

Acumen 7 User Guide



Attention: It is necessary to read the user manual carefully before first use the device, Keep the manual in a safe place so that you can refer to it whenever necessary.

MANUFACTURER	EU AGENCY
Curative Medical Technology Inc	Curative medical devices GmbH
No 9, PeiYuan Road, New District, Suzhou, 215163 P.R. China	Blasewitzer Str. 41, 01307 Dresden, Germany
Telephone: +86-0512-69217308	Phone: +49-351-450 4500
Fax: +86-0512-69217338	Fax: +49-351-450 4511
E-mail: info@ curativemedical.com	

CONTENTS

SYMBOLS	6
SYSTEM INTRODUCTION	7
USAGE	7
SCOPE OF APPLICATION	7
CONTRAINDICATIONS	7
CAUTIONS	8
WARNINGS	9
PRODUCT COMPONENTS AND DESCRIPTION	11
PRODUCT COMPONENTS	11
PRODUCT AND ACCESSORIES	12
SPECIFICATION OF DEVICE	13
SAFETY INSTRUCTIONS AND CLAIMS	14
HOW TO USE SAFELY	14
LIABILITY	15
CLEANING AND MAINTENANCE	15
CLEANING THE ACUMEN7	15

MAINTENANCE	15
DISPOSAL	16
QUALITY WARRANTY	ERROR! BOOKMARK NOT DEFINED.
SYSTEM INSTALLATION AND USAGE	17
SYSTEM CONNECTION	17
ACCESSORIES	18
CHEST AND ABDOMEN EFFORT SENSORS	18
OXIMETER PROBE	18
NASAL CANNULAR	18
USAGE OF ACUMEN7	19
SLEEP DATA COLLECTION	19
DATA DOWNLOAD	19
LED DISPLAY FUNCTION DESCRIPTION	20
COMMON PROBLEMS ANALYSIS AND TROUBLESHOOTING	21
AIRFLOW SIGNAL (NASAL CANNULA)	21
SNORING SIGNAL (SNORE MICROPHONE IN RECORDER BOX)	21
CHEST AND ABDOMEN EFFORT SIGNAL (CHEST AND ABDOMEN EFFORT SENSORS)	22
SPO2 AND PULSE SIGNAL (OXIMETER PROBE)	22
CONNECTION PROBLEM (USB CABLE)	24
DOWNLOAD DATA (USB CABLE)	24

APPENDIX A TERM DEFINITION

ERROR! BOOKMARK NOT DEFINED.

APPENDIX B ELECTROMAGNETIC COMPATIBILITY INFORMATION

26

SYMBOLS



CE Marked
indicating
conformance
to EC
Directive No.
93/42/EEC
concerning
medical
devices



Attention!

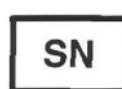
Consult
accompanying
documents



Manufacturer



Date of
manufacture



Serial
number

(printed
under the
back cover)



Type BF
applied part



Class II
Double
insulated



The device,
accessories
and the
packaging
have to be
disposed
correctly at
the end of
the usage.
Please
follow Local
Laws or
Regulations
for disposal



DC Power

SYSTEM INTRODUCTION

USAGE

- It is designed to be used with a 32-bit Microsoft operating systems including Windows 2000 SP3, Windows XP SP1 and above. It is not compatible with 64-bit operating systems.
- The software has case management capabilities and can be used to store and analyze the information of more than one patient.
- The Acumen 7 can collect store and analyze 8 parameters of Polysomnographic data including; Chest effort, Abdomen effort, Nasal airflow, Snore, SpO2, body position, pulse rate and CPAP pressure. (When used with a Curative CPAP device)

SCOPE OF APPLICATION

- The device can be used in the home or in medical units for clinical monitoring, analysis and diagnosis of relevant physiological signals including the thoracic and diaphragmatic respiration, nasal airflow, snoring, SpO2 and sleeping positions.
- The device is used in clinical sleep laboratories to assist in the diagnosis of sleep disorders by gathering, storing and analyzing data across 7 parameters of physiological events during sleep.
- This equipment can only be used under the directions of a qualified sleep clinician.

CONTRAINDICATIONS

There are no absolute contraindications to polysomnograph when indications are clearly established. However, risk-benefit ratios should be assessed if medically unstable inpatients are to be transferred from the clinical setting to a sleep laboratory for overnight polysomnography.

Explosion Hazard: Do not use the Acumen7 in an explosive atmosphere or in the presence of flammable anesthetics or gases.

CAUTIONS

- The PSG Acumen7 analyses overnight sleep information acquired from the raw data of the recorder. Any loss of raw data due to interferences caused by loss of power, incorrect use of the sensors and device, strong electromagnetic fields or human factors can all result in incorrect raw data and consequently incorrect analysis.
- It is important that the device is correctly calibrated as a device that is not correctly calibrated will not provide accurate data.
- No SpO2 or pulse rate alarm is provided.
- Operation of the device may be adversely affected by
 - Electromagnetic fields exceeding the level of 1V/m in the test conditions of EN 60601-1-2
 - The operation of high frequency (diathermy) equipment
 - Defibrillators, or short wave therapy equipment
 - Radiation (e.g., x-ray, CT)
 - Magnetic fields (e.g., MRI).
 - Avoid using this device in an MRI environment or proximity to a high EMI emission source.
- Do not submerge the device in water.
- Do not place liquids on or near the device.
- Do not use the device if you are wearing a nasal or full face mask for CPAP or bi-level therapy. This will affect the accuracy of the device.
- Do not use the device if you are wearing a cannula for therapy. This will affect the accuracy of the device.
- If any unexplained change in the performance of this device occurs, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken discontinue use and contact our service center.
- If any part of the device is broken, please stop using the device.
- Use only our supplied sensors and accessories. Use of other accessories could cause the device to malfunction.
- The device must be repaired or checked by qualified personnel. Do not open the device and change any part yourself.
- This equipment complies with International Standard EN 60601-1-2: 2007 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other

environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.

- Cardiogreen and other intravascular dyes may affect the accuracy of SpO2 measurements.
- The oximeter sensor might not work in cold extremities due to reduced circulation. Warm or rub the finger to increase circulation or reposition the sensor.
- Some nail polish colors or artificial nails can reduce light transmission and affect SpO2 accuracy.
- Before using any sensor, read the User Directions carefully. They contain the specific application duration for each sensor.
- Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor, the circulation and skin sensitivity of the patient. A patient's sensitivity to sensors may vary due to medical status or skin condition.
- Acumen7 should not be gas sterilized or autoclaved.
- The Acumen 7 uses size AA 1.5VX2 batteries. The batteries should only be replaced by professionals (instrument operators rather than the patient), Replace the cover after changing the batteries.
- Batteries should be used and disposed of appropriately to avoid leaks or explosions.
- Follow local government guidance and recycling instructions regarding the disposal or recycling of the device and its components, including batteries. Use only Size AA 1.5VX2 batteries. If the Acumen7 is not used for 30 days remove batteries.
- A functional teater cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

WARNINGS

- This equipment can't be used as a monitor of apnea, because it has no audible or visual apnea warning system.
- Skin irritation may occur as a result of the cannula or belt used by the patient.
- Discontinue using the device if skin reddening or inflammation appears
- The evaluation of the PSG Acumen7 electrical isolation must be conducted by a certified engineering or biomedical personnel who are qualified to make such an assessment.
- Patients with parasomnias or seizures may be at risk of injury that may occur due to movements during sleep.

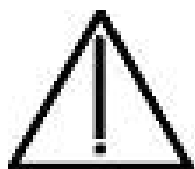
- Institution-specific policies and guidelines describing personnel responsibilities and appropriate responses should be developed.
- Do not smoke while wearing the Nasal Cannula.
- Avoid exposure to sources of direct airflow such as fans during the operation of the device.
- Do not allow the cables to become tangled, coiled, crossed, or wrapped around the neck, arms, or legs. This could result in strangulation.
- Do not operate the device in the presence of flammable substances such as anesthetics or cleaning agents.
- The device is not to be used for life support
- The device is not suitable for sporting activities.
- The device must be used under the instructions of doctor.
- The device must be used with CE-marked parts or our supplied parts. The use of other parts or materials may impact upon the safety of the device.
- A rechargeable Lithium Button Battery is used for the clock inside the device. Danger of explosion and fire may occur if battery is replaced incorrectly. Replace only with the same type of RTC battery. Model: TS621FE, 3.0 V, 3 mAh.
- Oximeter readings of the Acumen7 may be affected by the use of an electrosurgical unit (ESU).
- Use only pulse oximeter sensors that are provided with the Acumen7 as these are manufactured to meet the accuracy specifications for the Acumen7 system. Using other manufacturers' sensors can result in improper pulse oximeter performance.
- Do not use damaged sensors.

PRODUCT COMPONENTS AND DESCRIPTION

PRODUCT COMPONENTS

- 1 Recorder box
- 1 Chest effort Sensor with Belt, One Abdomen effort Sensor with Belt, One Oximeter Probe
- 1 Recorder Pouch
- 1 Acumen7 software CD
- 1 Nasal Cannula*
- 1 USB or RS232 cable*

Note: items with * can be supplied by the manufacturer or purchased from other vendors that are CE-marked.



- **Attention!** The data transmission interface is only used for transmitting data in hospital and connects to RS232 or the USB of a PC.
- **Attention!** Equipment connected to the analog or digital interfaces must comply with the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). All configurations shall comply with the current standard version for SYSTEMS IEC 601-1-1. If you have any doubt, consult the technical service department or your local representative.
- **Attention!** The sensor interfaces should be connected with correctly matched sensors.
- **Attention!** The MIC Sensor interface should not be filled with anything.

PRODUCT AND ACCESSORIES

Carefully unpack the Acumen7 and the accessories checking each item against the product component list. If there are any defects or missing accessories please contact the suppliers or the manufacturer.

Recorder Box



Chest and Abdomen Effort Sensor Belt



USB Cable



Pulse Oximeter Probe



Nasal Cannula



RS232 Cable



SPECIFICATION OF DEVICE

Body position whilst sleeping	The supine position		
	The left recumbent position		
	The right recumbent position		
	Prone		
Oximeter	Oxygen Saturation Range (%SpO2)	70% to 100%	
	Pulse Rate Range	20 to 255 pulses per minute	
	Accuracy: SpO2 Saturation (%SpO2)	70-100% ±2%	
	Accuracy: Pulse Rate	±3bpm	
Device Dimensions	Height - 4.94" (125mm)	Width - 2.75" (70mm)	Height - 0.94" (24mm)
Material	Recyclable ABS thermoplastic		
Weight	150g: without battery and sensors		
Data and Data Communication	Analogue to Digital converter (A/D)	10 Bit	
	Memory	64Mb	
	Communication Ports	USB/RS232	
Power supply	Battery Size	AA 1.5VX2 (DC 3V);	
	Continuous Operating Time	30 Hours	
	Battery Level Indication (what does this mean?)		
Classifications per IEC 60601-1	Type of Protection:	Internally powered (battery powered)	

Operation	Degree of Protection:	Type BF-Applied Part
	Enclosure Degree of Ingress Protection:	IPX0
	Mode of Operation:	Continuous
	Temperature	+5°C - +40°C
	Relative humidity	10% - 90% (non-condensing)
	Atmosphere pressure	700hPa - 1060hPa
Transport or storage	Temperature	-20°C - +55°C
	Relative humidity	10% - 93% (non-condensing)
	Atmosphere pressure	500hPa - 1060hPa

SAFETY INSTRUCTIONS AND CLAIMS

HOW TO USE SAFELY

- Before using the device, read the safety instructions carefully to avoid possible dangers:
- The device must be used by you exclusively under the instructions of your physician.
- The device should only be used with CE-marked parts provided or recommended by your authorized dealer.
- When your device doesn't work properly, contact your dealer immediately.
- For electric safety, read the following carefully:
 - Do not switch on the device if casing or cables are damaged.
 - In case of its failure, contact your authorized dealer. Do not open the device yourself.
 - Keep the device dry at all times.
 - Do not use the device in a damp room or a bathroom.
 - Do not place containers or glasses filled with liquid on the device or place the device near water e.g. bathtubs.

- Take the batteries out of the device before cleaning.

LIABILITY

The manufacturer shall not be held liable for any damages in case of:

- Tampering, modifying, adding expansion features or repair by persons who have not been authorized by the manufacturer.
- Using accessory or spare parts that are not recommended by us, or not officially registered.
- Using the device in a way that was not instructed in the manual.

CLEANING AND MAINTENANCE

CLEANING THE ACUMEN7

- Clean the enclosure of the Acumen7 recording box with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the Acumen7, and do not allow any liquid to enter any openings of the device. Allow the unit to dry thoroughly before reusing it.
- **IMPORTANT!** Do not immerse the Acumen7 in liquid, and do not use corrosive or abrasive cleaning agents on the Acumen7.
- Clean the Acumen7 and the sensors separately.
- For instructions regarding the cleaning of the Pulse Oximeter sensor and the Nasal Cannula refer to the appropriate product guides.

MAINTENANCE

- The advanced digital circuitry within the pulse oximeter of the Acumen7 requires no calibration or periodic maintenance.
- Field repair of the Acumen7 circuitry is not possible. Do not attempt to open the Acumen7 recorder box or repair the electronics. Opening the case will damage the Acumen7 and void the warranty. If the Acumen7 is not functioning properly, see “Troubleshooting.”

- In the case of any product issues contact our service center. Service of the Acumen7 should only be conducted by persons authorized by our company.
- Proper use and maintenance of the Acumen7 will extend the working life of the equipment. (see safety and cleaning instructions)
- Before maintenance ensure that the device is disconnected from any power source.
- The Acumen7 equipment should be managed by a specially assigned person.
- The Acumen7 and its accessories should be kept in a dry storage environment to prevent the device from damp and corrosion. The device should also be kept away from sources of strong electromagnetic fields that may cause interference.
- The Acumen7 has been accurately assembled by the manufacturer (Curative Medical Technology) and users should not disassemble or adjust the system randomly.
- When abnormal conditions occur or this system cannot operate normally please contact our company or local maintenance department.

DISPOSAL



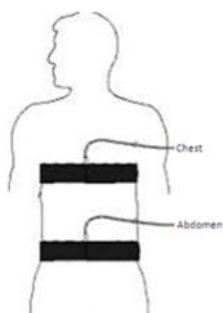
This device, its accessories and its packaging have to be disposed correctly at the end of the usage. Please follow Local Laws or Regulations for disposal.

SYSTEM INSTALLATION AND USAGE

SYSTEM CONNECTION



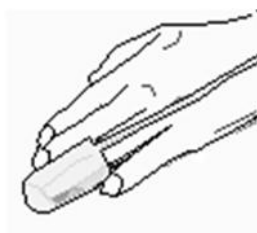
ACCESSORIES

CHEST AND ABDOMEN
EFFORT SENSORS


The chest and abdomen effort sensors are attached to the chest and abdomen belts.

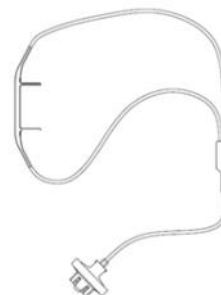
The chest and abdomen belts should be adjusted so they transmit the data effectively. If the belt is worn too loosely the signals received from the sensors may not be strong enough to transmit accurate data.

OXIMETER PROBE



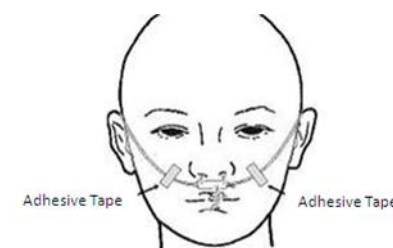
The Oximeter Probe can be clamped onto any finger. Use adhesive tape to secure the probe to the finger as to avoid the patient subconsciously removing the probe

NASAL CANNULAR



The Nasal Cannula is placed onto the nose of the patient. It uses pressure conduction mode to sense and respond to the pressure inside the nose and mouth.

Be careful not to let fluid enter into the cannula.



Note: Before turning the device on, all equipment must be connected properly and be worn by the patient.

USAGE OF ACUMEN7

SLEEP DATA COLLECTION

- Open the battery compartment, and install two AA batteries.
- Ensure that all the sensors are connected properly.
- To use the sleep data collection mode of the Acumen7 press the On/Off button for 2 seconds until both the green power light and the orange status light turn on.
- The system will automatically detect readings of SpO2 from the pulse oximeter within 5-10 seconds. When SpO2 readings are detected, the orange status indicator light will flicker slowly with an interval time of 1 second.
- To switch the Acumen7 off when the device is not in use press the On/Off button for 2 seconds until the status light and the power light are off.

DATA DOWNLOAD

Connect the USB data cable or the RS232 cable to the appropriate PC port and Acumen7 port.

To enter the data download mode of the Acumen7 press the On/Off button for 1 second until the green power light is switched on. (If the orange status light is also switched on the device is in data collection mode.)

LED DISPLAY FUNCTION DESCRIPTION

Function	Switch	Power LED	Status LED
Power off	Press 2s	No display	No display
Power on	Press 1s	Display in green	No display
Data collection mode	Press 1s	Display in green	Display in orange
Recording data		Display in green	Flashing in orange when Pulse Oximeter is detected. Display in orange when the Pulse Oximeter is not detected.

COMMON PROBLEMS ANALYSIS AND TROUBLESHOOTING

AIRFLOW SIGNAL (NASAL CANNULA)

Problem	Possible Cause	Possible Solution
<i>Unable to obtain a nasal cannula signal display on the bar graph.</i>	The cannula is not properly positioned.	<i>Adjust the cannula so the nasal prongs rest just inside the nostrils and re-check the display.</i>
	The cannula is not tightly connected to the main device.	<i>Make sure the cannula is firmly attached to the main device by turning the connector in a clockwise direction</i>
<i>Consistent invalid or incomplete measurements with ERR being displayed.</i>	The cannula is pinched/ kinked.	<i>Replace cannula. Contact medical provider for replacement.</i>
	The cannula is not secure on the head.	<i>Ensure the clear slide is against the chin to secure the cannula.</i>
	The patient is a restless sleeper and the nasal prongs are becoming displaced.	<i>Use small pieces of tape to secure the cannula prongs to the cheekbones. DO NOT PLACE TAPE OVER THE MOUTH OR NOSTRILS</i>

SNORING SIGNAL (SNORE MICROPHONE IN RECORDER BOX)

Problem	Possible Cause	Possible Solution
<i>No snoring waveform</i>	Snore Microphone may fail	<i>Contact Acumen7 Customer Support.</i>

CHEST AND ABDOMEN EFFORT SIGNAL (CHEST AND ABDOMEN EFFORT SENSORS)

Problem	Possible Cause	Possible Solution
<i>The chest and abdomen waveforms are too small or is a line</i>	The chest and abdomen belts are too tight	<i>Adjust the chest and abdominal belts</i>
	The chest and abdomen belts are too loose	<i>Adjust the chest and abdominal belts</i>
	The chest and abdomen effort sensors have broken	<i>Contact Acumen7 Customer Support.</i>

SPO2 AND PULSE SIGNAL (OXIMETER PROBE)

Problem	Possible Cause	Possible Solution
<i>Unable to obtain a green pulse display on the bar graph.</i>	The patient pulse strength is low.	<i>Reposition the finger or insert a different finger, and keep the sensor motionless for at least 10 seconds.</i>
	Circulation is reduced because of excess pressure on the sensor (between the sensor and a hard surface) after inserting finger.	<i>Warm the patient's finger by rubbing or covering with a blanket.</i> <i>Position the sensor at a different site (e.g., earlobe).</i> <i>Allow the hand to rest comfortably without squeezing or pressing the sensor on a hard surface.</i>
Note: In some occasions, patient perfusion may be inadequate for pulse		

detection.	The finger is cold.	<i>Warm the patient's finger by rubbing or covering with a blanket.</i> <i>Position the sensor at a different site (e.g. earlobe).</i>
Unable to obtain a green pulse displayed on the bar graph.	The sensor is applied incorrectly. There is possible interference from one of the following sources: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line The red LED is not illuminated in the finger insertion area.	<i>Apply the sensor correctly.</i> <i>Reduce or eliminate any interference. Make sure that the sensor is not placed on the same position being used for other patient therapies or diagnostics (e.g., blood pressure cuff).</i> <i>Ensure that the sensor is securely attached to the Acumen7.</i> <i>Check the sensor for any visible signs of deterioration</i> <i>Contact Acumen7 Customer Support.</i>
Frequent or steady pulse quality indication.	There is excessive ambient light. The Acumen7 is applied to a polished or artificial fingernail. The red LED is not illuminated in the finger insertion area. Patient motion is excessive.	<i>Shield the sensor from the light source.</i> <i>Apply the sensor to a finger with no artificial or polished nails.</i> <i>Position the sensor at a different site (e.g. earlobe).</i> <i>Ensure that the sensor is safely attached to the Acumen7.</i> <i>Check the sensor for any visible signs of deterioration.</i> <i>Contact Acumen7 Customer Support.</i> <i>Reduce patient motion.</i>
A dash (-) appears in the	A poor signal from the finger is	<i>Reposition the finger or insert a different finger and keep the sensor</i>

%SpO2 display.	being detected.	<i>motionless for at least 10 seconds.</i>
		<i>Position the sensor at a different site (e.g. earlobe).</i>
	The finger was removed from the sensor.	<i>Reinsert the finger and keep the sensor motionless for at least 10 seconds.</i>
	The Acumen7 is not functioning.	<i>Turn the unit off, check all connections, and retry.</i> <i>Contact Acumen7 Customer Support.</i>

CONNECTION PROBLEM (USB CABLE)

Problem	Possible Cause	Possible Solution
Unable to connect to device	Used error USB cable.	Check the cable; make sure that it is a USB cable.
Unknown device	USB driver is not installed.	Install the USB driver.
Communication error. Please check the device side and USB cable connection is good.	The cable and device loose connection.	Please fix the connection between cable and device.

