

DOC NO	17879
PAGE	1 OF 1
REV	1

PRINTED MATERIAL SPECIFICATION

Rev	Date	Details	Drn	Elec	Mech	Mkt	Prod	QA	RA	Proj Ldr	QC
1	22/01/99	ORIGINAL ISSUE	AOB								

AutoSet Portable II Plus Overview & Interpretation Guide

1. DETAILS

- Dimensions: American Letter (216 H x 279 W)
- Style: Printed double-sided on US letter sized 100 gsm, punched, and bound with Wiro.
- Cover: Front 4 colour cover, on 250 gsm. Back cover blank board.
- Colour of printing: Four colour cover throughout.
- Art Work: As shown on following pages. If re-typeset, the same styles and sizes must be maintained.
Number of pages: 98
- Manufacturer: Outside printer.
- Short runs may be produced in-house by ResMed.

2. SAMPLING, INSPECTION & TESTING

Refer R04 P 003; Sampling Regimen A. Refer to approved sample.

Note: Revision number on the artwork to read, 17879/1 99 01

Defects to be inspected:

1. Specification and revision number
2. Incorrect text
3. Text missing or crooked on page
4. Pages missing or out of order
5. Dimensions out of tolerance (refer to details above)
6. Dirt, grease, etc.
7. Incorrect colour (refer to details above)



AUTOSET PORTABLE II PLUS
OVERVIEW AND
INTERPRETATION GUIDE



AUTOSET[®] PORTABLE II PLUS
OVERVIEW AND
INTERPRETATION GUIDE

• **ResMed Corp** 10121 Carroll Canyon Road San Diego CA 92131-1109 USA Tel: +1 (619) 689 2400 or 1 (800) 424 0737 Fax: +1 (619) 689 2412

• **ResMed Ltd** 82 Waterloo Road North Ryde NSW 2113 Australia Tel: +61 (2) 9850 2300 or 1 800 658 189 Fax: +61 (2) 9887 4872

• **ResMed (UK) Limited** 67B Milton Park Abingdon Oxon OX14 4RX UK Tel: +44 (1235) 862 997 Fax: +44 (1235) 831 336

• **ResMed Priess GmbH & Co KG** Karstrasse 17A 41068 Moenchenglabach Germany Tel: +49 (2161) 837037 Fax: +49 (2161) 837072

• **ResMed SA** ActiVillage 1 Allée des Sorbiers F-69500 Lyon-Bron France Tel: +33 (04) 78 26 25 25 Fax: +33 (04) 78 26 28 13

• **ResMed Singapore Pte Ltd** 150 Kampong Ampat #06-06 KA Centre Singapore 368324 Tel: +65 284 7177 Fax: +65 284 7787

Internet: <http://www.resmed.com> **Email:** reception@resmed.com.au

Protected by: AU 691200, EP(DE,FR,GB) 0088761, JP 1697822, US 4944310, US 5199424, US 5245995, US 5522382, US 5704345. Other patents pending. Copyright subsists in ResMed products. "SULLIVAN[®]", "VPAP[®]", "AutoScan[™]", "AutoSet[®]", "AutoView[™]", "Bubble Cushion[®]", "Bubble Mask[®]", "HumidAire[™]", "Mirage[®]", "ResCap[®]", "SCAN[™]", and "SmartStart[®]" are trademarks of ResMed Ltd.

© 1998 ResMed. All rights reserved. 17897/1 99 01

CONTENTS

INTRODUCTION TO AUTOSET® PORTABLE II PLUS	1
OPERATING MODES	3
AUTOMATIC MODE	3
MANUAL - FIXED PRESSURE MODE	4
DIAGNOSTIC MODE	4
AUTOVIEW 98 SOFTWARE	5
AUTOVIEW WINDOWS	5
STUDY SCREENS	5
AUTOVIEW REPORTS	8
STUDY GRAPHS	13
OXYGEN SATURATION	13
HEART RATE	14
SNORING	14
NASAL VENTILATION	15
MASK LEAK	17
FLOW LIMITATION - FLATTENING INDEX	18
BODY POSITION	20
APNEAS & HYPOPNEAS	20
RESPIRATORY IRREGULARITIES	22
APNEA INDEX	22
APNEA & HYPOPNEA INDEX (AHI)	22
PRESSURE	24
PRESSURE RESPONSE	24
INCREASING PRESSURE	24
DECREASING PRESSURE	25
RESPIRATORY EFFORT	25
OBSTRUCTIVE APNEA	27
CENTRAL APNEA	28
MIXED APNEA	29
SAMPLE STUDIES	31
NO SLEEP DISORDERED BREATHING/ BENIGN SNORING	32
OBSTRUCTIVE SLEEP APNEA STUDY	36
MOVEMENT ARTEFACTS	42
ANALYSIS SCREEN	50
MIXED APNEA STUDY	56
CENTRAL APNEA STUDY	58
RESPIRATORY EFFORT	60
CHEYNE-STOKES STUDY	64
POOR QUALITY STUDY	66
UPPER AIRWAY RESISTANCE SYNDROME (UARS) OR	
RESPIRATORY EFFORT RELATED AROUSALS (RERAs)	68
UARS / RERAs STUDY	72

AUTOMATIC STUDY	74
SUGGESTED READING	79
FREQUENTLY ASKED QUESTIONS.	85
GLOSSARY	87
INDEX	A

INTRODUCTION TO AUTOSET® PORTABLE II PLUS

Limited resources and increased workloads mean more sleep clinics and specialists are turning to studies outside the sleep laboratory setting. The portability and simplicity of ResMed's AutoSet Portable II Plus system gives you the option of conducting respiratory studies in a variety of settings outside the sleep lab.

AutoSet Portable II Plus (PII Plus) can provide automatic positive airway pressure treatment to eliminate apnea and airway obstruction. The data collection capabilities of the system, in conjunction with the analysis provided by the AutoView™ 98 software, assist you in the diagnosis of Obstructive Sleep Apnea (OSA) and management of positive airway pressure treatment.

The PII Plus records:

- Respiratory effort
- Body position
- Heart rate
- Oxygen saturation
- Flattening index
- Nasal ventilation
- Continuous Positive Airway Pressure (CPAP)
- Mask leak
- Snoring
- Incidence and duration of apneas and hypopneas
- Respiratory irregularities

Traditionally, diagnosis and treatment of patients with OSA has been performed in the sleep laboratory using full polysomnographic analysis. This equipment measures a wide variety of neurological and respiratory data, allowing the diagnosis of many different sleep disorders.

The PII Plus is a computer-controlled system which complements full polysomnography (PSG) for assisting in the diagnosis and titration of OSA patients outside the sleep unit.

PII Plus has a built-in oximeter and provision for body position and respiratory effort sensors, which enable you to view the patient's heart rate, body position, and respiratory effort during the study, as well as breathing information recorded by nasal cannula.

Another feature of the system is its compatibility with the AutoSet Mirage® mask system, allowing patients to be fitted and trialed with the Mirage mask.

ResMed's patented AutoSet technology continuously monitors the state of the upper airway on a breath-by-breath basis. In titration mode, the PII Plus increases pressure in response to inspiratory flow limitation, snore index, and apnea duration.

For further information about AutoSet technology, refer to "Suggested Reading" on page 79.

OPERATING MODES

The PII Plus system operates in Automatic mode for automatic pressure titration, Manual - CPAP fixed pressure mode for assessing respiratory parameters at a given set pressure, or Diagnostic mode for OSA diagnosis.

AUTOMATIC MODE

In Automatic mode, the PII Plus administers automatic positive airway pressure while recording clinical data, used to assess the efficacy of treatment. Positive airway pressure is continuously and automatically adjusted **on a breath-by-breath basis**, to sufficiently prevent airway obstruction.

The patient wears a nasal mask containing a pneumotach that continuously takes accurate measurements on the status of the upper airway. The PII Plus increases pressure on a breath-by-breath basis in response to snore and inspiratory flow limitation, as indicated by pressure and flow changes detected by the pneumotach. This means that the PII Plus is able to deliver the lowest pressure required to prevent obstruction. If apneas are present, the PII Plus differentiates between open and closed airway events and only increases pressure when the airway is obstructed.

Following the study, the PII Plus provides a graphical summary report of all overnight respiratory events, pressure changes, oxygen saturation, respiratory effort, body position, heart rate, and a measurement of mask leak. The report also includes an apnea-hypopnea index, apnea index and a suggested pressure for home treatment.

In automatic mode the PII Plus continuously monitors the patient's upper airway and increases and decreases pressure based on the presence or absence of events. Events that cause increases in pressure are snore, inspiratory flow limitation, or a closed airway apnea. The PII Plus delivers pressures between 4 and 20 cmH₂O, based on the patient's requirements. These increases are proportional to the severity of upper airway obstruction.

NOTE



For more information about the pressure response of the PII Plus, please refer to "Pressure Response" on page 24.

When performing an automatic study, you must specify Waiting Time, Minimum Pressure, and Maximum Pressure using the slide bars.

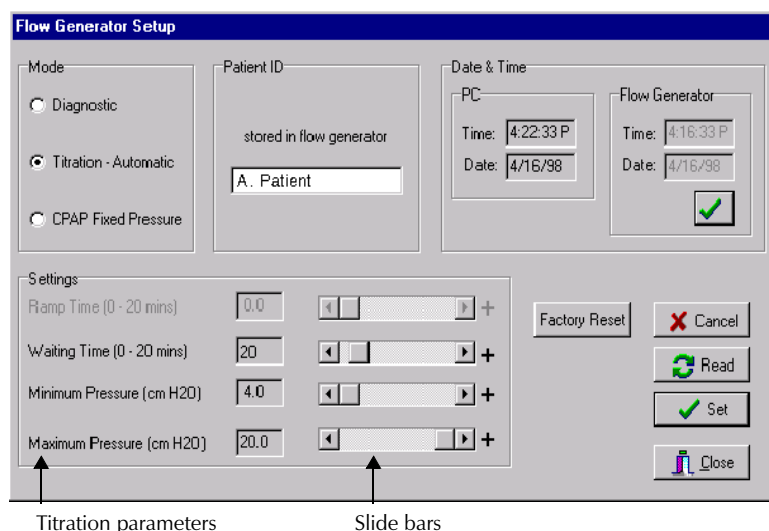


Figure 1 : Flow generator setup dialog box with Automatic mode selected. In this mode the titration parameters must also be specified.

WAITING TIME

This feature is also known as the settling time. This is the period before any automatic pressure adjustment occurs, allowing the patient to get comfortable before treatment begins. During this period the pressure remains at the selected minimum pressure and respiratory events are ignored so that pressure is not increased and no events appear in the summary for this time. Although the factory default is 3 minutes waiting time, you can select a time between 0 and 20 minutes. Each time the mask is removed and then replaced during treatment, the settling time recommences.

MINIMUM PRESSURE

This is the minimum amount of positive airway pressure the patient receives during treatment and is set at factory default of 4 cm H₂O.

MAXIMUM PRESSURE

This is the maximum amount of positive airway pressure the patient may receive during treatment and is set at factory default of 20 cm H₂O.

MANUAL - FIXED PRESSURE MODE

In Manual mode, the PII Plus provides a constant set pressure as in standard CPAP treatment (rather than autsetting pressures). The data is collected in the same manner as automatic mode. This mode is useful in assessing the efficacy of CPAP treatment.

In a Manual study:

- the clinician specifies the minimum and maximum pressure and ramp time.
- treatment starts at the set minimum pressure.
- Ramp time is similar to the standard feature on most CPAP machines. An option of 0 to 20 minutes is available. The ramp time allows the pressure to gradually increase from the minimum possible pressure of 4 cm H₂O to the designated maximum pressure for treatment.
- Waiting time is not applicable.
- Maximum pressure is the prescribed pressure.

DIAGNOSTIC MODE

In Diagnostic mode, overnight clinical data is recorded to aid in the diagnosis of sleep disordered breathing and the assessment of the patient's condition.

The patient wears nasal cannula instead of a mask, and no pressure is delivered. The nasal cannula generates an airflow signal that is then linearized by the software. The PII Plus records information only in this mode and provides data on snore, flow limitation, apneas, oxygen saturation, heart rate, and nasal ventilation. A summary report is provided with graphical representation of these parameters as well as an apnea/hypopnea index and apnea index.

The optional body position sensor supplies body position data while the respiratory band provides respiratory effort data. The latter enables apneas to be classified as obstructive, mixed, or central using AutoView software and the manual score option.

AUTOVIEW 98 SOFTWARE

AutoView 98 is a user friendly, software program that is Windows 95, 98 and NT4 compatible and Year 2000 compliant.

AutoView 98 allows you to view the downloaded study data in Session (eight-hour), One-hour or Detail (five-minute) screens, as well as providing an overall summary of the study in the analysis screen. You can change the position on the screen of the study graphs, adjust the scale of the graphs, change display colors, and blockout artefact data.

NOTE



For more information about using AutoView 98, please refer to the PII Plus clinical manual.

AUTOVIEW WINDOWS

STUDY SCREENS

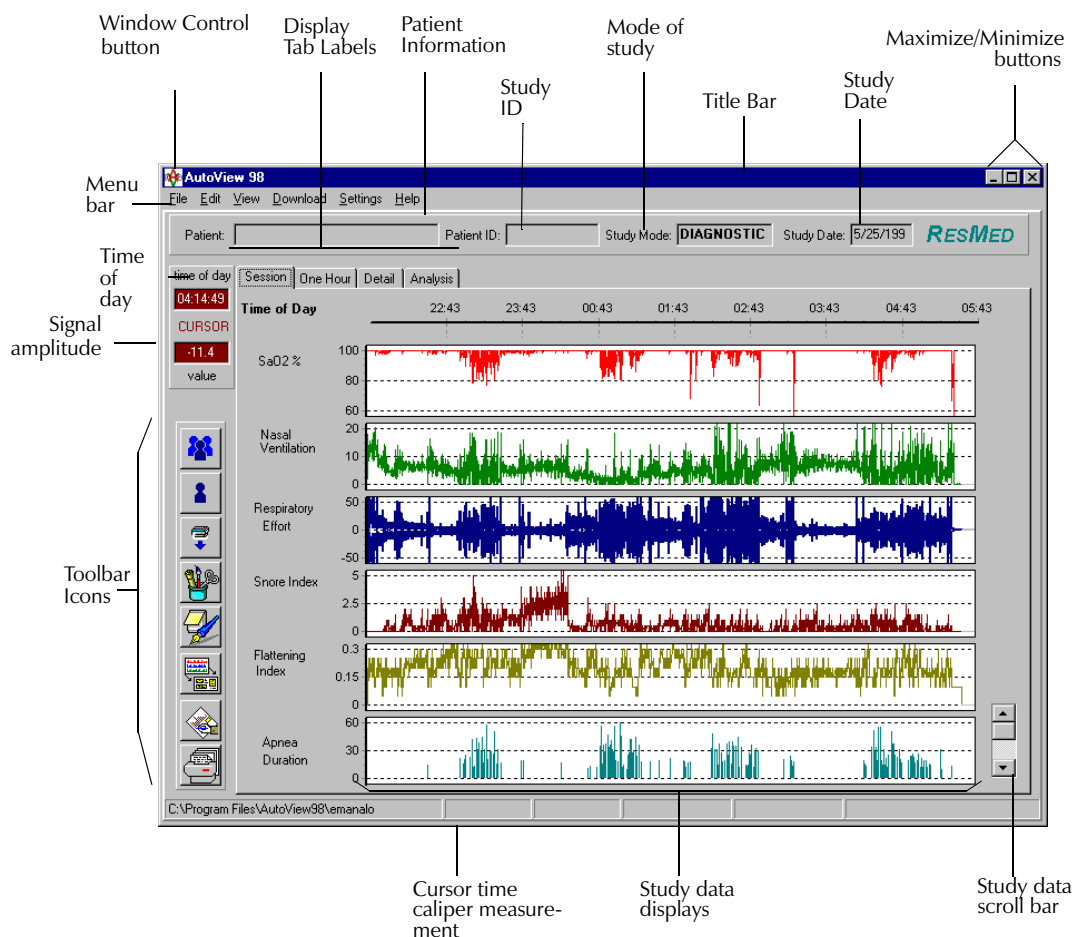


Figure 2 : The AutoView Main Window. Six study parameters are displayed on the screen at one time. To view the other parameters of the study, use the Study data scroll bar to move down.

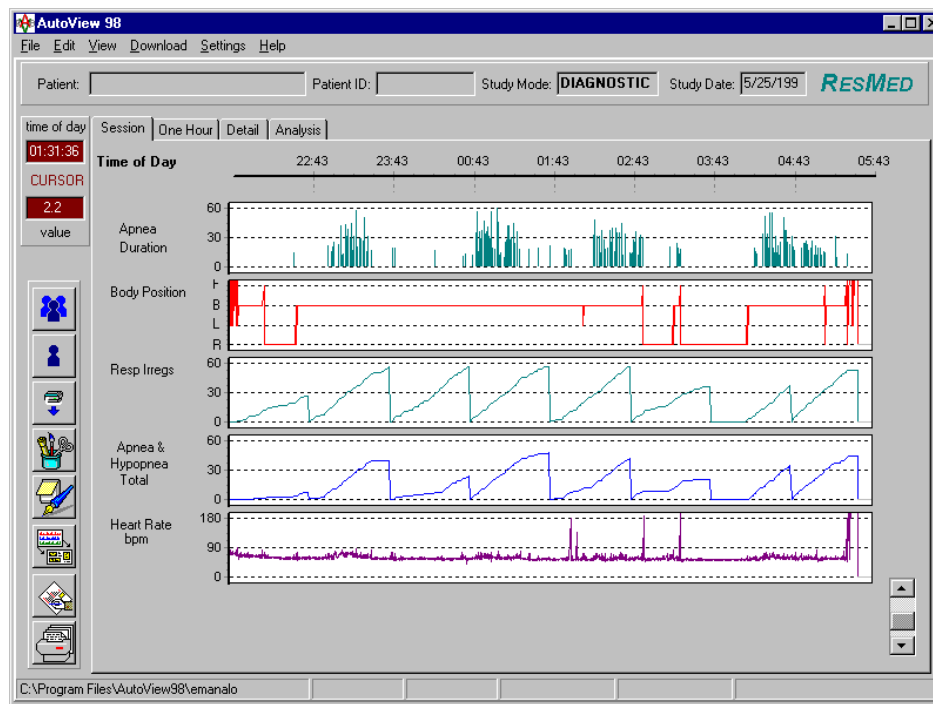


Figure 3 : The remainder of the study parameters displayed after scrolling down.

The entire study is displayed in the Session screen, which graphically depicts all parameters recorded. Six parameters of the study are shown in the main screen so it is necessary to scroll down to view the remaining graphs.

In addition to the the Session screen shown in Figure 2, the data can also be viewed in the One-hour and Detailed time frames.

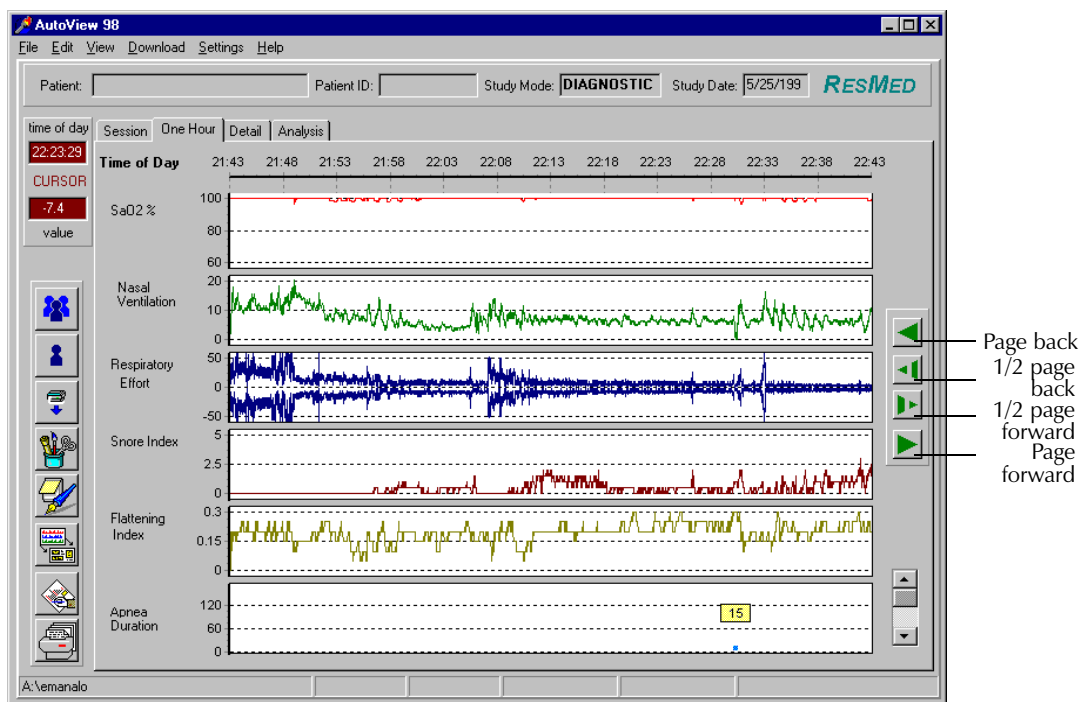


Figure 4 : One-hour AutoView frame.

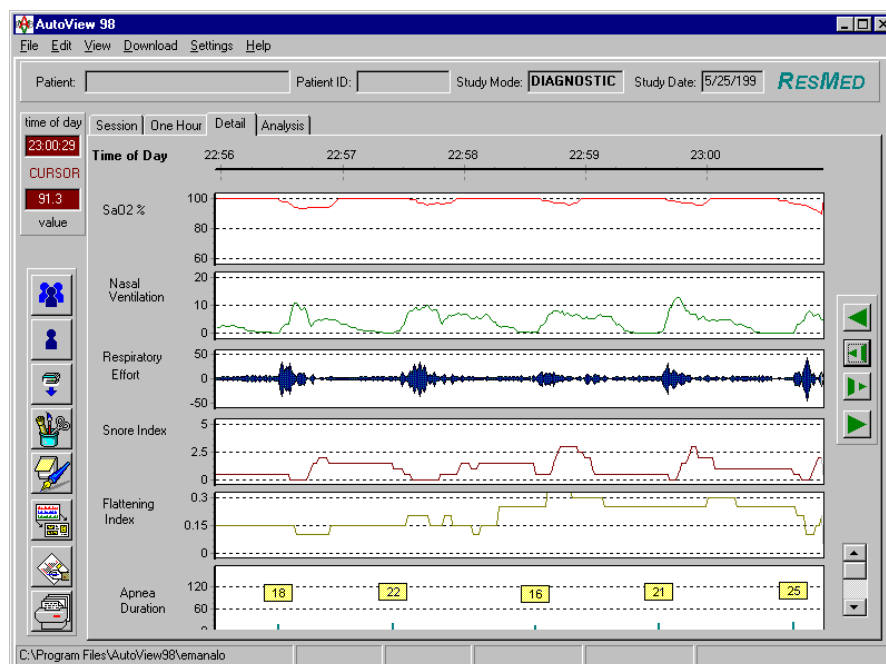


Figure 5 : Detailed five-minute AutoView frame.

ANALYSIS SCREEN

A summary of the statistical data can be displayed in the analysis screen mode. The elements of this screen vary depending on the type of study performed. In Diagnostic mode there is no differentiation between closed and open airway apneas, however, you can manually classify an event as obstructive, mixed, or central apneas, or unclassified, hypopnea, or artefact.

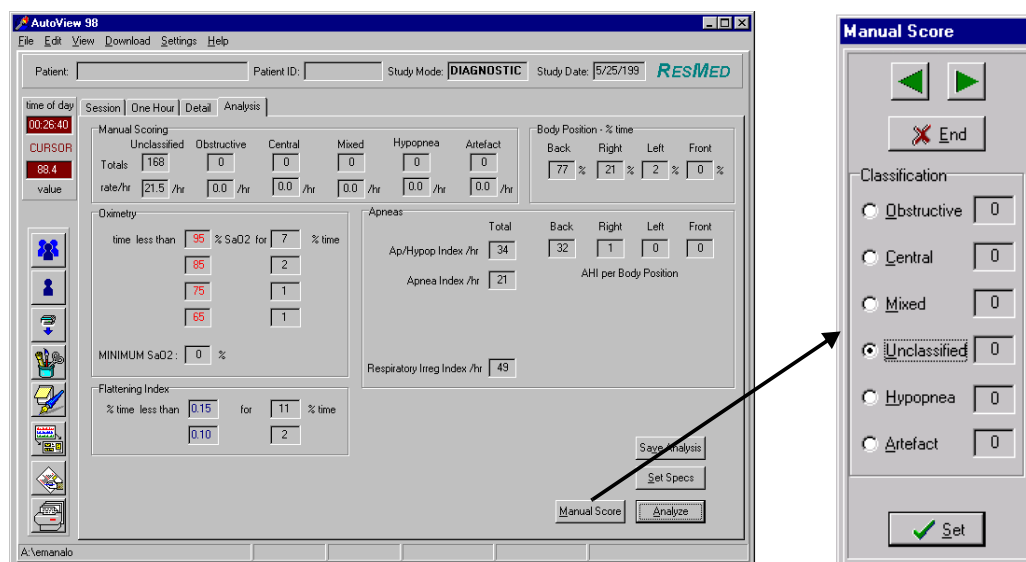
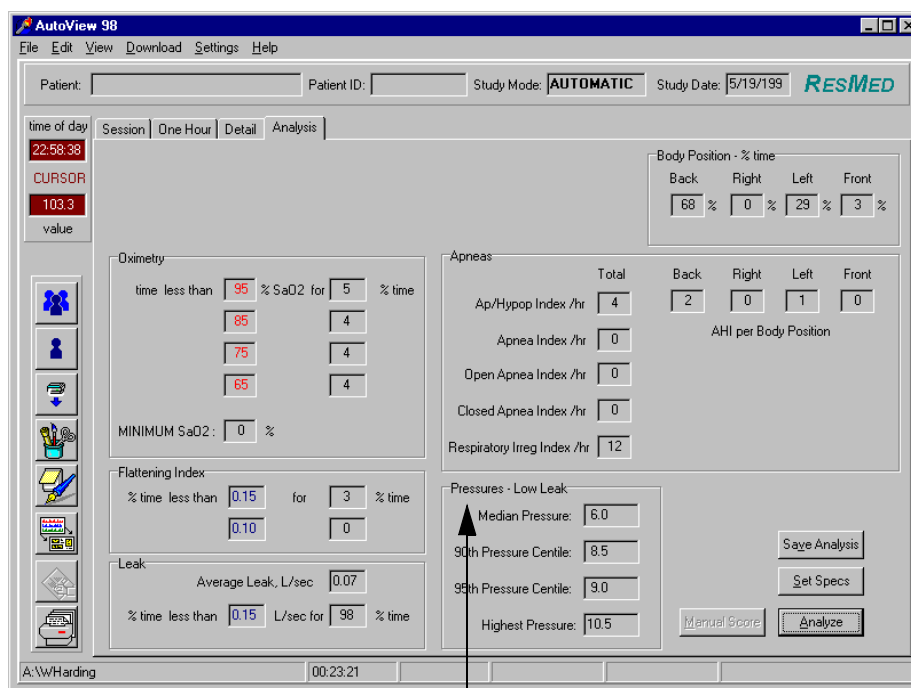


Figure 6 : Analysis screen from a Diagnostic study and the Manual Score dialog box.

In Automatic or Fixed CPAP mode, information regarding pressure, leak, and open and closed apneas is displayed. Manual scoring is not available.



Pressures field

Figure 7 : Analysis screen from an Automatic study.

AUTOVIEW REPORTS

A range of reports can be printed. The "Sleep Study Report" includes the patient's details, any patient notes and a "Session Data Report," which includes graphs of all the parameters recorded during the entire study. To print:

Print Option	Report Type	Included:
Print Report see Figures 8 to 11	Sleep Study Report	<ul style="list-style-type: none"> • Patient Details • Patient Notes • Two pages of study data
Print Data Page (see Figures 10 to 11)	Summary Data	<ul style="list-style-type: none"> • Study graphs available in Session, One-Hour and Detail options, depending on the screen displayed at the time of printing.
Print Data Screen (eg. Figure 7)	Screen Data	Print of the screen, available in color.

