will be

transmitter (but, do not hold it down). A "Test Page" will be sent indicating the current patient data (SPO2, and Pulse Rate). Note that

Test Page
Bed: xxxxx

SPO2: xxx

<Insert photo and or screen shot here>

The transmitter can only be turned off if it is not communicating with the patient monitoring equipment (i.e. the LED is RED). To turn off the

goes off.

Communications Not Established

Turn on the transmitter, as described above. The transmitter should not be attached to any patient monitoring equipment as this point. The LED on the front of the transmitter will be ORANGE to indicate that the transmitter is attempting to establish communications with the patient monitoring equipment. After 10 seconds of no communications, a page will be sent indicating that no communications have been established.

Bed: xxxx
Comm Fail
Retrying

<Insert photo and or screen shot here>

Every 10 minutes after that, another page will be sent indicating that communications have not been established. This will continue for one hour. At this point, a page will be sent indicating that the transmitter is turning off.

Bed: xxxx
Comm Fail
Tx Shut down

<Insert photo and or screen shot here>

Low Battery Warnings

If the battery becomes too low for proper transmitter functioning, an alarm will be sent indicating the low battery situation, and the transmitter will be shut down.

Bed: xxxx
Low Tx Battery
Tx Shut down

<Insert photo and or screen shot here>

Appendix A

Electromagnetic Interference

It is a known fact that electronic devices that emit radio frequencies may interfere with the operation of other electronic devices. This has become

proliferation of intentional electronic radiators such as cellular phones, paging systems, walkie-talkies, and wireless network LANs. The critical

are of special concern and incidents have been observed with apnea monitors, wheel chairs, and ventilators.

to address this complicated issue through their respective working groups. The ANSI C63.6 working group made up of industry and the

means to evaluate critical care medical devices for electromagnetic interference problems by the clinical and biomedical staff using an ad

EMI fundamentals. A possible outline for management of potential EMI sources and education of the hospital staff is as follows:

environment of their hospital and take actions on:
- managing (increasing) distance between sources of EMI and susceptible devices
  managing use of frequencies close to StatView™ System

-
  EMI
- lower power from internal EMI sources under hospital control (paging systems)
  labeling devices susceptible to EMI

- educating staff (nurses and doctors) to be aware of, and to recognize, potential EMI related problems
- conducting technical remedial action to eliminate EMI, such as shielding
- sharing relevant EMI/EMC information with others, especially in evaluation of new equipment purchases which may have emissions
- identifying critical areas where life-support devices are in use and restricting the use of personal communicators (cellular phones) in those critical care areas

Purchase critical care devices that comply with IEC 601-1-2 EMC standards:
- the required level of EMI immunity is 3 volts per meter
- the interference level that a medical device can radiate (emit) is 0.0014 volts per meter

The AlarmView™ System has a transmit power level of up to 1 watt peak at a pre selected RF frequency between 450 MHz to 466 MHz

Protection Distance Estimate

of	Immunity of Medical Device		
		2 V/meter	
	x ft	x ft	x ft
1 watt	x m	x m	x m

Appendix B

Terms Glossary

BNC Connector:	A type of connector used with coaxial cables. The basic BNC connector is a male type mounted at each end of a cable. This connector has a center pin connected to the center cable conductor and a metal tube connected to the outer cable shield. A rotating ring outside the tube locks the cable to any female connector. This is the type of connector that the antenna uses to connect to the transmitter.
IR Port:	Infrared port. An IR Port is used by the PDA to communicate with the transmitter.
PDA:	Personal Digital Assistant (Win CE Device)
POCSAG:	Post Office Code Standardization Advisory Group – the protocol used for pager communications
RF Transmissions:	Radio Frequency transmissions
RJ-45 Connector:	Short for Registered Jack-45, an eight-wire connector commonly used to connect computers. Looks similar to the connectors used for connecting telephone equipment, but they are somewhat wider.
UHF Band:	Ultra High Frequency Bandwidth
Windows CE:	The operating system of the PDA