DOWNLOAD DATA (USB CABLE)

Problem	Possible Cause	Possible Solution
<i>Communication error. Please check the device side and USB</i>	The cable and device loose connection.	<i>Please fix the connection between cable and device.</i>

cable connection is good.

Can not read device records.

Device connection error.

Please connect to PC again with USB cable, and click “Refresh” button to get records list.

APPENDIX B ELECTROMAGNETIC COMPATIBILITY INFORMATION

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

The Acumen 7 Polysomnograph is intended for use in the electromagnetic environment specified below. The customer of the user of the Acumen 7 Polysomnograph should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Acumen 7 Polysomnograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Acumen 7 Polysomnographic is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network which supplies buildings for domestic purpose.
RF emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

The Acumen 7 Polysomnographic is intended for use in the electromagnetic environment specified below. The customer or the user of Acumen 7 Polysomnographic should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. The manufacturer needs to recommend the ESD precautionary procedures to user.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be same levels with characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacture's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

The Acumen 7 Polysomnograph is intended for use in the electromagnetic environment specified below. The customer or the user of Acumen 7 Polysomnograph should assure that it is used in such an environment.			
Immunity test	IEC 60601 test	Compliance	Electromagnetic environment - guidance

	level	level	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	1 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Acumen 7 Polysomnograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	



NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Acumen 7 Polysomnograph is used exceeds the applicable RF compliance level above, the Acumen 7 Polysomnograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Acumen 7 Polysomnograph.

B) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m. stitched

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

The Acumen 7 Polysomnograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Acumen 7 Polysomnograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Acumen 7 Polysomnograph as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.35	0.12	0.23
0.1	1.11	0.37	0.74
1	3.5	1.17	2.33
10	11.1	3.69	7.38

100	35	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

ACUMEN 7 SOFTWARE

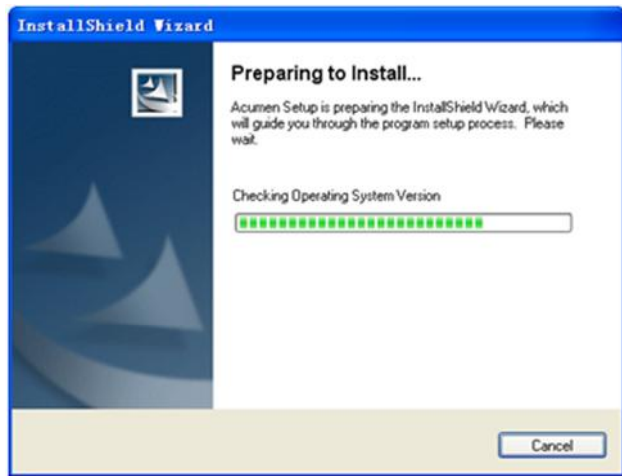
COMPUTER SPECIFICATIONS

	Minimal configurations	Recommended configurations
Processor	Pentium 4 1.6 GHz	Pentium 4 2.0 GHz
Memory	256M	512M
Cache memory	128K	512K
Hard disk	5G	80G
Power supply	220× (1±10%) Va.c 50×(1±2%)Hz	220× (1±10%) Va.c 50×(1±2%)Hz
Operation system	32 bit Windows 2000, Windows XP.....	

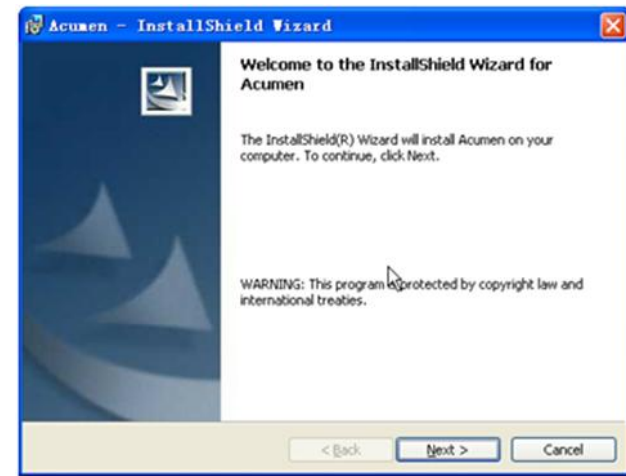
SOFTWARE INSTALLATION PROCEDURE

- Insert Acumen7 disk to your disk drive.
- The installation programs will automatically startup within 60 seconds. If it doesn't startup, the executable program Setup.exe inside the installation catalogue on the disk can be operated to start installation. Install the software as per the indication on the screen **(The software does not startup automatically)**

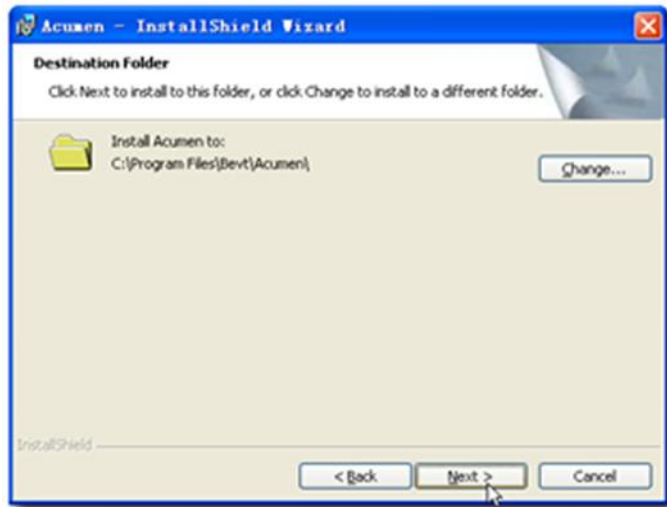
Step 1:
Double click the Setup.exe file to run the installation program.



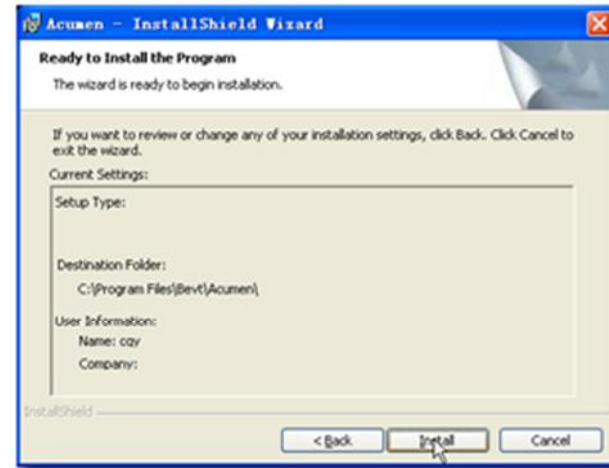
Step 2: Click "next" to continue the installation.



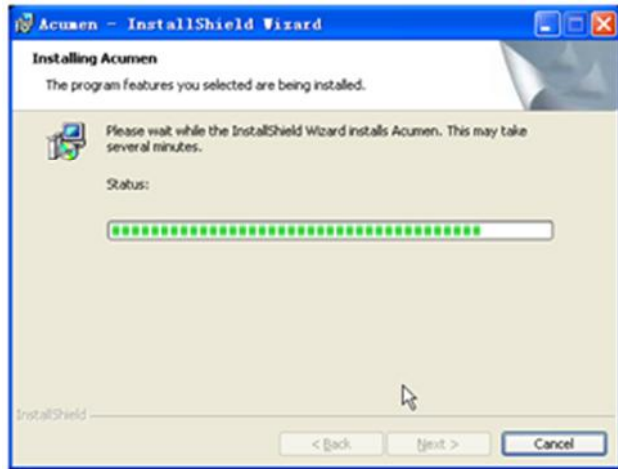
Step 3:
select the
installation
pathway
and click
next.



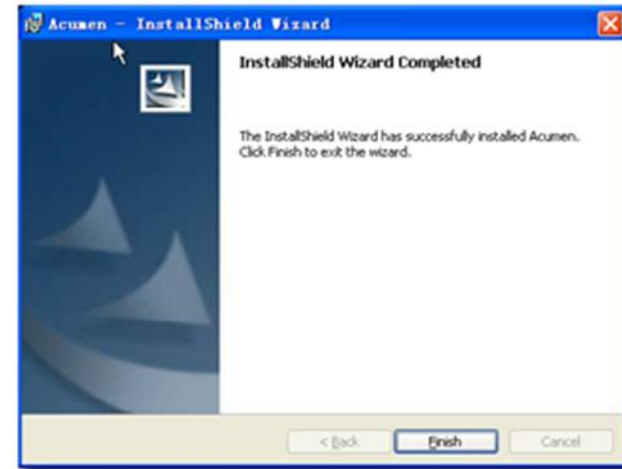
Step 4: After
having setting
up the
pathway, click
“Install” to
continue
installation of
software.



Step 5: wait for installation to complete.



Step 6: Click “Finish” to complete installation. Now there will be a shortcut on the program menu column of the system and a shortcut icon on the desktop.

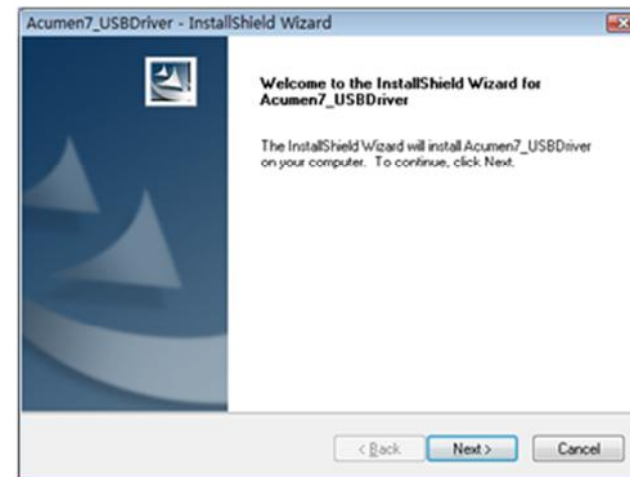


INSTALL USB DRIVER AUTOMATICALLY

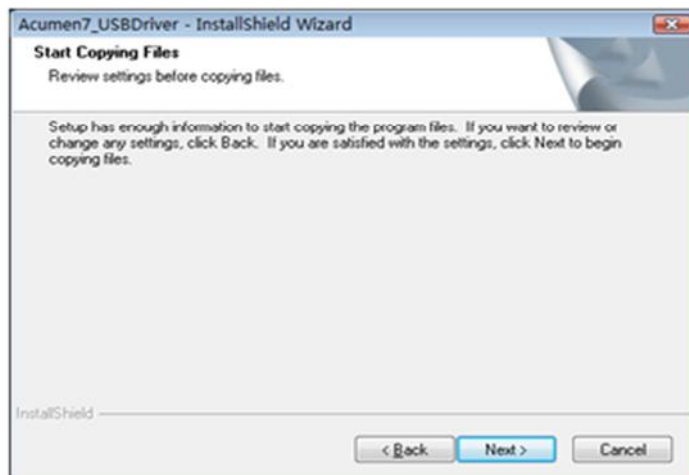
Step 1:
Insert
Acumen7
disk to
your disk
driver.
Copy the
file
“Acumen7
_USBDriver
_EN.rar” to
your PC
and extract
it. Double
click the
Setup.exe
file with
the mouse
to run the
installation
program



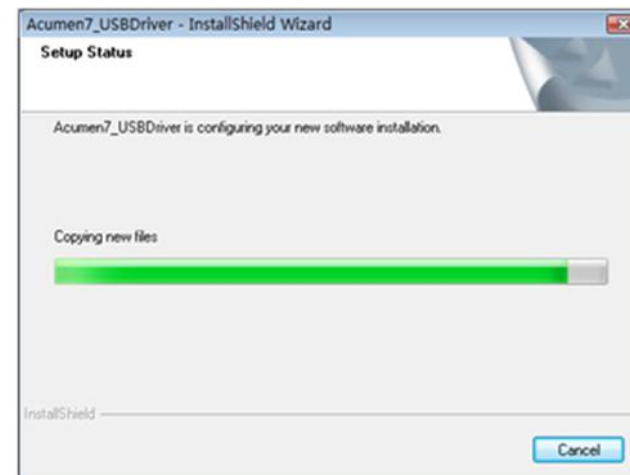
Step 2:
Click
“next” to
continue
the
installatio
n.



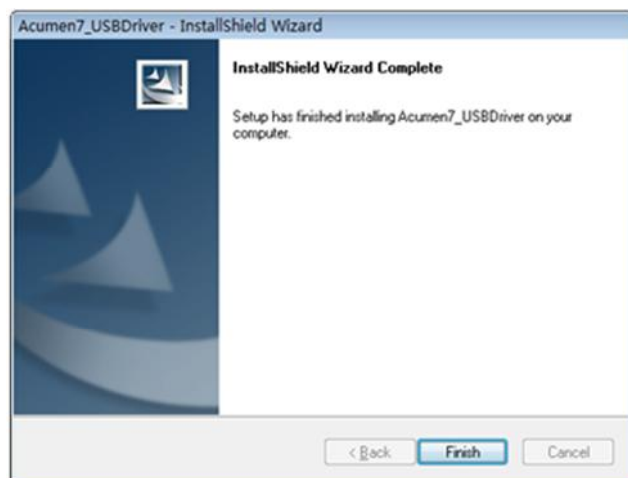
Step 3:
Click “next”
to continue
the
installation.



Step 4:
Wait for
files to
copy



Step 5: Click
“Finish” to
complete the
installation.

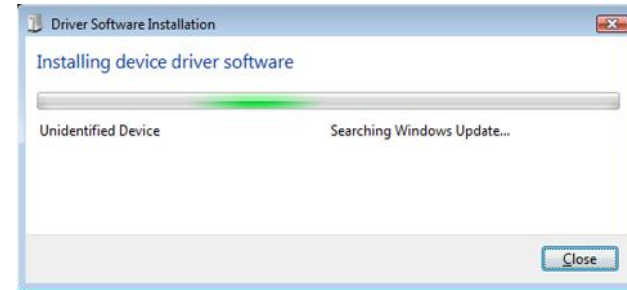


INSTALL USB DRIVER MANUALLY

Step 1: Connect the device to the PC using the USB or RS262 cable. When the computer finds the hardware, the “Found New Hardware” window will pop up. Select the first item: “Locate and install driver software (recommended)”

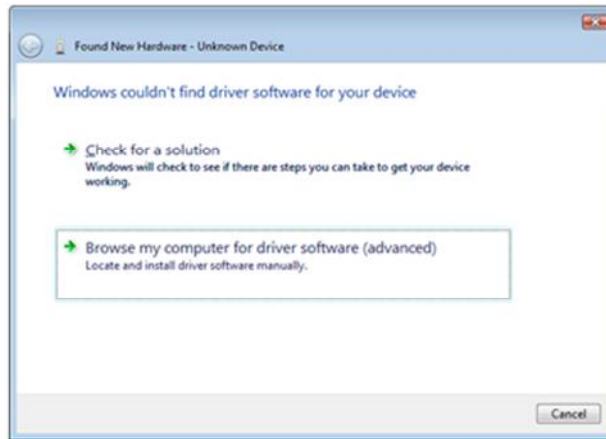


Step 2: Windows will search driver software automatically

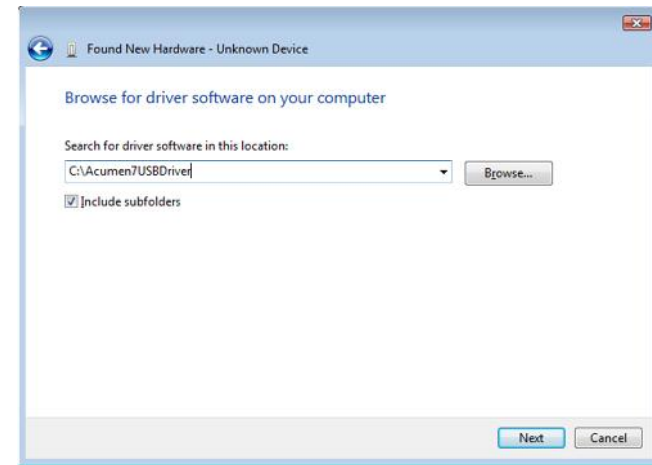


Step 3: If windows can not find the driver software for your device, it will ask you to locate and install driver software manually.

Please select the second item "Browse my computer for driver software (advanced)." Locate and install driver software manually.



Step 4: Click "Browse..." button to locate the driver software on your computer, find the Acumen7 software and click "next".