Sleep Study Report

Patient: **Smith, John G.**

ID: **10110001**

Physician: **Dr Wright**

ResMed Sleep Clinic
82 Waterloo Road
Sydney
NSW 2
Australia

Date of Birth: 5/25/1998	Study Date: 5/25/1998
Address: 18 Main Street Sydney NSW 2001 Australia	Weight: 100.00 Height: 170.00 Sex: MALE
Telephone(Home): 02 9555 2320	Ethnic Category: Caucasian
Telephone(Work): 02 9636 6578	Neck Circumference: 49 cm
Sleep Lab: ResMed	BMI: 34.6
Equipment Provider: ResMed	Systolic BP: 170
Insurance Co: Private Health Insurance	Diastolic BP: 100
SSN: 451-2236-69L	

Diagnostic Session

<p>MANUAL SCORING</p> <table style="width: 100%;"> <tr> <th style="text-align: left;">Class</th> <th style="text-align: right;">Total Rate/hr</th> </tr> <tr><td>unclassified</td><td style="text-align: right;">168 21.5</td></tr> <tr><td>obstructive</td><td style="text-align: right;">0 0.0</td></tr> <tr><td>central</td><td style="text-align: right;">0 0.0</td></tr> <tr><td>mixed</td><td style="text-align: right;">0 0.0</td></tr> <tr><td>hypopnea</td><td style="text-align: right;">0 0.0</td></tr> <tr><td>artefact</td><td style="text-align: right;">0 0.0</td></tr> </table> <p>OXIMETRY</p> <table style="width: 100%;"> <tr> <th style="text-align: left;">% time less than % SaO2</th> <th></th> </tr> <tr><td>7</td><td style="text-align: right;">95</td></tr> <tr><td>2</td><td style="text-align: right;">85</td></tr> <tr><td>1</td><td style="text-align: right;">75</td></tr> <tr><td>1</td><td style="text-align: right;">65</td></tr> </table> <p>Minimum SaO2 % = 0</p>	Class	Total Rate/hr	unclassified	168 21.5	obstructive	0 0.0	central	0 0.0	mixed	0 0.0	hypopnea	0 0.0	artefact	0 0.0	% time less than % SaO2		7	95	2	85	1	75	1	65	<p>FLATTENING INDEX</p> <table style="width: 100%;"> <tr> <th style="text-align: left;">% time less than index</th> <th></th> </tr> <tr><td>11</td><td style="text-align: right;">0.15</td></tr> <tr><td>2</td><td style="text-align: right;">0.10</td></tr> </table>	% time less than index		11	0.15	2	0.10	<p>BODY POSITION</p> <table style="width: 100%;"> <tr> <th style="text-align: left;">Position</th> <th style="text-align: right;">% time</th> </tr> <tr><td>back</td><td style="text-align: right;">77</td></tr> <tr><td>right</td><td style="text-align: right;">21</td></tr> <tr><td>left</td><td style="text-align: right;">2</td></tr> <tr><td>front</td><td style="text-align: right;">0</td></tr> </table> <p>APNEAS & HYPOPNEAS</p> <table style="width: 100%;"> <tr> <th style="text-align: left;">Position</th> <th style="text-align: right;">AHI/hr</th> <th style="text-align: right;">Apnea/hr</th> </tr> <tr><td>back</td><td style="text-align: right;">32</td><td></td></tr> <tr><td>right</td><td style="text-align: right;">1</td><td></td></tr> <tr><td>left</td><td style="text-align: right;">0</td><td></td></tr> <tr><td>front</td><td style="text-align: right;">0</td><td></td></tr> <tr><td>total</td><td style="text-align: right;">34</td><td style="text-align: right;">21</td></tr> </table> <p>Respiratory Irreg Index: 49</p>	Position	% time	back	77	right	21	left	2	front	0	Position	AHI/hr	Apnea/hr	back	32		right	1		left	0		front	0		total	34	21
Class	Total Rate/hr																																																											
unclassified	168 21.5																																																											
obstructive	0 0.0																																																											
central	0 0.0																																																											
mixed	0 0.0																																																											
hypopnea	0 0.0																																																											
artefact	0 0.0																																																											
% time less than % SaO2																																																												
7	95																																																											
2	85																																																											
1	75																																																											
1	65																																																											
% time less than index																																																												
11	0.15																																																											
2	0.10																																																											
Position	% time																																																											
back	77																																																											
right	21																																																											
left	2																																																											
front	0																																																											
Position	AHI/hr	Apnea/hr																																																										
back	32																																																											
right	1																																																											
left	0																																																											
front	0																																																											
total	34	21																																																										

Patient: Smith, John G.

ResMed AutoView 98

Study: 5/25/1998

Figure 8 : First page of a Sleep Study Report. This page includes the summary of patient information as well as a summary of the analysis of the study.

NOTES

Patient presents with morning headaches, snoring, irritability and tiredness.
His wife reports that he can't drive the car for longer than 20 mins without feeling sleepy.
She also reports he has periods of restlessness during the night and poor short term memory.

Blood pressure normal.
On no known medication.
Patient is overweight and has a high fat diet.
His cholesterol level is high.
Other medical history includes appendectomy and tonsilectomy.

Patient: Smith, John G.

ResMed AutoView 98

Study: 5/25/1998

Figure 9 : Second page of a Sleep Study Report. This page shows the comments or notes you have recorded about the patient.

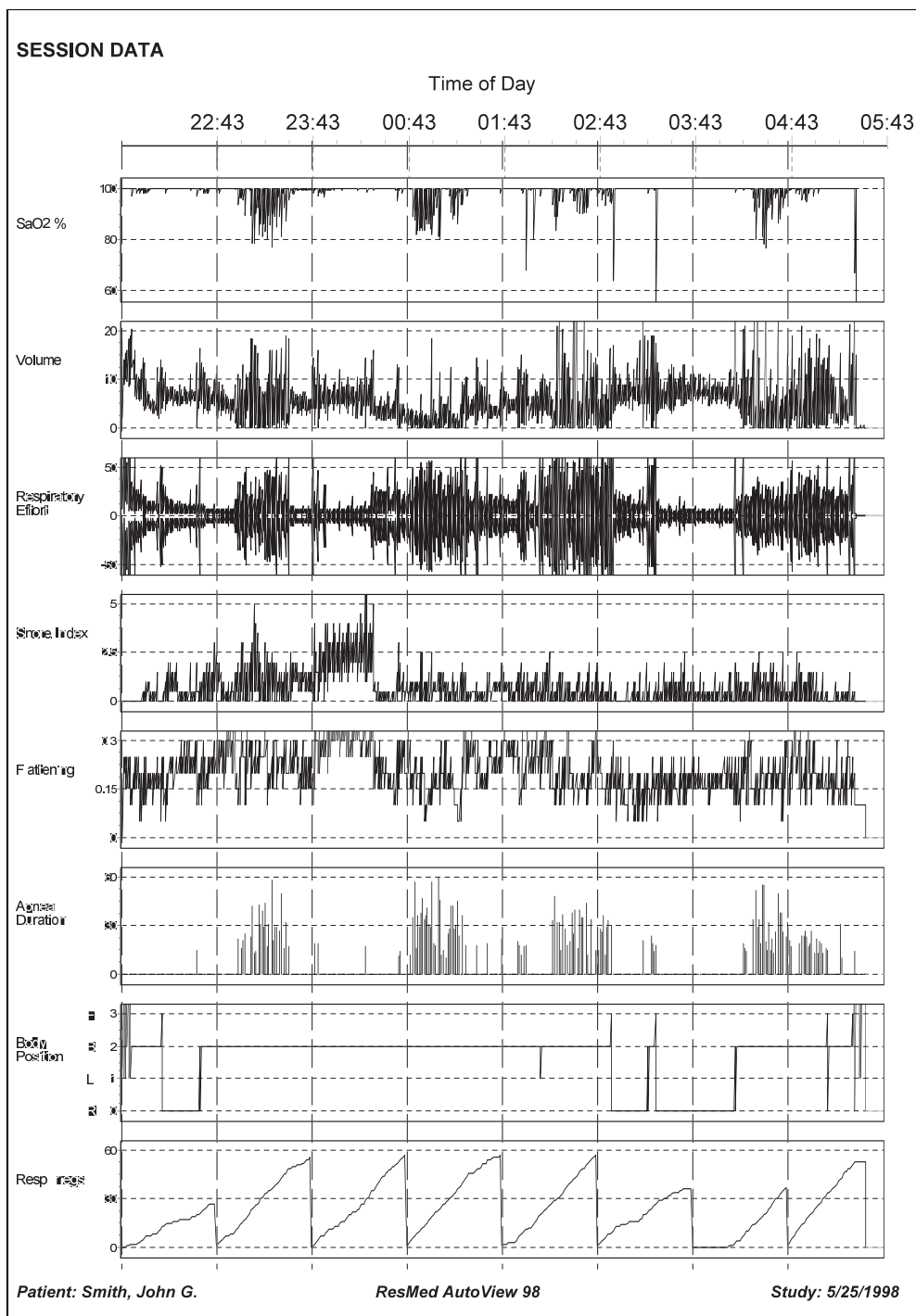


Figure 10 : Third page of a Sleep Study report showing the graphs of the study fields. This page can be printed separately as a "Data Page"

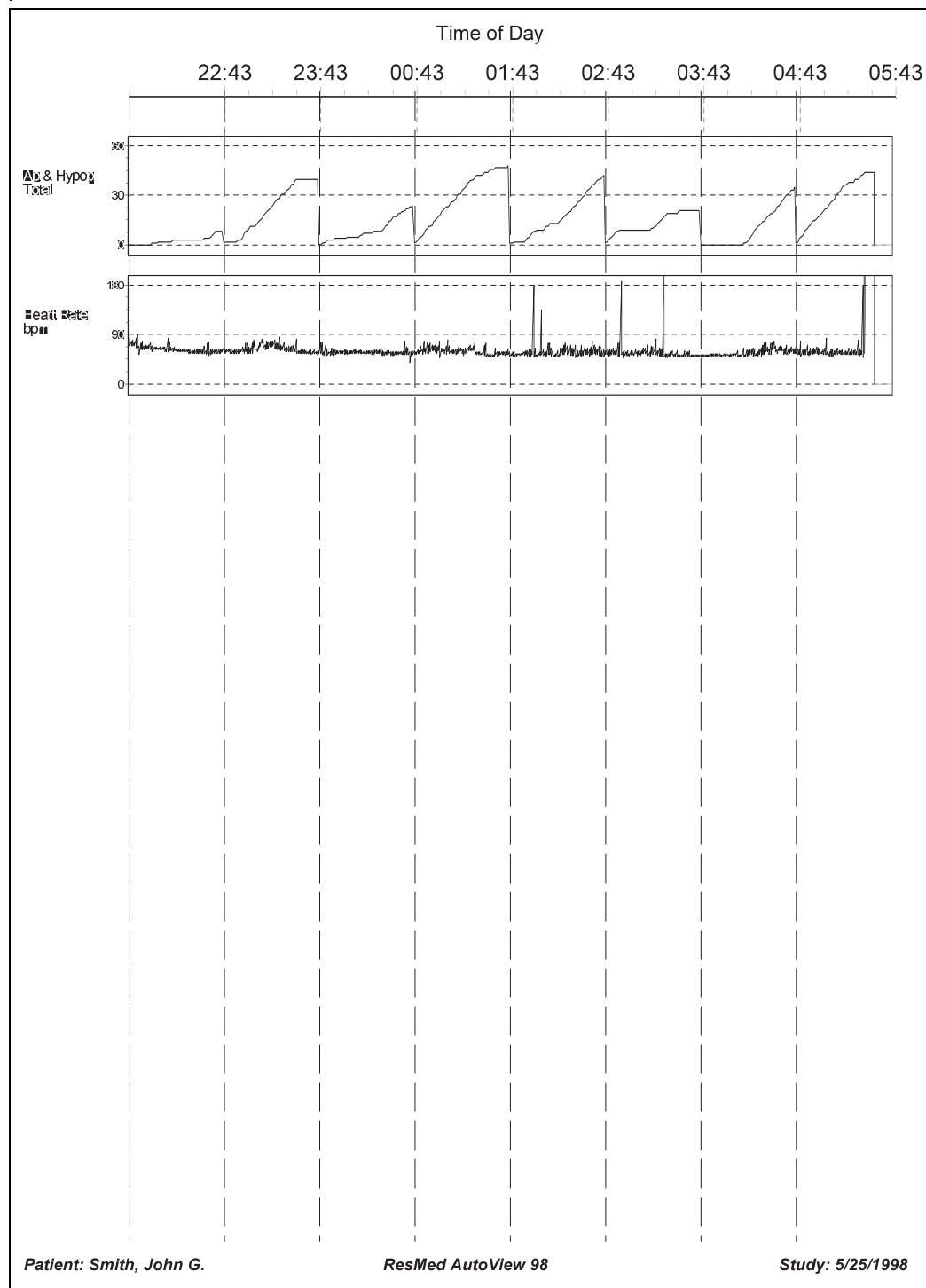


Figure 11 : Fourth page of the Sleep Study Report. This page shows the remaining study fields not shown on the third page of the report.

STUDY GRAPHS

This section is a guide to each parameter recorded by the PII Plus system with information to help you interpret and understand the representation of the study data.

IMPORTANT



When interpreting study data, always examine every parameter recorded before making any conclusions. It is crucial not to make any summations from one parameter only. This is especially important for studies conducted in Automatic or Manual mode, where a mask leak greater than 0.4 /l sec can reduce the accuracy and validity of other parameters.

OXYGEN SATURATION

The patient's oxygen saturation is recorded by a pulse oximeter. The PII Plus has an in-built Nonin oximeter from which an output signal may be obtained.

Oxygen saturation is recorded continuously during the study and is sampled, averaged, and logged every second. The oxygen saturation recorded is 0-100% and a typical reading for a normal, healthy patient is in the range of 95-100%.

Information from the oximetry is recorded only. It is not used in the algorithm to increase or decrease pressure in a CPAP study. PII Plus directly and primarily monitors the state of the upper airway and treats accordingly. Oxygen saturation artefact and inter-patient variability in response to apneic events is, therefore, not a confounding factor when treating upper airway obstruction.

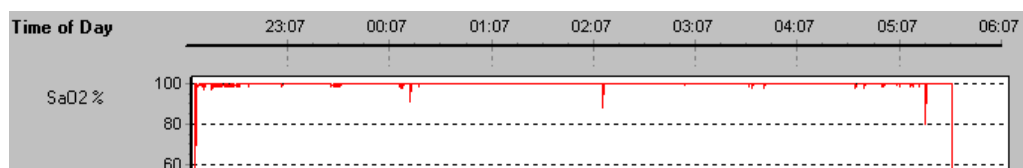


Figure 12 : Normal oxygen saturation recording. The oxygen saturation remains fairly constant with no significant desaturations.

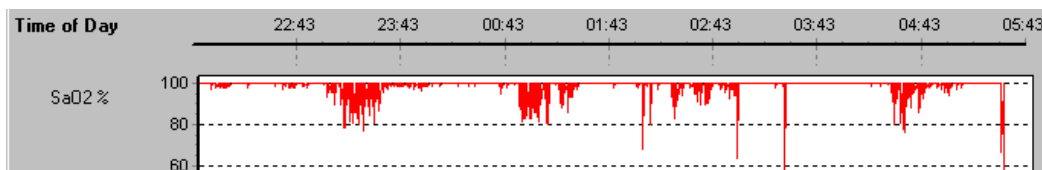


Figure 13 : Periodic oxygen desaturations which could represent REM associated sleep apnea or positional sleep apnea. A careful review of all parameters recorded, especially body position, will help you to determine the nature of this patient's apnea. For more information about determining positional or REM associated apneas, see "Obstructive Sleep Apnea Study" on page 36.

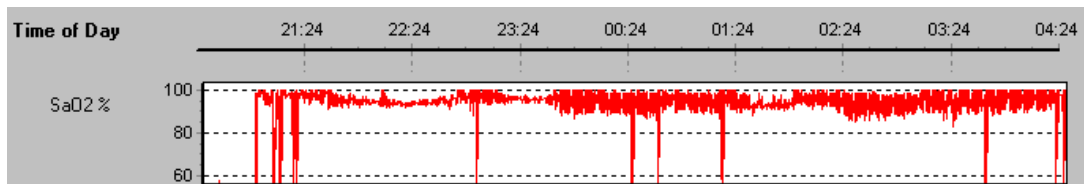


Figure 14 : Cyclic and repetitive oxygen desaturation, consistent with severe sleep apnea.

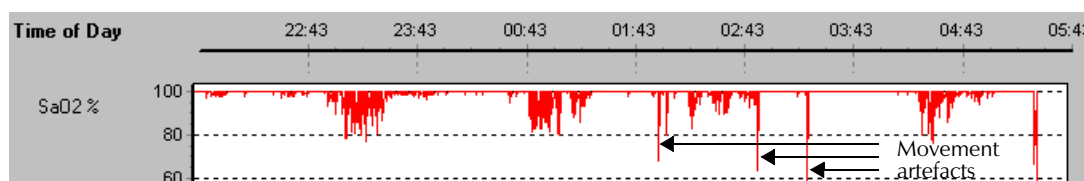


Figure 15 : Patient movement may produce “desaturation spikes” in the trace. These artefacts can be differentiated from true periods of desaturation by their brevity and by correlating their occurrence with simultaneous spiking in the heart rate trace.

HEART RATE

The heart rate is derived from the oxygen saturation probe and is graphically displayed as beats per minute.

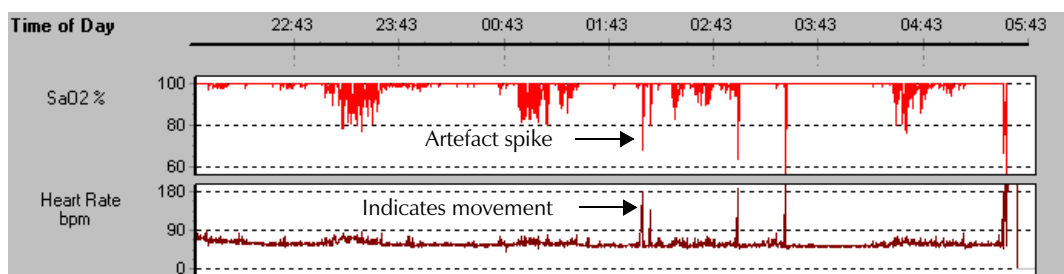


Figure 16 : When assessing the oxygen saturation trace, the heart rate trace should also be reviewed as artefact spikes can be easily identified.

SNORING

In diagnostic mode the patient wears nasal cannula only. The signal from the nasal cannula is measured by a pressure transducer in the flow generator and filtered to remove artefacts. Snore is averaged and logged every second and displayed in arbitrary units. Silent breathing generates less than 0.2 units and a value of 1 equates to approximately 75dBA (68dBC) measured 10cm from the nares.

0 = no noise
1 = “typical” snore
≥2 =loud snore

In CPAP modes, the pneumotach and sensor tubes measure snore in the same manner as the nasal cannula.

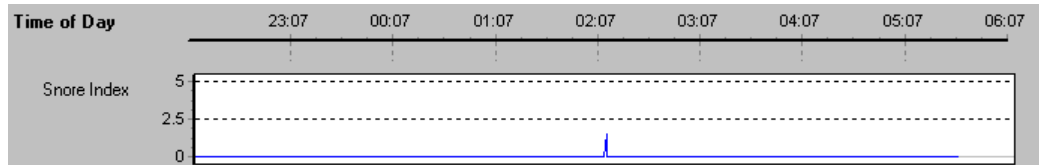


Figure 17 : A normal study with no significant snoring. Notice snoring remains at 0 for almost the entire study.

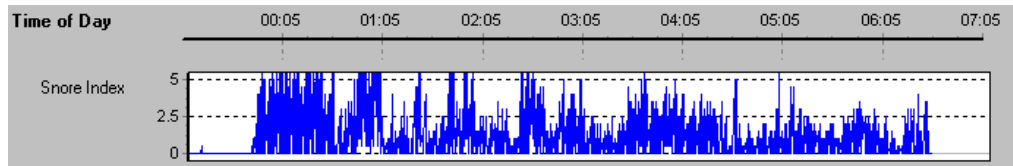


Figure 18 : Continuous loud snoring ranging from 0 to 5 units.

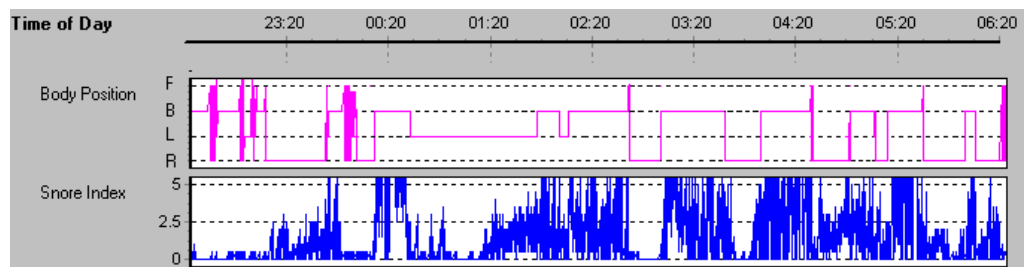


Figure 19 : Positional loud snoring. Notice the loud snoring occurs when the patient is on his/her back and the snoring lessens when he/she is in a lateral position.

NOTE



For more information on PII Plus pressure responses, see “Pressure Response” on page 24.

NASAL VENTILATION

The nasal ventilation signal provides a good indication of normal and disordered breathing. It can also help to determine if the patient is mouth breathing or, in diagnostic mode, the nasal cannula has become dislodged. In this circumstance, the nasal ventilation signal would read below 5 on the scale for a prolonged period. The nasal ventilation reading is semi-quantitative and therefore more useful than readings taken from nasal thermistors. Thermistors measure temperature changes, providing a qualitative indication of the presence or absence of breathing. However, nasal cannulae monitor pressure in the anterior nares and transfer the signal to a pressure transducer in the flow generator. The anterior nares pressure reflects flow and the PII Plus software monitors the contour of the inspiratory flow-time curve.

The Apnea/ Hypopnea Index (AHI) and Apnea Index are derived from separate algorithms. This means that when nasal ventilation is close to zero for an extended period, for example when a patient is mouth breathing, the Apnea Index may be higher than the AHI.

Nasal ventilation is averaged and logged every second. In treatment mode, the nasal ventilation is measured in l/min. In diagnostic mode, variations in nostril size, nasal cannula dimensions, and exact placement of the nasal cannula within the nostrils may effect nasal ventilation readings.



During periods of mouth breathing the nasal ventilation will be less than the true ventilation.

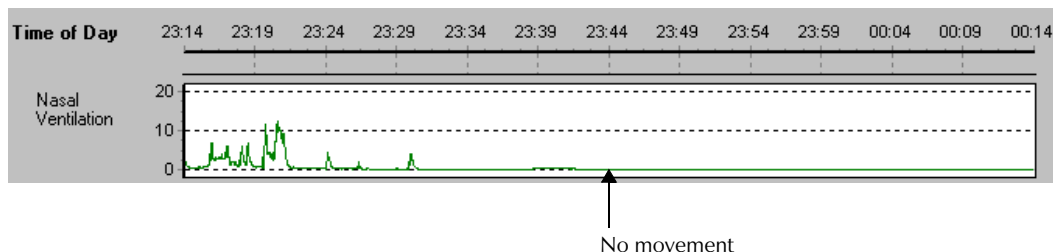


Figure 20 : Mouth breathing or dislodged nasal cannula. Notice most of the signal is very low at around 0 to 3 units. If the report showed long apneas present with no other signs of disordered breathing, you may need to disregard the data. For a detailed examination this study, see “Poor Quality Study” on page 66.

If the patient breathes entirely through the mouth the signal is lost. However, this degree of mouth breathing is rare. More frequently there may be partial mouth breathing for some of the night. This can be detected by inspection of the nasal ventilation signal. Any apneas detected when the nasal ventilation signal remains below 5 units for a period of time should be treated with caution. This is because during a typical apnea nasal ventilation will drop below 25% of the previous baseline, and subsequently increases when breathing resumes. If the nasal ventilation signal does not show this increase after the logged apnea, the event should be treated with caution.

Partial mouth breathing is depicted by a reduced nasal ventilation signal. Generally, sustained values of <5 units indicate mouth breathing. Despite this, if it is clear that the nasal ventilation signal closely matches the apnea and oximetry signals, the data is usable.

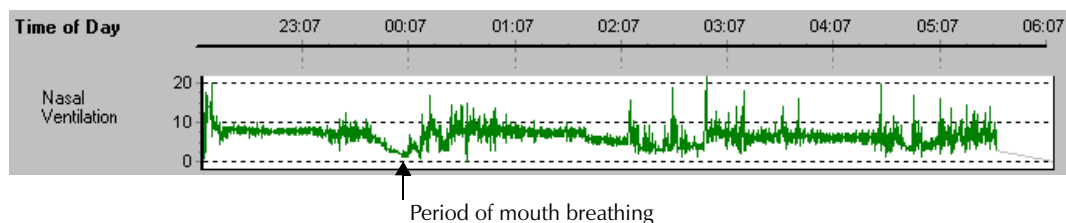


Figure 21 : A normal nasal ventilation signal. Periodic variations in the signal are likely to be sleep-state dependent. Notice at 00:07 the nasal ventilation falls towards 0 for a short period of time. This is associated with a brief period of mouth breathing.

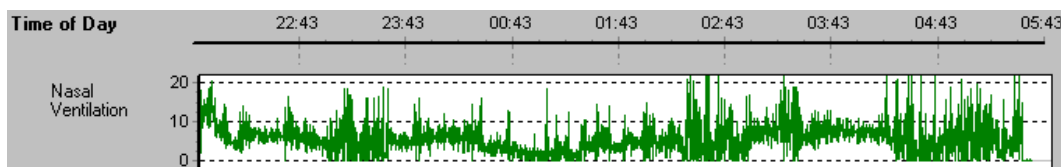


Figure 22 : High variation in the signal, with fluctuations from 0 to 20 units. This type of recording would typically be seen in a patient with significant sleep disordered breathing.

VOLUME L/MIN

In Automatic and CPAP Fixed Pressure modes, the Nasal Ventilation signal is called Volume. Because a nasal CPAP mask is used in these modes, a more accurate measure of airflow (in L/min) can be

obtained from the pneumotach attached to the mask. So while nasal ventilation in Diagnostic mode is in arbitrary units, nasal ventilation, or volume, in Automatic and CPAP Fixed pressure modes is recorded in L/min.

MASK LEAK

Mask leak is only recorded during automatic titration and fixed pressure studies. It is measured by analyzing inspiratory and expiratory volumes which should be approximately equal, leading to an average airflow of zero. This means that any long-term average airflow greater than zero is due to leak. If mask leak is above 0.4 l/sec, the PII Plus may inappropriately increase pressure. Therefore, the AutoSet algorithm changes slightly above this value, reducing the degree of pressure increase to snore, flattening, and apneas.

A measure of mask leak is also indicative of the patient's experience with the PII Plus and allows you to observe how much of the study is accurate. A mask leak value of ≤ 0.2 l/sec for the majority of the study equates to a well-fitting mask. Short periods of higher mask leak should not cause too much concern, however, long periods of high mask leak may affect the study quality and the patient's acceptance of positive airway pressure treatment.

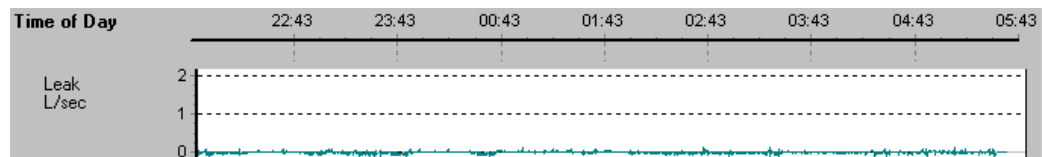


Figure 23 : A study with no mask leak.

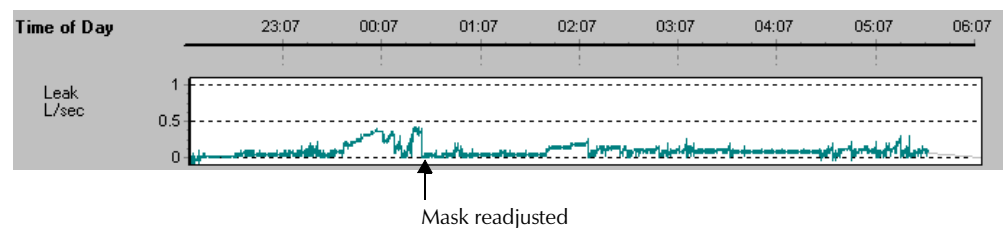


Figure 24 : An acceptable level of mask leak for the majority of the night. Note there is one episode of mask leak that reaches 0.4 l/sec for approximately 20 minutes. This was rectified by readjusting the mask. For the remainder of the night, mask leak was acceptable.

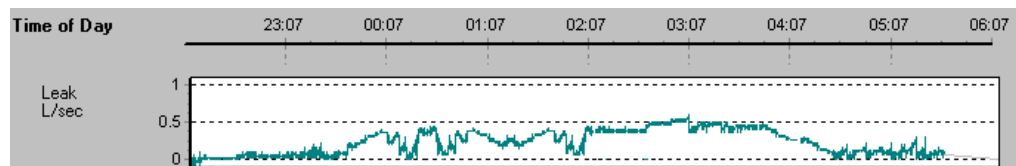


Figure 25 : Episodes of mask leak that are significantly above 0.4l/sec may cause inappropriate increases in pressure, and may also lead to ineffective treatment and poor patient compliance. This study should be discarded and repeated with a mask cushion of a different size.

FLOW LIMITATION - FLATTENING INDEX

Inspiratory flow limitation, also referred to as the flattening index, is a measurement of partial upper airway obstruction. This measurement is based on the **shape** of the inspiratory flow-time curve and is displayed as an arbitrary scale of 0 to 0.3 units. It is calculated each breath by averaging the previous 5 breaths. This reduces the effect of cardiogenic airflow which could disguise an otherwise flattened flow signal.

