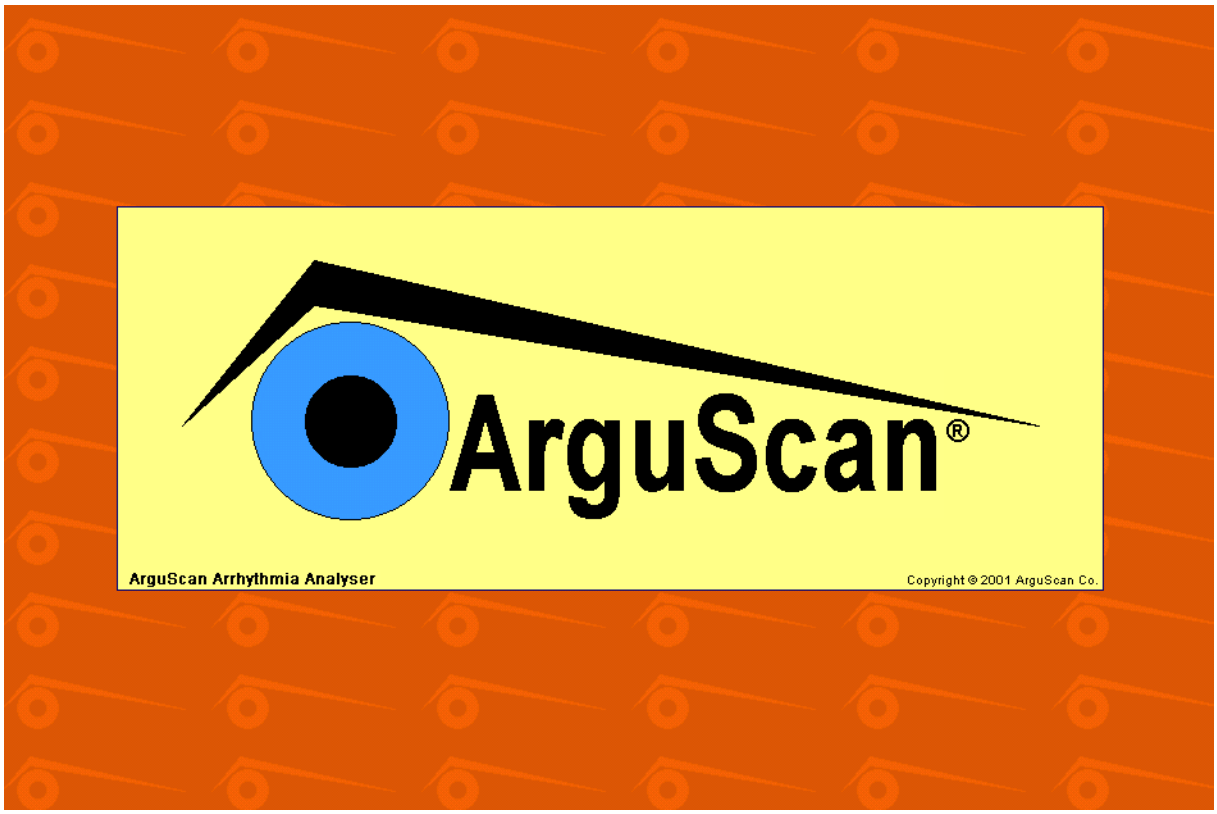
ArguScan Arrhythmia Analyser



Physician's Guide

v.4.16.

ArguScan Ltd.
2003

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This document has been created for version 4.16 of the **ArguScan** evaluation program.

Introduction

The ArguScan Holter system has been created to detect rhythm disorders under ambulatory conditions. When designing the program and the accessories our goal was to start the recording easily and quickly, to have the record quality approach diagnostic quality and to have it give an exact picture of the patient's condition.

An important consideration when creating the recorder's construction was to start the recording without turning on the evaluating computer and to monitor the channels to be stored on the recorder's LCD. The recorded independent bipolar channels make optimal electrode position selection possible, and independency gives enough insurance that at least one lead is appropriate quality for the evaluating algorithm. Due to the 0.05-62Hz-frequency transfer of the recorder's amplifier the ST-level does not distort and the quality of the samples in the report do not limit diagnosis creation. The safe hardware detection of the pacemaker spikes insures safe QRS detection. The recorder's electronics contains the most modern technical solutions; the flash memory allows the storage of records without a time limit. The recorder does not contain any moving electromechanical parts; the records are stored compressed, continuously.

The data transfer from the recorder to the evaluating computer takes 60-90 seconds. The data is transferred to a file on the computer's hard drive. The data file remains untouched during evaluation, it is only read from. This is important, because this makes it possible to evaluate previously made records, regardless of the evaluation program version.

The automatic analysis, which starts after data transfer, performs the complete arrhythmia and ST analysis in 1-1.5 minutes, depending on the evaluating computer's performance. During arrhythmia analysis the algorithm performs QRS detection, P-QRS-T wave parameter calculation, QRS morphological classification, arrhythmia detection, ST measurement, atrial-fibrillation analysis, HRV calculation, trend and statistics calculation. When designing the evaluation program the following were our main goals: the evaluator always gets a comprehensive picture of the currently examined subject (for example QRS classes, ventricular arrhythmias, atrial arrhythmias, atrial fibrillation, etc.), meaning that all related information is available on the screen simultaneously. If modification or reclassification is necessary, it should be performed on the same screen (no need for screen switching) with a few mouse clicks. During reclassification we give the option to reclassify one QRS, several QRS's, a few seconds, a few minutes, a few hours (atrial fibrillation). It is important that when a subject examination is complete where a reclassification took place, automatic re-analysis is performed, which causes all the trends, tables and statistics to be recalculated. We have taken great care to correct the evaluation of the noisy records with the help of a graphic noise-level adjusting module. To decrease the amount of evaluating time, we have developed fast calculating, search and display functions and data structures with Windows operating system's capabilities. With these, a report may be printed from an average record in a few minutes.

During the arrhythmia analysis algorithm development we have done intensive testing with our own database, containing 80 24-hour records recorded at an arrhythmia center, and on standard databases made specifically for arrhythmia analysis testing.

Signal compression

In the recorder the program compresses the ECG channel signals using an algorithm based on standard Huffman coding without any data loss.