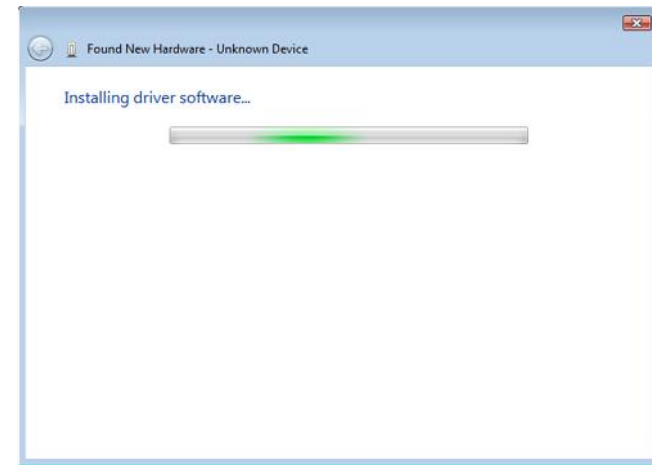
Step 5:

Windows security will ask you to install the driver software. Please select the second item “Install this driver software anyway”;

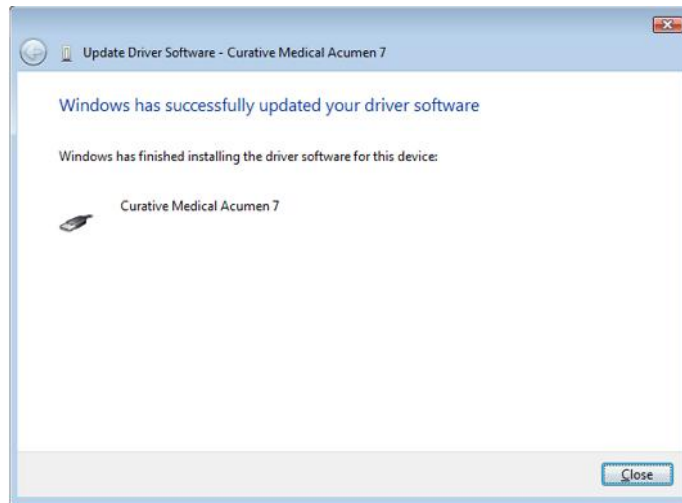


Step 6:

windows will begin to install the software.

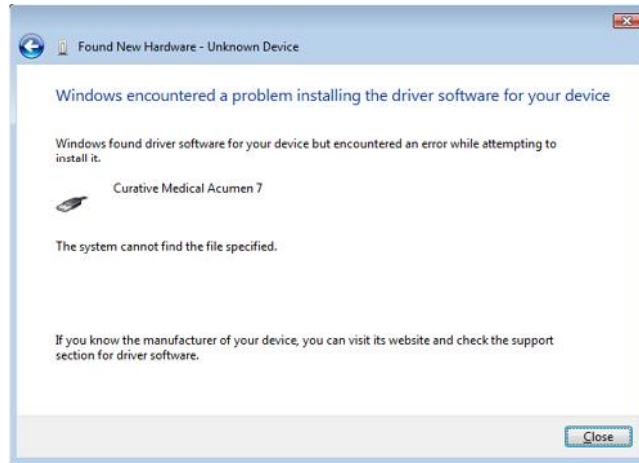


Step 7: If the driver software can be successfully installed windows will prompt that “Windows has successfully updated your driver software”.

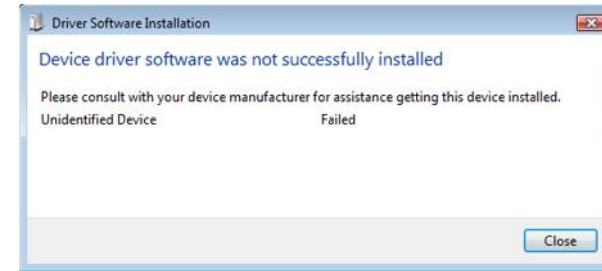


INSTALL USB DRIVER IS DRIVER SOFTWARE CANNOT BE SUCCESSFULLY INSTALLED

Step 1: If the driver software cannot be successfully installed windows will prompt that “Windows encountered a problem installing the driver software for your device”.



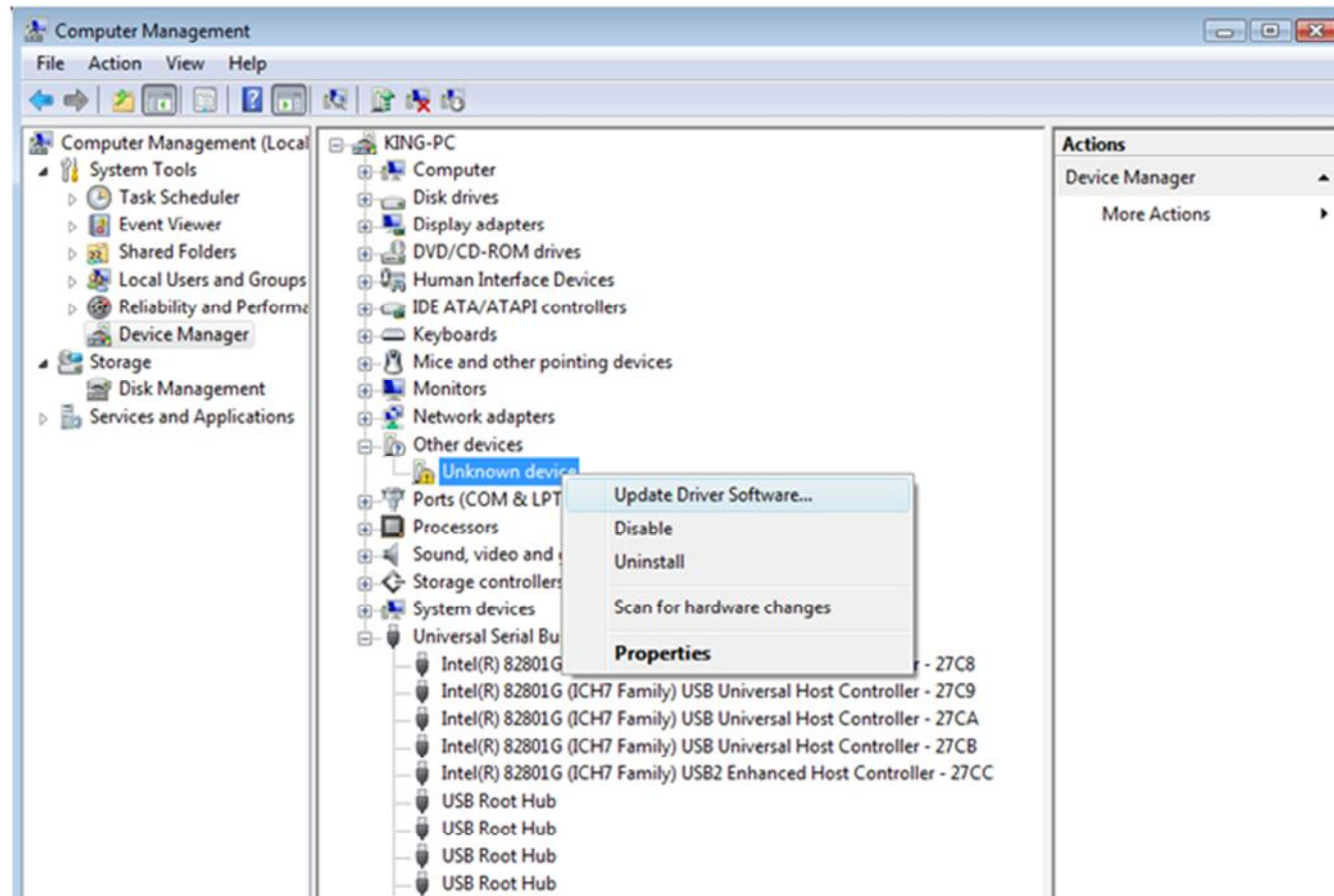
Step 2: Device driver software was not successfully installed.



Step 3: Open “Computer Management” by right clicking on “my computer” on your desktop.

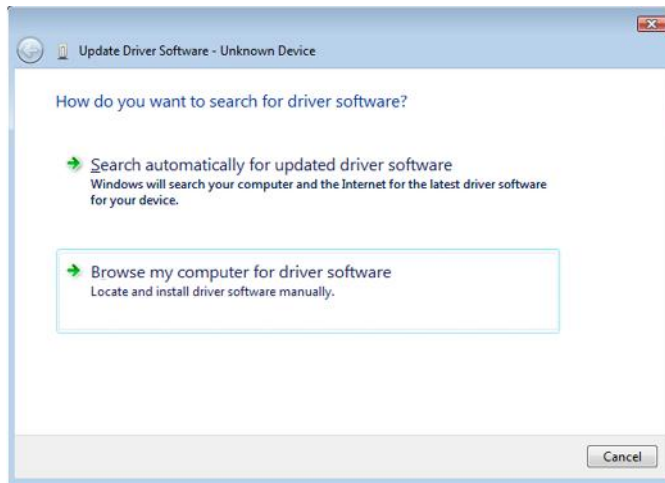
Right click “Other devices”
right click “Unknown device”
item and select
“Update Device
software...” menu.

**This section is not
explained well and I
cannot follow the
instruction easily and
some options are not
available.**

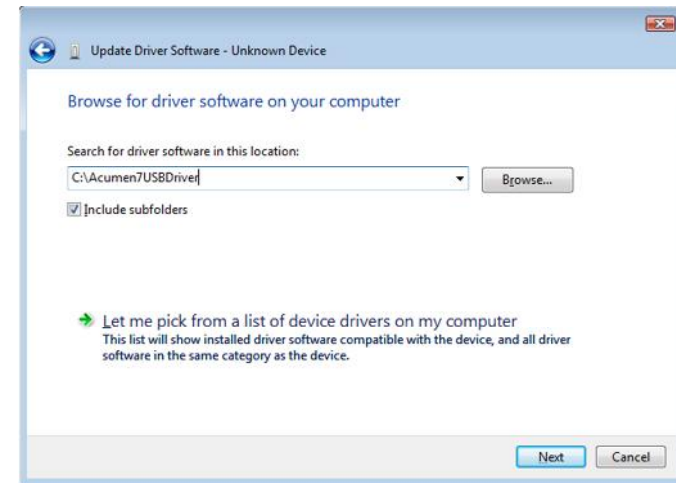


Step 4:

Please select the second item "Browse my computer for driver software (advanced)";

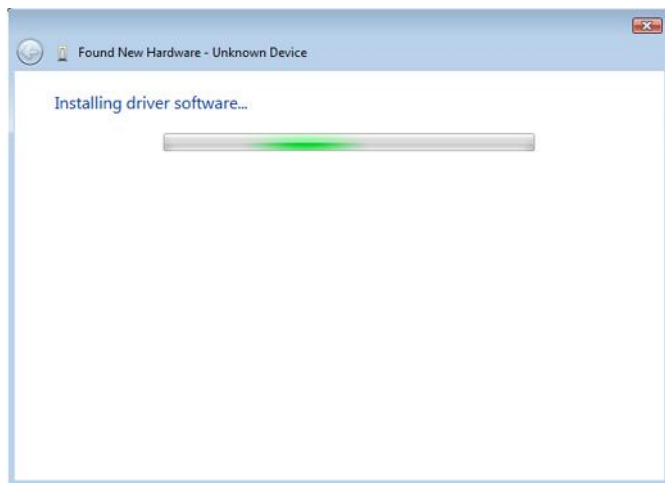


Step 5: Click "Browse..." to locate the driver software on your computer.



Step 6:

Windows will start to install the software.



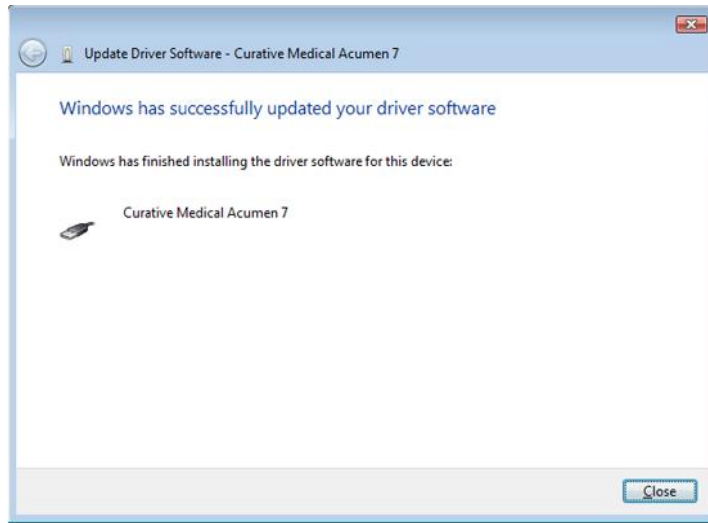
Step 7:

Windows security will ask if you want to install the driver software. Select "Install this driver"

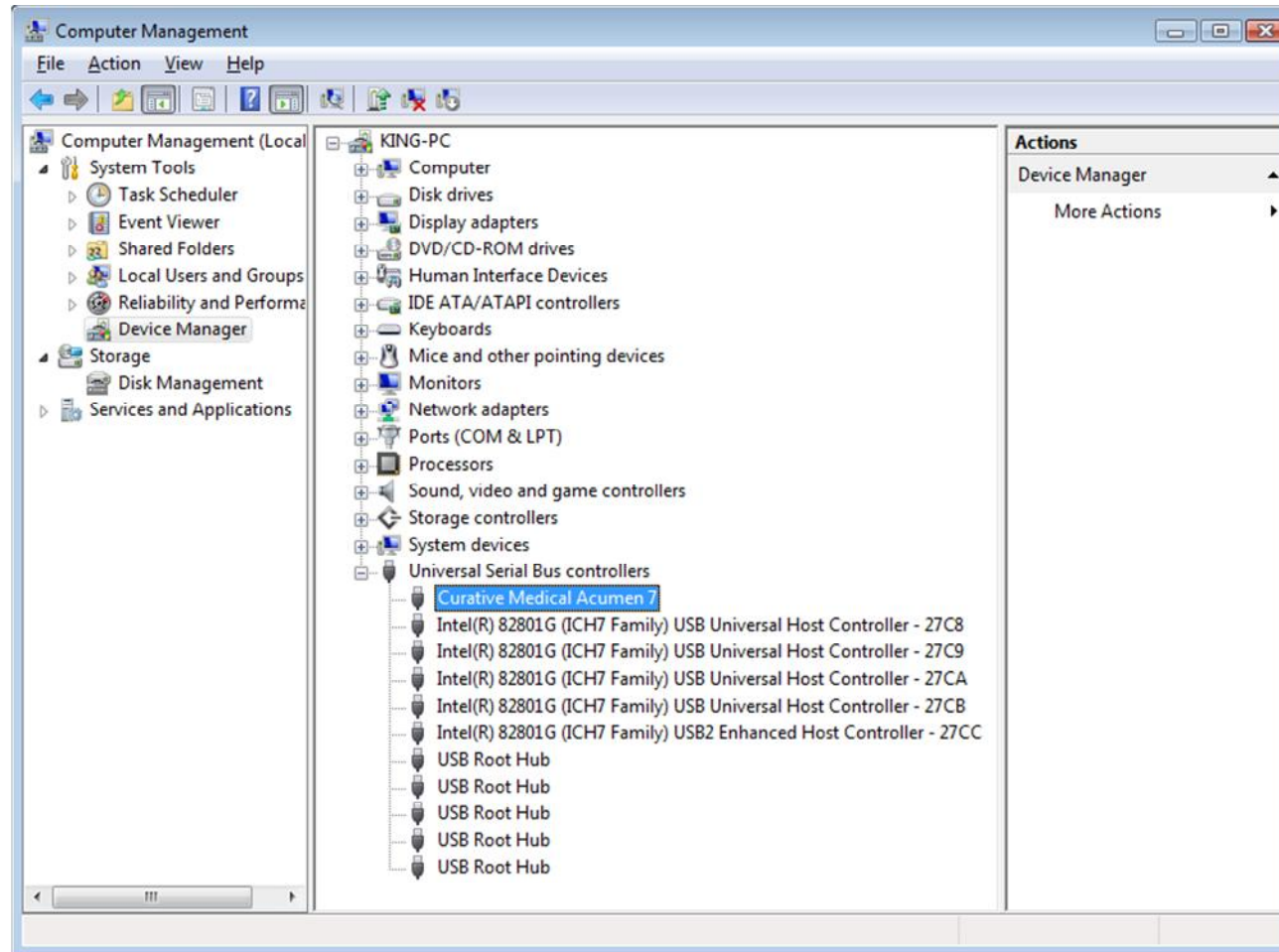


software
anyway”;

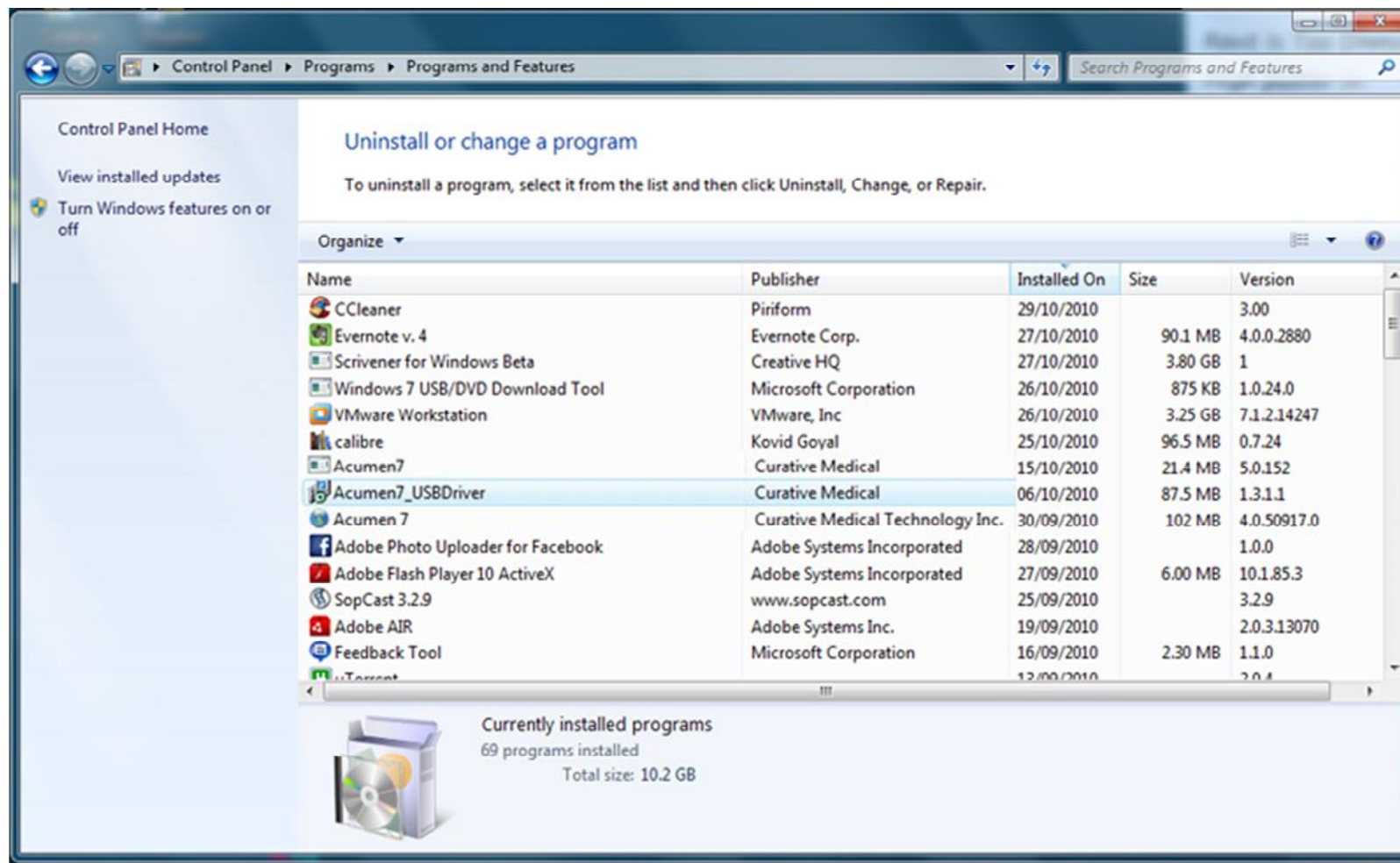
Step 8: If the driver software can be successfully installed, windows will prompt that “Windows has successfully updated your driver software”.