The measurement of the shape of the flow-time curve gives accurate information about the status of the upper airway. This measurement of flow limitation, taken in the middle-half of the inspiratory flow-time curve, is especially important when titrating CPAP levels, as partial obstruction precedes total obstruction. By responding to flow limitation, PII Plus acts pre-emptively.

A reading of 0.3 equates to a patent open airway. A normal breath has a value of about 0.2 or greater. A value of 0.15 or less reflects significant inspiratory airflow limitation and the flow-time curve looks flatter. A value between 0.05 and 0.1 represents a severely flow limited airway and a completely closed airway is represented by 0.00.

A Flattening Index is only calculated when inspiratory flow is present. This means that no index is derived during an apnea and a new index is calculated at the resumption of flow.

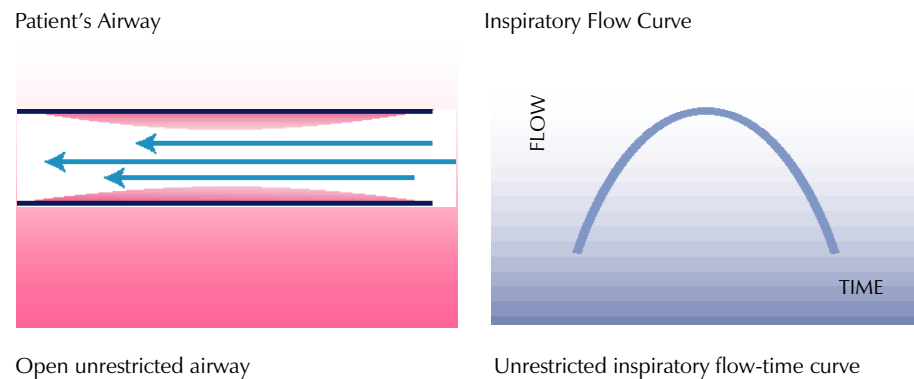


Figure 26 : A patent airway is represented by a rounded flow curve as depicted in this example. Normal breathing is considered to fall between 0.2 and 0.3 units.

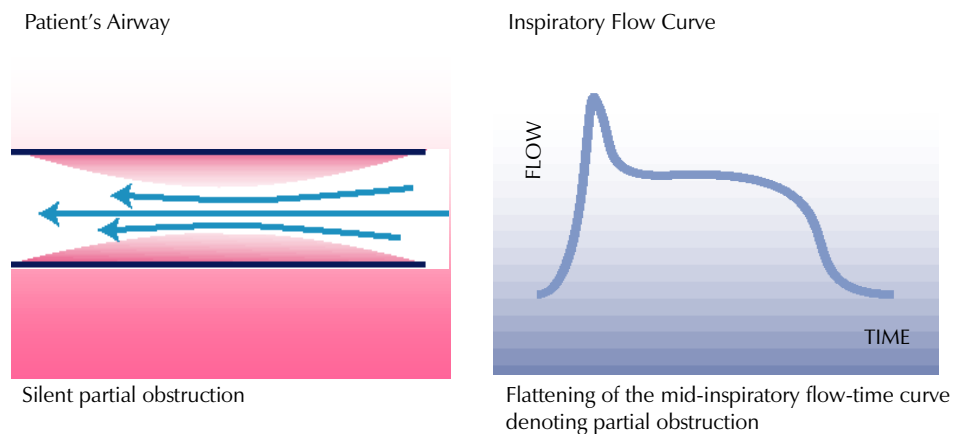
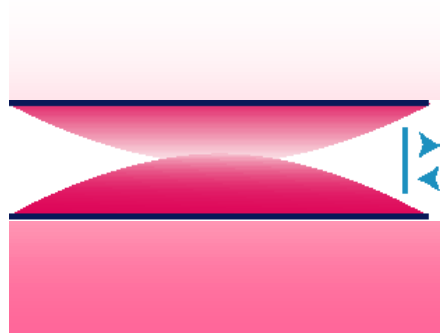


Figure 27 : Partial upper airway closure is represented by a flow-time curve where the mid point is flattened, as depicted in this example, and is represented as a value of 0.15 or less.



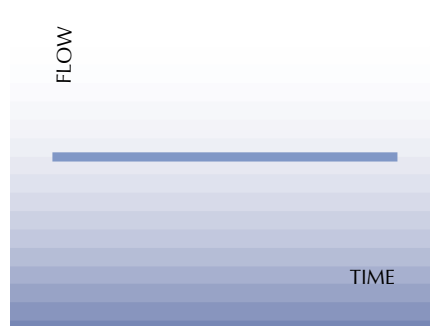
When a patient's upper airway is partially obstructed, the flattening index will drop. It will rise again when the airway is more open or upon arousal.

Patient's Airway



Complete airway collapse

Inspiratory Flow Curve



Absence of flow (>10 secs = apnea)

Figure 28 : When the upper airway is totally closed or obstructed, the inspiratory flow-time curve forms a square wave. Significant flow limitation produces a value below 0.15 on the Flattening Index. Very severe flow limitation, as in the case of an apnea, results in the Index reading below 0.1.

In Diagnostic mode the PII Plus records the flattening index, giving it a value between 0 and 0.3 units. In patients where mild sleep apnea or upper airway resistance is present, analyzing the flattening index gives a good indication of the first line of therapy to undertake.

In Automatic mode the PII Plus increases pressure when the flattening index is 0.15 or less. Increases in pressure related to flow limitation are often observed with sleep onset and REM sleep, and due to this pressure increase, apneas or total closure of the airway are rare. PII Plus pre-emptively increases CPAP pressure to prevent obstruction from occurring.

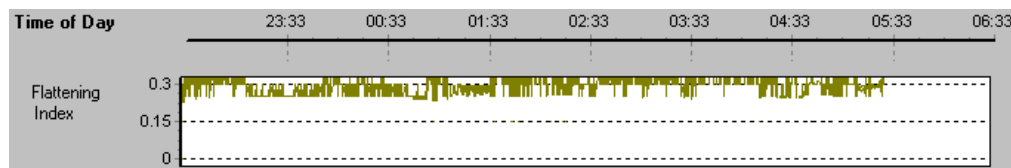


Figure 29 : This example demonstrates a normal flattening index as depicted by the PII Plus. The flattening index remains above 0.15 for the entire night, averaging 0.2.

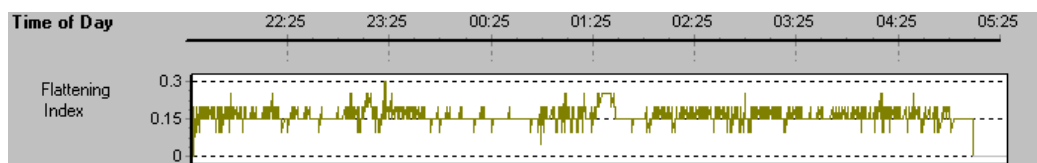


Figure 30 : This example demonstrates some flow limitation, where the index averages 0.15.

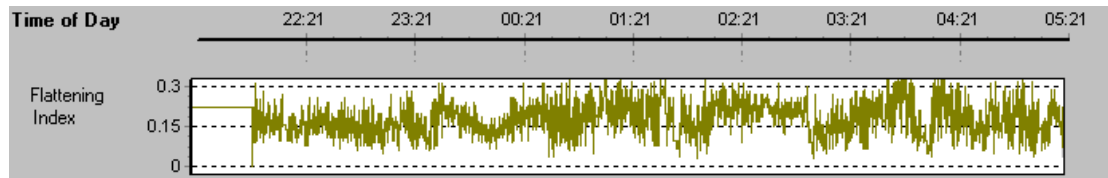


Figure 31 : This example depicts severe sleep disordered breathing. In response to obstructive apneas the flattening index fluctuates dramatically, falling below 0.15 for the majority of the night.

NOTE



By assessing the contour of the inspiratory flow-time curve on a breath-by-breath basis, the PII Plus pre-emptively treats apnea and snoring, normalizing work of breathing and reducing arousals from sleep. It fine tunes CPAP treatment on a breath-by-breath basis.

For more information on PII Plus pressure responses, please see “Pressure Response” on page 24

BODY POSITION

A body position indicator records the patient's position during the study. This information is displayed on the body position chart where:

F = FRONT

B = BACK

L = LEFT

R = RIGHT

Sudden movements by the patient can create spikes in the trace. These may be artefacts and are not clinically significant and may relate to periods of wakefulness.

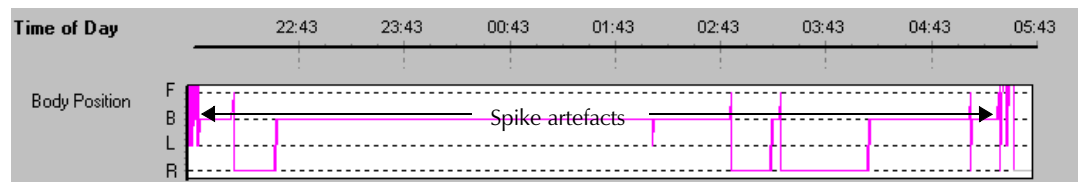


Figure 32 : Various sleeping positions. Note the spike artefacts at the beginning and end of the study in association with significant movement.

APNEAS & HYPOPNEAS

PII Plus defines an apnea as a >75% decrease in nasal ventilation for at least 10 seconds. An apnea is scored if the 2-second moving average ventilation drops below 25% of the recent average (time constant 100 seconds) for at least 10 consecutive seconds.

PII Plus defines a hypopnea as a 50% to 75% decrease in nasal ventilation. A hypopnea is scored if the 8 second moving average ventilation drops below 50% but not more than 25% of the recent average for 10 consecutive seconds. The recent average is calculated using a time constant of 100 seconds.

In Diagnostic mode, PII Plus records the number of apneas and hypopneas that occur. There is no attempt to differentiate types of apnea, although the manual classification option is available. During both Automatic and Manual modes, apneas are defined as either OPEN or CLOSED. Open airway apneas are central events that can occur at sleep onset, during REM sleep, or in patients with cardiac failure.

Closed airway apneas are events where the airway is closed, such as obstructive apnea. It is essential to differentiate between these events as CPAP pressure should be increased if the airway is closed and remain constant if the airway is open.

The PII Plus differentiates between open and closed apneas by sending a “pulse” of air at 4 Hz (cycles/second) at a pressure of ± 0.25 cm H₂O to measure airway conductance. If the PII Plus senses flow, it assumes the airway is open and logs the event but does not increase pressure. If no flow is detected, it assumes the airway is closed, logs the event and increases pressure.

NOTE



For more information on PII Plus pressure responses, see “Pressure Response” on page 24

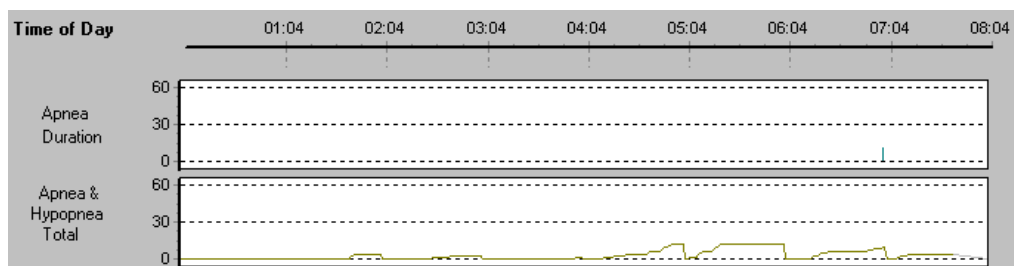


Figure 33 : A normal study with the Apnea Hypopnea Index well within normal limits (<5/hr). Only one apnea is logged in the apnea duration graph. This means the events displayed in the Apnea Hypopnea total are hypopneas.

NOTE



The Apnea and Hypopnea Total is cumulative over the hour intervals, returning to zero at the beginning of the each hour of the study.

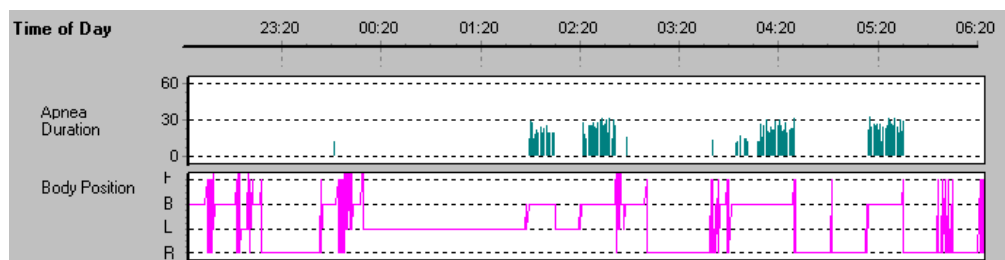


Figure 34 : Periods of apnea displayed in the apnea duration graph may be positional. Note the apneas occur when the patient is on his/her back.

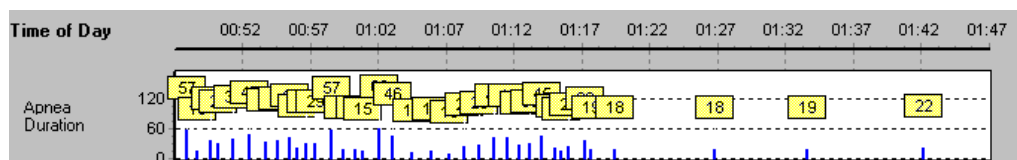


Figure 35 : Severe apnea, each event is logged with a line. In the 1-hour and 5-minute screens, AutoView displays in a box the length of each apnea in seconds.

In Automatic or Manual mode open apneas are represented on different graphs. Open apneas are

logged similarly to the apnea duration when in Diagnostic mode.

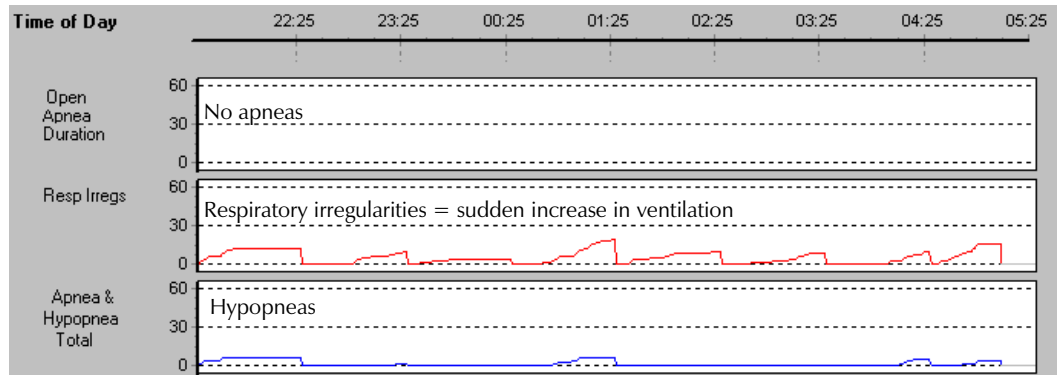


Figure 36 : Hypopneas are logged in the Apnea & Hypopnea Total graph. If no apnea has occurred in the apnea duration graph, yet the apnea hypopnea total has increased, the events logged are all hypopneas. This example shows the AHI increase, however, no apnea has been logged in the apnea duration graph. Note also the rise in respiratory irregularities.

RESPIRATORY IRREGULARITIES

Events logged in the Respiratory Irregularities index are characterized by a sudden and large increase in average ventilation. The index increases by 2 if there is a two-thirds increase in the 8 second moving average ventilation over any 15 second period. These include events such as increased ventilation associated with the termination of apneas and hypopneas, and sighs during wakefulness. They may also be associated with arousal from sleep. For example, high values are likely to be encountered if the patient was awake and restless for much of the night, or if he/she had many arousals or respiratory disturbances. Low values are likely to indicate the patient slept deeply and uneventfully.

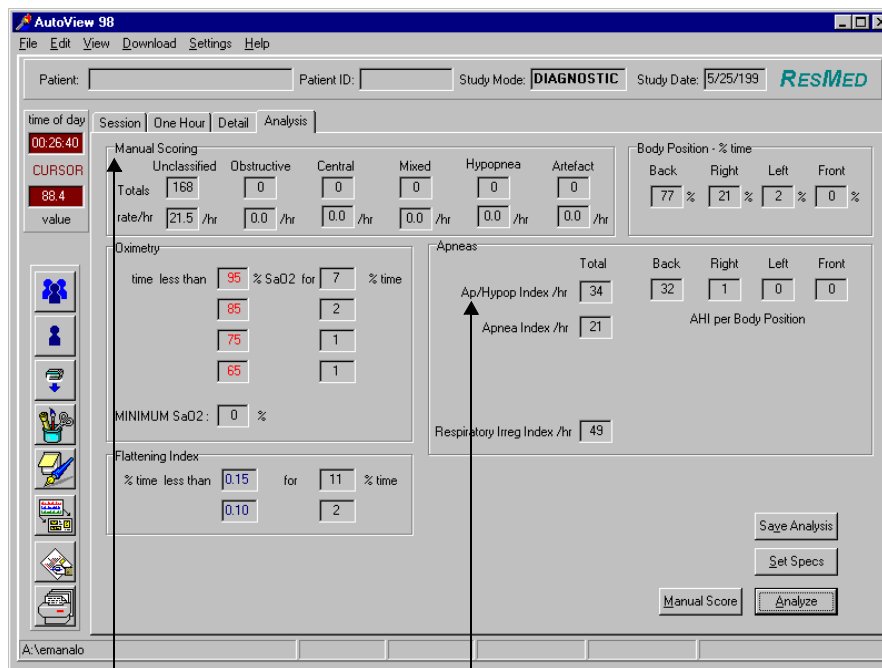
An elevation in the Respiratory Irregularities index may also provide an indication of Upper Airway Resistance Syndrome (UARS) / Respiratory Effort Related Arousals (RERAs).

APNEA INDEX

The Apnea Index is automatically calculated by the PII Plus. This index is the number of events divided by the total study time to give an index of events per hour. If you know the patient was awake for a period of time during the study, you may choose to remove this period from the Apnea Index. You can do this by using the blackout feature of the AutoView software or calculating the index yourself. For example, if the study lasted eight hours, but the patient was asleep for only six hours, then the number of apneas per hour of sleep is 8 divided by 6, times the number of apneas per hour of sleep recorded by PII Plus.

APNEA & HYPOPNEA INDEX (AHI)

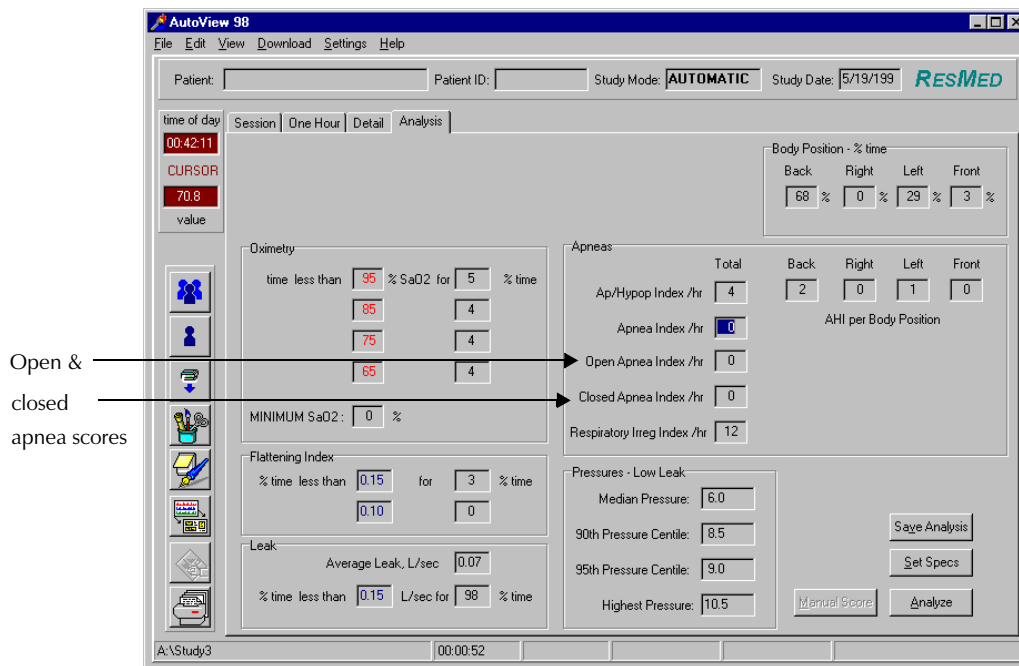
PII Plus determines the AHI by adding the total number of apneas and hypopneas the patient experienced during the study and dividing that figure by the total study time. When PII Plus calculates the AHI, it assumes that the patient slept for the entire study. If the patient did not sleep for a period of time during the study you can determine the true AHI by using the blackout feature of the AutoView software or calculating the index yourself. For example, if the PII Plus calculated an AHI of 25 events per hour but the patient only slept for 6 hours, you would multiply 25 by 8 to get 200, then divide 200 by 6 to get 33, the true AHI. If you use the blackout feature, PII Plus ignores the blocked out events when it performs analysis of the study data.



Manual scoring field

AutoSet-generated apnea scores

Figure 37 : Diagnostic analysis screen. The apnea/ hypopnea index, apnea index and the respiratory irregularities index are generated by PII Plus and will not alter when you perform manual scoring or classification.



Open &
closed
apnea scores

Figure 38 : Statistical analysis screen PII Plus for an Automatic/ CPAP study. Note how PII Plus differentiates between open and closed apneas in Automatic mode.

PRESSURE

Pressure is only measured and recorded during an automatic titration or Fixed Pressure study. In Automatic mode, mask pressure is increased in relationship to the severity of snore, inspiratory flow limitation, or closed airway apneas. For example, a snore value of greater than 0.2 results in pressure increasing by 0.2 cm H₂O/ sec. In response to a closed apnea of 15 seconds, the pressure will increase by 1 cm H₂O.

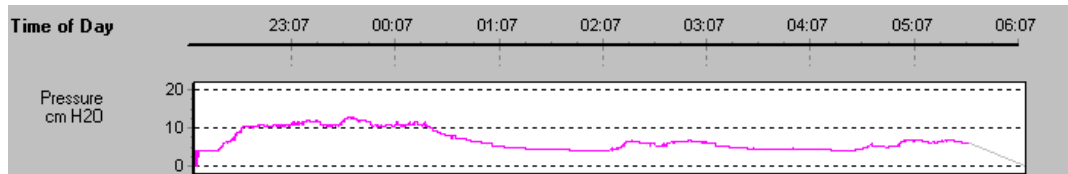


Figure 39 : Note the varying CPAP pressure overnight. These pressure changes are a result of flow limitation, snore and, more rarely, apneas. Of interest is the significant increase in CPAP pressure in the first 30 minutes of the study. This is typically associated with flow limitation at sleep onset.

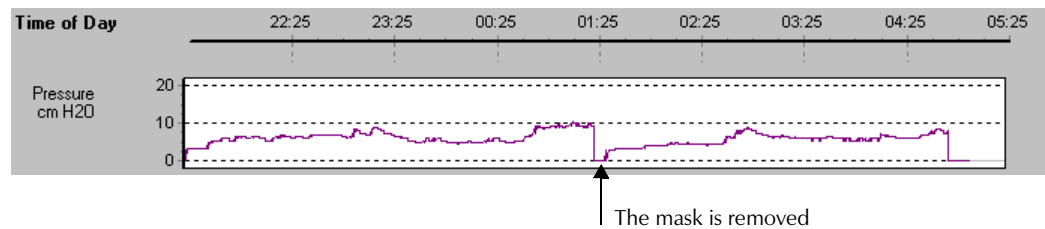


Figure 40 : Note in this example the pressure falls to 0 as the patient removes his/her mask for a short period of time.

PRESSURE RESPONSE

In Automatic mode the PII Plus increases and decreases pressure based on the status of the upper airway. Pressure increases are related to the severity of upper airway obstruction. **The maximum rate of increase in response to any event is 1 cm H₂O per second.**

INCREASING PRESSURE

SNORE

Snore is measured on an arbitrary scale called snore units. PII Plus monitors snore on a breath-by-breath basis. When a snore over 0.2 units is detected, PII Plus increases pressure in relation to the severity of the snore, by a maximum of 0.2 cm H₂O per second, until snore is detected at less than 0.2 units. For example, a snore value of 1 unit causes a greater increase than a snore value of 0.5 units. The pressure increase in response to snore is less once the pressure is already ≥ 10 cm H₂O.

FLATTENING INDEX

The flattening index is measured on a scale of 0 to 0.3 units, with ≥ 0.2 being a normal reading. The index provides a measure of inspiratory flow limitation. Inspiratory flow is averaged every five breaths and when this average is 0.15 units or less, PII Plus increases pressure by 0.3 cm H₂O for every 0.01 unit below 0.15 units. It does this to a maximum pressure increase of 1.5 cm H₂O per minute until the flattening index is measured at >0.15 units.

The recognition of respiratory flow limitation during treatment is influenced by the magnitude of leak. If the mask leak is above 0.4 l/sec, the amount of pressure increase in response to flow limitation is decreased in relation to the severity of the mask leak. **Once mask leak exceeds 0.7 l/sec, there will be no increase in response to flattening.** When pressure is already at 10 cm H₂O or more, a greater severity of flattening is required to initiate further pressure increases.

NOTE



A leak of more than 0.4 l/sec is commonly associated with greater patient discomfort, disturbance of sleep, and reduced efficacy of treatment.

CLOSED APNEAS

The pressure increase in response to closed airway apneas is 1 cm H₂O per 15 seconds of apnea. The purpose of increasing the pressure is not to terminate the current apnea, but to prevent a subsequent one. Terminating an apnea in progress requires high pressures to overcome surface tension and very high suction forces. This may wake the patient, impair subsequent return to sleep and generally cause unnecessarily high pressure levels. PII Plus increases pressure on termination of the apnea.

DECREASING PRESSURE

Pressure decreases when there are no further abnormalities in the upper airway. The reduction is exponential, with a time constant of 20 minutes for snore and flow limitation and 40 minutes for apnea. The pressure decreases at a slower rate for apnea because if an apnea did occur, it may indicate that the snore and flattening index algorithms were not acting pre-emptively for that particular patient, and there may be grounds for holding the pressure higher for longer.

RESPIRATORY EFFORT

The respiratory effort chart displays the amplitude of respiratory effort averaged over one second. This helps to classify respiratory disturbances. The AutoView 98 implementation of this display differs from traditional polysomnographic representation of respiratory effort.

NOTE



When classifying respiratory events it is imperative to assess not only the respiratory effort, but also nasal ventilation, oxygen saturation and flattening index. If performing either an automatic or manual CPAP study it is also necessary to first check the status of the mask leak.

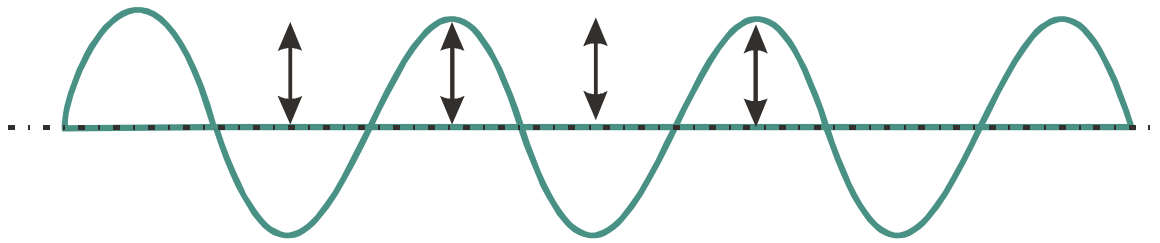


Figure 41 : Raw data (a signal that varies the band tension with breathing) from the respiratory band.

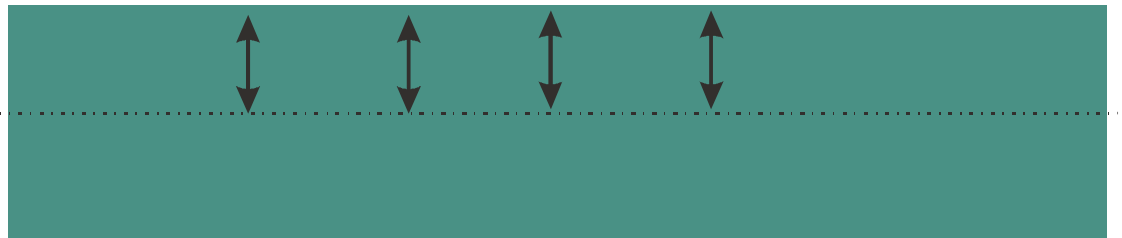


Figure 42 : The resultant traced is then mirrored below the base line and shaded to produce the AutoView 98 trace.

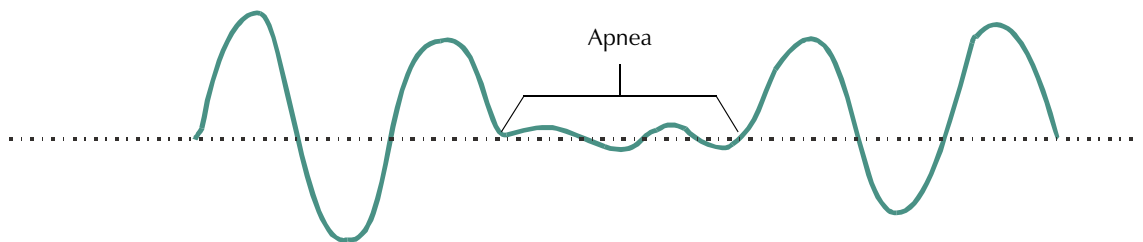


Figure 43 : This is the raw data example of an apnea.