QRS detection

The most important base module of the arrhythmia analysis program is the QRS detector. Since the arrhythmia analysis is simply the determination of the QRS types (N, VES, SVES, etc.), the determination of the QRS P-, T-wave parameters, and the characterization of the P-QRS-T repetition in time, the arrhythmia analysis cannot give an acceptable result if the QRS detector cannot find the QRS's or detects other waves as QRS's. The QRS detector is a context sensitive algorithm adaptively processing parallel operating symmetrical finite impulse response filter outputs. The most important features of the QRS detector is that it reliably detects in noisy environments (Figure 1), exactly detects both small (Figure 2) and large QRS's, and adaptively, taking into account the environment, marks the most QRS-like wave as QRS (Figure 3).

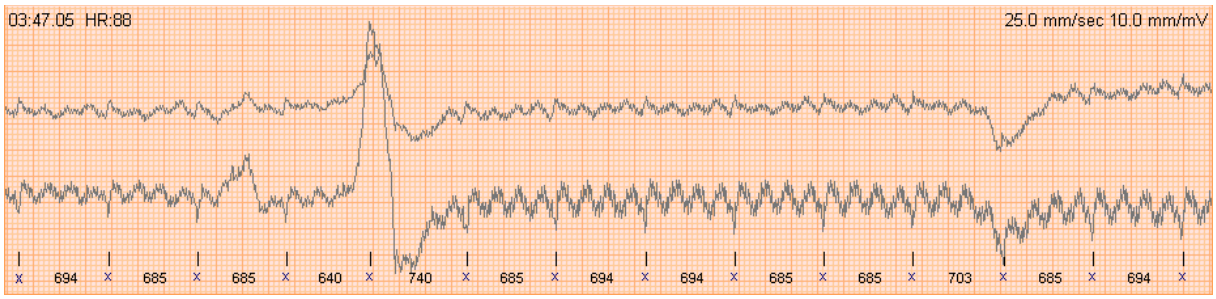

Figure 1.

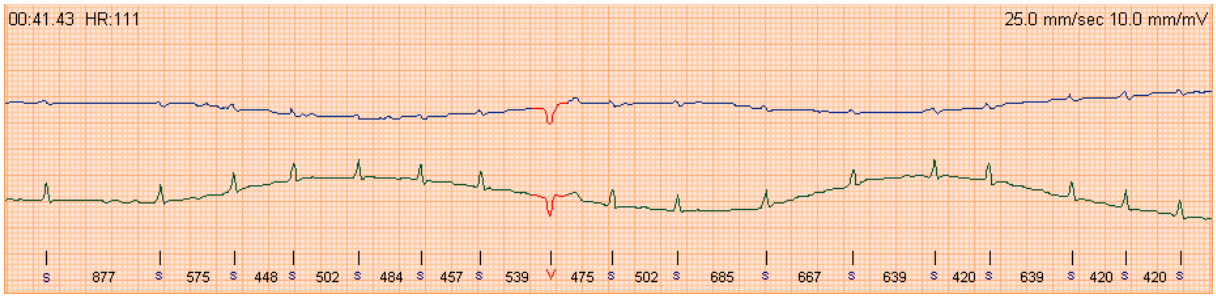

Figure 2.

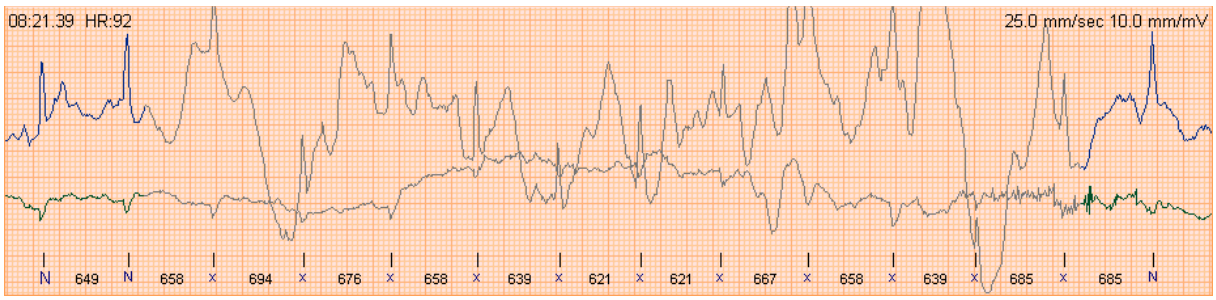

Figure 3.

P-analysis

P-wave detection with ambulatory ECG records is a hard job, since the P-wave amplitudes fall into the same magnitude as the normal base noise amplitude. P-analysis is an indispensable requirement if the arrhythmia analysis program has to recognize bundle branch block beats (Figure 4) and isolate them from ventricular beats (Figure 5), and atrial fibrillation (Figure 6) has to be detected reliably.

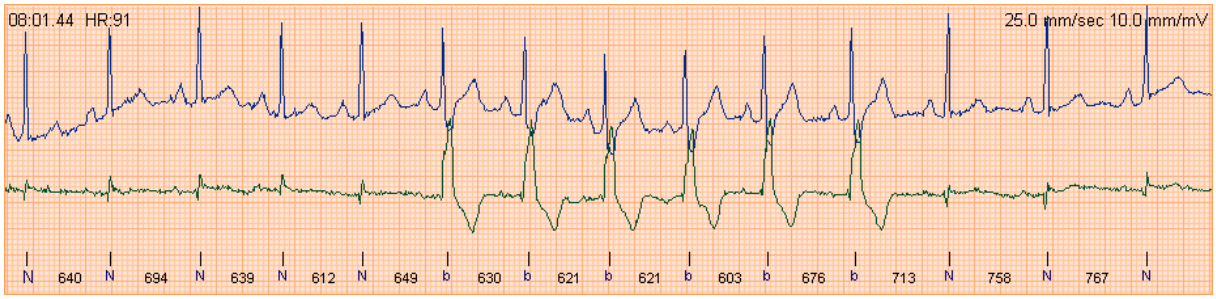

Figure 4.

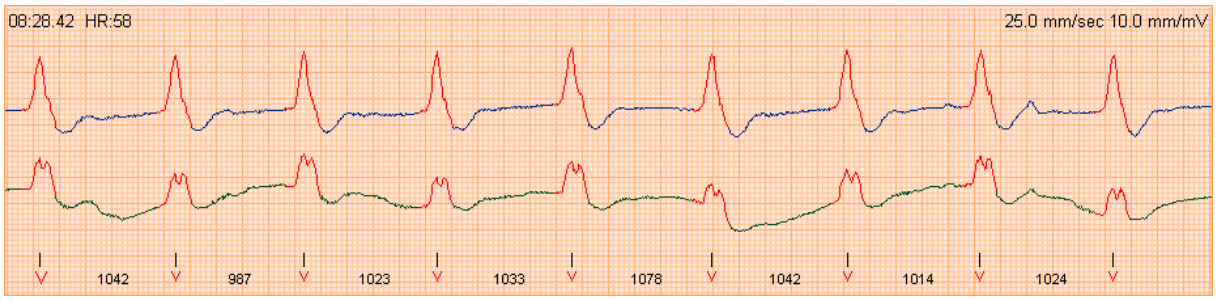

Figure 5.