Step 9: If the driver software has successfully installed you will find “Curative Medical Acumen7” in Computer management > Device Manager > Universal Serial Bus controllers



Step 10: Open “Control Panel” > “Programs and features”, we can find “Acumen7_USBDriver” item in the list such as the follow picture.



INTRODUCTION TO THE ACUMEN 7 SOFTWARE

The Acumen 7 software is used to:

- Download data from the device.
- Analyse and display data across the 7 channels.
- Create plots to compare and diagnose sleep conditions.
- Produce Respiratory Event Summary and SpO2 Scored Summary Reports.
- **Add any other functionalities**

START UP

To start the Acumen 7 software either select the shortcut on your desktop or, if Acumen 7 does not have a shortcut on the desktop select: Start menu > Programs> Curative Medical > Acumen 7.

MAIN TOOLBAR

The main toolbar provides instant access to the most commonly used functions of the software



New Record

Show Video

Time Periods

Sleep stage

Open Record

View a Multi Trend Plot

Navigation keys

Jump to Event

Print

Scan File

Light on and Light off.

EVENT SCROLL BAR



The event scroll bar can be used to scroll from one event to the next. You can scroll between apnea events, hypopnea events and desaturation events.

STATUS BAR

Record Time: 01:01:30

Epoch: 124

The status bar at the bottom of the screen displays the recorded time and the period of time.

SETTING THE PERIOD LENGTH

30 60 2m 5m 10m

There are 5 different time period lengths that you can view the data in 30 seconds, 60 seconds 2minutes, 5minutes and 10minutes. You can adjust this on the toolbar.

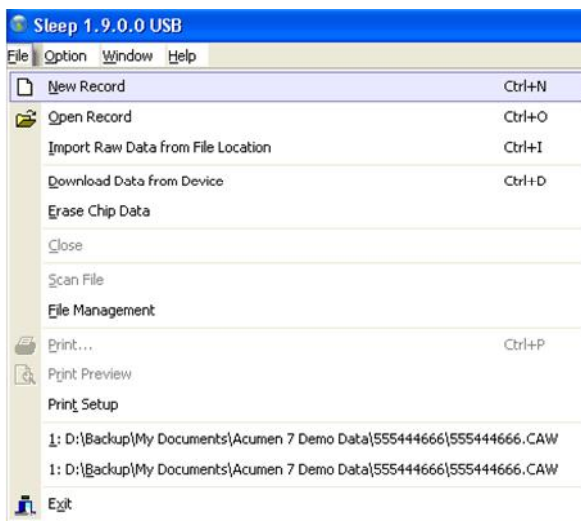
LIGHT ON AND LIGHT OFF



The Light on and Light off function on the toolbar is used to indicate the time that the patient was asleep during the data collection. By using Lights on and Lights off you can eliminate data that was collected when the patient was awake.

CREATE A NEW RECORD

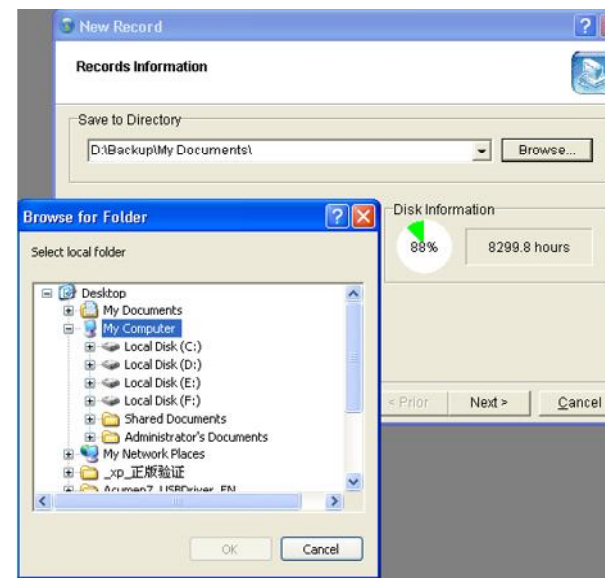
Step 1:
Select
“New
Record”
from File
tab.



Step 2: Select
“Browse” and
then select
where you
would like to
store your
data.

Attention!
Ensure that
you know the
location of the
file.

*You can also
see the
available disk
space in this
window and
the amount of
recording time
available.*



Note: the remaining time displayed on the above plot is based on the current hard disk partition. If the remaining hard disk space is less than 500M, it should be noted to collect spatial processing. What does this mean?

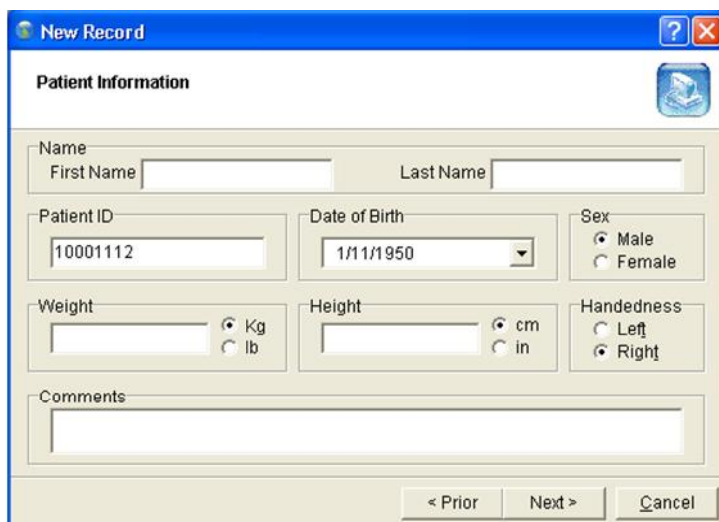
Appropriate measures should be adopted, for example: changing the storage pathway, backing up files, and deleting useless files to clean the adequate hard disk space for usage in the next data acquisition.

Step 3:

Select, "Next" to input the next item of information.

Important!

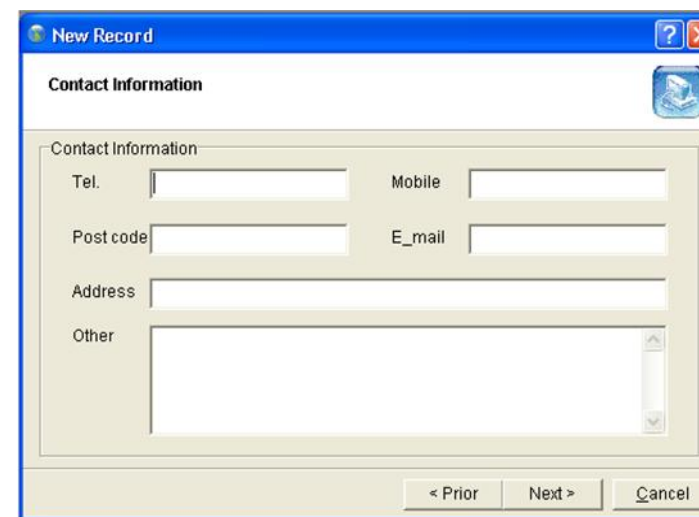
A Patient ID must be entered.



Step 4: Input

Contact Information

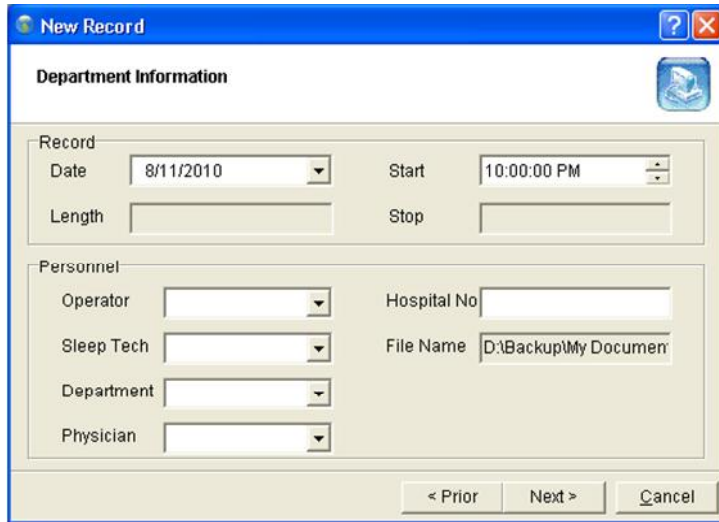
Select "Next"



Step 5:

Input
correct data
of
department
information

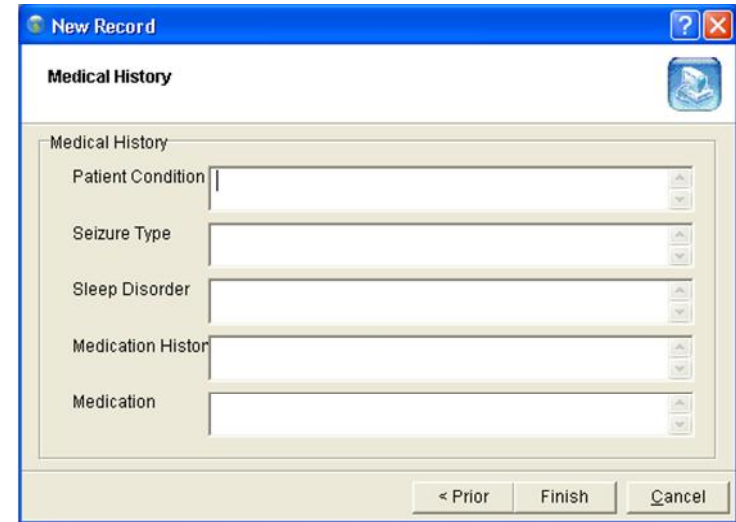
Select
“Next”



Step 6: Input
correct data
of medical
history

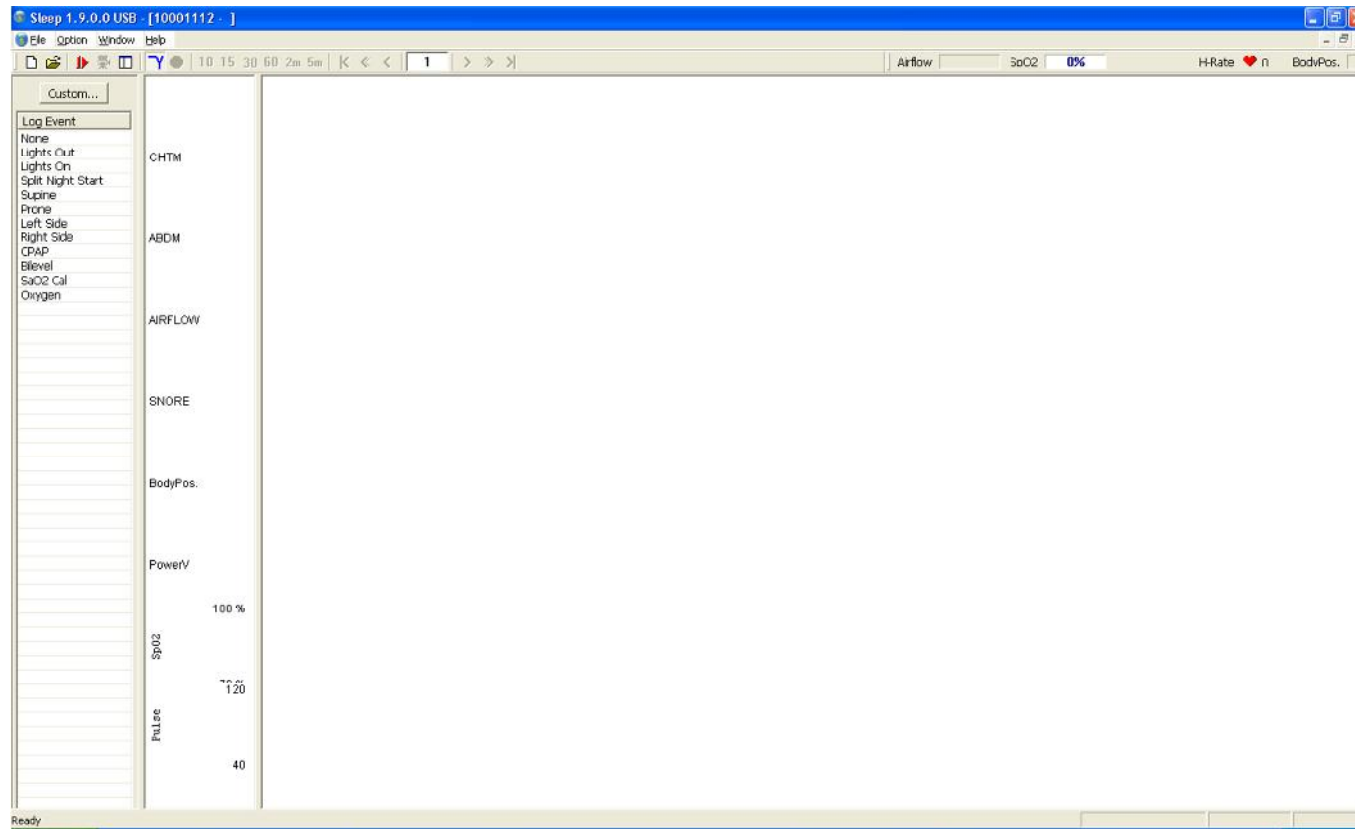
Click “Finish”
button to
collect
Real-time
data.

???????



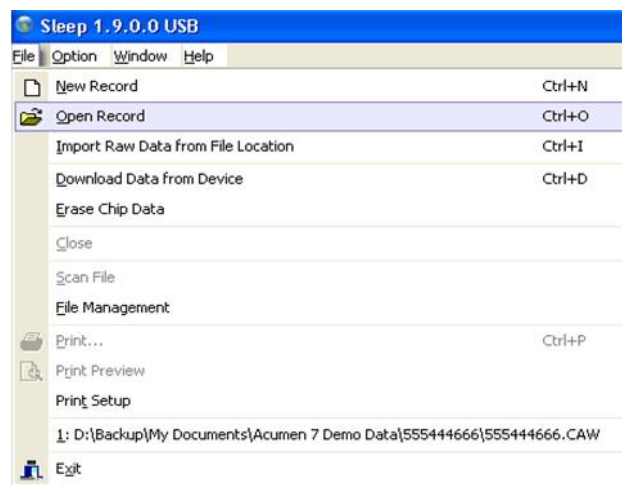
Step 6: When the patient information has been completed you will be taken to the main screen of the Acumen 7 software.

The main screen is used to display data that has been downloaded from the Acumen 7 device or imported from a file.

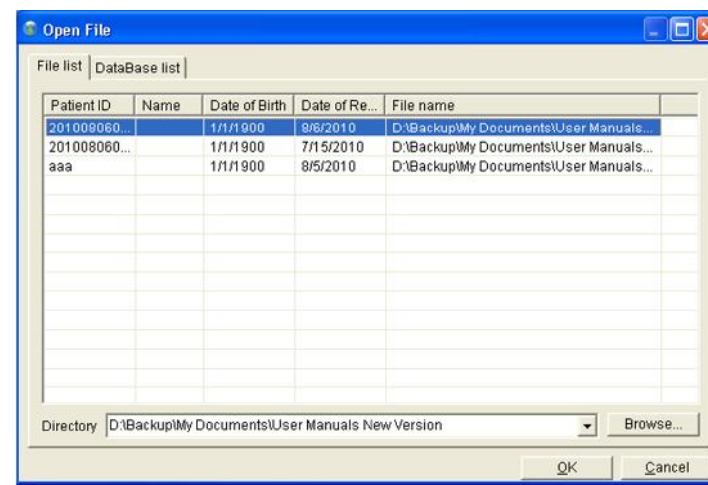


OPENING A RECORD

Step 1: Select
“Open
Record” from
File tab.



Step 2:
Select
the
record
you want
to open.

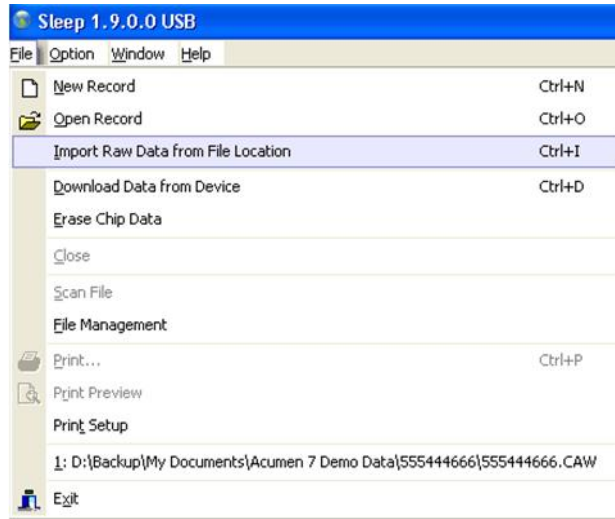


[illegible]

IMPORTING DATA FROM FILE LOCATION

Step 1:

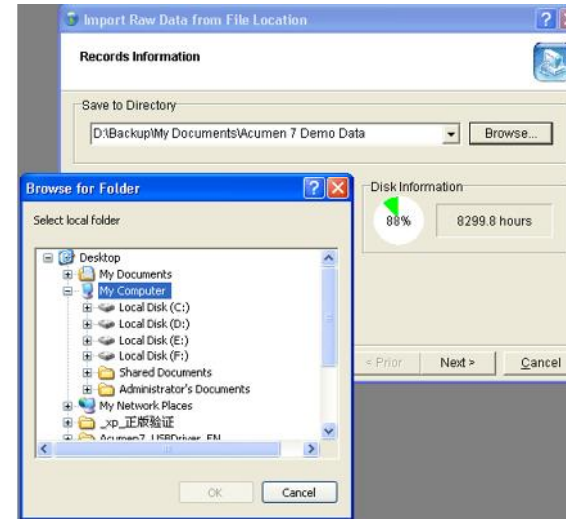
Select
“Import
Data from
File
Location”
from File
tab.



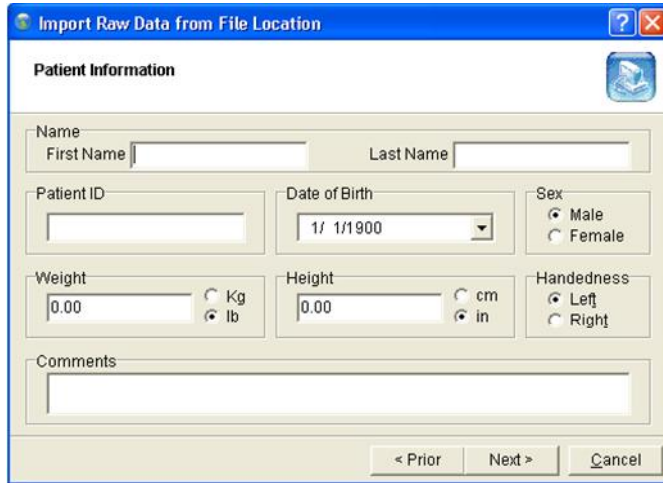
Step 2:

Browse to
find a
location
where the
data can be
saved.