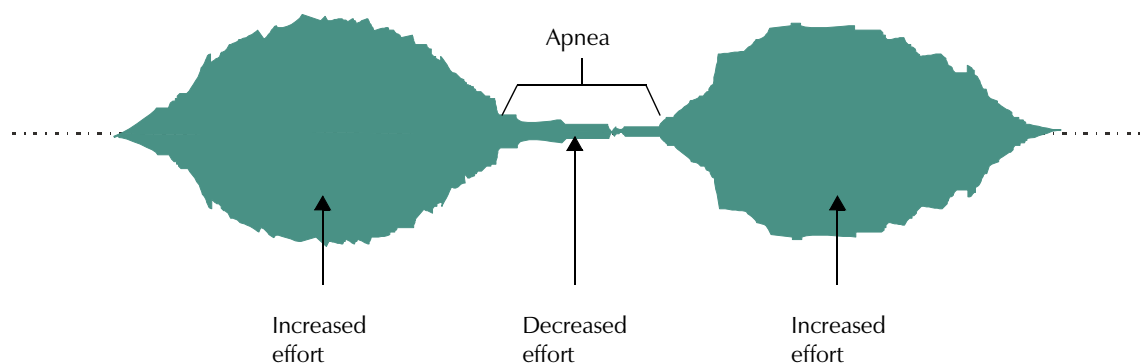
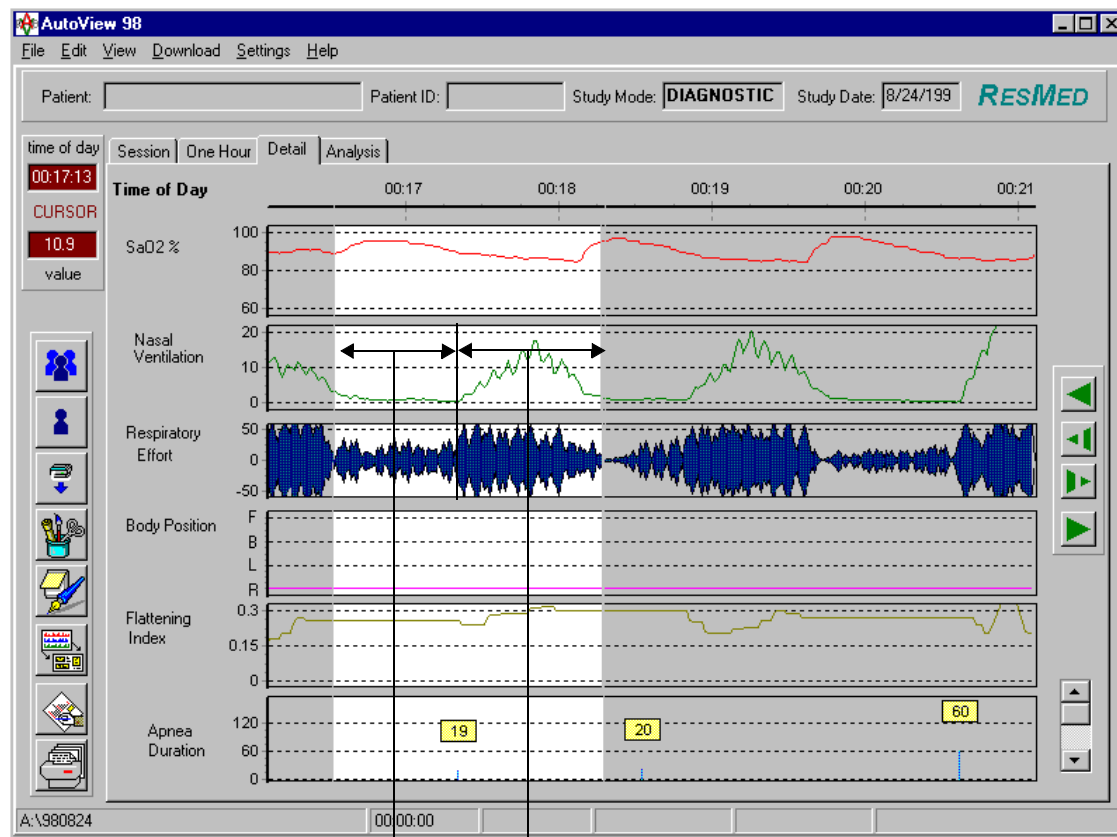


Figure 44 : This is the same apnea displayed by AutoView 98. Notice how the mirrored trace and shading clearly depicts episodes of increased and decreased respiratory effort.

OBSTRUCTIVE APNEA



STUDY GRAPHS

Reduced
respiratory effort
and nasal
ventilation

Explosive excursions
in nasal ventilation
and respiratory effort
following apnea
event.

Figure 45 : Detail screen from a patient with OSA.

Analysis of the respiratory effort trace can assist in differentiating respiratory events. The presence of some respiratory effort with a reduction or cessation of nasal ventilation during an event is a strong indication of an obstructive apnea. Both the nasal ventilation and respiratory effort show an explosive excursion following the event.

CENTRAL APNEA

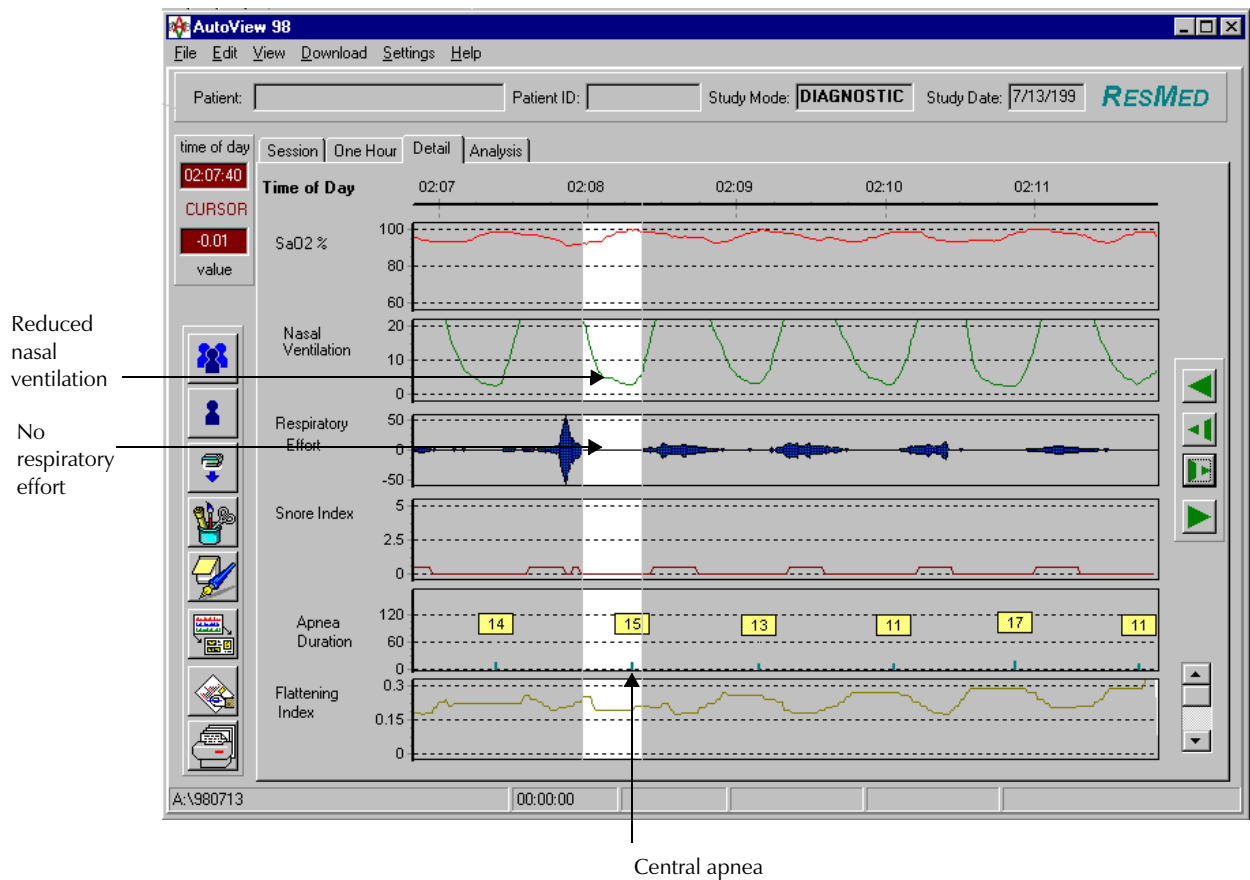
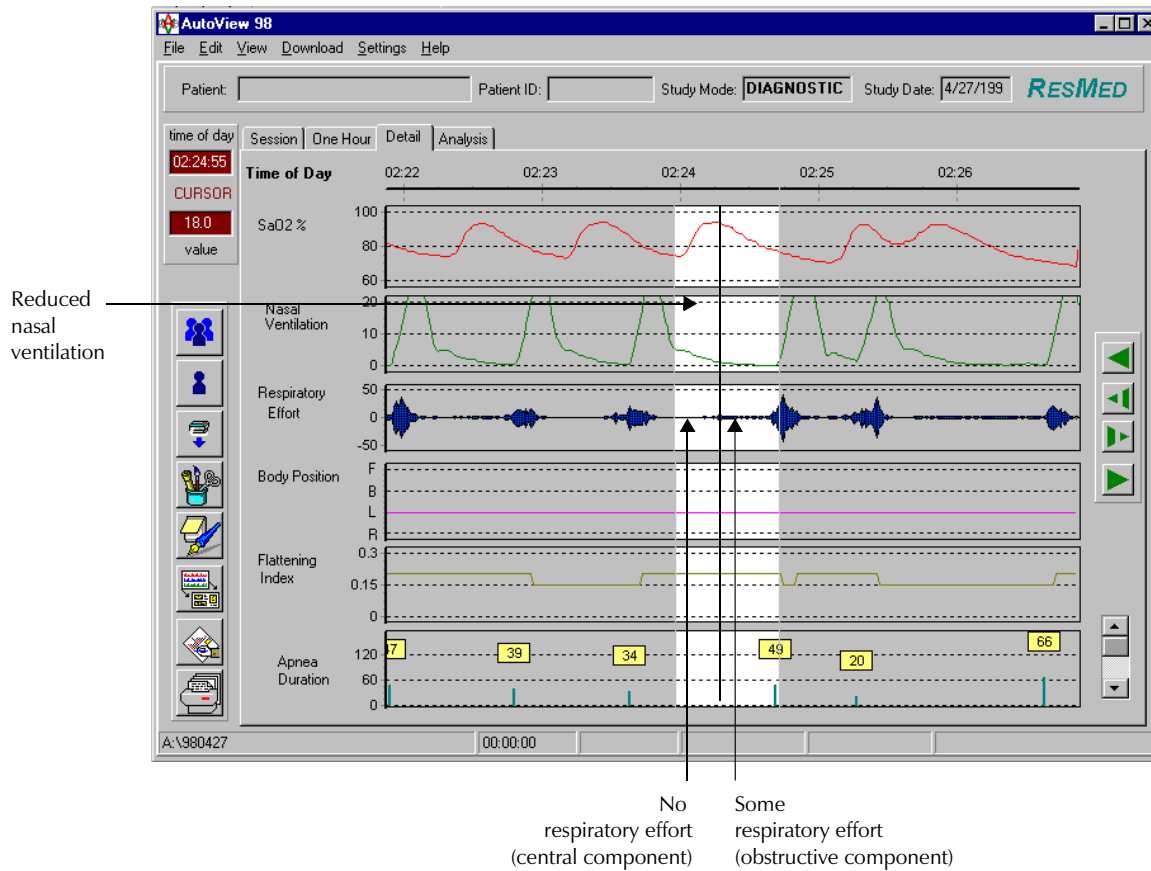


Figure 46 : Detail screen from a patient with Central Apnea

If the respiratory effort trace shows zero or near zero, without any increase in amplitude and the nasal ventilation drops below 25% of previous baseline ventilation, the event is likely to be central.

MIXED APNEA



STUDY GRAPHS

Figure 47 : Detail screen from a patient with Mixed Apnea

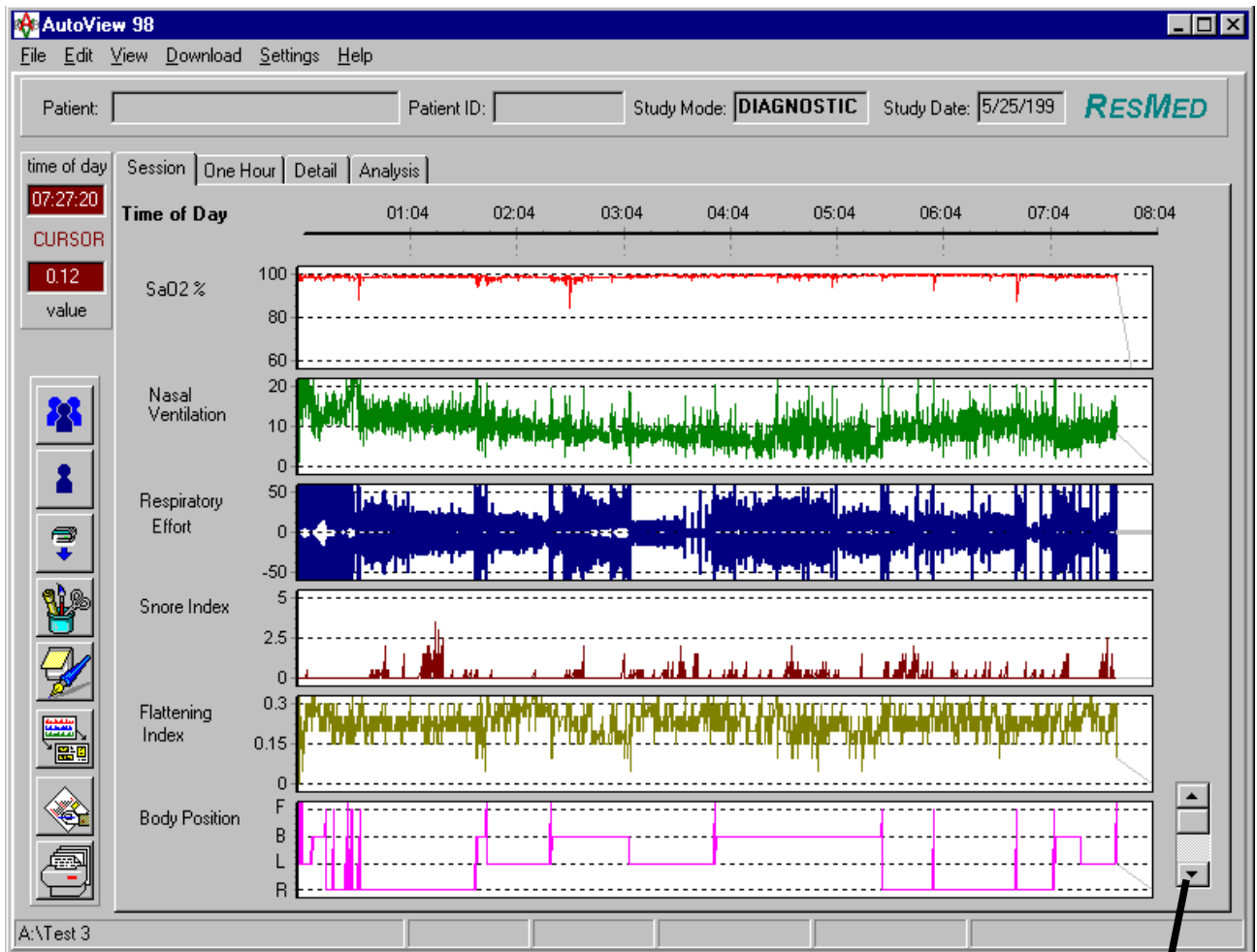
Cessation in the respiratory effort, with a reduction or cessation of nasal ventilation, suggests central apnea. However, if the respiratory effort amplitude increases during this event, and the reduced nasal ventilation remains low, the event is classified as a mixed apnea.

SAMPLE STUDIES

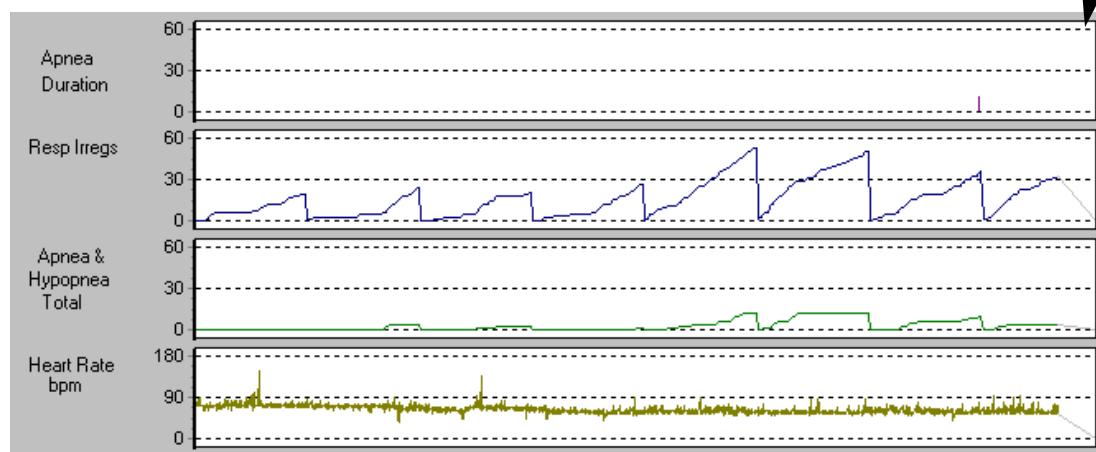
The following studies are intended to illustrate some features of both the PII Plus and the AutoView98 software and to help you recognise different sleep disordered breathing conditions.

Any study performed by PII Plus and reviewed in AutoView 98 may be examined on the computer screen or in printed form. If you prefer to print the study data to analyze it, you should be looking for the same patterns in the study data as described in this chapter.

NO SLEEP DISORDERED BREATHING/ BENIGN SNORING



For the purpose of illustrating this study in full, the remaining fields, which you have to scroll down to see in AutoView, have been inserted.

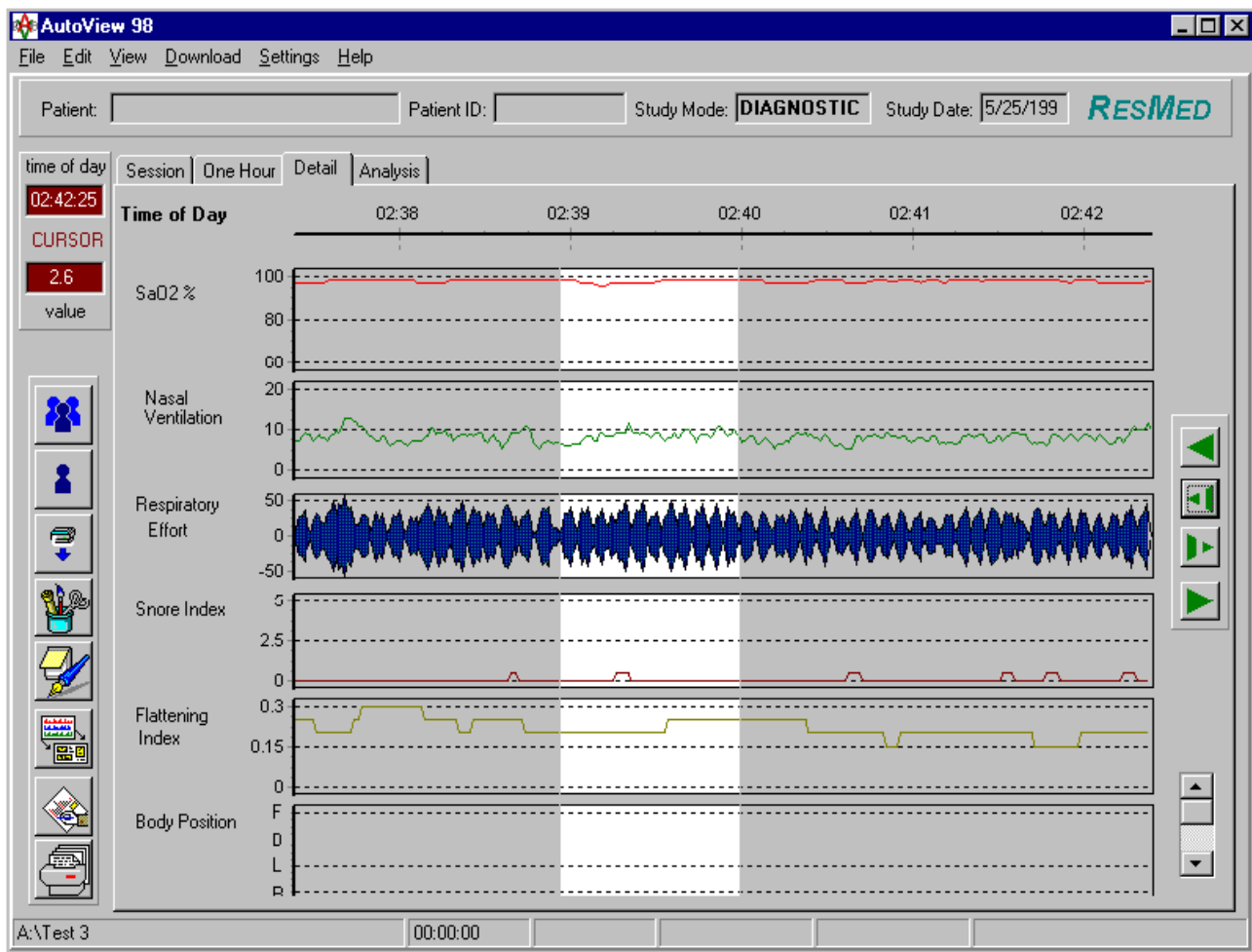


This is a study displayed in the Session (8-hour) view.

SAO ₂	The oxygen saturation is stable, remaining above 95% for the majority of the study. There are a few movement artefacts at approximately 12:30; 02:40; 06:04 and 06:50 hours.
NASAL VENTILATION	Nasal ventilation averages 10 units for most of the study, which is within normal limits.
RESPIRATORY EFFORT	Respiratory effort remains reasonably constant, with changing amplitudes in association with body position changes.
SNORE INDEX	There is significant snoring.
FLATTENING INDEX	Flattening index remains above 0.15 for almost the entire study.
APNEA DURATION	Only one apnea is logged during the entire study at approximately 06:55. This is well within normal range and would not be considered evidence of OSA.
RESPIRATORY IRREGULARITIES	Respiratory irregularities are most likely attributable to the increased ventilation associated with the benign snoring.
AHI	As only one apnea was logged for the entire study, the remaining events must be hypopneas. The Apnea Hypopnea Index is well within normal range.
HEART RATE	Heart rate remains stable. Occasional fluctuations are noticeable and can be associated with movement.

NO SLEEP DISORDERED BREATHING/ BENIGN SNORING

DETAIL VIEW



The is the Detail screen from the previous study, of a patient with no significant sleep disordered breathing.

SAO₂ SaO₂ is relatively stable.

NASAL
VENTILATION The nasal ventilation is stable.

RESPIRATORY
EFFORT A respiratory rate of 11 breaths per minute can be counted in the highlighted section, which represents stable breathing.

SNORE INDEX Snoring is below 1 unit, which is typical snoring range.

FLATTENING
INDEX The flattening index remains above 0.15 which indicates no upper airway obstruction.

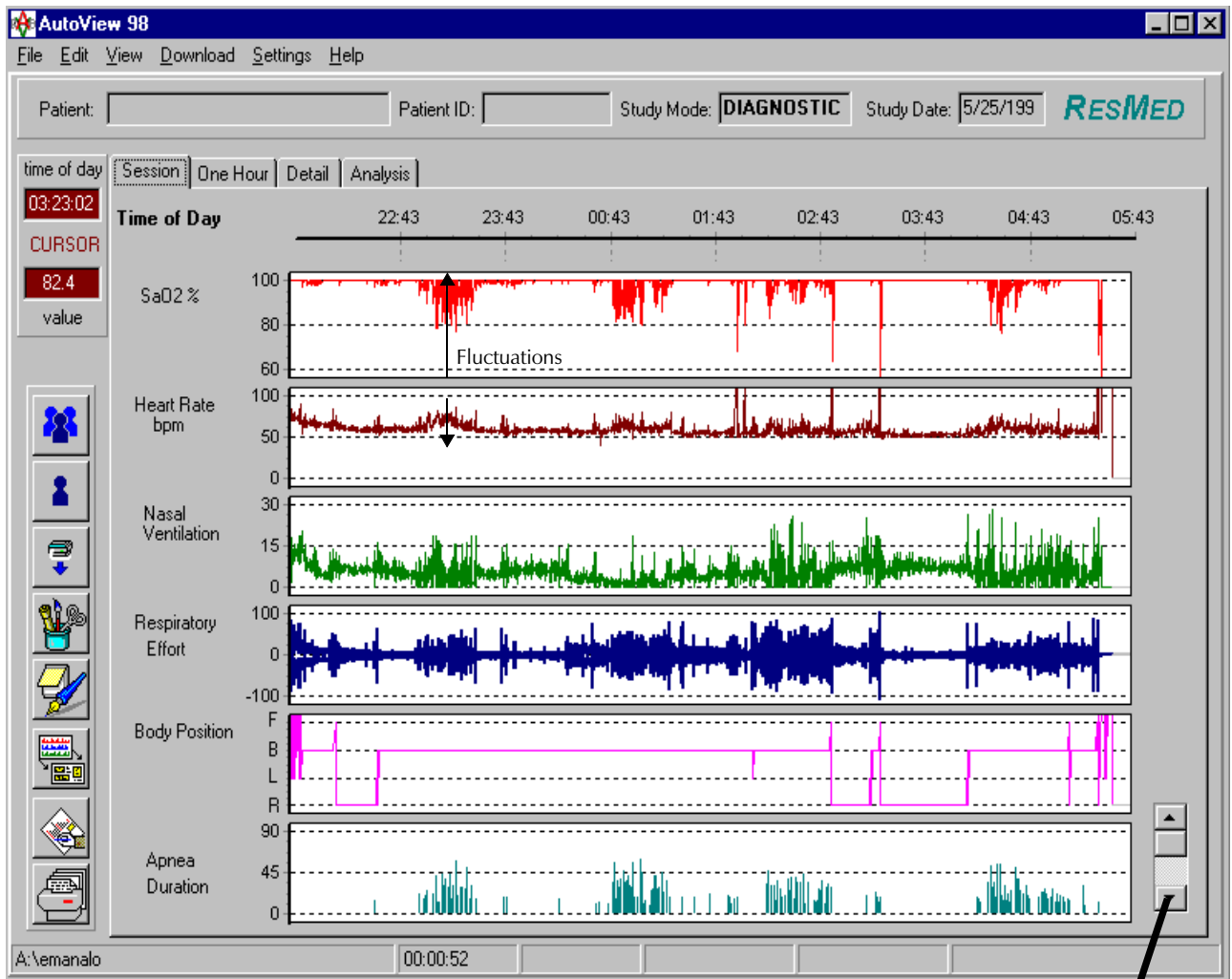
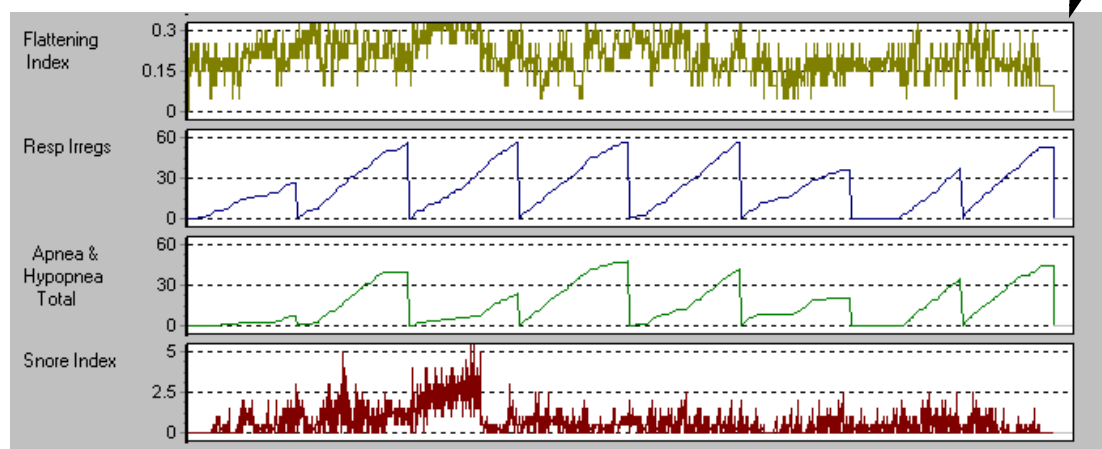
BODY POSITION There is no body movement for the entire study.