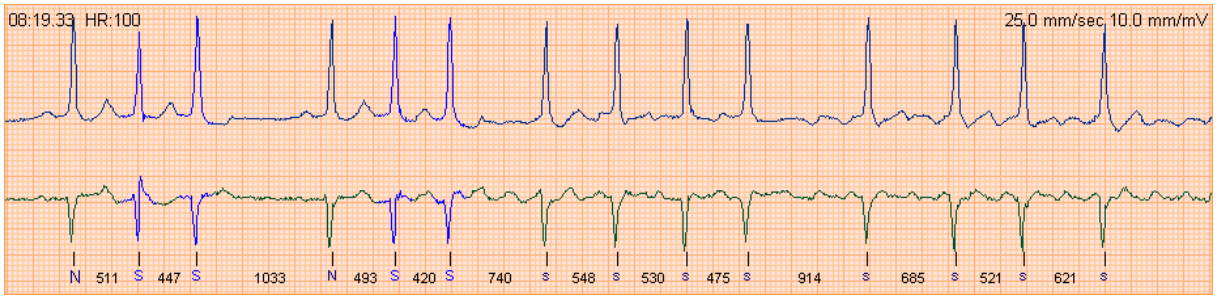

Figure 6.

The ArguScan arrhythmia analysis performs P-analysis, but only in low-noise and noise-free periods and in case of P-waves exceeding 150µV (where it is clear to see). The P-analysis result (is there or isn't there P-wave before the QRS) only increases or decreases the statistical probability of certain arrhythmias, since if the algorithm finds a P-wave then there is great chance that there is a P-wave, but if it cannot find any, it does not mean there is no P-wave. Considering the above let us stress the importance of selecting the electrode setup, so there is always a P-wave on at lease one channel.

The more QRS's there are, the heavier the P-detection weighs in the statistics, i.e.: in case of a wide QRS the existence of the P-wave weighs less (the chance of a P-artefact is considerably high in a beat) at the branching of the ventricular or bundle branch block beat decision, but in case of a series of wide QRS's where the P-wave and the P-Q fluctuation is low, the P-wave existence weighs heavily in the decision if it is a bundle branch block beat series. The

algorithm, with the help of the P-analysis, evaluates the section to be sinus rhythm where there is a P-wave in at least 8-10 QRS's (not necessarily continuous) and the P-Q time fluctuation is less than 40 msec.

QRS morphological classification

In case of the strict comparison of the QRS-waves in a Holter record, each QRS can be found different, but if the comparison is set to more and more coarse, you can get to the point where all the QRS's of a 24-hour record can be classified into a few classes. There are Holter systems that perform QRS classification based on a fix QRS-wave "dictionary", meaning they compare all of the record's QRS-waves to the QRS-waves in the "dictionary" and rate the current QRS-wave to the closest match. There are Holter systems that build a new "dictionary" when evaluating each record, based on the current record. The number of registered QRS classes number from a few (4-5-6-11) to several hundred.

The ArguScan system builds the individual QRS classes during the analysis process and maximum 1000 QRS classes can be created. When designing the automatic QRS classification algorithm we found differentiating based on fine differences to be optimal, and made the management of a large number of QRS classes possible (Figure 7).

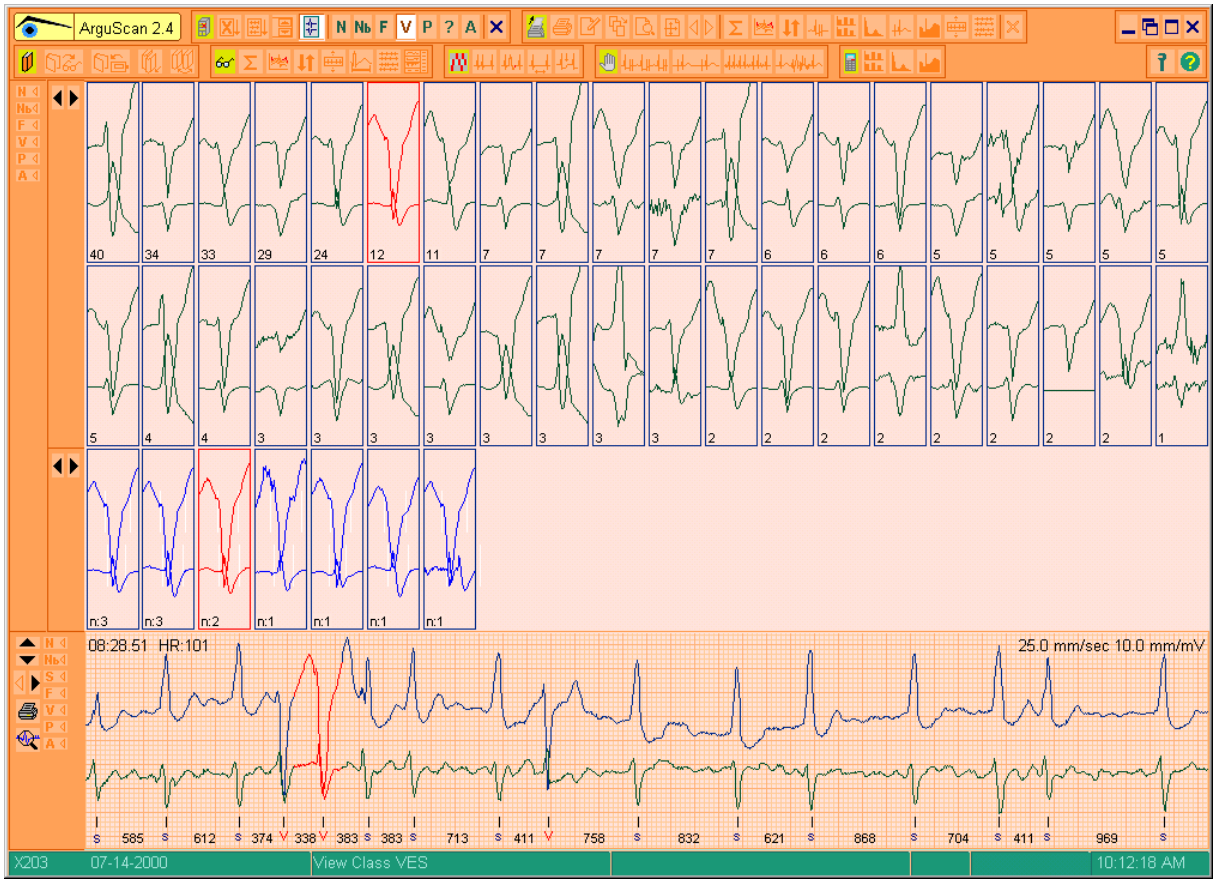

Figure 7.