Click “Next”

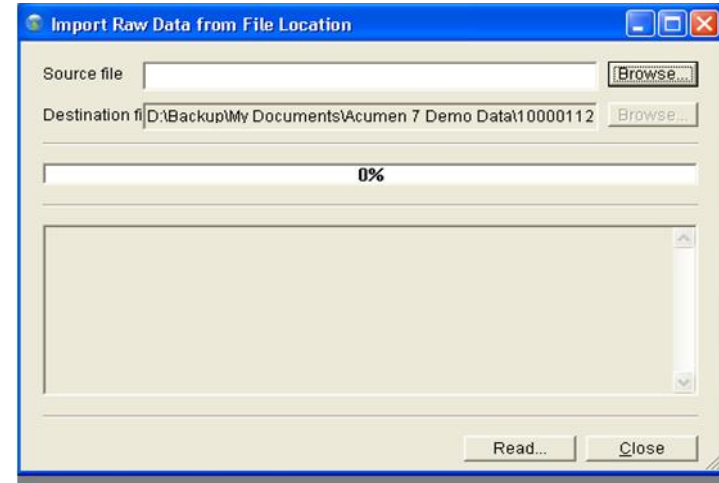


Step 3:
Input
patient
information
as directed
in Create a
New
Patient.



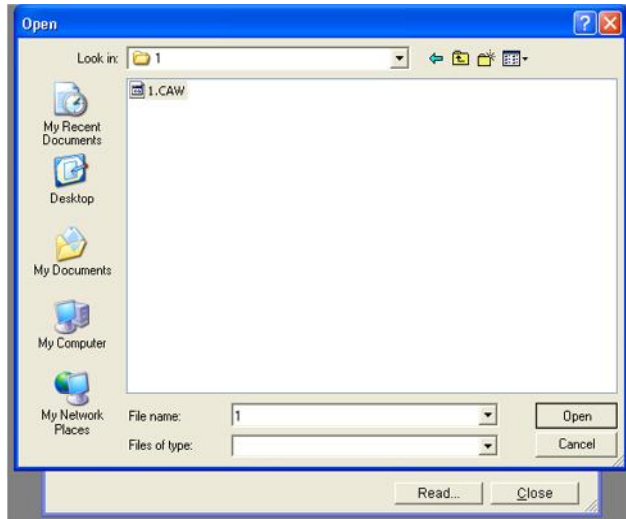
Step 4:
Browse to
find the
source file
that holds
the data
you are
importing.

Important:
imported
file must be
in
*.Rawdat,
or *.DAT
format.



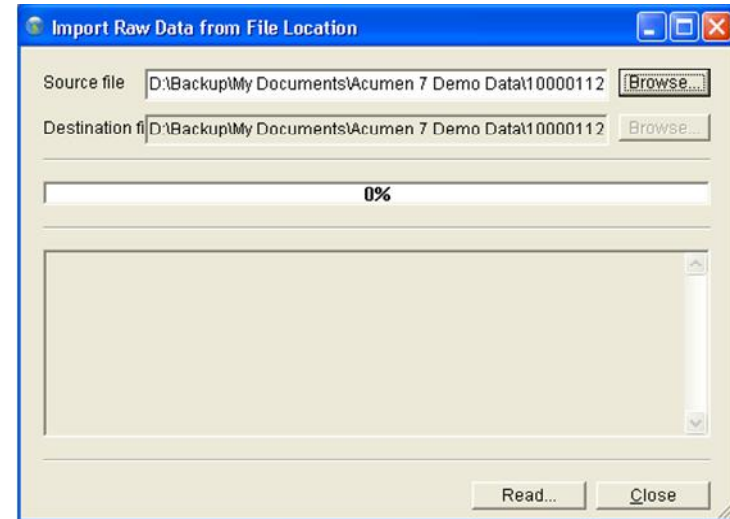
Step 5:

Select the data you want to import and click "Open"



Step 6:

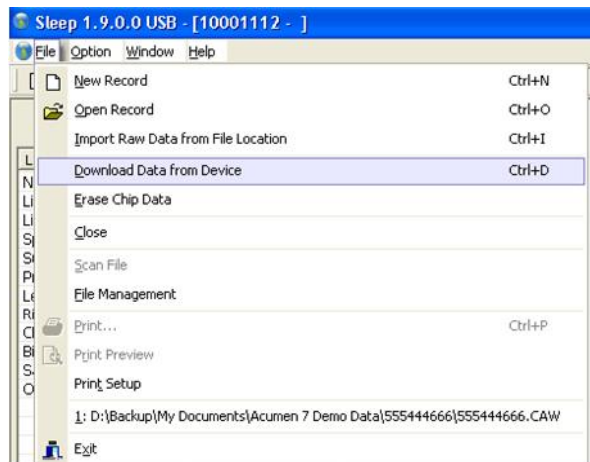
Once you have selected your data to import click "Read" to import the data.



DOWNLOADING DATA FROM THE DEVICE

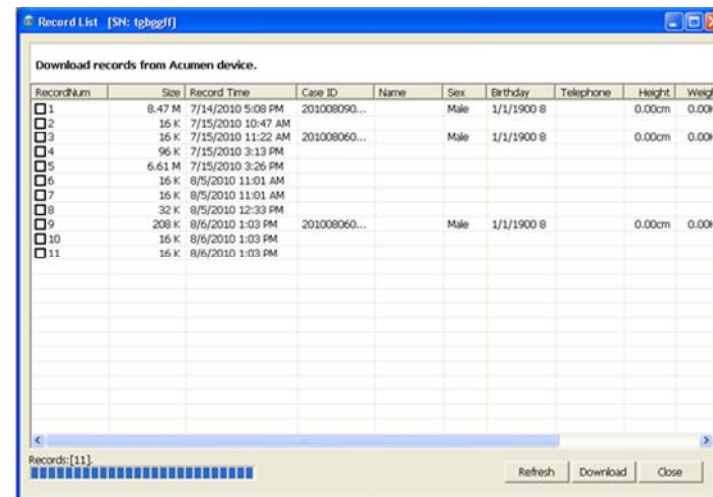
Step 1:

Select
“Download
data from
Device”
from File
tab



Step 2: The
next screen
will show
the records
from the
Acumen 7

Select the
record that
you want to
download.

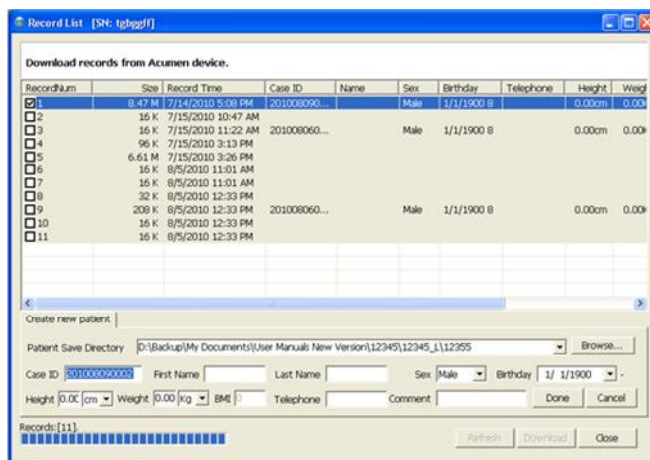


Step 3:

Choose the location that you want to download the data to

Fill in any missing information.

Click “done”



Record List [SN: tpgpff]

Download records from Acumen device.

RecordNum	Size	Record Time	Case ID	Name	Sex	Birthday	Telephone	Height	Weight
☒ 1	8.47 M	7/14/2010 5:08 PM	201008090...		Male	1/1/1900 8		0.00cm	0.00K
☐ 2	16 K	7/15/2010 10:47 AM							
☐ 3	16 K	7/15/2010 11:22 AM	201008060...		Male	1/1/1900 8		0.00cm	0.00K
☐ 4	96 K	7/15/2010 3:13 PM							
☐ 5	6.61 M	7/15/2010 3:26 PM							
☐ 6	16 K	8/5/2010 11:01 AM							
☐ 7	16 K	8/5/2010 11:01 AM							
☐ 8	32 K	8/5/2010 12:33 PM							
☐ 9	208 K	8/5/2010 12:33 PM	201008060...		Male	1/1/1900 8		0.00cm	0.00K
☐ 10	16 K	8/5/2010 12:33 PM							
☐ 11	16 K	8/5/2010 12:33 PM							

Create new patient

Patient Save Directory: D:\Backup\My Documents\User Manuals New Version\12345\1\12355

Case ID: 2010000000000 First Name: Last Name: Sex: Male Birthday: 1/1/1900

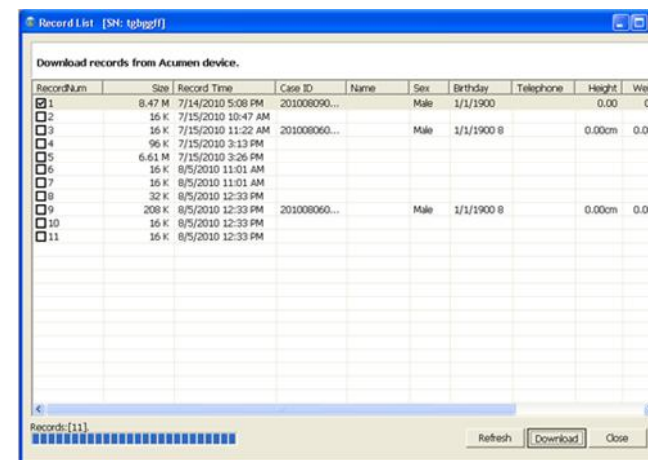
Height: 0.00 cm Weight: 0.00 kg BMI: Telephone: Comment: Done Cancel

Records: [11]

Refresh Download Close

Step 4:

Click “Download” to begin the data download.



Record List [SN: tpgpff]

Download records from Acumen device.

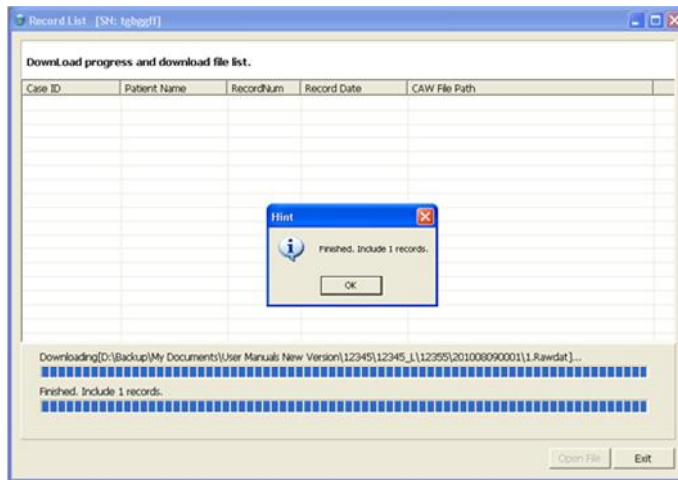
RecordNum	Size	Record Time	Case ID	Name	Sex	Birthday	Telephone	Height	Weight
☒ 1	8.47 M	7/14/2010 5:08 PM	201008090...		Male	1/1/1900		0.00	0.00
☐ 2	16 K	7/15/2010 10:47 AM							
☐ 3	16 K	7/15/2010 11:22 AM	201008060...		Male	1/1/1900 8		0.00cm	0.00K
☐ 4	96 K	7/15/2010 3:13 PM							
☐ 5	6.61 M	7/15/2010 3:26 PM							
☐ 6	16 K	8/5/2010 11:01 AM							
☐ 7	16 K	8/5/2010 11:01 AM							
☐ 8	32 K	8/5/2010 12:33 PM							
☐ 9	208 K	8/5/2010 12:33 PM	201008060...		Male	1/1/1900 8		0.00cm	0.00K
☐ 10	16 K	8/5/2010 12:33 PM							
☐ 11	16 K	8/5/2010 12:33 PM							

Records: [11]

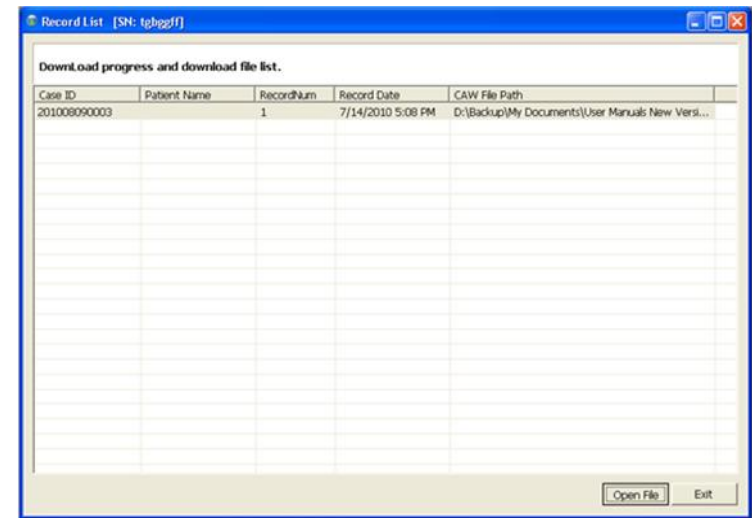
Refresh Download Close

Step 5: Wait for data to download.

When the download has finished click OK.



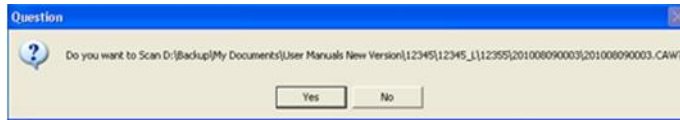
Step 6: Select the record and click “Open File”



Step 7:

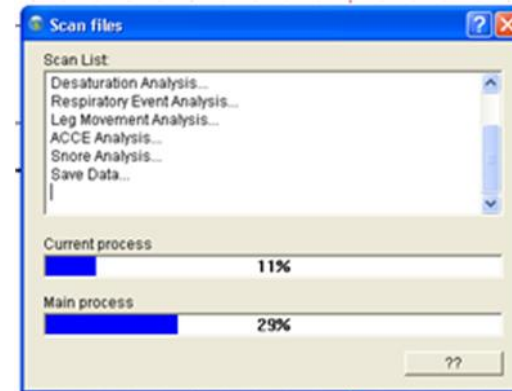
Once the file is open you will be asked if you want to scan the file.

Select “Yes” and scan the file to process the data.



Step 8: Final screen showing progress on scanning files.

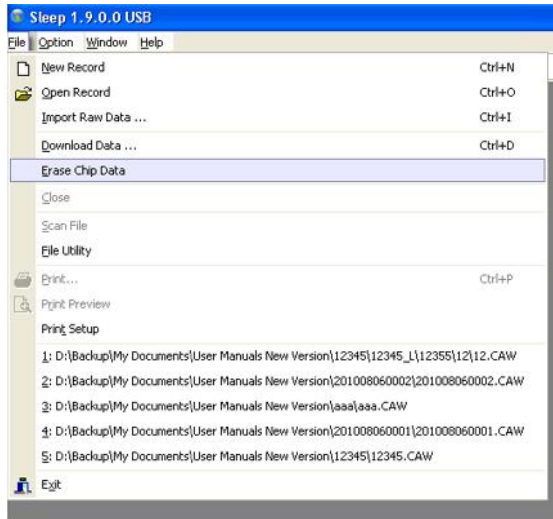
When scanning is complete you can see that data in the chart formats.



ERASE CHIP DATA NEW TITLE NEEDED

Step 1:
Select
“Erase Chip
data” from
File tab

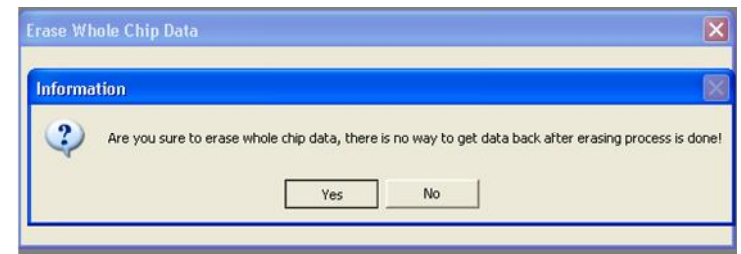
Note: The
device can
store 49
records.
When the
amount of
records
exceeds 49,
new
records will
be saved
over the
oldest
records.



Step 2: Click
“Erase”.



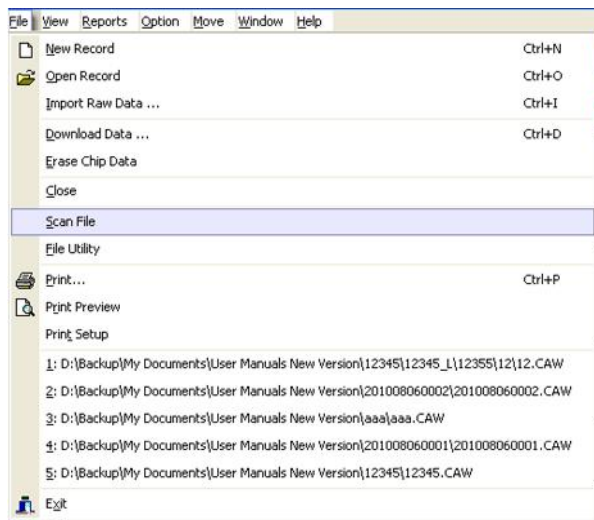
Step 3:
Check that
you do want
to erase the
data.



SCANNING FILES

Step 1:

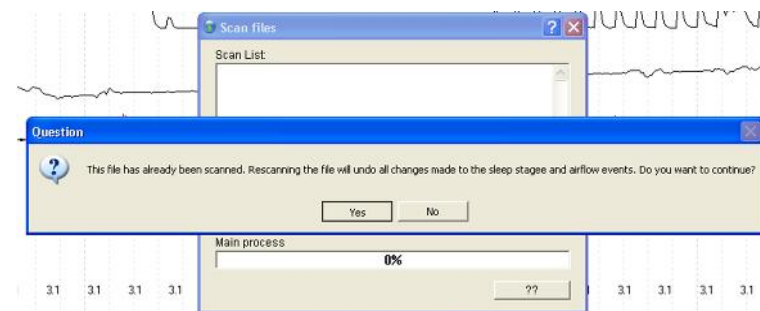
Select “Scan File” from File tab



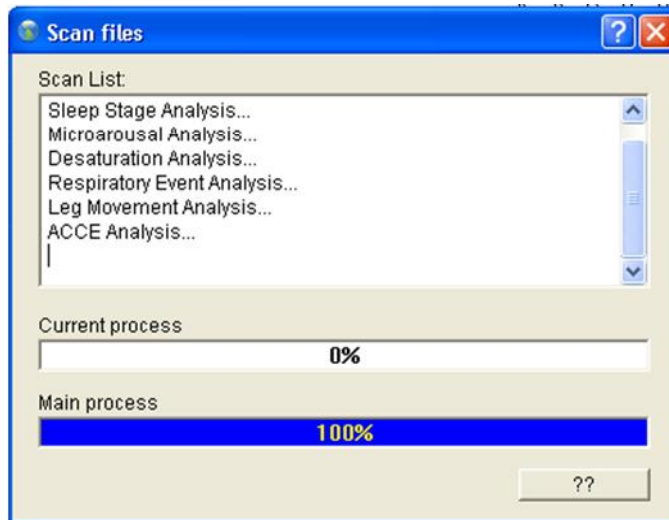
Step 2:

If file already scanned you will be asked whether you want to scan the file again.

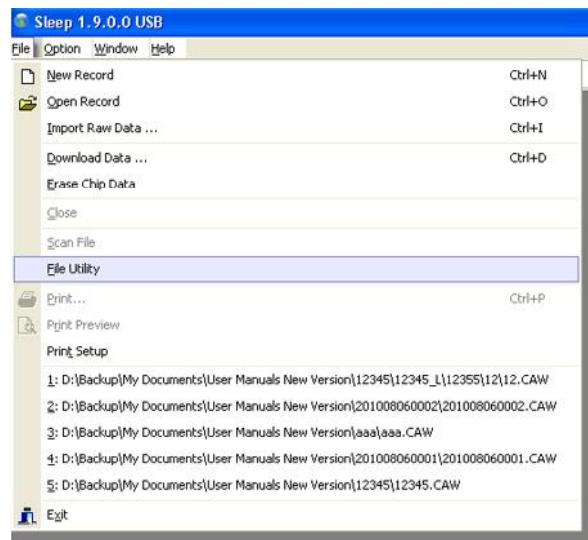
Select “Yes” or “No”



Step 3:
Scanning
the file.