This study shows no significant sleep disordered breathing, although some benign snoring evident. This is essentially a normal study.

OBSTRUCTIVE SLEEP APNEA STUDY

NOTE

The following 10 screens have been taken from the same study.

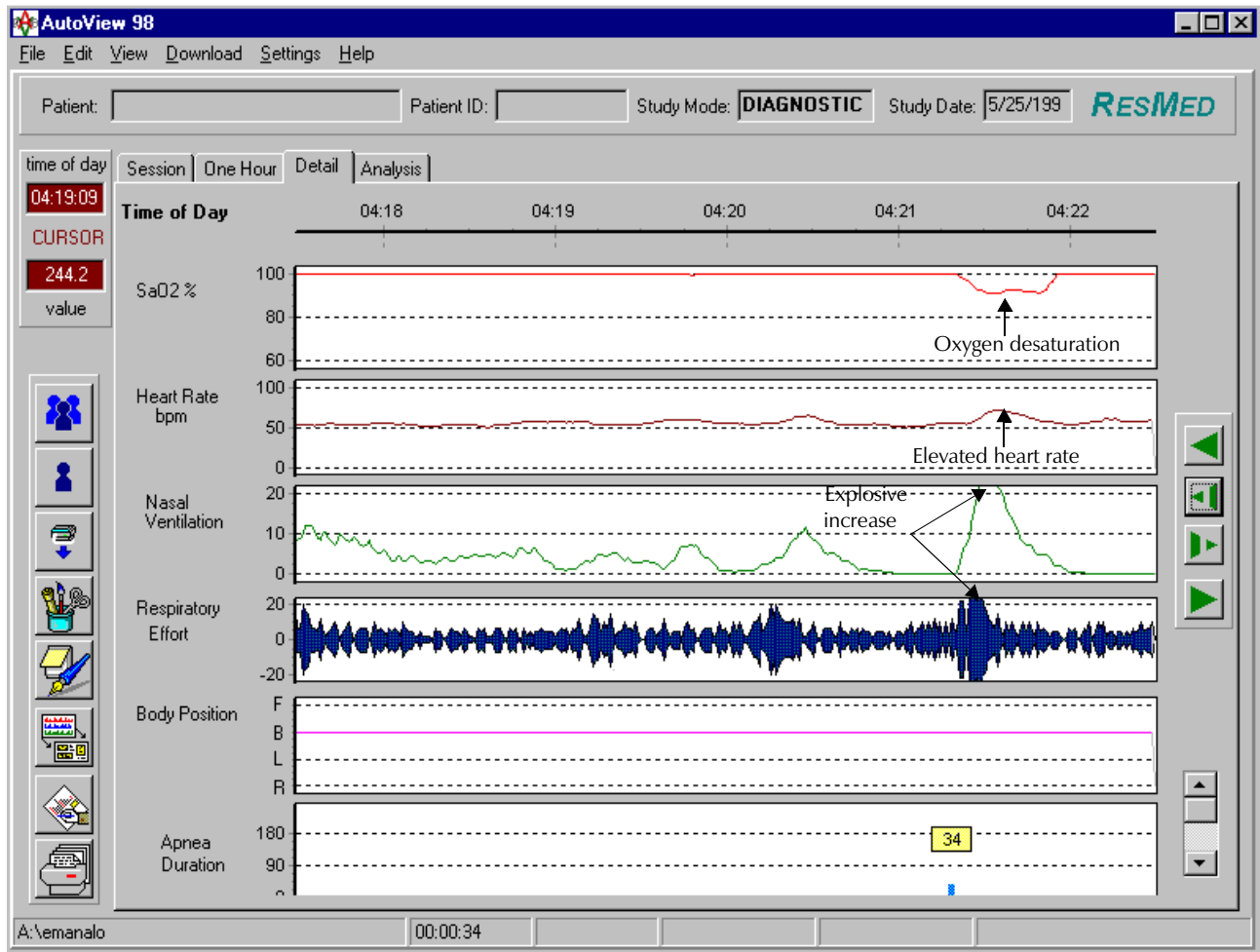


This figure shows a full study in the *Session* screen. The horizontal time scale is *Time of Day* and the meter at the upper left of the display shows the location of the cursor as *time of day*. Notice that the vertical scales of each chart have been adjusted to accommodate any extreme values taken during the session.

SAO ₂	Four significant episodes of desaturation are visible. There are also periods of stability present between the periods of desaturation. Spike desaturations at 01:50, 01:55, 02:50 and 03:15 may be artefact if similar spikes are reflected in other charts.
HEART RATE	Fluctuations in heart rate can be aligned with the four periods of spike desaturation. Note the spike artefacts duplicate the spikes in the SaO ₂ graph. Some may be related to body movement.
NASAL VENTILATION	Nasal ventilation fluctuates significantly in association with the SaO ₂ % and Heart Rate graphs. Periods of stability are also duplicated in the SaO ₂ and Heart Rate charts.
RESPIRATORY EFFORT	Fluctuations in respiratory effort mirror the graphs of SaO ₂ %, Heart Rate and Nasal Ventilation.
BODY POSITION	This patient spent most of the study in a supine position with occasional movements noted. At the beginning and end of the study significant movement is evident, suggesting wakefulness. Long periods of inactivity in the Body Position chart where desaturations are evident suggest sleep state dependence of OSA (possibly REM-associated OSA).
APNEA DURATION	Automatic analysis has been performed and apnea occurrence and duration has been charted. Periods of apnea occur in the same four periods of oxygen desaturation, and fluctuating respiratory effort, nasal ventilation and heart rate. This confirms that these apneas are legitimate.
FLATTENING INDEX	There are episodes where the flattening index is equal to or below 0.15, suggesting flow limitation.
RESPIRATORY IRREGULARITIES	Respiratory irregularities are elevated in association with apneas, hypopneas and snoring.
AHI	Apnea Hypopnea Index averages 30 events per hour, which is associated with significant OSA.
SNORE INDEX	The patient exhibits continuous loud to very loud snoring. Looking at the study in its entirety allows you to zoom in on periods where readings fluctuate, indicating possible abnormalities.

OBSTRUCTIVE SLEEP APNEA STUDY

DETAIL SCREEN



This figure depicts a *Detail* section of five minutes duration toward the end of the session.

The vertical scales have been adjusted for the Respiratory Effort, Nasal Ventilation and SaO₂ charts to enhance the pattern.

SAO₂ SaO₂ exhibits stability until 04:21 where a significant desaturation occurs.

HEART RATE Heart rate fluctuates down to 50bpm during the apnea at 04:21 and elevates during the explosive ventilation at the end of the event.

NASAL VENTILATION Nasal ventilation drops to zero at 04:21 and rises explosively, marking the termination of the event.

RESPIRATORY EFFORT Respiratory effort is reduced concurrently with the drop in nasal ventilation and explosively increases at the end of the event.

BODY POSITION The *Body Position* chart shows no gross movement, the patient remaining on their back.

APNEA DURATION An apnea, which lasts 34 seconds is shown. The changes in the SaO₂, Heart Rate, Nasal Ventilation and Respiratory Effort are associated with this apnea.

OTHER FEATURES When this screen was captured, the cursor was resting at the top of the logged apnea. The meter shown shows the measurement function of the mouse, and confirms the duration of the apnea.

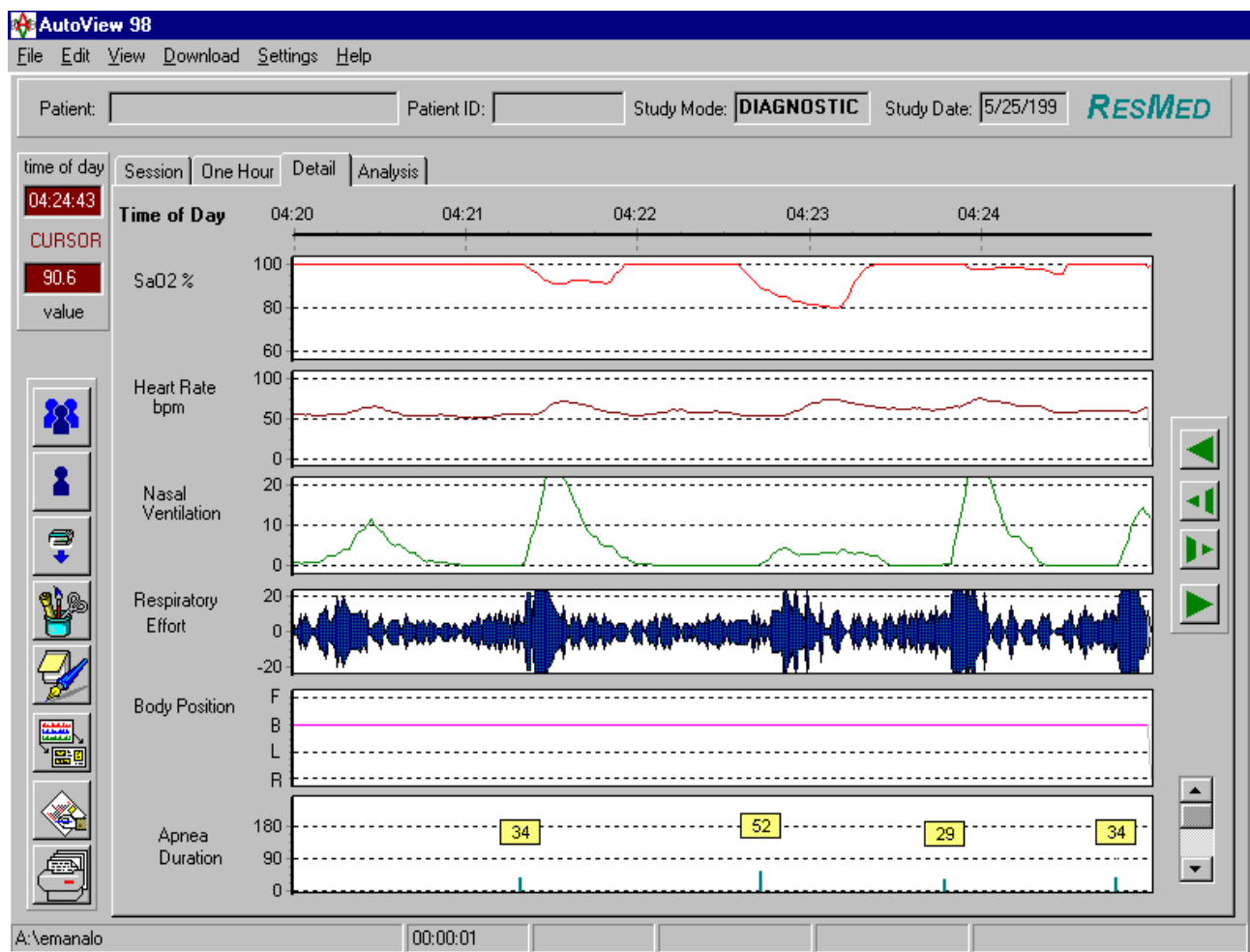
The key observation in this figure is that during a 34 second period where nasal ventilation approaches zero, respiratory effort recognizably continues. At the point where the apnea terminates, respiratory effort and ventilation increases explosively. There is also a desaturation associated with the event. These are the features of an obstructive apnea.

NOTE



You have the option of printing the study data in a number of report formats. The printed reports should be examined and interpreted in the same manner as described in this section. Refer to "AutoView Reports" on page 8, for information about how to printing study data.

OBSTRUCTIVE SLEEP APNEA STUDY -
DETAIL SCREEN ADVANCED HALF A PAGE



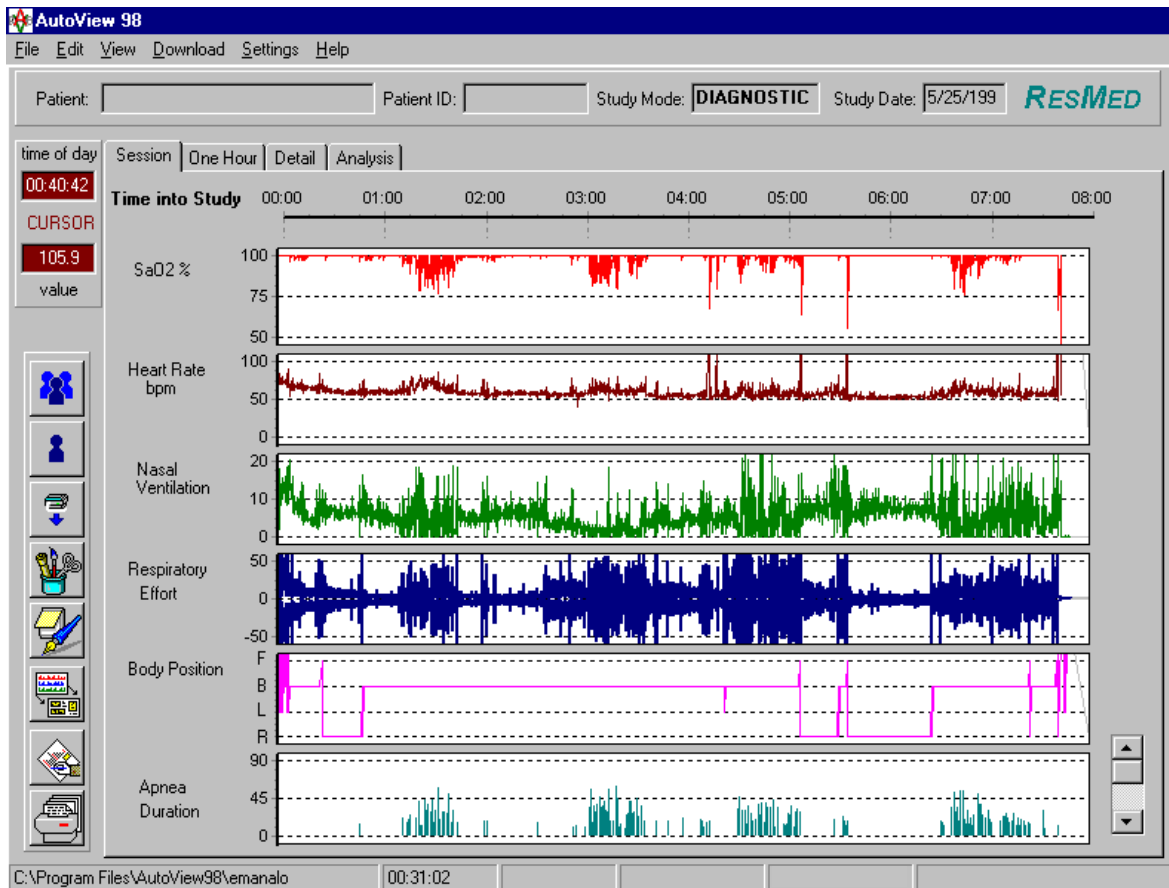
This figure shows the same data advanced one half-page from the previous figure.

SAO ₂	Desaturates to 80% in response to four apneas logged.
HEART RATE	Changes in heart rate are attributable to the apneas logged and the fluctuations in the breathing effort.
NASAL VENTILATION	The signal fluctuates significantly. The zero readings indicate no ventilation and total obstruction of the airway. They are followed by explosive increases to over 20. This signal reading is suggestive of obstructive apnea.
RESPIRATORY EFFORT	Fluctuations in this signal also confirm that the apneas are obstructive as there is continued respiratory effort without nasal ventilation.
BODY POSITION	Body position chart remains unchanged in the supine position.
APNEA DURATION	The scale of the graph has been automatically expanded to accommodate the labelling for each apnea. The same 34 second apnea is shown in this screen along with 3 other apneas. The duration of each apnea is recorded in the yellow box above the graphed event. The same types of changes in the graphs occur for each period of apnea.

This is a typical example of obstructive sleep apnea.

MOVEMENT ARTEFACTS

The next five examples detail the process of deciphering artefacts from legitimate data, and how to remove these artefacts from the final analysis statistics.



This figure shows the horizontal time scale configured as *Time into Study*, and subdivisions into one hour segments. To change the horizontal time scale, position the cursor over the text and right click the mouse. You can choose *Time into Study* or *Time of Day*. The cursor position meter always shows *time of day*.

SAO₂ In the fifth and sixth hours of the study there are four extraordinary desaturations.

HEART RATE The four spikes in the heart rate chart in the fifth and sixth hours of the study mirror similar excursions in the SaO₂ chart.

BODY POSITION The body position chart exhibits examples of gross body movement as demonstrated in the fifth and sixth hours.

Three of the four extraordinary events in the *SaO₂* and *Heart Rate* charts (which are derived from the same sensor), coincide with three gross movements in the *Body Position* chart in the same time period. This is a good indication that these spikes may be artefacts. However, closer inspection of these events is recommended before removing them from the study.

MOVEMENT ARTEFACTS

ONE HOUR SCREEN



This figure shows the *One Hour* page used to inspect two periods of movement that have effected the other charts in the study.

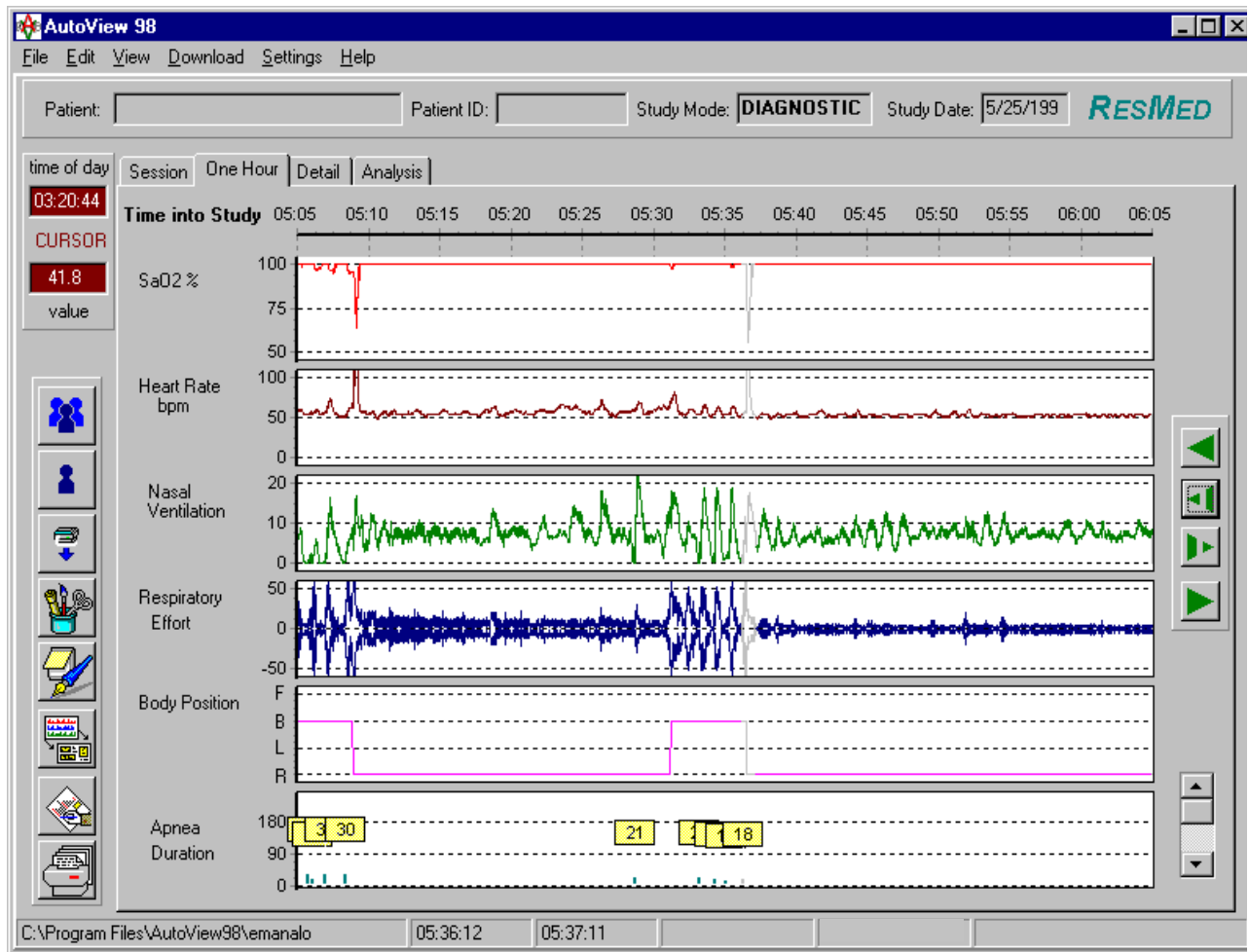
SaO₂ Two significant desaturations below 70% are clearly evident at 05:08 and 5:37.

HEART RATE Two high elevations in the Heart Rate chart to above 100 bpm align with the two significant desaturations in the SaO₂ chart.

BODY POSITION Three changes in body position are evident. The movements at 05:08 and 05:37 coincide with desaturations in the SaO₂ and fluctuations in the Heart Rate chart. These fluctuations are clearly attributable to the change in the patient's body position and may be dismissed as artefact. However, the movement at 05:31 did not result in artefact spikes in SaO₂ or Heart Rate.

APNEA DURATION In the period of the study shown, 16 apneas have been logged. Two of these apneas appear to occur at the same time as the body position changes, which may have caused fluctuations in SaO₂ and Heart Rate.

USING THE BLOCKOUT FEATURE ON MOVEMENT ARTEFACTS



59 seconds

Blockout is a feature of AutoView 98 that allows you to “remove” or “exclude” artefacts from the study analysis.

To use this feature, position the cursor over the artefact, hold the CTRL button and the left mouse button while dragging across the artefacts from left to right. To remove the blockout, hold the CTRL and left mouse button again, and drag from right to left.

NOTE



For more information on using the AutoView software, please refer to the PII Plus Clinical Manual.

SAO₂

The desaturation at 05:37 has been blocked out. Note that blocking out the event on one chart, blocks out the same time period in all charts.

APNEA DURATION

The 18-second apnea has been blocked out.

OTHER FEATURES

The two meters in the lower bar show the period (*ie. 59 seconds*) that has been blocked out. These meters use the same configuration as the horizontal time scale (*ie. Time of Day or Time into Study*).

IMPORTANT

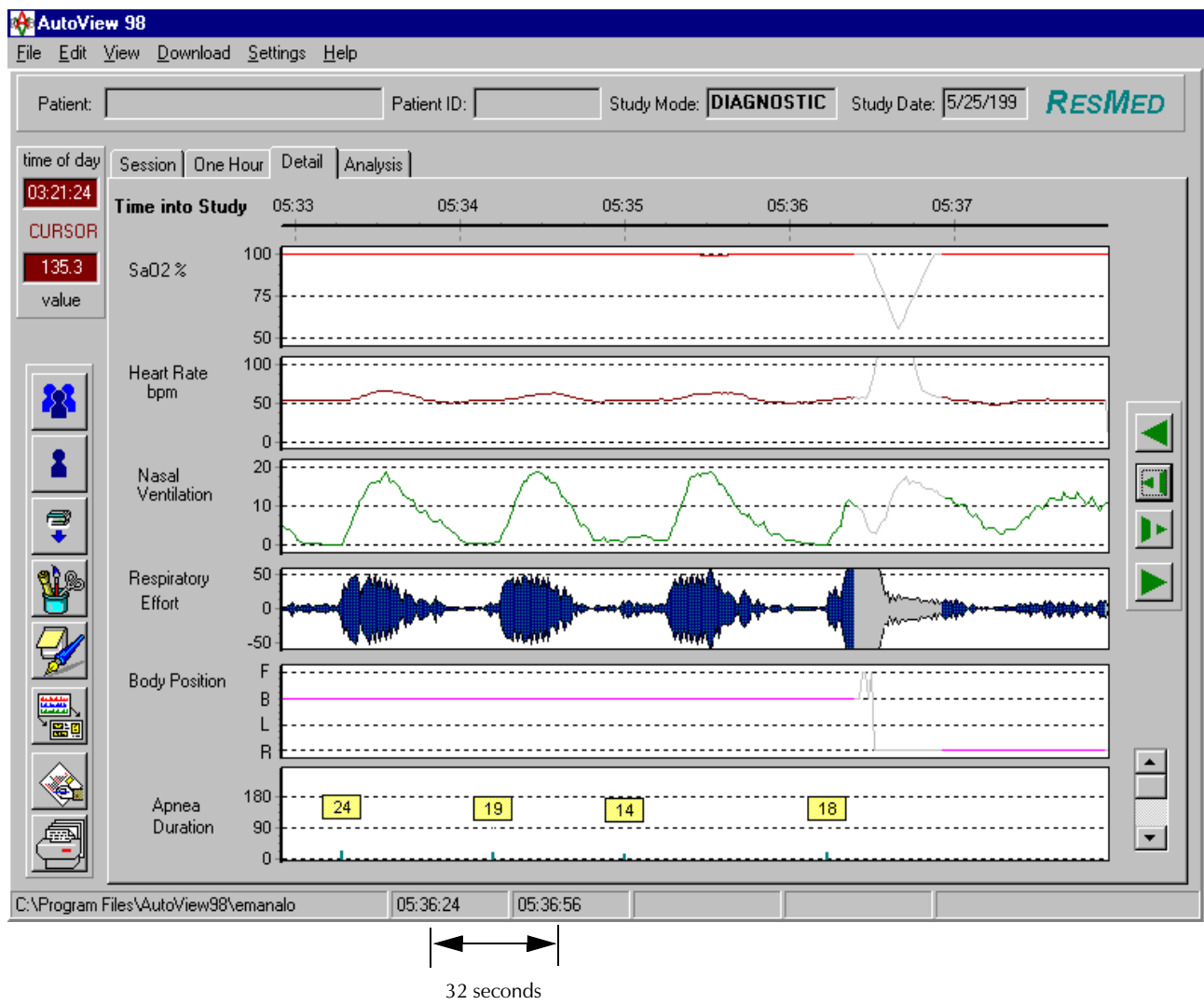


Using the blockout feature of AutoView while in the one hour time scale is generally not advisable as the time frame may be too large to mask discretely. You should perform a close examination of the data before excluding recorded information. Moving to the 5 minute detail screen to blockout artefacts is more accurate.

Also, changing the SaO₂ to a range of 0 to 100 and viewing the study in its entirety ensures that all desaturations and falls to zero (*ie. at the end of the study*) can be examined and blocked out if necessary.

BLOCKING OUT MOVEMENT ARTEFACTS

DETAIL SCREEN



This figure shows the artefact data at 05:37 of the previous study, in the *Detail* screen.

SAO₂ The desaturation between 05:36 and 05:37 has been blocked out.

HEART RATE Blocking out the SaO₂ fact has blocked out the spike in the heart rate at the same time.

APNEA DURATION Note that blocking out the artefact data in the Detail screen leaves the 18 second apnea unblocked.

OTHER FEATURES The two time meters in the lower bar show the period (*ie. 32 seconds*) which has been blocked out. Examining the study in the Detail screen clearly shows that the 18-second apnea is not related to the fluctuations in the SaO₂, Heart Rate, Nasal Ventilation, and Respiratory Effort caused by the change in body position.

NOTE



The Detail screen is particularly useful for blocking out artefacts precisely without removing genuine, clinically significant events.

ANALYSIS SCREEN

DIAGNOSTIC MODE

AutoView 98

File Edit View Download Settings Help

Patient:

Patient ID:

Study Mode: **DIAGNOSTIC**

Study Date: **RESMED**

time of day
02:57:09
CURSOR
104.1
value

Manual Scoring

Unclassified

Obstructive

Central

Mixed

Hypopnea

Artefact

Totals

rate/hr

16800000

21.5 /hr0.0 /hr0.0 /hr0.0 /hr0.0 /hr0.0 /hr

Body Position - % time

Back

Right

Left

Front

77 %21 %2 %0 %

Oximetry

time less than

% SaO2 for

% time

957

852

751

651

MINIMUM SaO2:

0 %

Flattening Index

% time less than

for

% time

0.1511

0.102

Apneas

Total

Back

Right

Left

Front

Ap/Hypop Index /hr

Apnea Index /hr

AHI per Body Position

3432100

Respiratory Irreg Index /hr

49

Save Analysis

Set Specs

Manual Score

Analyze

C:\Program Files\AutoView98\veranalo

05:37:50

05:33:53

50

ResMed Corp. - Ex. 1026
Page 56

This figure shows the *Analysis* page from a diagnostic study.

MANUAL SCORING	Manual Scoring has not been performed as the classification fields still display at 0. A total of 168 apneas in the session are noted as unclassified. The rate/hour is the number of events per hour and is rounded up or down according to the duration of the study.
OXIMETRY	The percentage of time below given oxygen levels are thresholds values. The minimum SaO ₂ is shown as 0%. This may be due to artefact desaturations which have not been blocked out.
APNEAS	The apnea indices represent the PII Plus analysis and do not alter when manual classification/ scoring is performed. For manual score statistics, refer to the indices in the manual score box only. The Apnea Index/hr should be equal to the sum of the rate/hr fields in the Manual Scoring box.