We have selected differentiating based on fine differences, because this way we gave the evaluator the possibility to make the detection of small, but occasionally essential differences easier (part of the normal beats on Figure 8. are WPW).

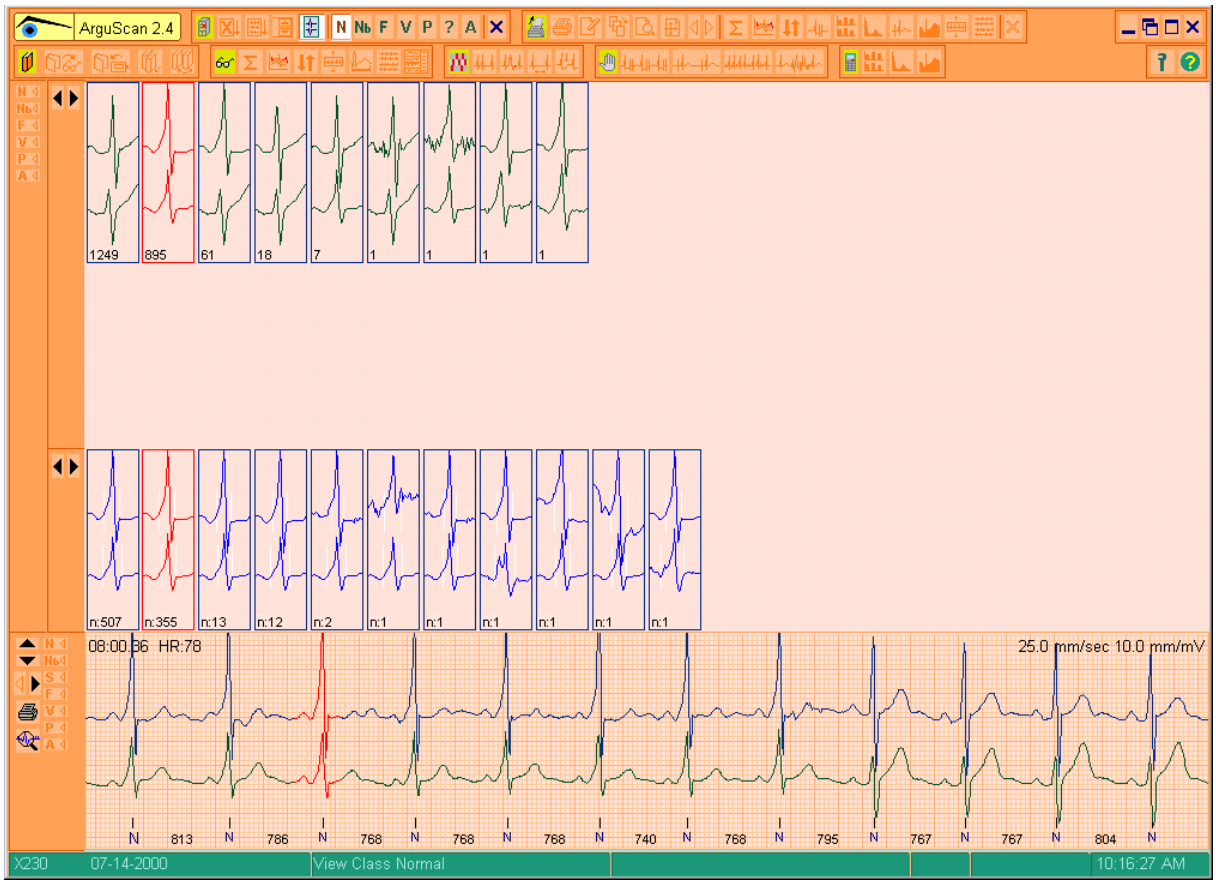

Figure 8.

Due to the large number of QRS classes a special comparison algorithm had to be designed in the arrhythmia analysis program, since, in the worst case there are 100.000 * 1000 QRS comparisons in a 24-hour record analysis, the QRS class display had to be handled and the fast reclassification performed.

The QRS classes were sorted by type (N, Nb, F, V, P, ?, A) and into main classes within the individual types. The number of main classes depends on how sensitive the QRS classification was set in the analysis criterion. If it was set to fine, there will be more main classes and fewer sub-classes, while setting the criterion to coarse creates less main classes and more sub-classes.

Atrial fibrillation

A necessary requirement of atrial fibrillation detection in the ArguScan arrhythmia analysis program is for the QRS's to follow each other in random times (within physiological limits), i.e. the rhythm is chaotic (Figure 9).

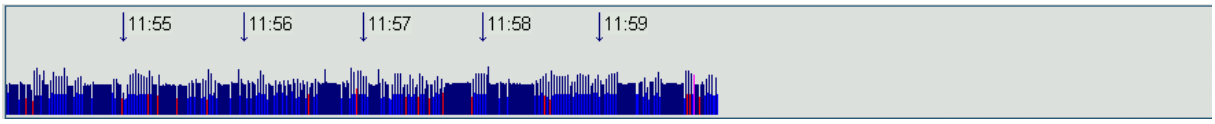

Figure 9.

In case of a chaotic rhythm, the program examines if there are sinus beats among the irregular QRS's. The operation of the P-analysis program is the requirement of the sinus beat examination. If the P-analysis program requirements are met (low noise, clear P-wave), the P-analysis program decides if there are any sinus beats near the examined moment. If there are

sinus beats, the arrhythmia analysis program detects a supraventricular arrhythmia, otherwise it detects atrial fibrillation. Based on the R-R distance graph on Figure 9., there are a few 10-15 seconds long sections within the 5 minutes, where the rhythm is chaotic, but the P-analysis program detects the sinus beats (Figure 10.) and the arrhythmia analysis program detects the supraventricular extrasystoles.