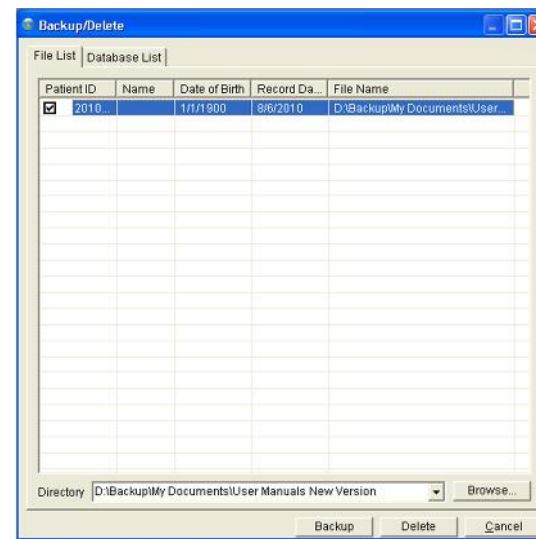


Step 1: Select “File management” from File tab



Step 2:
Select Files
to delete or
backup
from File list
or Database
list.

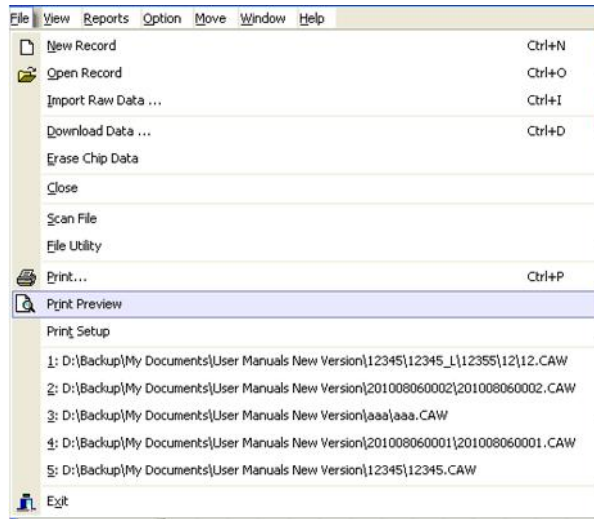
You can
browse
different
directories
to find files.



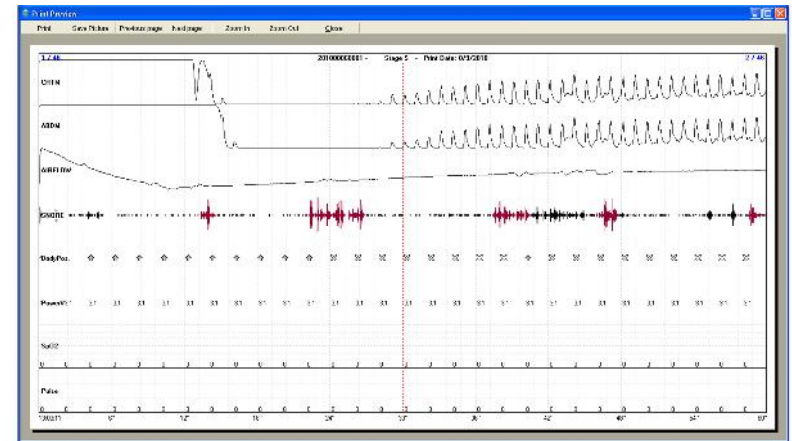
PRINTING

Step 1: For a quick print select “Print”

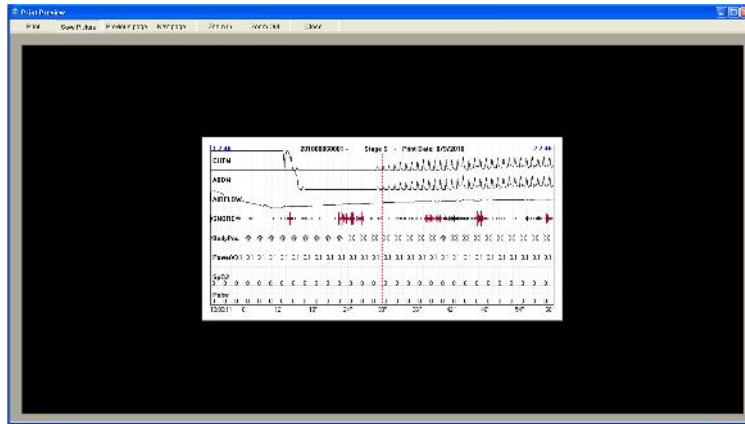
To view the document before printing select “Print Preview”



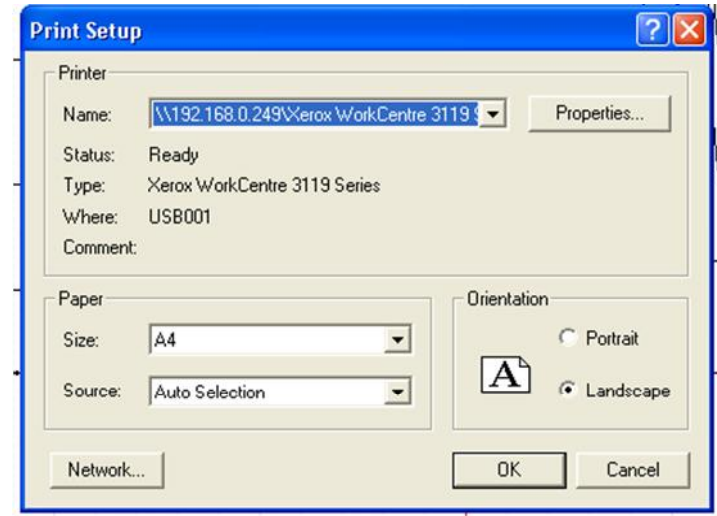
Step 2: The “Print Preview” can zoomed in and out and be saved as a picture before printing



Step 3:
View of
document
zoomed
out.



Step 4: Use
the “Print
Setup” to
change
printer or
adjust any
print
settings.



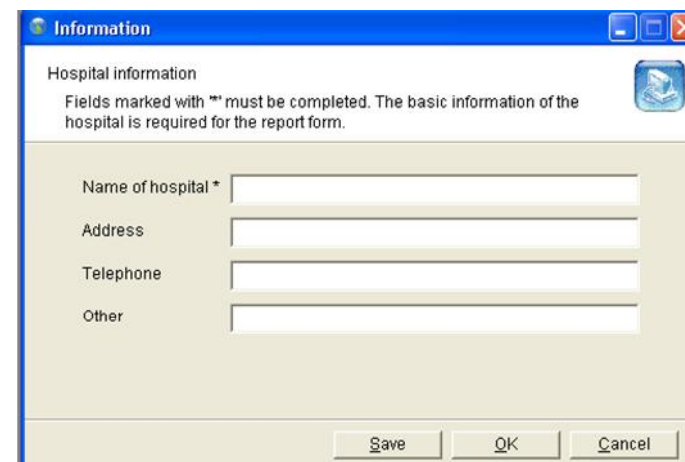
The screenshot shows a 'Print Setup' dialog box with a blue title bar. The dialog is divided into several sections. The 'Printer' section at the top shows the printer name as '\\192.168.0.249\Xerox WorkCentre 3119', with a 'Properties...' button next to it. Below this, the 'Status' is 'Ready', the 'Type' is 'Xerox WorkCentre 3119 Series', and the 'Where' is 'USB001'. The 'Comment' field is empty. The 'Paper' section has a 'Size' dropdown set to 'A4' and a 'Source' dropdown set to 'Auto Selection'. The 'Orientation' section has two radio buttons: 'Portrait' (which is selected) and 'Landscape'. At the bottom, there are three buttons: 'Network...', 'OK', and 'Cancel'.

HOSPITAL INFORMATION AND TIME SYNCHRONIZATION

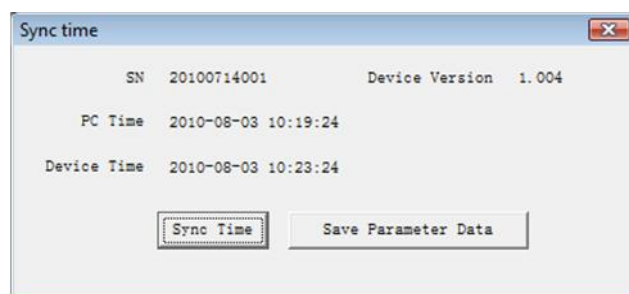
Step 1: Hospital Information and Sync. Time can be found in Option tab.



Step 2: Enter the hospital information so that it can be shown on the cover of the report.



Step 3: To sync the time of the device with the computer clock click "Sync Time"



To save parameter data click "Save Parameter Data"

Attention: please connect the device to PC with USB cable; synchronize the device time before you use this device. Make sure that the PC time is correct.

DATA PLAYBACK

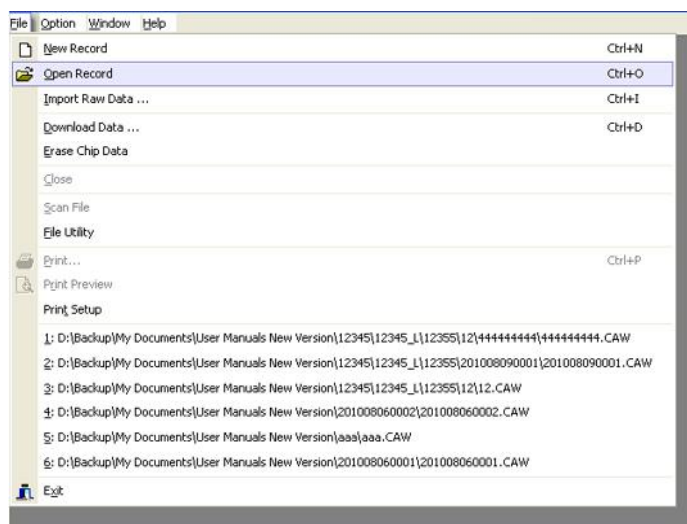
SCAN FILE FUNCTION

The scan file function processes the raw sleep data and uses it to create waveform graphs that enable the user to easily analyze the Polysomnographic data.

It takes 2 to 5 minutes to scan an 8-hour file depending on the computer.

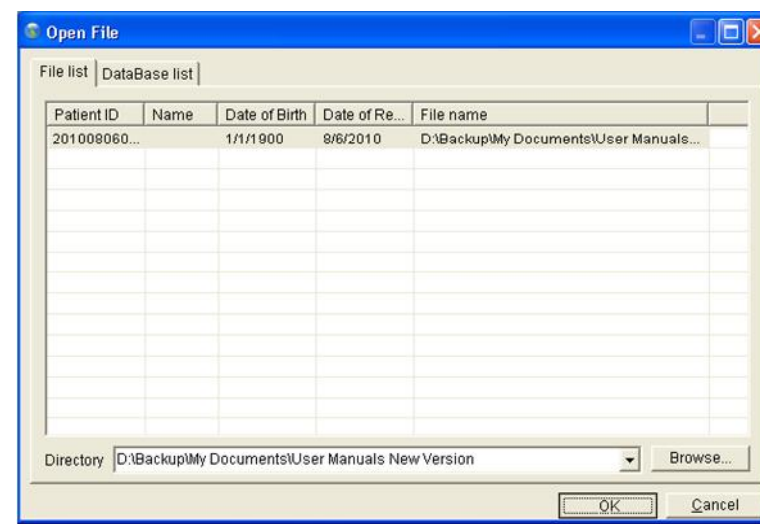
SCANNING FILES

Step 1: Select
“Open
Record” from
File tab

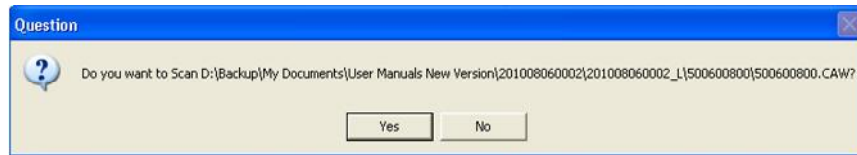


Step 2: Now
you have
access to the
stored
records.

Select a file
and click “OK”

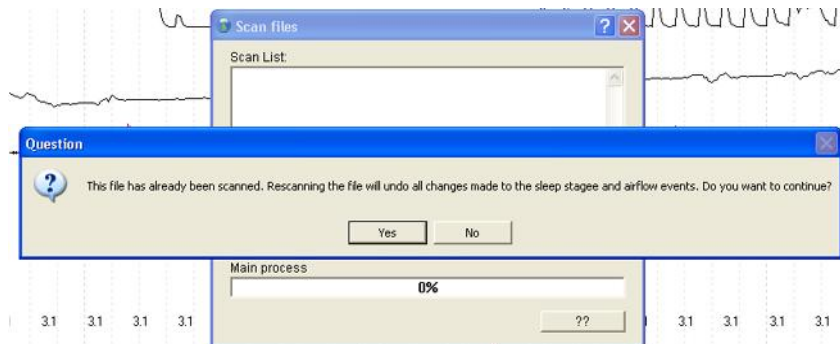


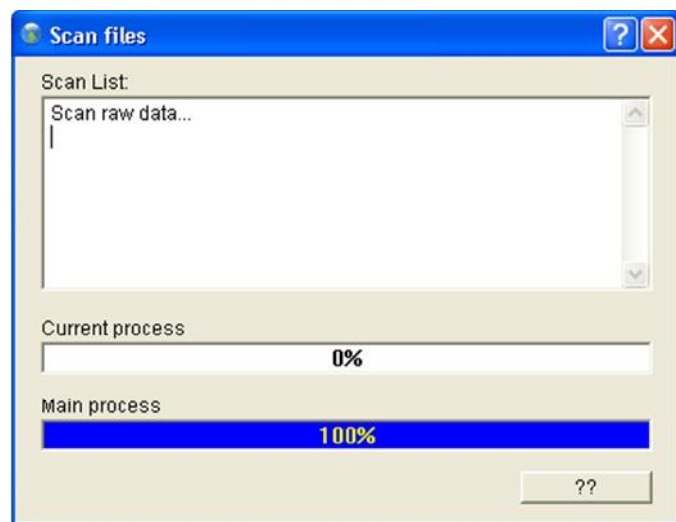
Step 3: If the file has not been scanned previously then you will asked whether you want to scan the file



Step 4: If the file has already been scanned you will be reminded that it has.

You will then be asked whether you would like to scan the file again.





REVIEWING RECORDED DATA

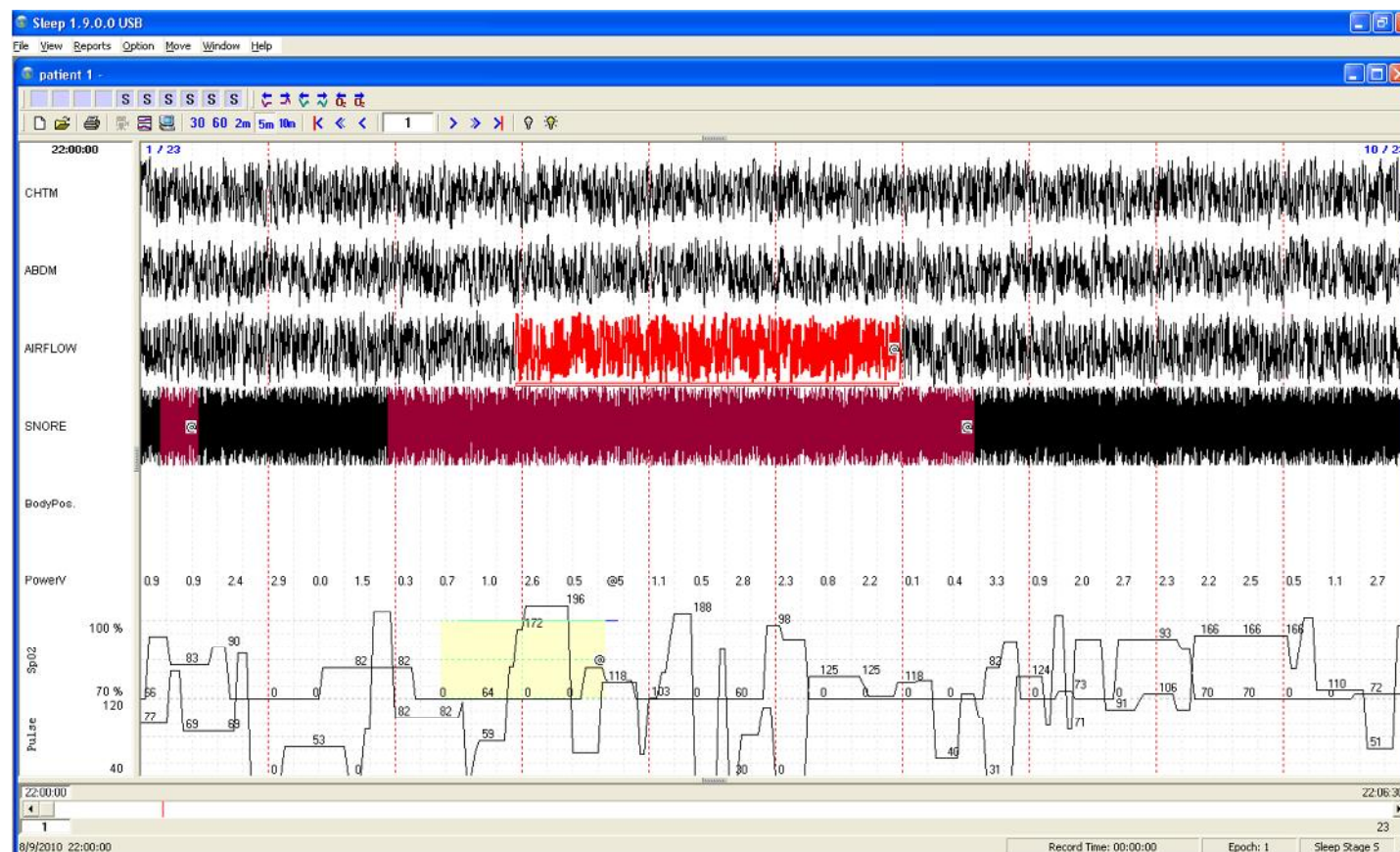
To review recorded data, select the file that you wish to review in the open record function or select a recently opened file from the File tab.

If the file hasn't been scanned, there will be no reports or trend plots. To scan files refer to the previous section.

This is the view of a scanned file.

It displays the following channels:

- Chest Respiratory Effort
- Abdomen Respiratory Effort
- Air Flow
- Snore
- Body Position
- Battery Voltage
- SpO2
- Pulse Rate

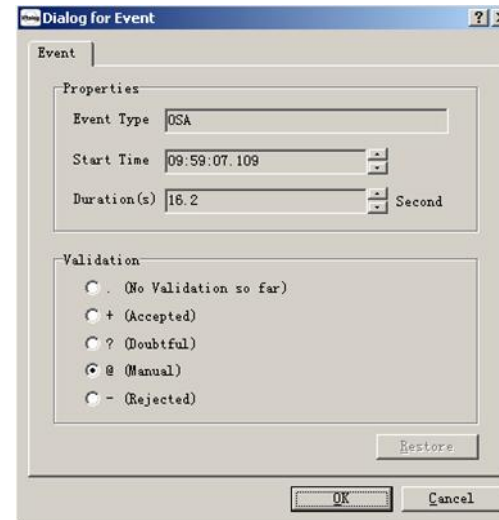


EDITING EVENTS

After the software has identified the sleep events, the user is then able to access the properties of each event, to mark the status of that event.