ANALYSIS SCREEN AFTER BLOCKOUT

AutoView 98
File Edit View Download Settings Help

Patient: _____ Patient ID: _____ Study Mode: **DIAGNOSTIC** Study Date: 5/25/199 **RESMED**

time of day **23:47:10**
CURSOR
101.3
value

Session | One Hour | Detail | Analysis |

Manual Scoring

	Unclassified	Obstructive	Central	Mixed	Hypopnea	Artefact
Totals	164	0	0	0	0	0
rate/hr	22.4 /hr	0.0 /hr	0.0 /hr	0.0 /hr	0.0 /hr	0.0 /hr

Body Position - % time

Back	Right	Left	Front
81 %	19 %	0 %	0 %

Oximetry

time less than	% SaO2 for	% time
95	6	
90	3	
80	0	
70	0	

MINIMUM SaO2: 68 %

Flattening Index

% time less than	for	% time
0.20	63	
0.15	9	

Apneas

Total	Back	Right	Left	Front
Ap/Hypop Index /hr 34	33	1	0	0
Apnea Index /hr 22	AHI per Body Position			

Respiratory Irreg Index /hr 50

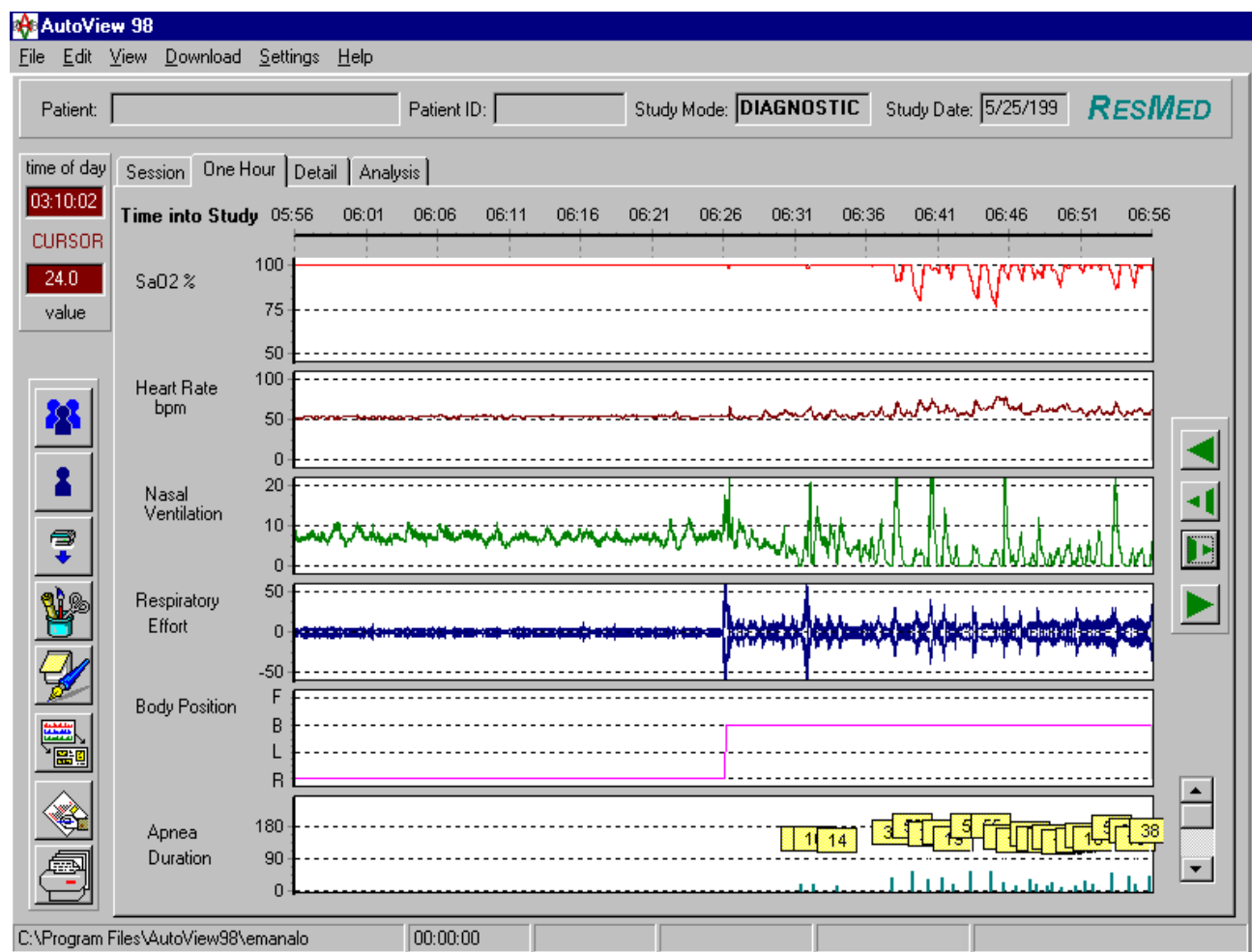
Save Analysis
Set Specs
Manual Score Analyze

C:\Program Files\AutoView98\emanalo 05:08:00 05:15:54

MANUAL SCORING	Apneas now considered relevant total 164 as masking artefacts has removed 4 apneas. Manual scoring has not been performed. The apnea indices have also altered as a result of masking.
OXIMETRY	Threshold values (in red) have been altered using <i>Set Specs</i> . The minimum SaO ₂ shown is now 68% as masking has removed artefacts that extended beyond the scale in the previous example.
APNEAS	Apnea indices have been amended due to the removal of artefact data. The Respiratory Irregularities index has also been increased due to a reduction of the total study after using the blackout feature.
FLATTENING INDEX	<p>Threshold values (in blue) for the <i>Flattening Index</i> have been altered using <i>Set Specs</i>.</p> <p>Using the One-hour and Detail representations of the study allows you to characterize individual events from a session. Data masking improves the accuracy and relevance of the analysis to the character and severity of the sleep related breathing disorder.</p>

MOVEMENT ARTEFACTS

ONE HOUR SCREEN

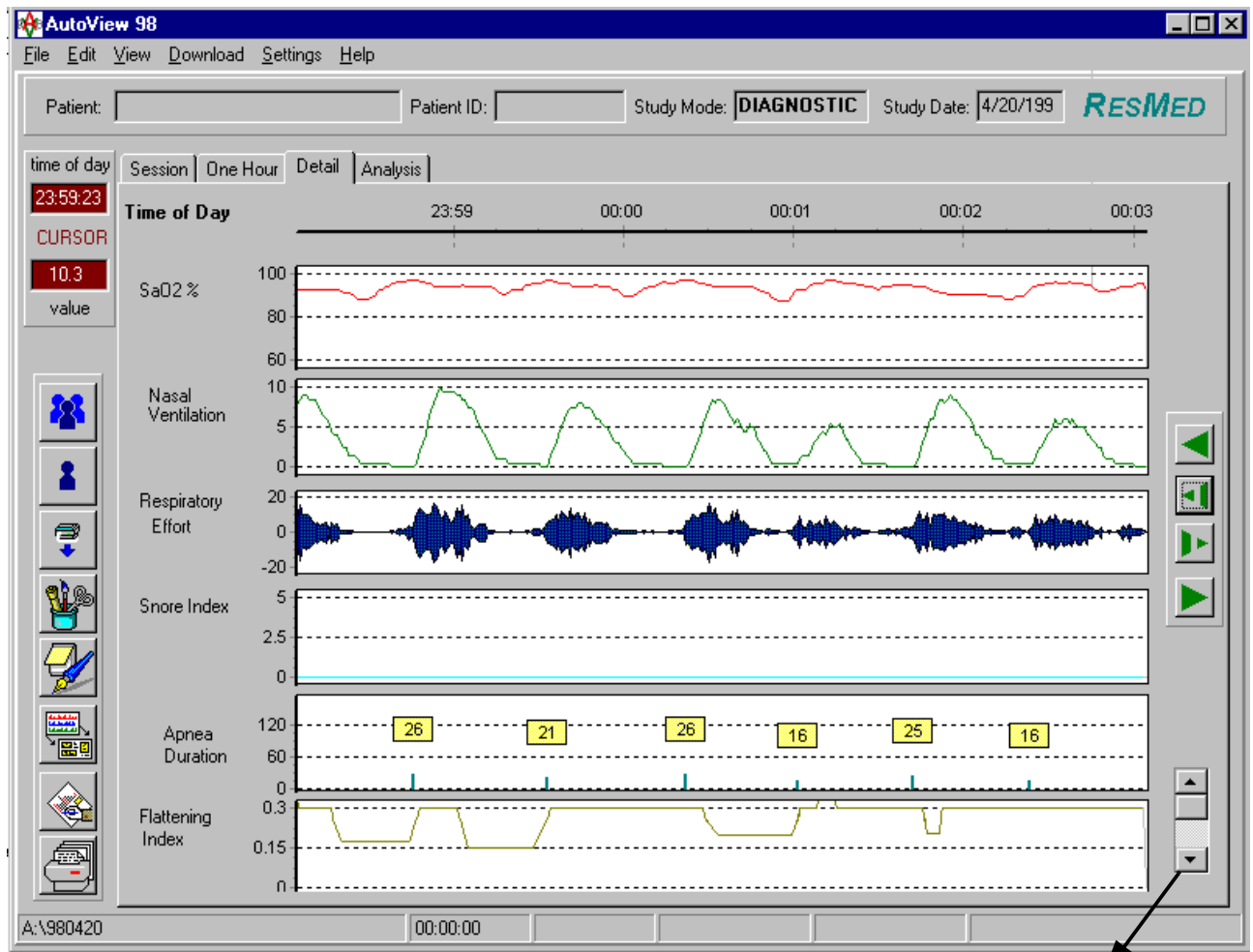
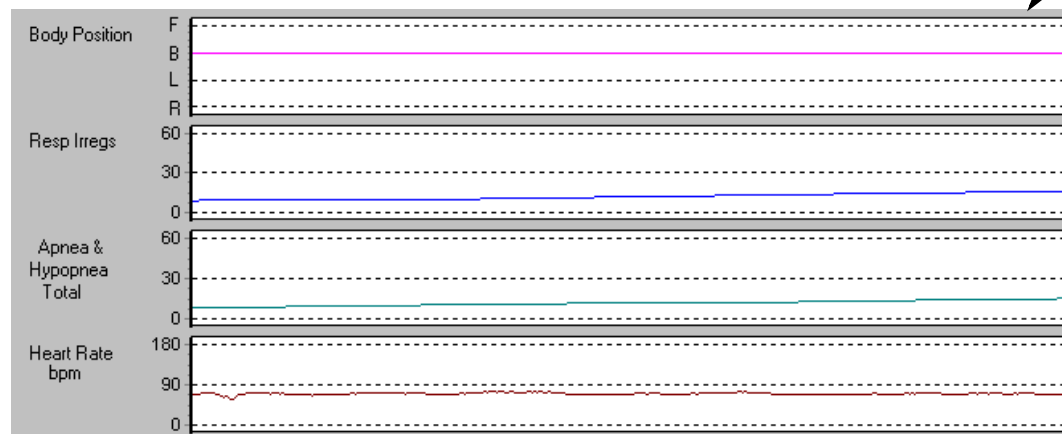


In this figure, the *One Hour* page has been selected to view a single change shown in the *Body Position* chart during the seventh hour of the study.

SAO ₂	SaO ₂ remains stable until 06:26, when periods of desaturation become evident.
HEART RATE	The heart rate trace presents a similar pattern to the SaO ₂ chart, showing stability until 06:26 then increasing amounts of fluctuation.
NASAL VENTILATION	The ventilation signal reflects the patterns of the heart rate and SaO ₂ charts. A stable signal is recorded until 06:26, after which large fluctuations are present.
RESPIRATORY EFFORT	The pattern of the SaO ₂ , heart rate, and nasal ventilation is again repeated in the respiratory effort chart.
BODY POSITION	<p>Examination of the body position chart shows the reason for the change in the SaO₂, heart rate, heart rate, and nasal ventilation signals. At 06:26 the patient moves to a supine position</p> <p>The period following the movement shows onset of repetitive fluctuation in the <i>Respiratory Effort</i> and <i>Nasal Ventilation</i> charts, repetitive apneas, and repetitive desaturations, associated with supine (back position) sleep.</p> <p>Although apneas and oxygen desaturations are evident after the position change, this is not positional OSA as the patient does sleep for periods on his/her back without apneas or desaturations. The patient's sleep disorder is more likely to be REM-associated OSA.</p> <p>This highlights the importance of inspecting the entire study in the session screen initially, and then using the finer resolution to inspect the data in greater detail.</p> <p>The early part of this page is useful for arriving at a baseline for the pattern of <i>Respiratory Effort and Nasal Ventilation</i> during quiet breathing in this study.</p>

MIXED APNEA STUDY

DETAIL SCREEN



A mixed apnea event is characterized by a central and an obstructive component. This figure is the Detail screen from a diagnostic study.

SAO₂ Cyclic oxygen desaturations are evident.

NASAL
VENTILATION The nasal ventilation fluctuates dramatically, dropping to 0.

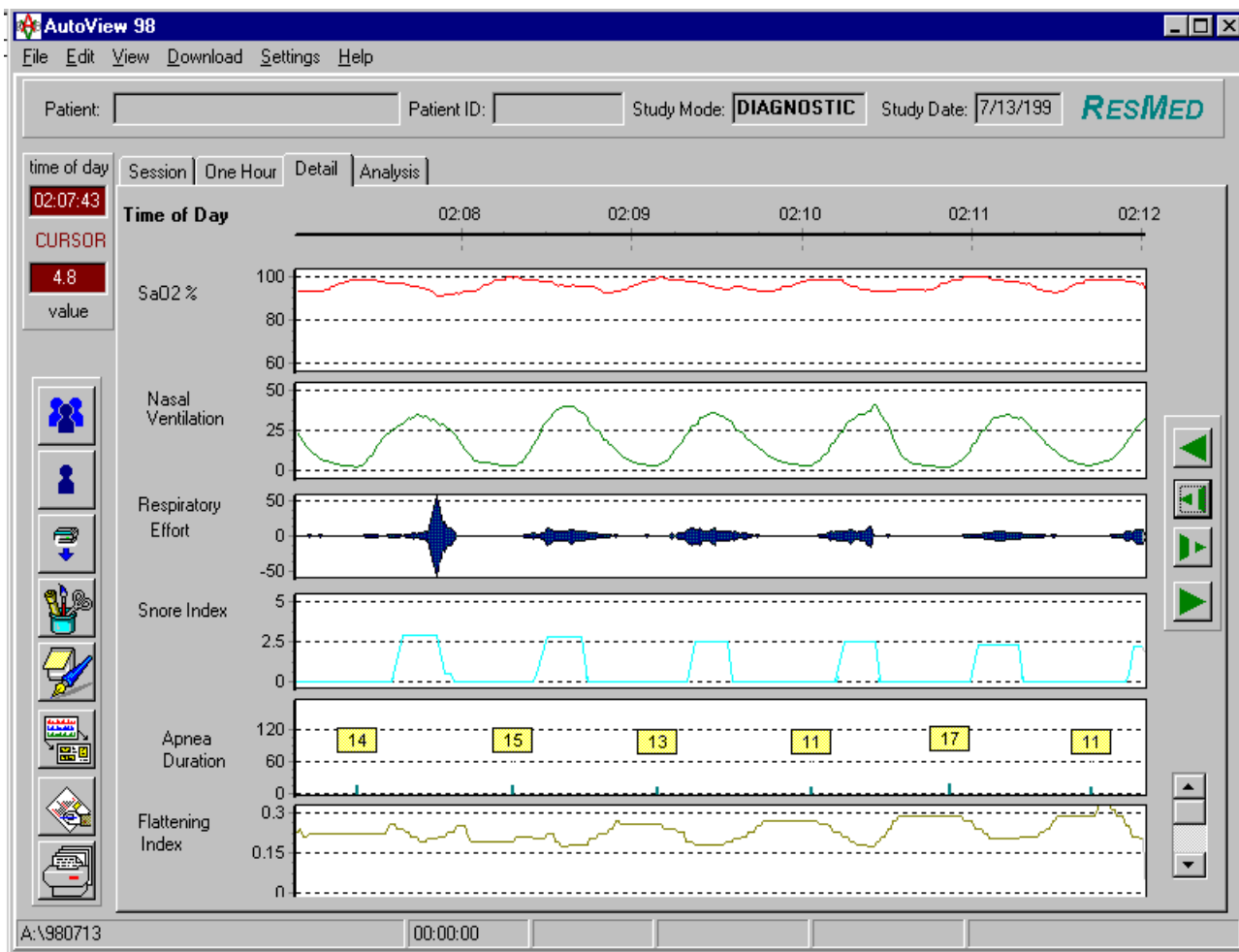
RESPIRATORY
EFFORT Respiratory effort shows waxing and waning. There are periods, with apneas occurring, where no effort is evident (flat line - central component) alternating with bursts of effort. This is suggestive of *classic mixed apnea*, as the return of effort occurs before the return of ventilation and the termination of the apnea.

APNEA DURATION The termination of each apnea is recorded at the start of each explosive breathing effort and nasal ventilation.

FLATTENING
INDEX Flattening index lowers to 0.15 on one occasion, remaining above 0.15 for most of the period displayed.

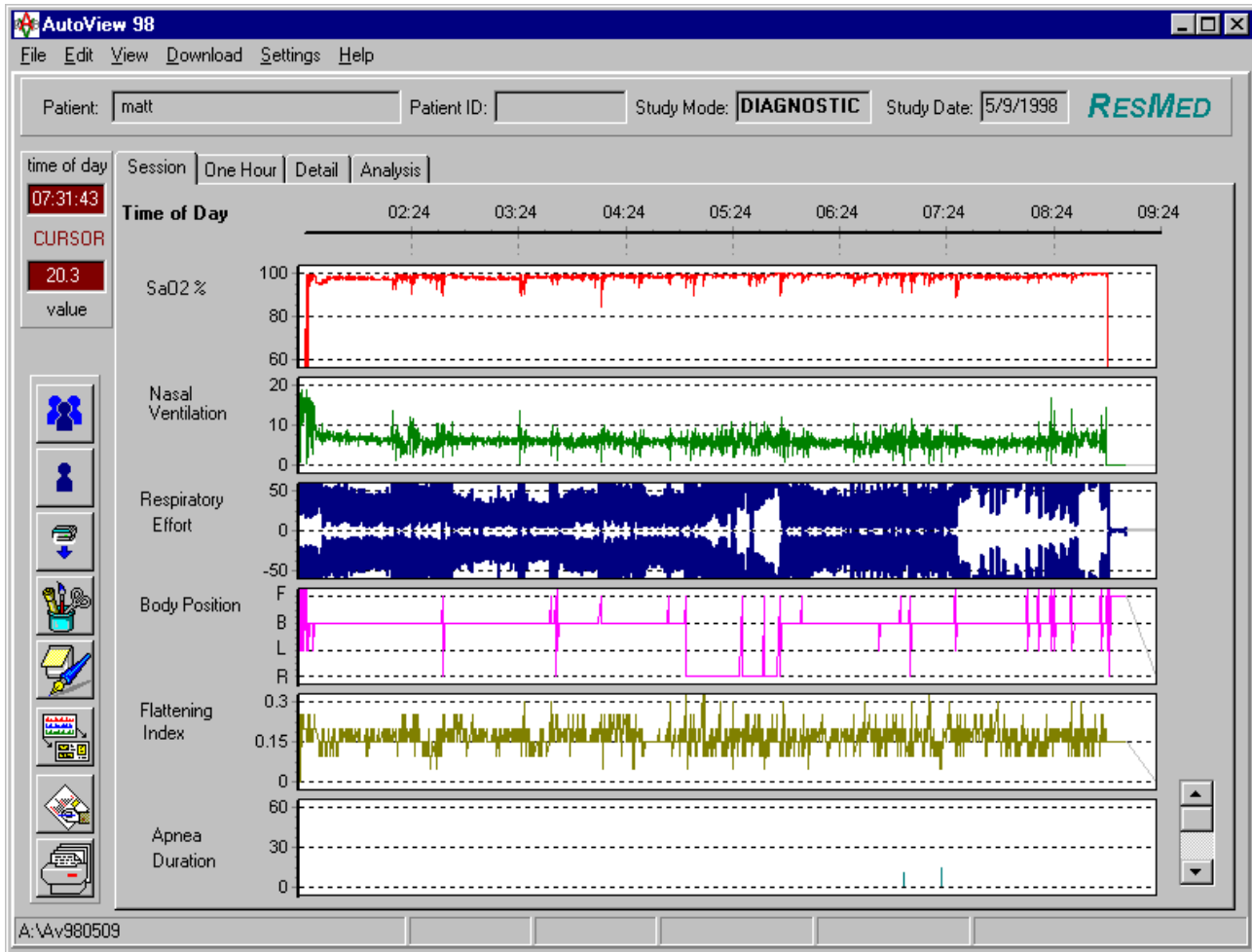
CENTRAL APNEA STUDY

DETAIL SCREEN



SAO2	Cyclic desaturations are evident.
NASAL VENTILATION	Nasal ventilation shows periodic variations. There are episodes of dramatic increase, reaching 40, and episodes of severe reduction, where nasal ventilation drops below 5.
RESPIRATORY EFFORT	Respiratory effort reveals lengthy episodes of virtually no effort at all and then bursts of activity. Note the lack of respiratory effort at 02:08. This example suggests <i>classic central apnea</i> .
SNORE INDEX	Snore index shows very loud snoring correlating with the increase in nasal ventilation and respiratory effort.
APNEA DURATION	Apnea duration values are marked at the termination of each event.
FLATTENING INDEX	There are fluctuations in this index in association with logged apneas. The signal remains above 0.15 as these events are primarily central, not obstructive.

RESPIRATORY EFFORT



This example depicts an entire study session. The unusual traces present in the Respiratory Effort and Body Position charts required close examination.

RESPIRATORY EFFORT

There are areas where respiratory effort trace seems to “split”, particularly at 05:30 and 07:30. The mirror image of the respiratory band appears to be moving apart and away from the baseline. This problem occurs if the respiratory band has moved on the patient or has loosened. Both the scale and detail of the picture must be altered. This is best done in the Detail screen.

BODY POSITION

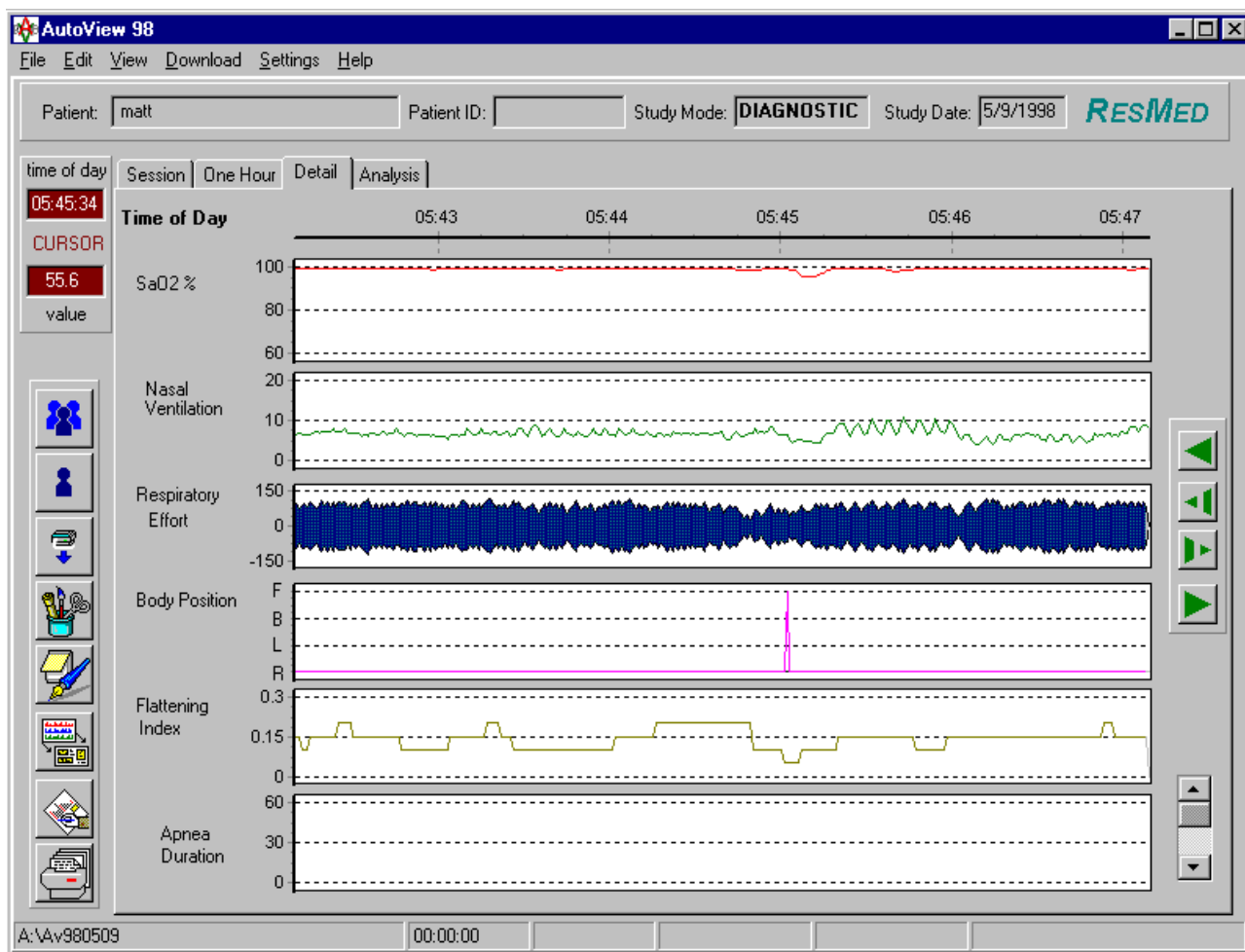
The body position chart depicts invalid positions, particularly at the start of the study and between 08:15 to 08:45. The graph shows movement above the “F”, for front position. This most commonly occurs if the patient stands or sits upright or moves quickly during a recording or during the course of any position change. However, the sensor quickly reverts back to a valid position.

If the sensor remained in an invalid position, it could indicate that the patient had elevated his/her position with extra pillows, the sensor may need to be checked or it may have been incorrectly applied.

It is imperative that patients understand how to position and tighten the band correctly if they need to reapply it during the study.

RESPIRATORY EFFORT

DETAIL SCREEN



The same study from the previous example is shown in the Detail screen. A number of modifications have been made to the study to make the data easier to interpret.

RESPIRATORY
EFFORT

The respiratory effort scale has been altered from 0-50 to 0-150. Effort is now clearer to interpret and shows stable breathing.

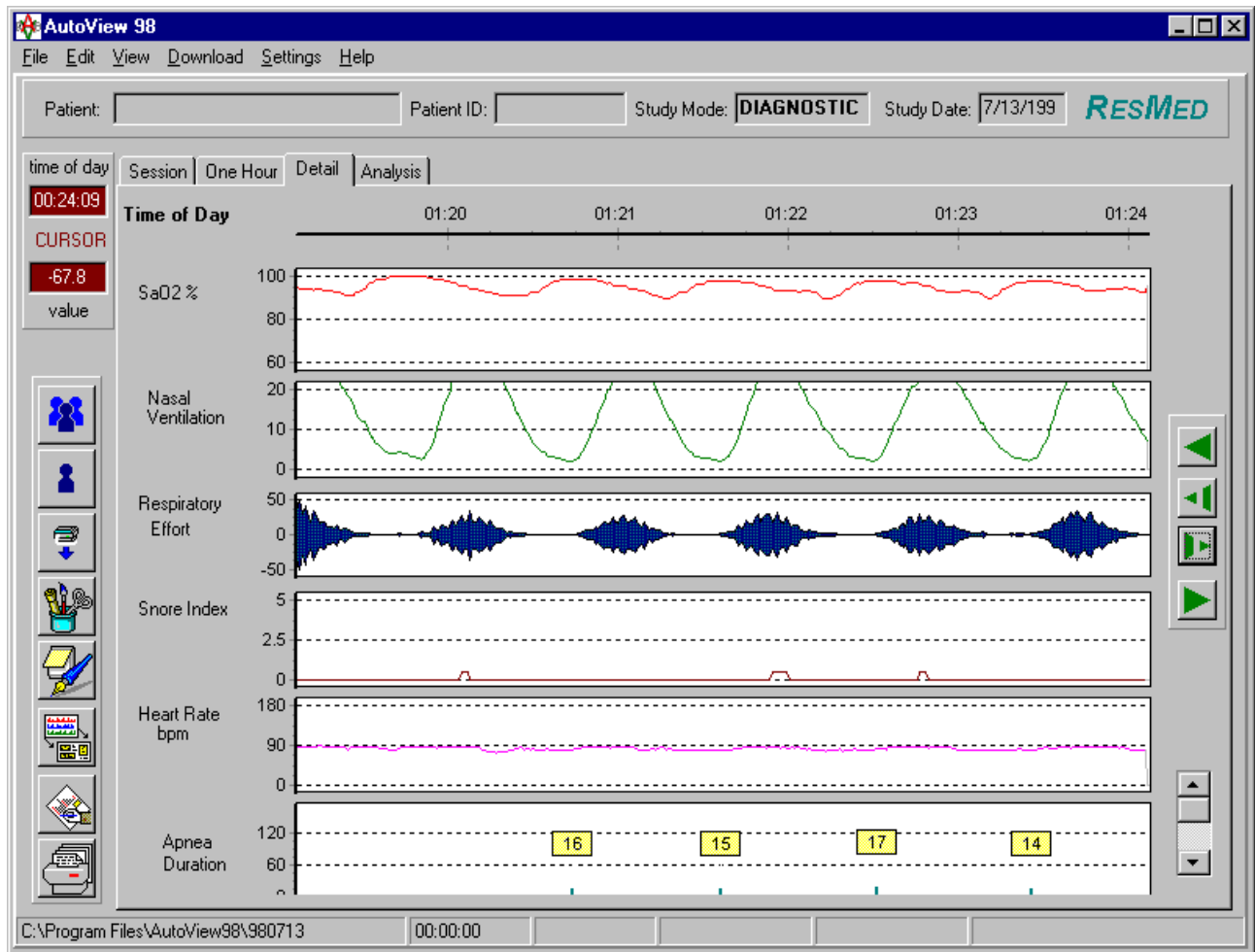
BODY POSITION

The body position chart shows one brief, gross movement at 05:45, which is expected in normal sleep.