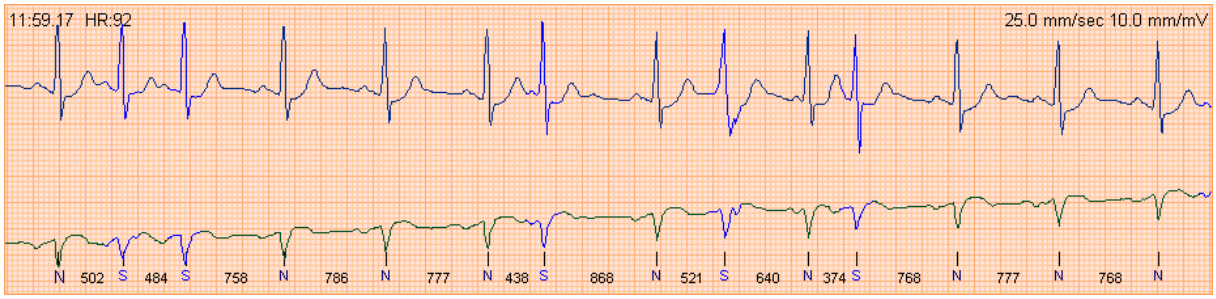

Figure 10.

In case the P-detector operating requirements are not met (low noise, clear P-wave), the arrhythmia analysis program decides the atrial fibrillation section detection based on the chaotic rhythm (Figure 11).

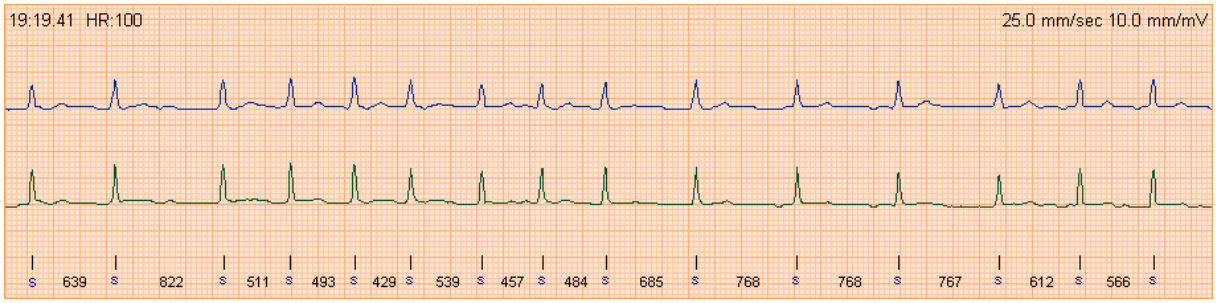

Figure 11.

If the rhythm is chaotic and the P-detector detects a lot of P-waves on the baseline (Figure 12), the arrhythmia analysis program detects atrial fibrillation.

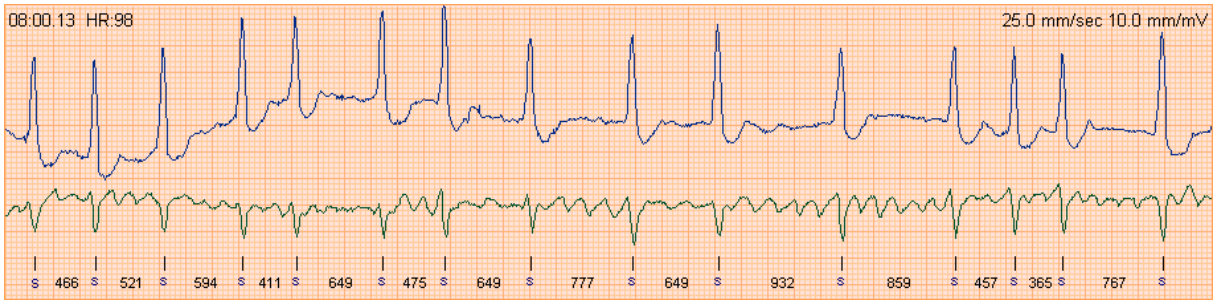

Figure 12.

The arrhythmia detector marks the atrial fibrillation starting points as the atrial fibrillation analysis result and indicates the atrial fibrillation ranges on the trends (yellow stripes). When designing the ArguScan system we created an independent window to make atrial fibrillation evaluation easier (Figure 13), where the atrial fibrillation sections can be simply checked and modified.

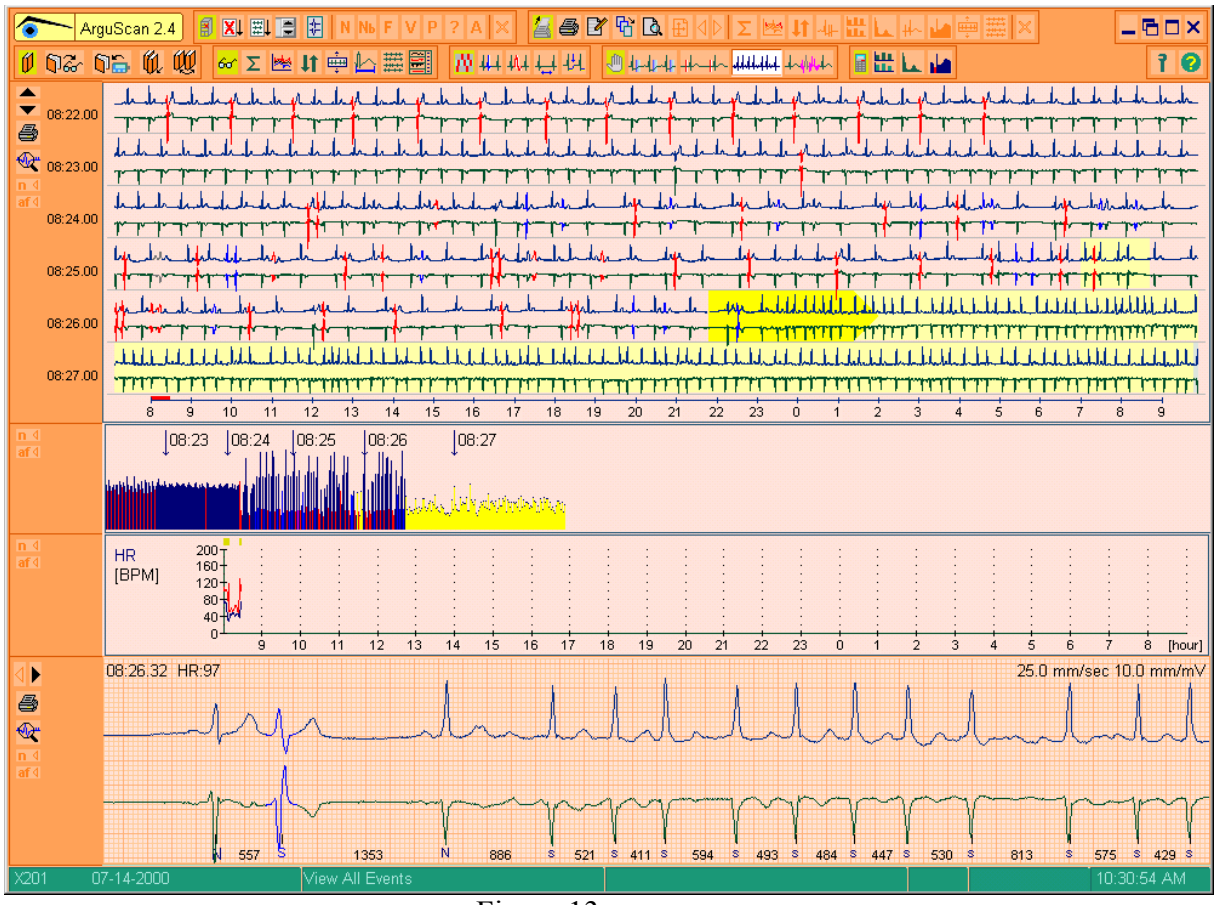
ArguScan 2.4
08:22.00
08:23.00
08:24.00
08:25.00
08:26.00
08:27.00
08:23
08:24
08:25
08:26
08:27
HR
[BPM]
[hour]
08:26.32 HR:97
25.0 mm/sec 10.0 mm/mV
X201
07-14-2000
View All Events
10:30:54 AM