The event can be marked in 5 different ways

1. No Validation so far (No status)
2. Accepted (Event is confirmed)
3. Doubtful (Event is unconfirmed)
4. Manual (Event can be edited manually)
5. Rejected (Event is deleted)



The screenshot shows a window titled "Dialog for Event" with a tab labeled "Event". The window is divided into two main sections: "Properties" and "Validation".

Properties Section:

- Event Type:** A text field containing "OSA".
- Start Time:** A time field showing "09:59:07.109".
- Duration(s):** A numeric field showing "16.2", followed by a unit dropdown menu currently set to "Second".

Validation Section:

This section contains five radio button options for marking the event's status:

- ☐ . (No Validation so far)
- ☐ + (Accepted)
- ☐ ? (Doubtful)
- ☒ @ (Manual)
- ☐ - (Rejected)

At the bottom right of the Validation section is a "Restore" button. At the very bottom of the dialog are "OK" and "Cancel" buttons.

EDITING FLOW EVENTS

A textbox will automatically pop-up to display detailed information of these events.

MARKING AN EVENT

When reviewing the recorded data using the Acumen7 software you can log sleep events and mark these on the waveform graphs.

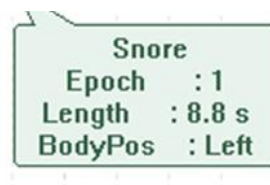
The channels that can be marked are:

- Airflow
- Snore
- Power
- SpO2

All events across all channels can be marked by clicking on the beginning of the event on the waveform graph and dragging the mouse to the point where the event ends.

The details of each event can also be access by single clicking the left mouse button.

The event shown here is an Obstructive Apnea (OSA) event, however all events marked across all channels will display the event information in this format when you single click the left mouse button

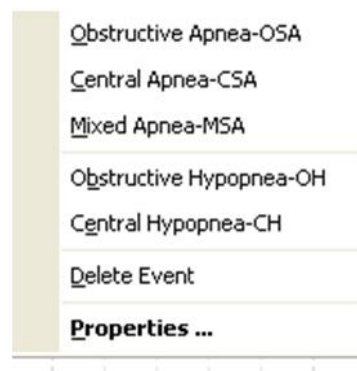


on the event.

AIRFLOW EVENTS

Airflow events can be marked as:

- Obstructive Apnea
- Central Apnea
- Mixed Apnea
- Obstructive Hypopnea
- Central Hypopnea

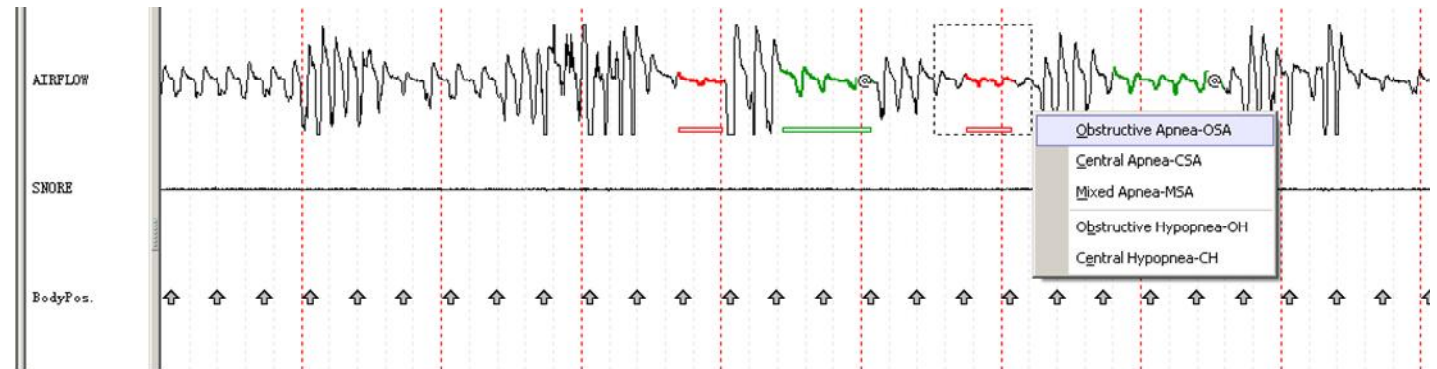


Color Key

	Obstructive Apnea
	Central Apnea
	Mixed Apnea
	Obstructive Hypopnea
	Central Hypopnea

Each type of airflow event uses a different color, as shown in the color key.

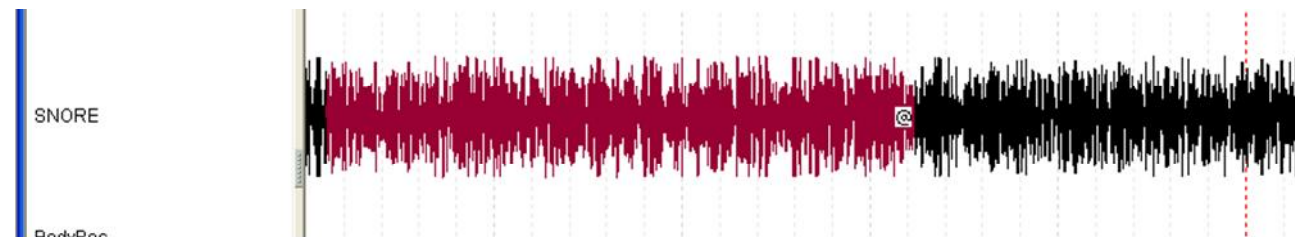
This is an example of the Airflow waveform graph been marked with different events.



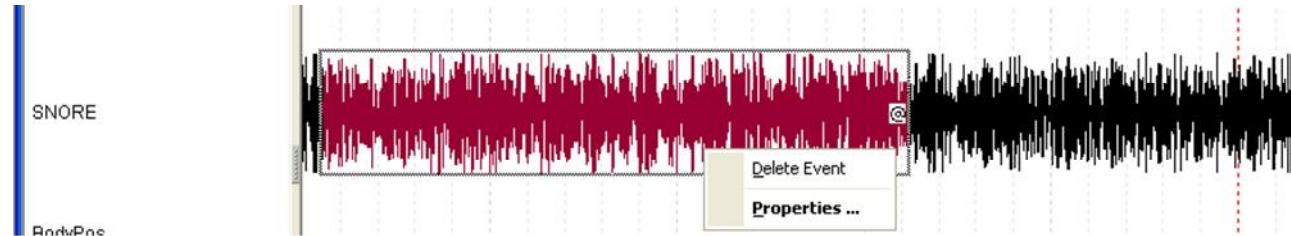
SNORE EVENTS

This is an example of a SNORE waveform graph been marked with an event

As there is only 1 type of SNORE event there is no need to use different colors so these events are displayed in Red as standard.



To delete an event single click on the right mouse button and select "Delete Event"



POWER EVENTS

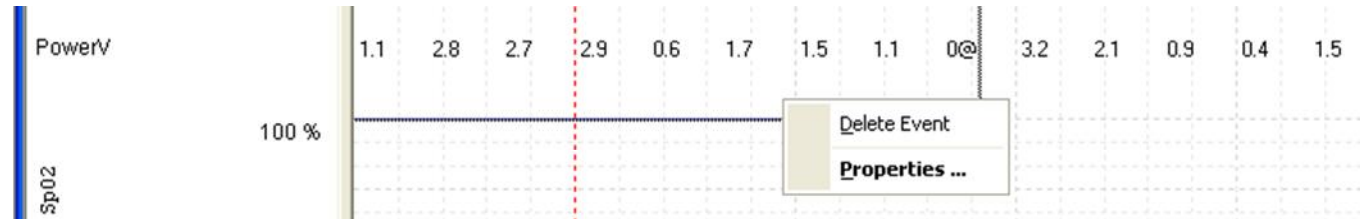
This is an example the power waveform graph been marked with an event.

As there is only 1 type of power event there is no need to use different colors so these events are



displayed using blue.

To delete an event single click on the right mouse button and select "Delete Event"

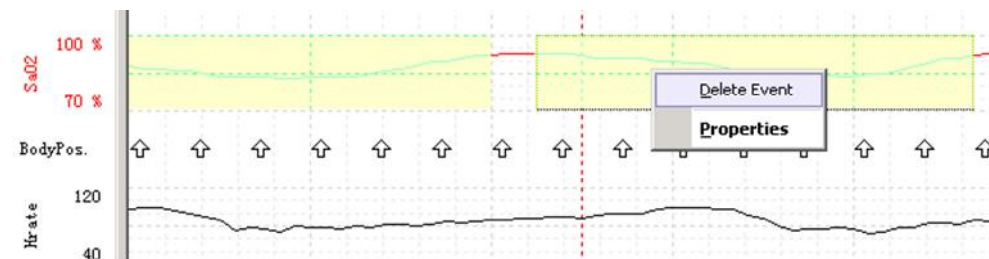
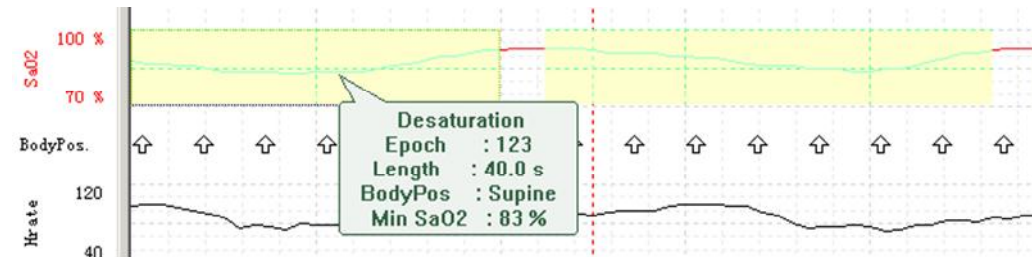


OXYGEN DESATURATION EVENTS

This is an example of a SpO2 waveform graph been marked with events

As there is only 1 type of oxygen desaturation event there is no need to use different colors so these events are displayed in yellow as standard.

To delete an event single click on the right mouse button and select "Delete Event"



VIEWING AND UNDERSTANDING TREND PLOTS

VIEWING TREND PLOTS

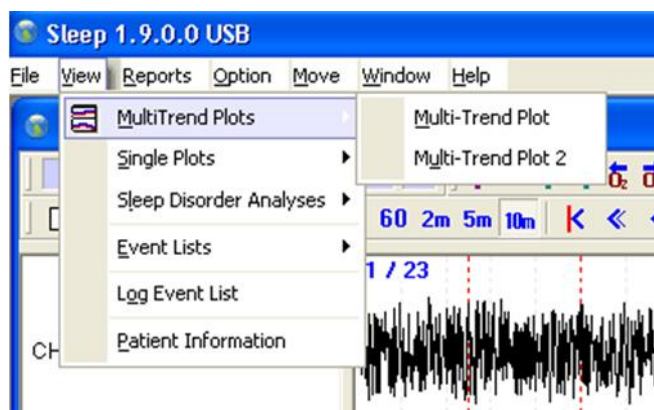
There are two different types of trend plots that can be viewed using the Acumen 7 software. There are Multi-trend plots and single trend plots.

VIEWING MULTI TREND PLOTS AND SINGLE PLOTS

Step 1: To view MultiTrend Plots.

Select “MultiTrend Plots” from View tab.

Choose between “Multi-Trend Plot” or “Multi-Trend Plot 2”



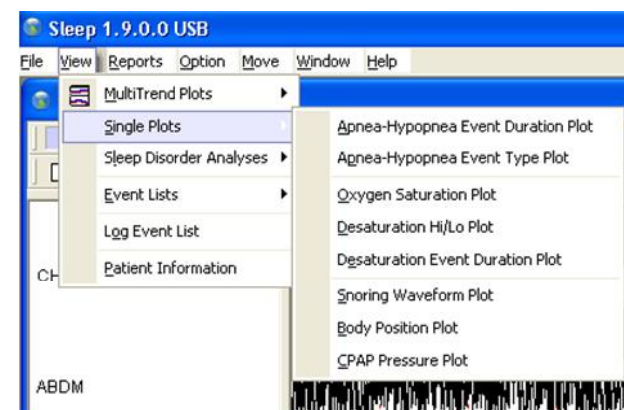
Multi-Trend Plot

Multi-Trend Plot 2

Step 2: To view Single Plots.

Select “Single Plots” from View tab.

Choose from the list of Single Plots available



Single Plots

Apnea-Hyponea Event Duration Plot

Desaturation Event Duration Plot

Apnea-Hyponea Event Type Plot

Snoring Waveform Plot

Oxygen Saturation Plot

Body Position Plot

Desaturation Hi/Lo Plot

CPAP Pressure Plot

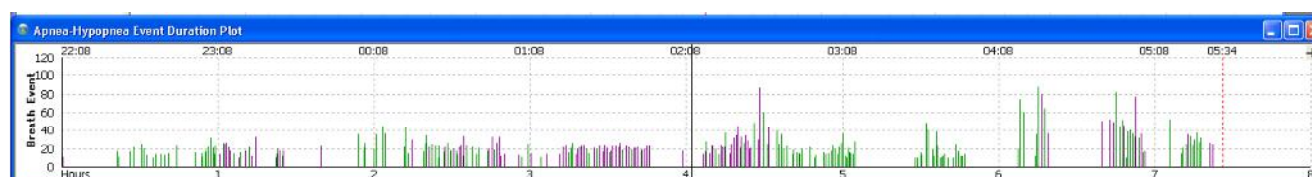
UNDERSTANDING THE DIFFERENT PLOTS AND WHAT THEY MEAN

Apnea-Hypopnea Event Duration Plot

This plot displays the frequency and length of apnea and hypopnea events during sleep.

The vertical axis shows the length of the apnea or hypopnea event in seconds and the horizontal axis displays the length of time the patient has been asleep in hours.

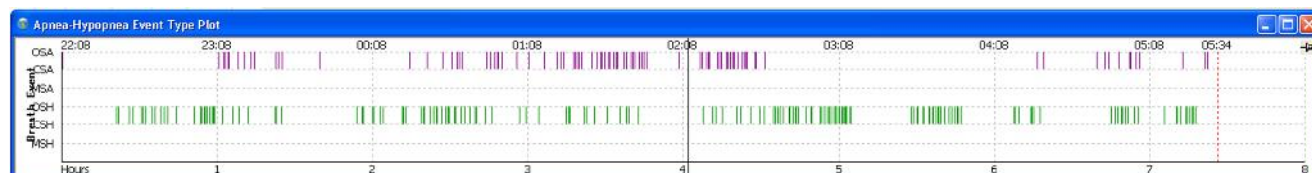
The different colours of the bars denote the type of apnea or hypopnea event.



Apnea-Hypopnea Event Type Plot

This plot displays the distribution of apnea or hypopnea events during sleep.

The vertical axis shows the different types of apnea or hypopnea and the horizontal axis displays the length of time the patient has been asleep.



Oxygen Saturation Plot

This plot displays the oxygen saturation level in the blood during sleep. **Need to check base level setting**

The vertical axis shows the % level of oxygen saturation in the blood. The horizontal axis displays the length of time the patient has been asleep.

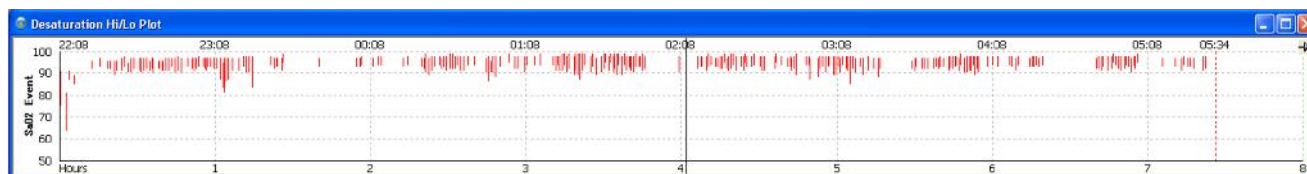
When the oxygen saturation level is below 95% it is displayed in green.



Desaturation Hi/Lo Plot

This plot displays the High and Low points of the oxygen saturation level in the blood during sleep.

The vertical access shows the % level of oxygen saturation in the blood. The horizontal axis displays the length of time the patient



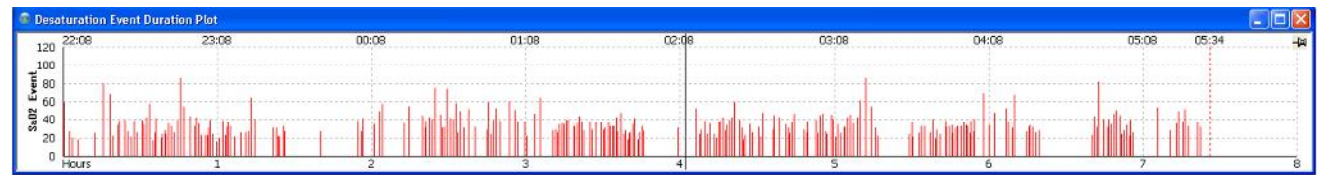
has been asleep.

Need explanation

Desaturation Event Duration Plot

This plot displays the duration of the oxygen desaturation events during sleep

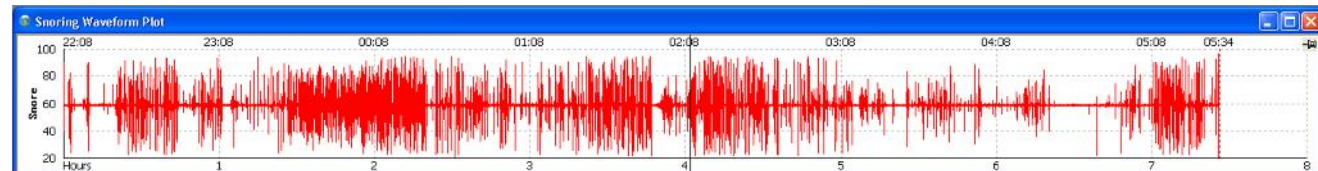
The vertical axis shows the length of the event in seconds and the horizontal axis displays the length of time the patient has been asleep in hours.



Snoring Waveform Plot

This plot displays the frequency and decibel level of snoring events during sleep.

The vertical axis shows the decibel level of the snoring event and the horizontal axis displays the length of time the patient has been asleep in hours.



Body Position Plot

This plot displays the body position of the patient during sleep.

The vertical axis shows the body position of the patient:

- S=supine position
- L=left recumbent position
- P=prone position
- R=right recumbent position

The horizontal axis displays the length of time the patient has been asleep in hours.

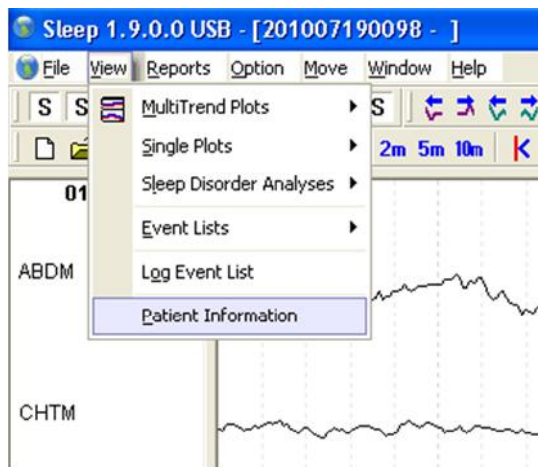


VIEWING DIFFERENT PERIODS OF THE DATA

When viewing the Multi-Trend plot or Single plots there is a black vertical index line on the left hand side that indicates the time period of data you are viewing on the plot. The time period the plot shows depends on the time period you view the data in before viewing the plot. For example; if you view the data in 2 minute periods then the interval periods on the plot will be 2 minutes. To move the index line you can use your mouse, either using point and click or the scroll. Alternatively you can use the arrow keys on your keyboard.