FLATTENING
INDEX

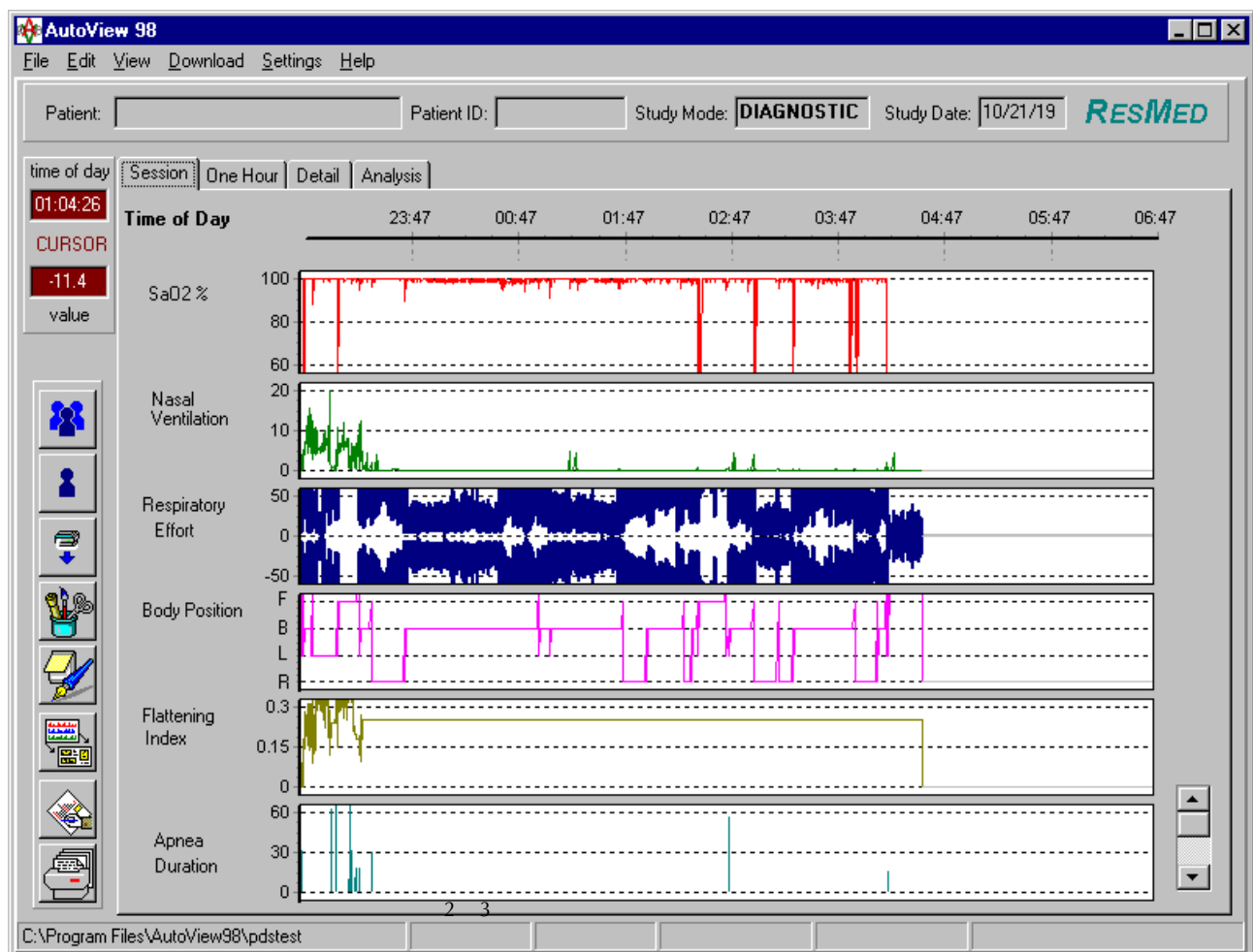
Subtle air flow limitation, at slightly below 0.15 is present. However, this is not significant enough to cause apneas.

CHEYNE-STOKES STUDY



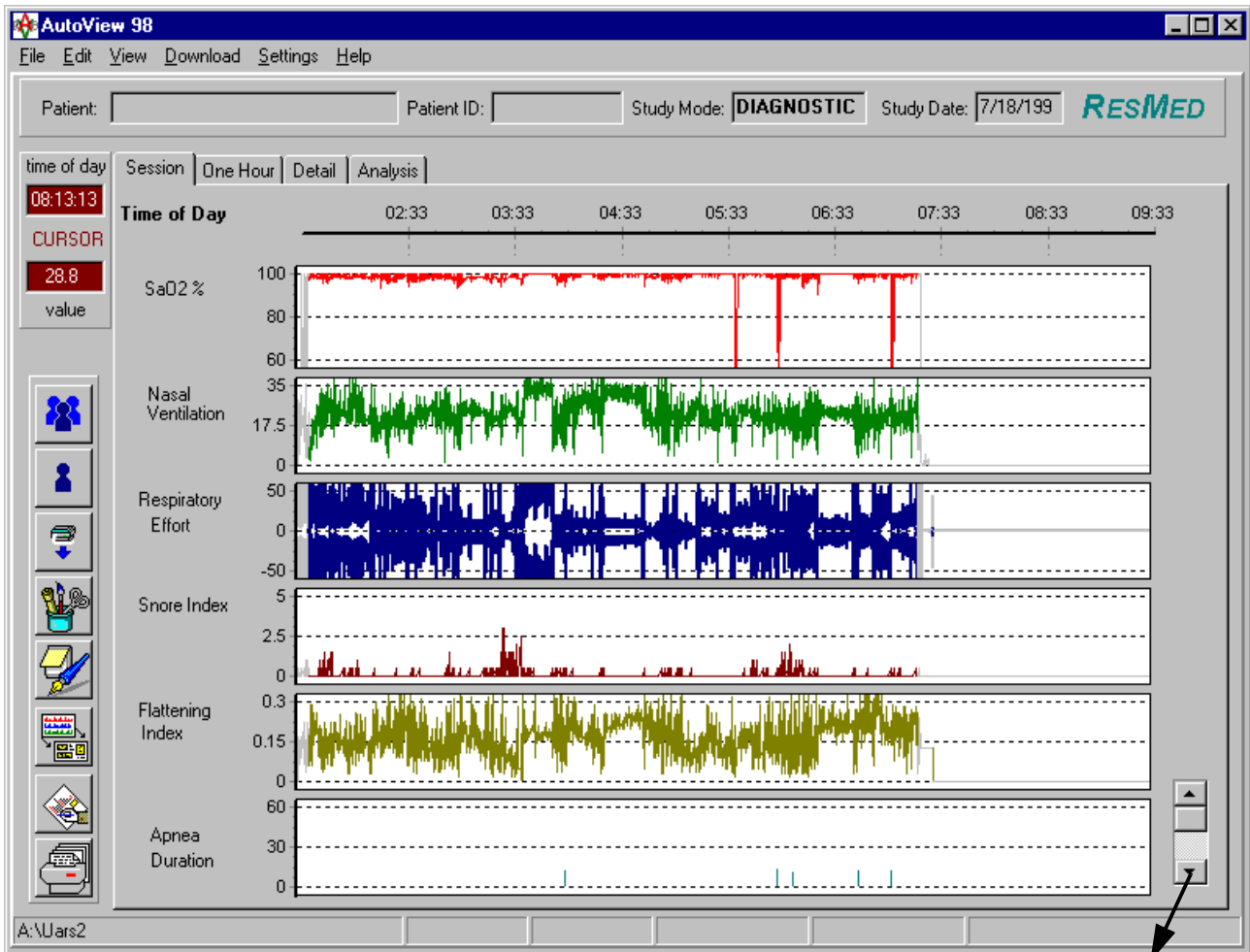
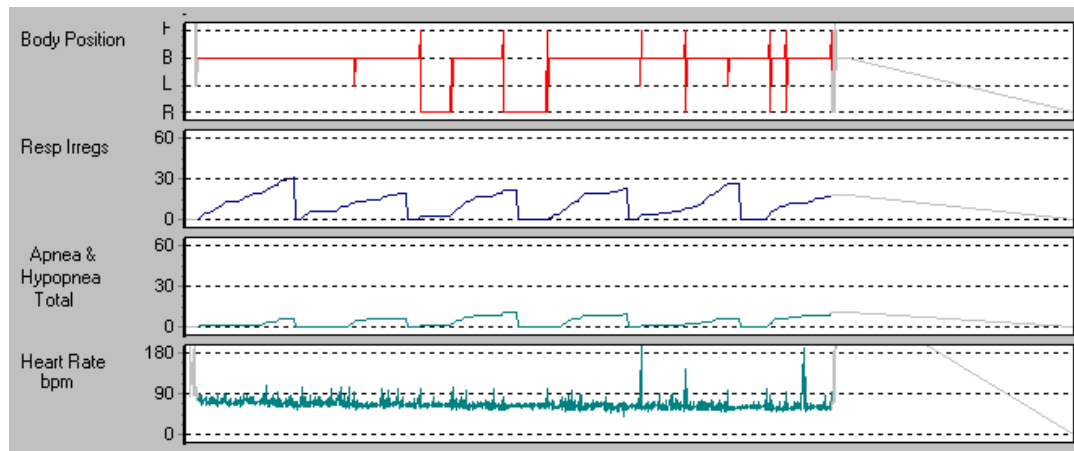
SAO ₂	Fluctuations in SaO ₂ are evident, with desaturations to 88%.
NASAL VENTILATION	There are significant variations in the nasal ventilation signal, although it does not reach zero.
RESPIRATORY EFFORT	The waxing and waning pattern of the respiratory effort mirrors the increase and decrease in nasal ventilation. The crescendo-decrescendo pattern in the respiratory effort trace, which forms a distinctive 'diamond' shape, is typical of Cheyne-Stokes Breathing. Note also in this example there is a central component following each decrescendo, indicated by the 'flat line' effect.
SNORE INDEX	Mild snoring is present at the peak of the respiratory effort.
HEART RATE	The heart rate trace fluctuates in association with the respiratory events and the oxygen desaturations.
APNEA DURATION	Apneas are marked at the termination of each event. The distinctive crescendo/decrescendo pattern is typical of Cheyne-Stokes breathing (see "Cheyne-Stokes Respirations" on page 87).

POOR QUALITY STUDY



SAO ₂	Frequent SaO ₂ spike artefacts which appear to be attributed to body movement.
NASAL VENTILATION	Nasal ventilation is evident for only 30-40 minutes at the beginning of the study - the nasal cannula has most likely been dislodged.
RESPIRATORY EFFORT	Respiratory effort is evident and reveals periods of stable breathing.
BODY POSITION	The frequent body position changes suggest restlessness. The spikes in the SaO ₂ graph can be attributed to some of the movements in this chart.
FLATTENING INDEX	Note the flattening index has ceased to function correctly - a further indication that the nasal cannula had become dislodged.
APNEA DURATION	<p>The abnormally long apneas logged are associated with cessation of nasal ventilation, again due to the dislodged nasal cannula.</p> <p>Only a minor amount of the data collected is clinically usable and the study should be discarded and repeated. The absence of usable data suggests that the patient was either non-compliant or further instruction about how to apply the sensor and what they are used for is required. Perhaps the nasal cannula could be secured with tape and further reassurance to the patient regarding the study and equipment could reduce the restlessness noted in this study.</p>

UPPER AIRWAY RESISTANCE SYNDROME (UARS) OR RESPIRATORY EFFORT RELATED AROUSALS (RERAs)



SAO ₂	Oxygen saturation exhibits 5 artefacts related to gross movement. They should be removed from the final analysis of the study. For most of the study, SaO ₂ remains ≥90%.
NASAL VENTILATION	The scale has been adjusted to a maximum of 35 due to the fluctuations in the signal. You may conclude, from the size of the signal, that the nasal cannula has been positioned high up into the nares and that the patient's nostrils are small.
RESPIRATORY EFFORT	The fluctuations in the respiratory effort signal mirror those present in the nasal ventilation graph.
SNORE INDEX	Occasional mild to loud snoring has been recorded.
FLATTENING INDEX	The flattening index drops below 0.15 for at least half of the study. This indicates significant flow limitation.
APNEA DURATION	Only five apneas were logged for the entire study.
BODY POSITION	Occasional body position changes have been recorded during the study. However, they do not appear to be clinically significant.
RESPIRATORY IRREGULARITIES	The Respiratory Irregularities Index elevates to a peak of 30 per hour, averaging at 25 per hour for the entire study.
AHI	As only 5 apneas have been logged for the entire study, the rest of the events recorded in the AHI must be hypopneas and these average 9 per hour.
HEART RATE	The heart rate trace exhibits 5 artefacts, attributable to the changes in body position.

ANALYSIS SCREEN FROM UARS/ RERAS STUDY

AutoView 98 File Edit View Download Settings Help

Patient: _____ Patient ID: _____ Study Mode: **DIAGNOSTIC** Study Date: 7/18/199 **RESMED**

time of day: 03:29:47
CURSOR
94.3
value

Session One Hour Detail Analysis

Manual Scoring

	Unclassified	Obstructive	Central	Mixed	Hypopnea	Artefact
Totals	5	0	0	0	0	0
rate/hr	0.9 /hr	0.0 /hr	0.0 /hr	0.0 /hr	0.0 /hr	0.0 /hr

Body Position - % time

Back	Right	Left	Front
88 %	12 %	0 %	0 %

Oximetry

time less than	% SaO2 for	% time
95	1	
85	1	
75	1	
65	0	

MINIMUM SaO2: 0 %

Flattening Index

% time less than	for	% time
0.15	34	
0.10	13	

Apneas

Total	Back	Right	Left	Front
Ap/Hypop Index /hr	9	8	1	0
Apnea Index /hr	1			

Respiratory Irreg Index /hr 25

Save Analysis
Set Specs
Manual Score Analyze

C:\Program Files\AutoView98\Uars2

MANUAL SCORING The five apneas noted in the Session screen, have been recorded in the manual scoring box. Manual scoring has not been performed.

BODY POSITION The patient spent 88% of the study in the supine position.

APNEAS The AHI and Apnea Index, scored at 9 and 1 events per hour respectively, do not suggest the patient suffers from OSA. The Respiratory Irregularities Index is scored at 25 per hour. This elevated reading may suggest UARS / RERAs. However, further inspection of the study data is required.

FLATTENING INDEX The Flattening Index shows that for 34% of the study time, the index was below 0.15. This suggests that flow limitation was detected. In conjunction with the elevated Respiratory Irregularities Index, this reading indicates possible UARS / RERAs. The data should be examined in closer detail before drawing conclusions.

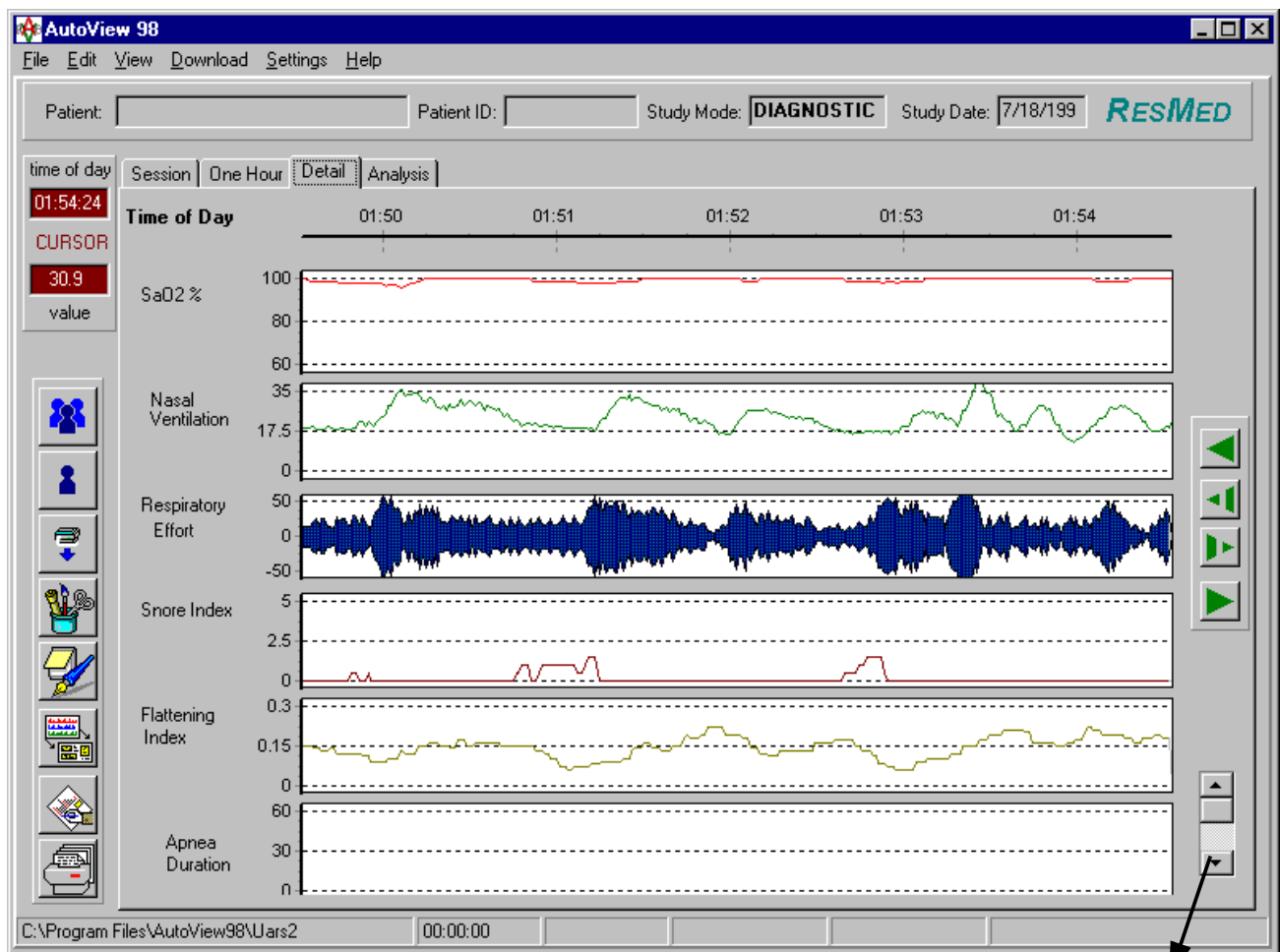
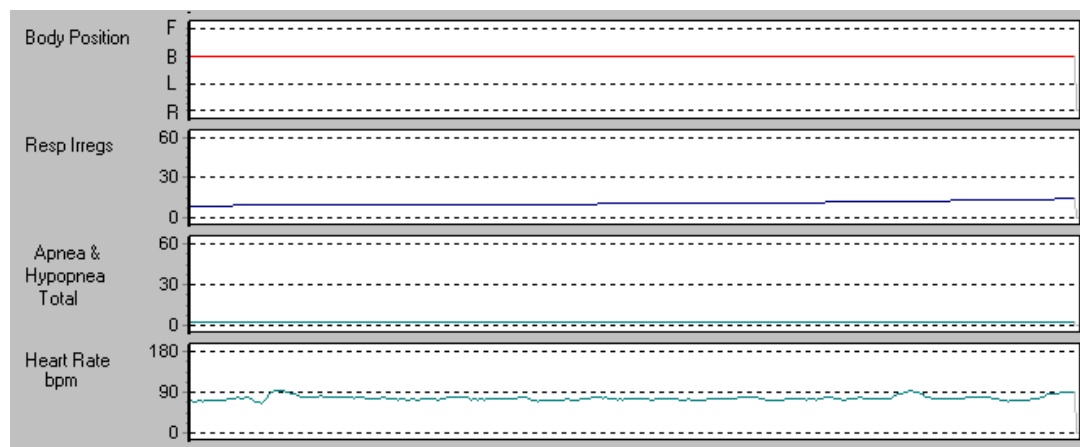
To determine UARS/ RERAs it is important to closely examine the nasal ventilation, flattening index, and respiratory irregularities index. Key indicators of UARS/ RERAs are:

- flattening index drops below 0.15
- no or few hypopneas and apneas present
- elevated respiratory irregularities index
- fluctuating nasal ventilation.

A detailed examination of the study data is required.

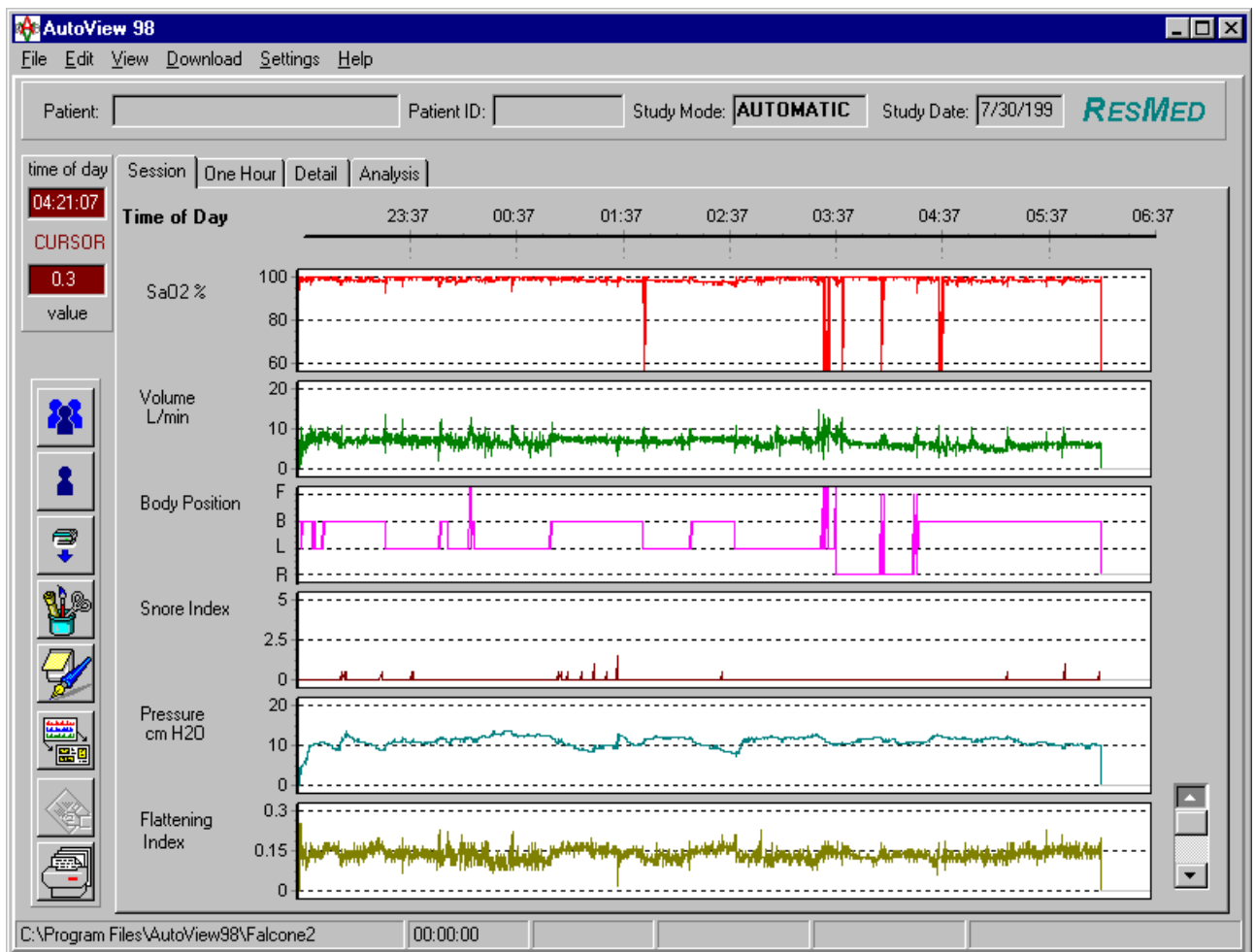
UARS / RERAS STUDY

DETAIL SCREEN



SAO ₂	There are minor changes in oxygen saturation.
NASAL VENTILATION	Nasal ventilation fluctuates significantly although not enough to be considered hypopneas. For information about how PII Plus defines hypopneas, see "Apneas & Hypopneas" on page 20.
RESPIRATORY EFFORT	Significant respiratory effort occurs throughout the period on screen.
SNORE INDEX	Moderate snoring has been recorded.
FLATTENING INDEX	The flattening index falls below 0.15, indicating flow limitation.
APNEA DURATION	No apneas have been logged in this period.
RESPIRATORY IRREGULARITIES	The Respiratory Irregularities index rises four times during this time period. This represents four events or elevations in nasal ventilation in five minutes.
AHI	No hypopneas or apneas have been logged during this period.
HEART RATE	Heart rate is relatively stable.

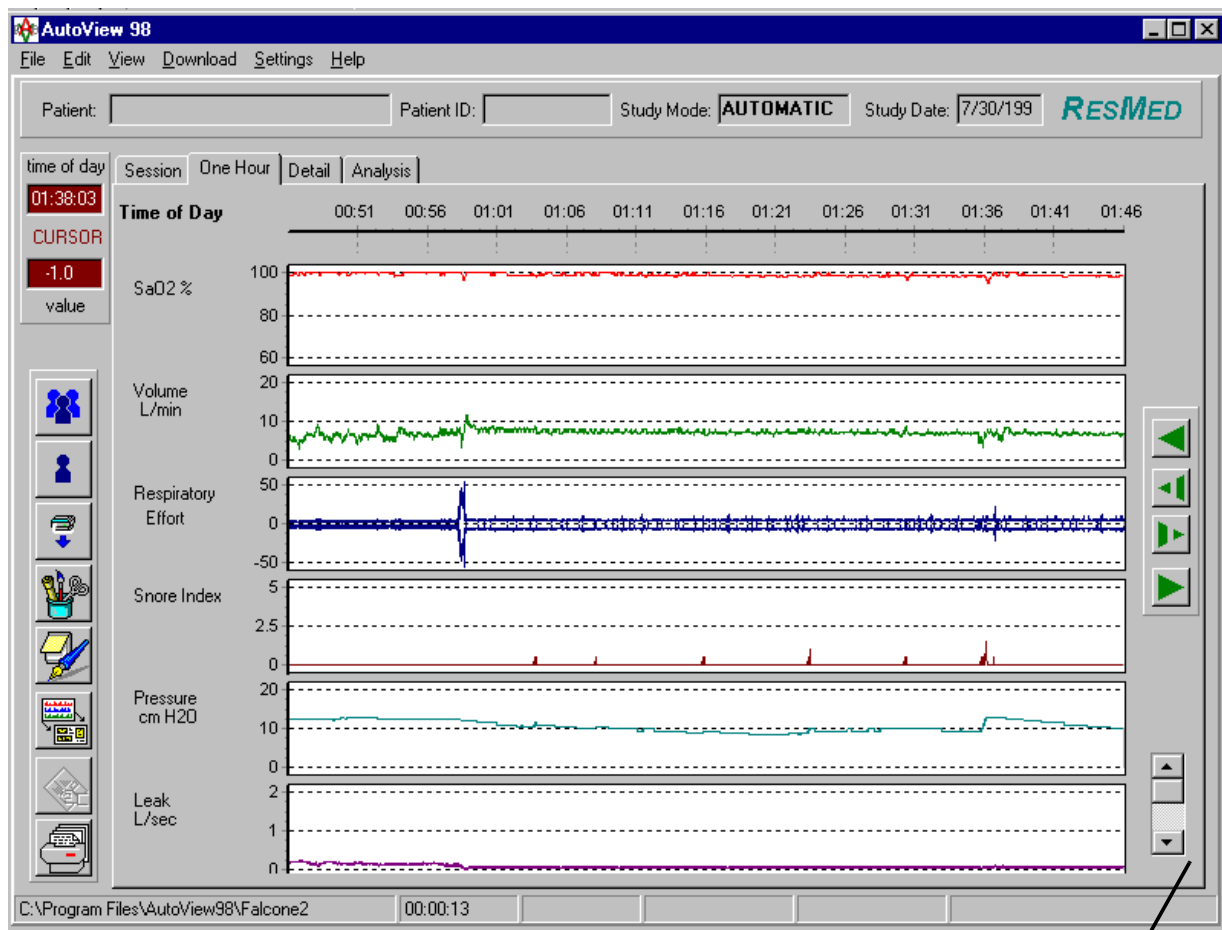
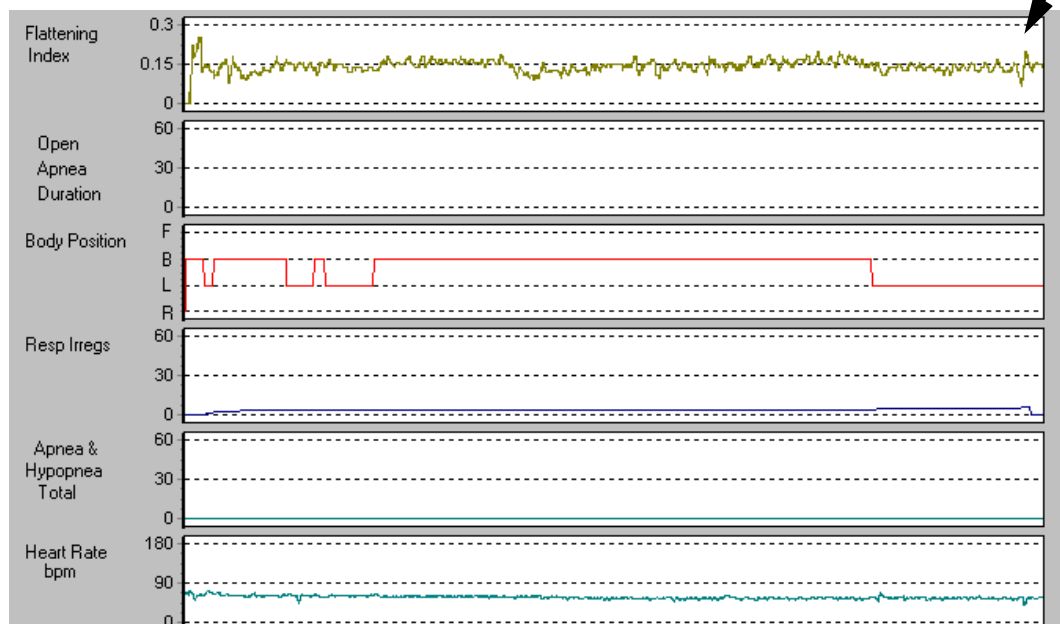
AUTOMATIC STUDY



SAO ₂	SaO ₂ is maintained above 90% for most of the study, apart from the clearly identifiable movement artefacts.
VOLUME L/MIN	Nasal ventilation is measured in Volume l/min in Automatic studies. Ventilation remains reasonably stable.
BODY POSITION	Changes in the body position chart are responsible for the spike oxygen desaturations.
SNORE INDEX	Occasional mild snoring is evident with an increase in pressure occurring in response to the snore.
PRESSURE CM H ₂ O	Pressure varies over the session due to changes in the upper airway caused by snore and flow limitation and the return to normal flow.
FLATTENING INDEX	Flattening index is maintained at approximately 0.15. When the flattening index does fall below 0.15, the pressure delivered by the PII Plus prevents apnea and high levels of snore.