Figure 13.

Artefact handling

One of the most important questions of ambulatory ECG record analysis is reliable noise detection and noise handling. During Holter measurements there are countless occasions, where a record cannot be evaluated because it contains too much noise due to measurement techniques. The ArguScan noise measurement module measures the noise level from muscle noise and low-frequency baseline movement, beat-by-beat. Where the noise level exceeds the value set in the criterions, the ECG curve is displayed in gray, and in the noisy section all arrhythmia analysis related modules cease to operate. If the record is noisy for several minutes, there is a break in the trends.

The ArguScan system offers an efficient solution to make noisy record evaluation easier. With the help of the noise setting window (Figure 14), the optimal noise level can be set for each channel, to evaluate those that can be, and leave out those that cannot be evaluated. Noise level setting is made easier with the noise trends, since they display the measured minimum and maximum noise levels per minute. The noise trend values are signal-noise percentage values. Trying a single noise level takes a few-second re-analysis.

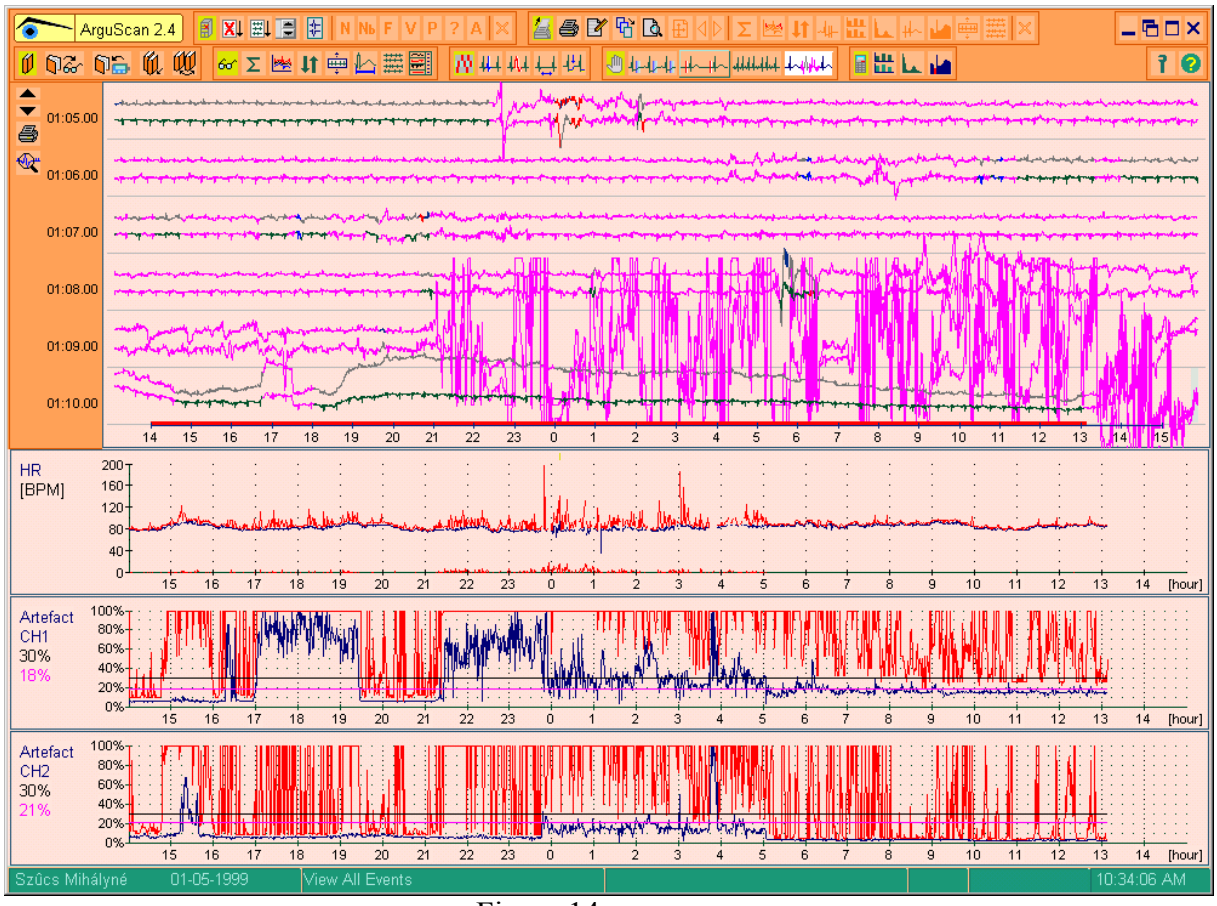

Figure 14.