VIEWING AND EDITING PATIENT DATA

Step 1: Select “Patient Information” from View tab



Step 2: There are 5 tabs that are requires completion.

Patient Information

Department Information

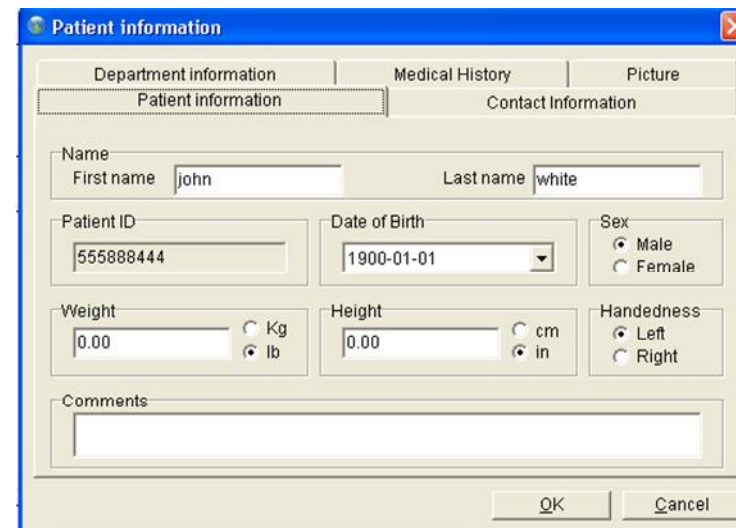
Medical History

Contact Information

Picture

Fields which can be edited are displayed in white.

Fields that cannot be edited are displayed in grey.



REPORTS

Reports can be generated using the Acumen 7 software to provide detailed analysis of a patient's sleep data.

The reports that the Acumen 7 produces are:

- Respiratory Event Summary Report
- SpO2 Scored Summary Report

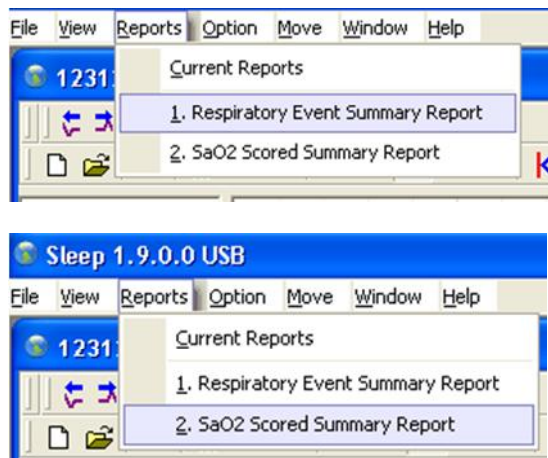
VIEWING REPORTS

LOADING REPORTS

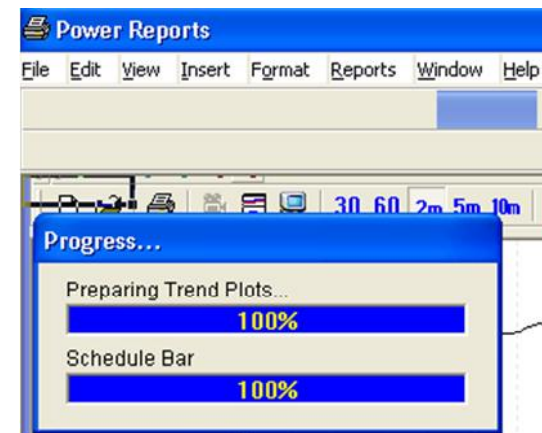
Reports can be generated as a Microsoft Word documents.

Step 1:

Select
“Respiratory
Event
Summary
Report” or
“SpO2
Scored
Summary
Report”
from the
Reports tab.



Step 2: The
reports will
automatically
open into a
Microsoft
Word
document.

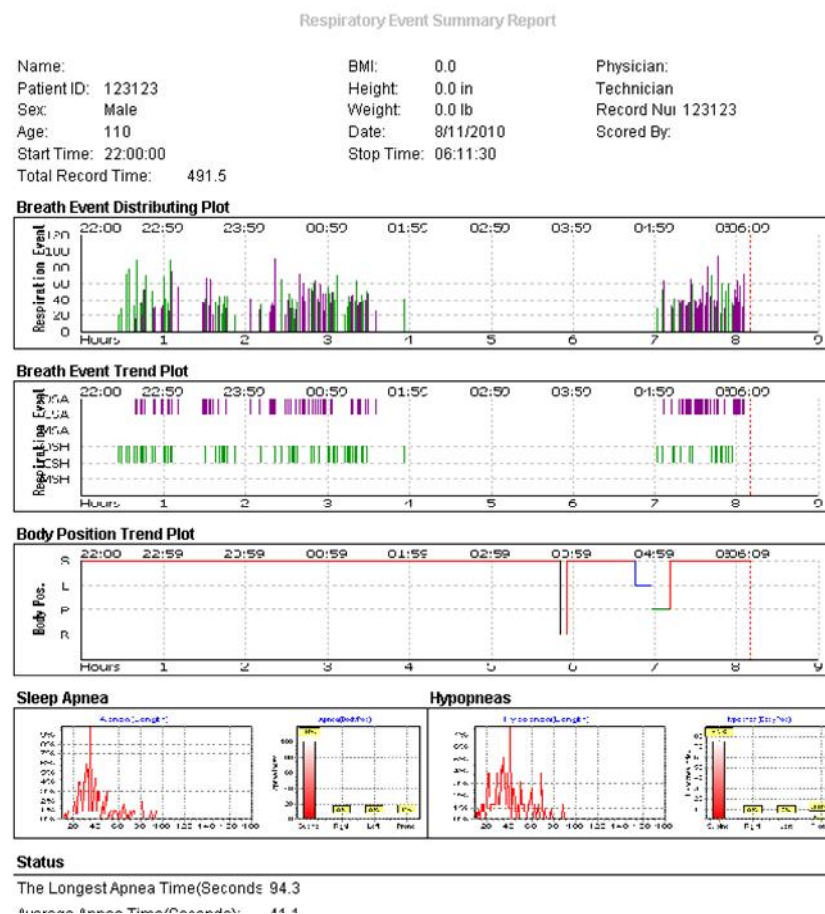


RESPIRATORY EVENT SUMMARY REPORT

Step 3: The respiratory summary report provides analysis on:

View
Respiratory
Event
Summary
Report

The respiratory event trend plot, respiratory event distributing plot, body position trend plot, apnea, hypopnea and the longest apnea time during sleep, the average apnea time, the total time and total number of apneas, apnea index and disorder index.



SPO2 SCORED SUMMARY REPORT

Step 4: The SpO2 summary report View provides analysis on: SpO2 Scored Summary Report The SaO2 Trends, SaO2 Distribution, O2 distribution and a SaO2 scorecard.

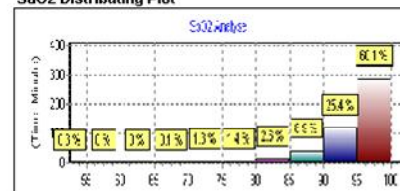
SaO2 Scored Summary Report

Name: BMI: 0.0 Physician:
 Patient ID: 123123 Height: 0.0 in Technician
 Sex: Male Weight: 0.0 lb Record Num: 123123
 Age: 110 Date: 8/11/2010 Scored By:
 Start Time: 22:00:00 Stop Time: 06:11:30
 Total Recording Time: 491.5

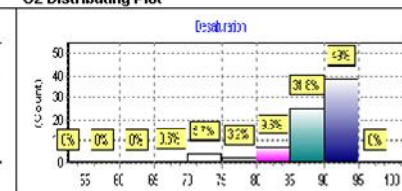
SaO2 Trend Plot



SaO2 Distributing Plot



O2 Distributing Plot



SaO2%	Time(minutes)	Percentage	SaO2 Time(S)	SaO2 Index(F/Hr)
95--99	287.5	60.1	0	0.0
90--94	121.5	25.4	77	38.0
85--89	42.5	8.9	50	70.6
80--84	12.5	2.6	15	72.0
75--79	6.5	1.4	5	46.2
70--74	6.0	1.3	9	90.0
65--69	0.5	0.1	1	0
60--64	0.0	0.0	0	0
55--59	0.0	0.0	0	0

SAVING AND PRINTING REPORTS

Reports can be saved and printed using Microsoft Word. It is important when saving reports to ensure they are saved to a known location such as My Documents.

SLEEP DISORDER ANALYSIS

The sleep disorder analysis plots allow you to look at related sleep data to help with the diagnosis of sleep disorders.

There are 3 Sleep Disorder Analysis plots:

- Respiration Event Analysis
- Oxygen Saturation Analysis
- Snoring Analysis

VIEWING SLEEP DISORDER ANALYSIS PLOTS

Step 1.
Select
“Sleep
Disorder
Analysis”
from View
tab

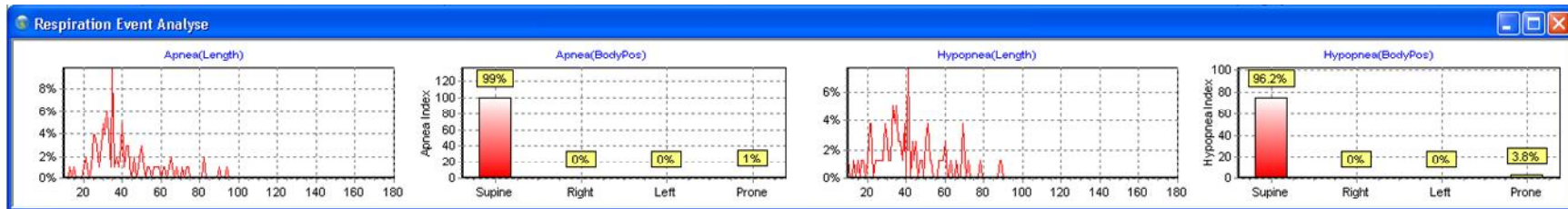


Step 2.
Choose
between
the 3
Analysis
shown.



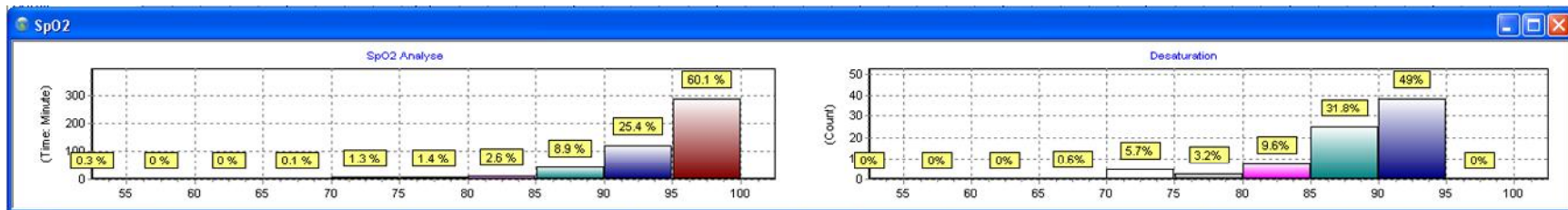
RESPIRATION EVENT ANALYSIS

Respiration Event Analysis displays apnea length and apnea body position and also hypopnea length and body position. This analysis helps to see if there is a correlation between the body position when asleep and the occurrence of apnea or hypopnea.



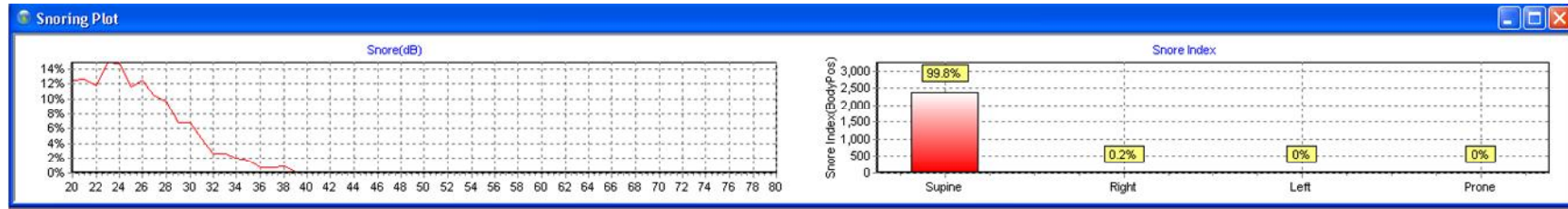
OXYGEN SATURATION ANALYSIS

Oxygen Saturation Analysis displays the frequency as a percentage the SpO2 levels over time and the Desaturation levels of oxygen as a percentage in the blood.



SNORING ANALYSIS

The Snoring Analysis plot displays the sound level (dB) of the snoring and the percentage of snoring that was at that sound level. Snoring analysis also displays the percentage of snoring that was experienced in different sleeping positions.



EVENT LISTS

There are two types of event list:

- Respiration Event List
- Desaturation Event List

RESPIRATORY EVENTS

The Respiration Event List displays each respiration event that has been marked and shows the data that is relevant to that event:

Epoch	Channel	Start time	Duration(s)	Event Type	Sleep Stage	Body Position	Max SaO2	Min SaO2	Max HRate	Min HRate
46		21:24:20	13.0	OSA	Stage 1	Supine	95	94	89	81
47		21:24:41	16.7	OSA	Stage 1	Supine	93	88	91	83
48		21:25:15	10.9	MSA	Stage 1	Supine	95	92	88	81
49		21:25:28	12.0	OSA	Stage 1	Supine	95	89	92	87
50		21:25:59	25.2	OSA	Stage 1	Supine	96	91	90	82
51		21:26:34	23.5	OSA	Stage 1	Supine	96	86	93	80
52		21:27:12	24.2	OSA	Stage 1	Supine	99	92	91	80
53		21:27:49	26.4	OSA	Stage 1	Supine	96	85	93	81

It displays the page of all respiratory events, start time, duration, type, sleep stage, body position, the max and min SpO2, and the max and min heart rate.

OXYGEN DESATURATION EVENTS

The Desaturation Event List displays each respiration event that has been marked and shows the data that is relevant to that event:

Epoch	Channel	Start time	Duration(s)	Event Type	Sleep Stage	Body Position	Max SaO2	Min SaO2	Max HRate	Min HRate
40		21:21:07	37.0	Oxygen	Wake	Supine	95	90	93	81
47		21:24:28	27.0	Oxygen	Stage 1	Supine	95	88	95	83
48		21:24:57	22.0	Oxygen	Stage 1	Supine	94	89	95	81
48		21:25:21	45.0	Oxygen	Stage 1	Supine	95	86	97	82
50		21:26:08	43.0	Oxygen	Stage 1	Supine	96	86	99	80
52		21:26:53	31.0	Oxygen	Stage 1	Supine	98	90	103	80
53		21:27:26	37.0	Oxygen	Stage 1	Supine	99	85	100	81
54		21:28:05	39.0	Oxygen	Stage 1	Supine	96	83	103	83
55		21:28:46	39.0	Oxygen	Stage 1	Supine	95	82	100	84

It displays the page of all desaturation events, start time, duration, type, sleep stage, body position, the max and min SpO2, and the max and min heart rate.

APPENDIX A TERM DEFINITION

REPORT ANALYSIS CONTENT

- Report content is between Light-out and Light-on

SLEEP PARAMETERS

- Light-out: the clock time of the first page of the stage
- Light-on: the clock time of the last page of the stage

RESPIRATORY PARAMETERS

- Sum total of apneas: the total number of obstructive (OBS), central (CEN) and mixed (MIX) apneas occurring during total sleep time (TST)
- Sub total of apneas*: the total number (count) of obstructive, central and mixed apneas between Light-out and Light-on.
- Respiratory distress index (RDI): respiratory distress index is defined as apneas and hypopneas divided by the total sleep time (events per hour). $\left[\text{apneas and hypopneas (count)} / \text{TST (minutes)} \right] \times 60$.
- Average sleep incubation period: The first sleep phase from Light-out.
- Average REM incubation period: The first REM phase from the beginning of sleep.
- Number of REM phase (there is only one REM phase in each phase of sleep): including the total number of phases of sleep containing REM.
- Average all phases of sleep results to calculate the average value.

OXYGEN DESATURATION PARAMETERS

- Based on the transducer parameters set for the user, arterial SpO2 saturation degree is lower than the total sum (#) % (count). ACUMEN 7 report view program displays the following SpO2 saturation degree percentage: <90%, <80%, <70%, <60%, <50%, <40% and <30%.
- The longest respiratory events and min correlated SpO2 value (occurring within 30 seconds after the respiratory events).

- Min SpO2 in PSG report displays min SpO2 and the duration of correlated respiratory events.
- Min SpO2: Min SpO2 reading occurs during oxygen desaturation stage.
- The average of electrocardiograms within 30 seconds: ACUMEN 7 calculates the dynamic average of heart rates within the last 30 seconds. The average heart rate is the reciprocal of the average of QRS wave within the last 30 seconds. The average heart rate is the reciprocal of the average of wave within the QRS clip; period of excessive noise is not calculated.
- The maximum and minimum values of electrocardiogram: the maximum and minimum heart rates calculated based on the average within 30 seconds in each QRS wave time. The period of excessive noise is not included in calculation, and the heart beat intervals in which the difference compared with the current average is more than 50% are also not included in calculation.
- Tachycardia: the average heart rate with continuous two or more than two QRS waves within 30 seconds exceed 100 beats / minutes.
- Bradycardia: the average heart rate with continuous two or more than two QRS waves within 30 seconds is lower than 60 beats / minutes.

SUMMARY REPORT

- The maximum and minimum heart rates: these values are based on the maximal and minimum values within the whole recording clip. Individual calculation is used for sleep clip and awaking clip.
- Average heart rate: the average of the maximum and minimum values within each clip (the average of maximal plus min / 2) is taken to calculate this value; the clip with the maximum or minimum value of zero is not counted.
- Trend plot (heart rate): heart rate trend plot is based on the average of the maximum and minimum values within 30 seconds of each clip. The clips with the minimum value of zero and clips with no data are not included.
- Patient information: the first part of the report consists of the patient information, medical history and remarks. These fields are generated with entered information during recording. The demographic data of the patients should be entered in a consistent form, because this information will be used to generate normalized results and intersect the patients' statistical data. Other fields are used to store the detailed information of the laboratory.

RESPIRATORY INFORMATION

- This part lists the summary information of respiratory events, including apneas and hypopneas. Apnea table lists the total number of apneas listed according to event types: obstructive, mixed and central apnea. This table will be further classified according to body positions, Rapid Eye Movement and Non Rapid Eye Movement. If there is no body position information in the file or body position is not defined. For example the sitting position, this body position will be listed as unknown. Hypopnea table will list the central and obstructive hypopneas according to body positions, Rapid Eye Movement and Non Rapid Eye Movement. Respiratory distress index (RDI) table will list apnea and hypopnea indexes according to body positions and event types. The overall respiratory distress index displays under the table.

DATA BACKUP /DELETION

- Managing the database is a necessary task. After some time of database operation, there tends to be some generated fragment which will cause the database become large and slow; systemizing the database will remove all irrelevant data and make it simple and smooth.

PSG Acumen7

User manual

No. 00 version

Curative Medical Technology Inc