AUTOMATIC STUDY

ONE-HOUR SCREEN



This is a One-hour screen from an Automatic study.

SAO ₂	Oxygen saturation is stable.
VOLUME L/MIN	Nasal ventilation, recorded in l/min, is relatively stable.
RESPIRATORY EFFORT	Respiratory effort graph shows one explosive excursion, possibly related to the body position movement, and remains stable for the rest of the period displayed.
SNORE INDEX	Six snores have been recorded by the PII Plus, with the largest snores recorded at 01:36.
APNEA HYPOPNEA TOTAL	As you would expect in a treatment study of OSA, no apneas or hypopneas are logged.
PRESSURE CMH ₂ O	Changes in treatment pressure have been recorded in response to respiratory events, such as snore, especially at 01:36. Pressure decreases when no events have occurred.
LEAK L/SEC	Mask leak is minimal, remaining at or near zero, suggesting the mask selected has an excellent seal and fit.
FLATTENING INDEX	The index is maintained at 0.15. With the constant increases and decrease in pressure, due to the positive airway pressure treatment, the flattening index alters slightly.
OPEN APNEA DURATION	No apneas are evident indicating that the patient has no central apnea and all obstructive events have been prevented by treatment.
BODY POSITION	Patient movement is recorded.
RESPIRATORY IRREGULARITIES	Occasional respiratory irregularities are noted. These are most likely in response to snore.
AHI	No apneas or hypopneas have been detected.
HEART RATE	The Heart rate, like the SaO ₂ , is very stable.

SUGGESTED READING

AUTOSET CLINICAL LITERATURE

VALIDATION OF AUTOSET TITRATION MODE

Schwartz ER, Veit CA, Schwartz JRL. **A Comparative Study of Commercially Available Auto-Titrating Devices for Obstructive Sleep Apnea.** *Sleep* 1998;21:94.

Teschler H, Berthon-Jones M, Thompson AB, Hinkle A, Henry J, Konietzko N. **Automated Continuous Positive Airway Pressure Titration for Obstructive Sleep Apnea Syndrome.** *Am J Respir Crit Care* 1996;154:734-740.

Lloberes P, Ballester E, Montserrat JM, Botifoll E, Ramirez A, Reolid A, Gistau C, Rodriguez-Roisin R. **Comparison of Manual and Automatic CPAP Titration in Patients with Sleep Apnea/Hypopnea Syndrome.** *Am J Respir Crit Care Med* 1996;154:175-8.

Teschler H, Ferrat AA, Exmoor V, Konietzko N, Berthon-Jones M. **AutoSet Nasal CPAP Titration: Constancy of Pressure, Compliance and Effectiveness at 8 Month Follow-up.** *Eur Respir J* 1997;10:2073-8.

Gagnadoux F, Rakotonanahary D, Hausser-Hauw C, Barros S, Lebeau B, Fleury B. **Automatic Calibration of Nasal Continuous Positive Airway Pressure with AutoSet.** ALA/ATS 1997 International Conference [[B33]][Poster:701].

deMaine J, Sandblom R, Hert R, Bloss R. **Utilization and Cost of Evaluating Obstructive Sleep Apnea (OSA) in Managed Care – Effect of an Integrated Home and Sleep Lab Testing Clinical Pathway.**

Wallace M, Chow CM, Page D, Chan CS. **Comparison of Manual and ResMed AutoSet CPAP Titration.** *Proc Australasian Sleep Assoc, Perth, Australia* 1996;P196.

Teschler H, Thompson AB, Henkel A, Berthon-Jones M, Konietzko N. **Continuous Positive Airway Pressure Titration for Obstructive Sleep Apnea Syndrome by a Self-Setting Device.** *ATS* May 1995.

Lloberes P, Ricou C, Arteta E, Alarcon A, Ballester E, Montserrat JM. **Comparison of Polysomnography with the ResCare AutoSet System in the Titration of CPAP in Patients with Sleep Apnea.** *From Snoring to Sleep Apnea Syndrome: Therapeutic Approach*, Lyon, France Nov. 9-10 1995.

Bagnato MC, Moura SMT, Tufik S, Nery LE. **Comparison Between Manual and Automatic CPAP Pressure Setting in Obstructive Sleep Apnea (OSA).** ALA/ATS 1997 International Conference [B33][Poster:702]

Speer T, Stuber K, Fayle R. **Portable AutoSet is an Effective Procedure to Titrate OSA Patients.** *APSS* 1997 Sleep Research 26:215.

Miyazaki S, Itasaka Y, Yamakawa K, Ishikawa K, Togawa K. **Evaluation of the Auto CPAP Efficacy by Upper Airway Pressure Measurement.** *Sleep* 1998;21:108.

VALIDATION OF AUTOSET DIAGNOSTIC

Gugger M. **Comparison of ResMed AutoSet (version 3.03) with Polysomnography in the Diagnosis of the Sleep Apnoea/Hypopnoea Syndrome.** *Eur Respir J* 1997;10:587-91.

- Bradley PA, Mortimore IL, Douglas NJ. **Comparison of Polysomnography with ResCare AutoSet in the Diagnosis of the Sleep Apnoea/Hypopnoea Syndrome.** *Thorax* 1995;50 (11):1201-3.
- Kiely JL, Delahunty C, Matthews S, McNicholas WT. **Comparison of a Limited Diagnostic System (ResCare AutoSet) with a Computerized Polysomnography System for the Diagnosis of Sleep Apnoea.** *Am J Respir Crit Care Med* 1996;Med 153(4pt2):A871. Presented at ATS, 1996.
- Fleury B, Rakotonanahary D, Hausser-Hauw C, Lebeau B, Guilleminault C. **A Laboratory Validation Study of the Diagnostic Mode of the AutoSet System for Sleep-Related Respiratory Disorders.** *Sleep* 1996;19 (6):502-5.
- Mayer P, Meurice JC, Phillip-Joet F, Paquereaut J, Veale D, Pepin JL, Levy P. **Validation of ResCare AutoSet for Diagnosis of Sleep Apnea/Hypopnea Syndrome. Multicenter French Study.** *Am J Respir Crit Care Med* 1996;153 (4pt2): A871. Presented at ATS, 1996.
- Xizhen H, Yi X, Ding Z, et al. **Diagnosing Sleep Apnea Syndrome by AutoSet Clinical System.**
- Grunstein RR, Willson GN, Piper AJ, Flynn W, Lawrence S, Berthon-Jones M. **AutoSet versus Polysomnographic Apnea + Hypopnea Index.** *APSS* 1996.
- Gugger M, Mathis J, Bassetti C. **Accuracy of an Intelligent CPAP Machine with In-Built Diagnostic Abilities in Detecting Apnoeas: A Comparison with Polysomnography.** *Thorax* 1995;50(11):1199-1201.
- Cantu N, Reece E, Henke KG. **Use of AutoSet to identify respiratory events during sleep.** *APSS* 1996.
- Madrid M, Reece E. **Effectiveness of an Auto-Adjusting CPAP Device.** *APSS* 1995.
- Piper AJ, Flynn W, Willson GN, Lawrence S, Berthon-Jones M, Grunstein RR. **Use of the AutoSet device in the diagnosis and management of sleep disordered breathing in patients with nocturnal hypoventilation syndromes.** *APSS* 1996.
- Potter N, Simmonds AK. **Variation in CPAP requirement using an intelligent CPAP device.** *Thorax* 1995;50 (4):477P.
- Nery LE, Bagnato M, Moura SMT, Bittencourt LR, Tufik S. **Comparison of AutoSet (As) In the Diagnostic Mode with Standard Polysomnography (PSG), in the Evaluation of Apnea-Hypopnea Events.** *ALA/ATS 1997 International Conference* [A41][Poster:H31].
- Carlson PC, Kline LR. **Use of the Auto-Set in Attended Split Night Studies.** *APSS 1997 Sleep Research* 26:644.
- Carlson P, Kline L. **Utility of the AutoSet NCPAP Device During Split-Night Studies.**
- Bagnato MC, Nery LE, Moura SMT, Bittencourt LR, Tufik S. **Diagnostic Evaluation of Apnea-Hypopnea Events by AutoSet (As) As Compared to Polysomnography (PSG).** *Sleep* 1998;21:116.
- Yamakawa K, Souichiro, Miyazaki, Togawa K, Usami M. **Analysis of Auto CPAP in Obstructive Sleep Apnea Patients.** *Sleep* 1998;21:122.

VALIDATION OF AUTOSET AS TREATMENT DEVICE FOR OSA

- Berthon-Jones M, Lawrence S, Sullivan CE, Grunstein R. **Nasal Continuous Positive Airway Pressure Treatment: Current Realities and Future.** *Sleep* 1996;19(6):S1131-5.
- Teschler H, Berthon-Jones M. **Intelligent CPAP systems: clinical experience.** *Thorax* 1998;53.

Speer TK. **Patient's Response to Multiple Treatment Modalities for Obstructive Sleep Apnea.**

Lloberes P, Ballester E, Montserrat JM, Botifoll E, Ramirez A, Reolid A, Gistau C, Rodriguez-Roisin R. **Comparison of Manual and Automatic CPAP Titration in Patients with Sleep Apnea/Hypopnea Syndrome.** *Am J Respir Crit Care Med* 1996;154:175-8.

Berthon-Jones M, Lawrence S, Grunstein R. **The AutoSet Self-Adjusting Nasal CPAP System.**

Henke KG, Cantu N. **Efficacy of the AutoSet CPAP in Patients with OSA and COPD.** *Proc Ninth Annual Meeting APSS* 1995;P139.

Willson GN, Grunstein RR, Doyle J, Lawrence S, Sullivan CE, Berthon-Jones M. **Domiciliary Use of AutoSet Nasal Continuous Positive Airways pressure (NCPAP) – Feasibility, Efficacy, and Night-to-Night Variability.** *APSS* 1996.

Cantu N, Henke KG. **Changing CPAP Requirements Throughout the Night.** *APSS* 1995.

Chow MC, Wallace M, Page D, Chan SC. **A Description of nCPAP Mask-fitting.** *Proc Australasian Sleep Assoc* 1996:P200.

Grunstein RR, Willson GN, Lawrence S, Flynn W, Piper AJ, Sullivan CE, Berthon-Jones M. **Automatically adjusting nasal CPAP – one year experience in a sleep laboratory.** *APSS* 1996.

Kendrick AH, Wiltshire N, Catterall JR. **Comparison of AutoSet (Therapeutic Mode) to a Predictive Equation to Set the Continuous Positive Airway Pressure.** *Proc Australasian Sleep Assoc* 1996:P193.

McDannold MD, Berthon-Jones M, Zaretsky N, Hux G, Scharf MB. **Night-To-Night Variability in Optimal CPAP Pressures Using Auto CPAP Titration in a Single Patient.** *APSS* 1994.

Rakotonanahary D, Fleury B, Hausser-Hauw C, Lebeau B, Guilleminault C. **A Laboratory Validation Study of the Diagnostic Mode of the AutoSet System for Sleep Related Respiratory Disorders.** *From Snoring to Sleep Apnea* 1995.

Keller-Wossidio H, Suter N, Wiesner B, Keller RR. **Titration and Follow-Up of nCPAP-Therapy by a Self-Adapting Pressure Adjustment Device (AutoSet) in Patients with Obstructive Sleep Apnea Syndrome.** *ALA/ATS 1997 International Conference* [B33][Poster:705].

DiPhillipo MA, Goldberg R, Curran K, Fry JM. **CPAP vs. APAP Titration: Short Term Clinical Response.** *Sleep* 1998;21:112.

FLOW LIMITATION

Montserrat JM, Ballester E, Olivi H, Reolid A, Lloberes P, Morello A, Rodriguez-Roisin R. **Time-Course of Stepwise CPAP Titration: Behavior of Respiratory and Neurological Variables.** *Am J Respir Crit Care Med* 1995;152:1854-9.

Rees K, Wraith PK, Berthon-Jones M, Douglas NJ. **Shape of the Inspiratory Flow Time Profile Versus Resistance in Normal Subjects.**

Condos R, Norman RG, Krishnasamy I, Peduzzi N, Goldring R, Rapoport DM. **Flow Limitation as a Noninvasive Assessment of Residual Upper-Airway Resistance During Continuous Positive Airway Pressure Therapy of Obstructive Sleep Apnea.** *Am J Respir Crit Care Med* 1994;150:475-80.

Ayappa I, Norman RG, Hosselet JJ, Gruenke RA, Walsleben JA, Rapoport DA. **Relative Occurrence of Flow Limitation and Snoring During Continuous Positive Airway Pressure Titration.** *Chest* 1998 Sept;114 (3):685-690.

Hosselet JJ, Norman RG, Ayappa I, Rapoport DM. **Detection of Flow Limitation with a Nasal Cannula/Pressure Transducer System.** *Am J Respir Crit Care Med* 1998;157:1461-67.

Meurice JC, Paquereau J, Denjean Aa, Patte F, Series F. **Influence of correction of flow limitation on continuous positive airway pressure efficiency in sleep apnea/hypopnea syndrome.** *European Respiratory Journal* 1998;11(5):1121-7.

Hosselet JJ, Rapoport DM, Rosen A, Norman RG, Ayappa I, Rapoport DM. **Effect of Position and Sleep Stage on Flow Limitation Events in Mild-Moderate Obstructive Apnea Syndrome.** *Sleep* 1998;21:139.

HOME (UNATTENDED) CPAP TITRATION

Lantin M, Lacasse D, Remsburg S, Garpestad E, Lawee M, Coppolla M, O'Brien J, Weiss JW. **Home Titration of Nasal CPAP Using an Auto-Titrating CPAP Machine.** *APSS* 1996.

Speer T, Stuber K, Fayle R. **Portable AutoSet Is an Effective Procedure to Titrate OSA Patients.** *APSS* 1997 *Sleep Research* 26:215.

Sandblom R, Hert R, Kapur V, deMaine J. **Comparison of Unattended Automated Nasal CPAP Titration to Self Titration for Treatment of Obstructive Sleep Apnea.** *ALA/ATS 1997 International Conference* [B33][Poster:707].

Baratz DM, Anthony SR, Levine BE. **Comparison of Treatment Outcome Based on In-Laboratory Polysomnography Vs. Home AutoSet Studies.** *Sleep* 1998;21:58.

Farrell J. **Sleep diagnostics: Will home-based testing pan out?** *HME News* 1998 Aug;4:24-26.

SELF-SETTING CPAP DEVICES

Berthon-Jones M. **Feasibility of a Self-Setting CPAP Machine.** *Sleep* 1993;16:S120-S123.

Berthon-Jones M, Lawrence S, Sullivan CE. **A Self-Adjusting CPAP Device for OSA.** *APSS* 1994.

COMPETITIVE SYSTEMS

Series F, Marc I. **Efficacy of Automatic Continuous Pressure Therapy That Uses an Estimated Required Pressure in the Treatment of the Obstructive Sleep Apnea Syndrome.** *Annals of Internal Medicine* 1997;127:588-595.

Lucas EA, Behbehani K, Bradshaw CM, Burk JR, Knauer S, Wexler DM. **Comparison of Continuous Positive Airway Pressure (CPAP) to AutoCPAP (APAP) in the Diagnosis and Treatment of Obstructive Sleep Apnea (OSA).** *Sleep* 1998;21:106.

Schutte S, et al. **A Comparison of Continuous Positive Airway Pressure (CPAP) and Autoadjust Positive Airway Pressure (AAPAP) in the Treatment of Obstructive Sleep Apnea Syndrome (OSAS).** *Sleep* 1998;21:95.

Stradling JR, Barbour C, Pitson DJ, Davies RJ. **Automatic Nasal Continuous Positive Airway Pressure Titration in the Laboratory: Patient Outcomes.** *Thorax* 1997;52 (1):72-5.

Sharma S, Wali S, Pouliot Z, Peters M, Neufeld H, Kryger M. **Treatment of Obstructive Sleep Apnea with a Self-Titrating Continuous Positive Airway Pressure (CPAP) System.** *Sleep* 1996;19(6):497-501.

Juhasz J, Schillen J, Urbigkeit A, Ploch T, Penzel T, Peter JH. **Unattended Continuous Positive Airway Pressure Titration: Clinical Relevance and Cardiorespiratory Hazards of the Method.** *Am J Respir Crit Care Med* 1996;154:359-65.

Scharf MB, Brannen DE, McDannold MD, Berkowitz DV. **Computerized Adjustable Versus Fixed NCPAP Treatment of Obstructive Sleep Apnea.** *Sleep* 1996;19(6):491-6.

Meurice J, Marc I, Series F. **Efficacy of Auto-CPAP in the Treatment of Obstructive Sleep Apnea/Hypopnea Syndrome.** *Am J Respir Crit Care Med* 1996; 153: 794-8.

Vazquez JC, Masuda A, Hajduk A, Iyer S, Tanguay S, Flemons W, Whitelaw W, Issa F, Remmers JE. **Hospital and Home Digital Monitoring of Sleep-Disordered Breathing Using Arterial Oxygen Saturation and Snoring Sound.**

Pouliot Z, Kryger M, Hardy W. **The Performance of Two Self-Titrating Nasal CPAP Devices With and Without Humidification in Patients with Obstructive Sleep Apnea.** *Sleep* 1998;21:110.

Akre H, Skatvedt O. **Outpatient CPAP Titration by Automatic CPAP (Devilbiss Horizon AutoAdjust) Compared to Conventional Titration with Simultaneous Nocturnal Polysomnography.** *Sleep* 1998;21:121.

MISCELLANEOUS

Teschler H, Berthon-Jones M, Wessendorf T, Meyer HJ, Konietzko N. **Influence of Moderate Alcohol Consumption on Obstructive Sleep Apnoea with and without AutoSet Nasal CPAP Therapy.** *Eur Respir J* 1996;9.

Wessendorf TE, Teschler H, Berthon-Jones M, Meyer FJ, Costabel U, Konietzko N. **Effect of Moderate Alcohol Intake on NCPAP Pressure Determined by AutoSet.** *Am J Resp Crit Care* 1996;153(4pt2):A871.

FREQUENTLY ASKED QUESTIONS

DOES PII PLUS TREAT ALL APNEAS?

No. It will differentiate between open and closed airway apneas during treatment mode. At six seconds into a period of zero or near zero airflow, indicating the commencement of apnea, PII Plus sends pulses of air into the mask - 0.5 cm H₂O at 4 Hz. If no flow is detected, the apnea is classified as closed and the CPAP pressure is raised by 1 cm H₂O for every 15 seconds of apnea once the apnea is terminated. However, if flow is detected, the apnea is classified as open and the CPAP pressure is not increased. Clinicians can be confident that patients will not be compromised by inappropriate pressure increases especially in those patients with increased work of breathing.

For information about how PII Plus defines apneas and hypopneas, see "Apneas & Hypopneas" on page 20.

DOES PII PLUS INCREASE THE CPAP PRESSURE BY THE SAME AMOUNT FOR EVERY TYPE OF EVENT?

No.

Event	Pressure Increase
Open airway	None
Closed airway	1cm H ₂ O for every 15 seconds of apnea
Loud snoring	Approximately 1cm H ₂ O and less pressure for lesser snores
Flow limitation	Approximately 0.3cm H ₂ O when the moving average of the last 5 breath's flattening index is <0.15.

WHAT CRITERIA DOES PII PLUS USE TO DECREASE THE CPAP PRESSURE?

If there is no evidence of further snore, obstruction, or flow limitation, there will be a gradual decrease in CPAP pressure towards 4cm H₂O.

The time constant for the pressure decrease is 20 minutes for snore and flow limitation and 40 minutes for apnea.

Pressure will decrease more quickly if it is increased in response to snoring and flow limitation, and more slowly if it is increased in response to apnea.

WHAT IS THE 95TH PRESSURE CENTILE?

It is the pressure which is exceeded only 5% of the night, after excluding any periods with a leak >0.4 l/sec.

CAN THE PII PLUS FLOW AND PRESSURE SIGNAL BE DISPLAYED ON THE POLYGRAPH?

Yes. The analog outputs on the back of the PII Plus allow data to be transferred to the polygraph. The 3.5mm mono jack connectors for PII Plus are available. These connectors provide the most secure connection and should be used at all times in the PII Plus analog outputs. Two conductor 24

gauge shielded cables are used and the appropriate connector used for the polygraphs. There needs to be an available DC amplifier for the signal. It is especially useful to display the airflow signal on the polygraph when labs are evaluating the PII Plus in conjunction with a polygraph. This way PII Plus can be fairly evaluated.

CAN PATIENTS BE ACCLIMATIZED TO CPAP USING THE PII PLUS?

Yes. An anxious patient is less likely to tolerate treatment. Therefore, it is important to introduce the patient to the mask and the sensation of receiving treatment before going home. Prior to CPAP titration you can set the PII Plus to an arbitrary CPAP level for a period of time (15 - 20 mins) and then objectively evaluate the fit by downloading the data. You can therefore objectively evaluate the mask fit by assessing the mask leak. For example, if there is a detectable or troublesome leak at 4 cm H₂O, it is likely that when the CPAP pressure is increased, mask leak would be exacerbated. Once you have established that a particular mask fits well and the patient has tolerated certain CPAP pressures, you can send the patient home either on automatic or manual mode.

IS IT POSSIBLE TO DETECT OPEN AIRWAY APNEAS IN DIAGNOSTIC MODE?

PII Plus cannot test the airway in diagnostic mode because nasal cannula are used instead of the PII Plus CPAP mask system, which has a flow sensor incorporated inside. It is this pneumotach which allows the differentiation of apneas. Therefore, in diagnostic mode all apneas are recorded and logged by duration. However, by using the respiratory effort and manual score options, you can classify the events as you see fit, thus making it possible to differentiate between events post acquisition.

HOW DOES PII PLUS DEFINE HYPOPNEAS?

Hypopneas are defined as a 50% to 75% decrease in nasal ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50% but not more than 25% of the recent average for 10 consecutive seconds. The recent average is calculated using a time constant of 100 seconds.

GLOSSARY

APNEA	Cessation of breath or without breath. It is commonly obstructive in origin.
APNEA INDEX	A measure used to ascertain the severity of sleep apnea, that is achieved by determining the number of apneic events per hour.
APNEA/ HYPOPNEA INDEX	The total number of apnea and hypopnea events per hour. A measure used to ascertain the severity of sleep apnea.
AUTOSET	Computerized technology developed by ResMed to analyze the status of the upper airway and treat partial or total airway obstruction on a breath-by-breath basis.
BPM	Heart rate displayed in beats per minute.
CPAP	Continuous positive airway pressure delivered via a nasal mask to treat obstructive sleep apnea.
CENTRAL APNEA	An apnea that is caused by some irregularity in the brain's control of breathing. It is said to be central in origin, hence the name central apnea. During a central apnea there is no respiratory effort, whereas during an obstructive apnea respiratory effort continues.
CHEYNE- STOKES RESPIRATIONS	A repetitive breathing pattern in which the rate and depth of breathing increases smoothly (crescendos) to a peak then decreases smoothly (decrescendos) to the point of apnea.
FLOW LIMITATION	Partial closure of the upper airway. Displayed in graphic form with an index of 0 to 0.3.
HYPOPNEA	Shallow breathing in which the airflow in and out of the airway is less than half that of normal baseline.
MIXED APNEA	Sleep apnea that is a combination of obstructive and central apnea.
NREM SLEEP	Non Rapid Eye Movement sleep.
OBSTRUCTIVE APNEA	Sleep apnea caused by a blockage of the airway.
OXYGEN SATURATION	The amount of oxygen being carried in the blood. Often used as a measure of the severity of sleep apnea. Normal oxygen saturation is about 95%, with some decrease with age and smoking.
POLY- SOMNOGRAPHY	The recording of a person's physiological sleeping signs overnight. These include the recorded parameters of brain activity, heart rate, body position, respiratory effort, leg movements, eye movements and muscle tone.
PRE-AMP	A small amplifier used to amplify signals from the respiratory band.

REM SLEEP	Rapid Eye Movement sleep. The active stage of sleep, during which the most vivid dreaming occurs.
RESPIRATORY EFFORT	The effort generated by breathing. This is recorded using a band placed around the chest.
SAO ₂	See "Oxygen Saturation".

INDEX

A

Analysis Screen 7
 Apnea 22, 89
 Apnea & Hypopnea Index 24
 Apnea Index 17, 24, 89
 Apnea/ Hypopnea Index 17
 Apnea/Hypopnea Index 89
 Apneas & Hypopneas 22
 Automatic Mode 3
 AutoView 98 5
 AutoView Main Window 5
 AutoView Reports 8

B

Benign Snoring 34
 Blockout 50, 54
 Blockout Feature 48
 Body Position 22
 BPM 89

C

Central Apnea 60, 89
 Cheyne-Stokes 66, 89
 Closed Apneas 27
 CPAP 89

D

Decreasing Pressure 27
 Diagnostic mode 4

F

Fixed Pressure mode 4
 Flattening Index 20, 26
 Flow Limitation 20, 89
 flow-time curve 20

H

Heart Rate 16
 Hypopnea 22, 89

I

Increasing Pressure 26

M

Manual mode 4
 Mask Leak 19
 Maximum Pressure 4
 Minimum Pressure 4
 Mixed Apnea 58, 89
 Mixed apnea 31
 Mouth breathing 18
 Movement Artefacts 44, 46, 48, 50, 56

N

nasal cannula 4
 Nasal Ventilation 17
 nREM Sleep 89

O

Obstructive Apnea 29, 89

Obstructive Sleep Apnea Study 38
 Operating Modes 3
 Oxygen Saturation 15, 90
 Oxygen saturation 89

P

Partial upper airway closure 20
 patent airway 20
 pneumotach 3
 Polysomnography 89
 Positional loud snoring 17
 Pre-amp 89
 Pressure 26
 Pressure Response 26
 pulse oximeter 15

R

REM sleep 90
 RERAs 72
 Respiratory Effort 27, 62, 64, 90
 Respiratory Effort Related Arousals 24, 70, 72, 74
 Respiratory Irregularities 24

S

Sleep Study Report 8
 Snore 26
 Snoring 16

U

Upper Airway Resistance Syndrome 24, 70

V

Volume L/min 18

W

Waiting Time 4

b