Arrhythmia detector

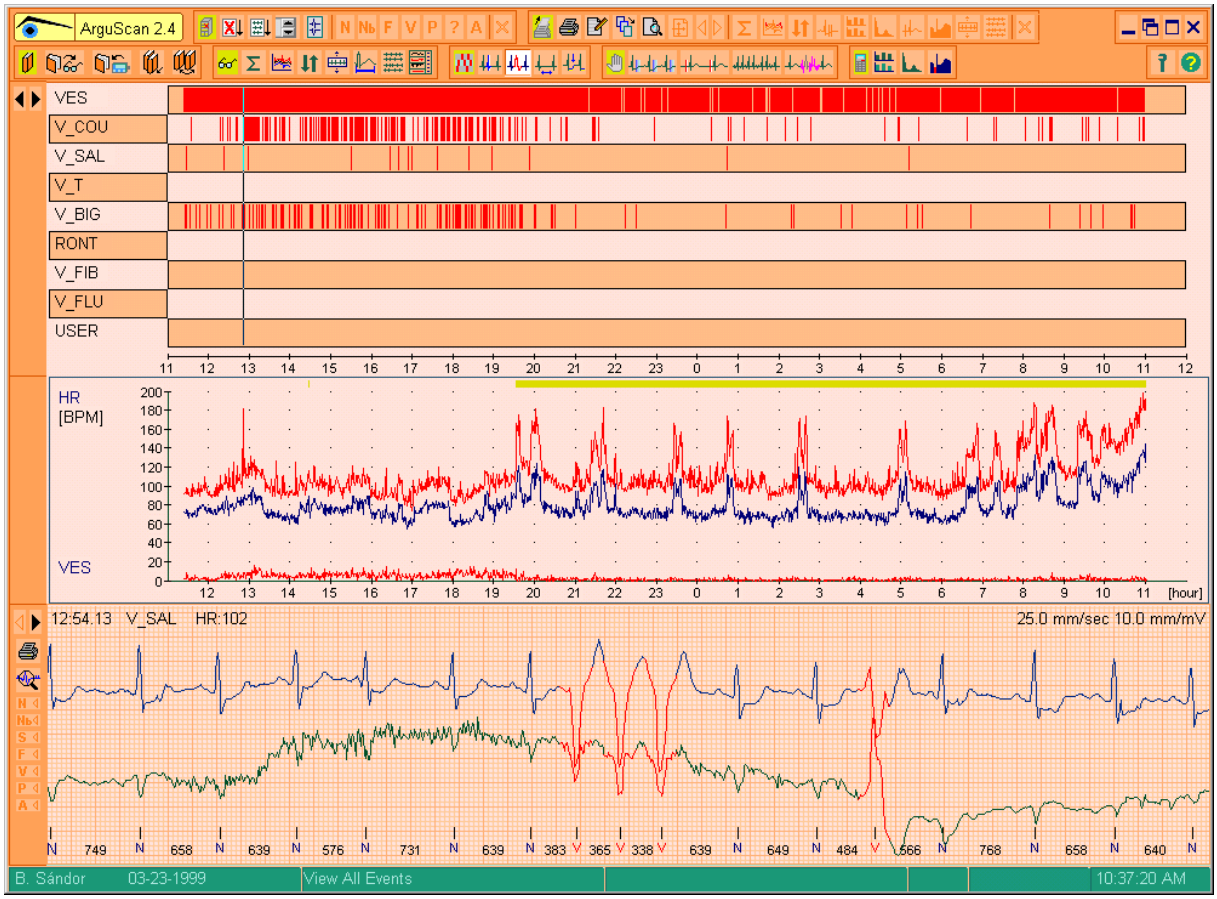

Figure 15.

The arrhythmia detector, considering the morphological classification, the P-analysis, the atrial fibrillation analysis and noise measurement results, detects the rhythm disorders based on the simultaneous QRS's positions relative to each other and their environments (couplet, bigeminia, run, etc.). The ArguScan system displays the rhythm disorder events in different windows based on atrial, ventricular and slow-rhythm categories (Figure 15). The bar graph graphically indicates the time distribution of the arrhythmia types. A red line in the bar graph indicates an event.

Testing the arrhythmia analysis program

We are testing the new design results of the ArguScan Holter system under clinical conditions in three arrhythmia centers. We have selected a database of 80 24-hour records containing critical arrhythmias from several hundred records, which we continually use to test our new modules. According to the ANSI/AAMI-EC 38 international standard for arrhythmia analysis programs, we have tested the QRS and VES detection accuracy of the ArguScan arrhythmia analysis program on 44 30-minute signals.

QRS SENS:	99.90%
QRS PPA:	99.82%
VES SENS:	96.62%
VES PPA:	96.92%

HRV analysis

The HRV analysis is exclusively interpreted on the sinus beat distances (RR) in both the time and frequency range. The sinus beats in the ArguScan system are classified as normal (N) and bundle branch block beat (Nb) beats. It follows that exact HRV analysis is only possible after correct arrhythmia analysis (QRS classification). In sections of the analysis, where there are a lot of "non compos mentis" RR-distances (due to arrhythmia or noise), HRV analysis ceases. What this means, is that the HRV frequency range analysis can only be performed, if the number of non sinus beats in the 256-second time range does not exceed 12% of all the beats.

HRV calculation in the time range

During HRV in the time range analysis the parameters in international standards are calculated. These are: SDNN, SDANN, ASDNN, NN50, pNN50, rMSSD, RR distance distribution, NRR distance distribution, the RRn-1 = f(RRn) and NRRn-1 = f(NRRn) functions.

SDNN

Nature's course – including the formation of RR-distance lengths – is most simply and realistically described with error distribution. Even those not familiar with mathematical statistics are familiar with this, if they have met the Gauss or bell-shape concept (for example, population distribution by age).

The SDNN (standard deviation of NN intervals) parameter gives spread of the distribution of normal RR-distances. What this means, is that approximately 68% of the RR-distances appear within +/- SDNN distance of the normal RR-distances, and 95% of them appear within +/-2 SDNN distance.

Figure 16 shows the calculated values of the SDNN in 5-minute intervals with a solid line, and the hourly values with little squares.

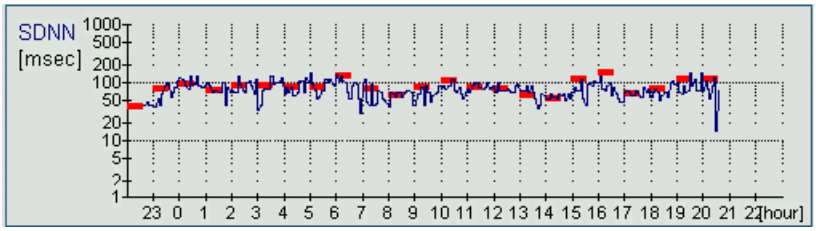

Figure 16.

SDANN

The SDANN (Standard deviation of the averages of NN intervals) value in a time interval gives the spread of the RR-distance averages of 5-minute time segments within the interval.

ASDNN

The ASDNN (Average of standard deviation of NN intervals) value in a time interval gives the average of the normal RR-distance spread of 5-minute time segments within the interval.

NN50

The NN50 parameter in a time interval gives the number of continuous normal RR-distances in the interval, which lengths deviate by at least 50ms

pNN50

The pNN50 parameter in a time interval gives what percent the calculated NN50 number for the interval is of all the normal RR-distances.

rMSSD

We calculate the rMSSD (The square root of the mean of the sum of the squares of differences) parameter for a time interval by taking the square root of the average of the square of the difference of the continuous normal RR-distances.
This number is usually proportional with the calculated pNN50 value.

RR distribution

During measurement, the program sorts the RR-distances by their lengths. In sorting, it considers RR-intervals 0-2000msec. Sorting takes place in 8msec breakdown, meaning the program sorts the RR intervals into 2000 / 8 = 250 “compartments”. At the end of the analysis, the number in the nth compartment shows how many RR’s were between (n*8) and ((n+1)*8) msec. Considering the graph, the function’s x-axis is the RR distances in msec, and the y-axis is the numbers in the “compartments” (Figure 17).

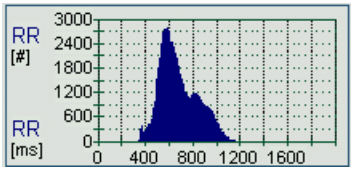

Figure 17.

NRR distribution

The NRR distribution function calculation is the same as the previously mentioned RR distribution function, the only difference being that the algorithm only uses the sinus (N, Nb) beats.

RRn-1 = f(RRn)

The function on Figure 18. shows the relation of continuous RR distances. The x-axis shows the nth RR distance in msec, and the y-axis shows the previous (n-1)th RR distance in msec). Therefore, if we select a point in the function, then we can see its RR distance on the x-axis and the previous RR distance on the y-axis. The coloring indicates the occurrence frequency:
blue: n>0 and n<(2 +(all/10.000))
green: n>=(2 +(all/10.000)) and n<(20 +(all/1.000))
red: n>=(20 +(all/1.000))

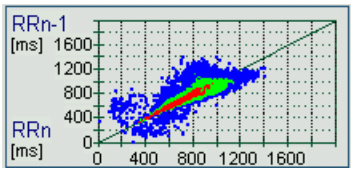

Figure 18.

NRRn-1 = f(NRRn)

The NRRn-1 = f(NRRn) function calculation is the same as the previously mentioned RRn-1 = f(RRn) function, the only difference is that here the algorithm only use the NRR's belonging to the sinus (N, Nb) beats.

HRV calculation in the frequency range

The pulse-change frequency spectrum is created during arrhythmia analysis. The power spectrum calculation is performed with 1024 point FFT on 256 seconds of data. Spectrum calculation starts at the beginning of every minute, so the number of power spectrums equals to the length of the record in minutes.
Figure 19. shows a spectrum-map, where the coloring of the minute-by-minute power spectrums next to each other give the effect of a map's elevation lines.

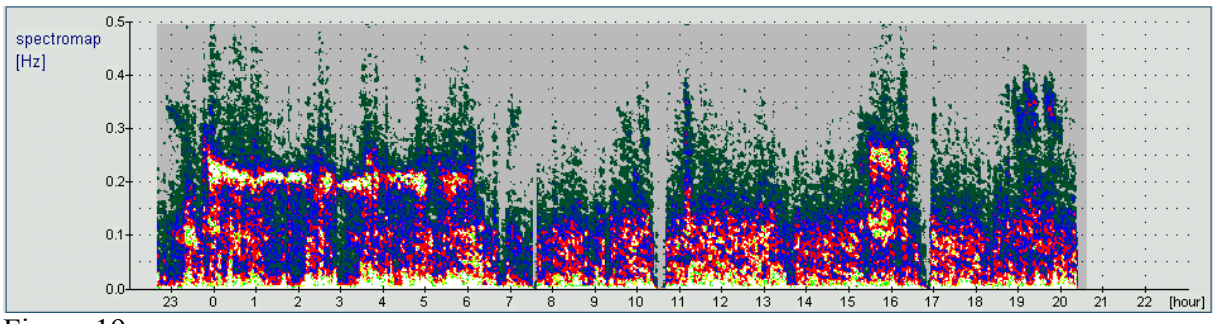

Figure 19.

Figure 20. shows a patient's nighttime power spectrum average, and different frequency range calculated power values.

VLF (Very Low Frequency)	0	- 0.04 Hz
LF (Low Frequency)	0.04	- 0.15 Hz
HF (High Frequency)	0.15	- 0.4 Hz

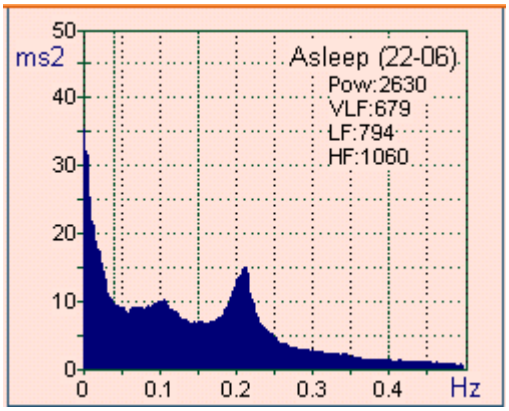

Figure 20.

Pacemaker analysis

The pacemaker detector in the recorder stores the detected pacemaker spike positions in a separate channel, simultaneously with the ECG signal storing. The detector senses the thin steep impulses generated by the pacemaker electrode, but erroneous detection is possible due to steep noise impulses. The pacemaker detector cannot distinguish the pacemaker originating impulses from the noise generated ones. The job of the pacemaker module is to distinguish the pacemaker generated impulses from the noise.

The thin and low energy spikes of the modern pacemakers do not always show up in the stored ECG signal, because impulses measured on the body surface are thinner than the ECG signal's sampling frequency, and in this case only the detector signals are visible in the ECG record. However, there are pacemakers which impulses are so great (Figure 21) that in many cases they exceed the QRS amplitudes measured on the body surface, thus interfering with the R-detector's exact operation, because instead of the QRS it detects the pacemaker spikes as QRS's.

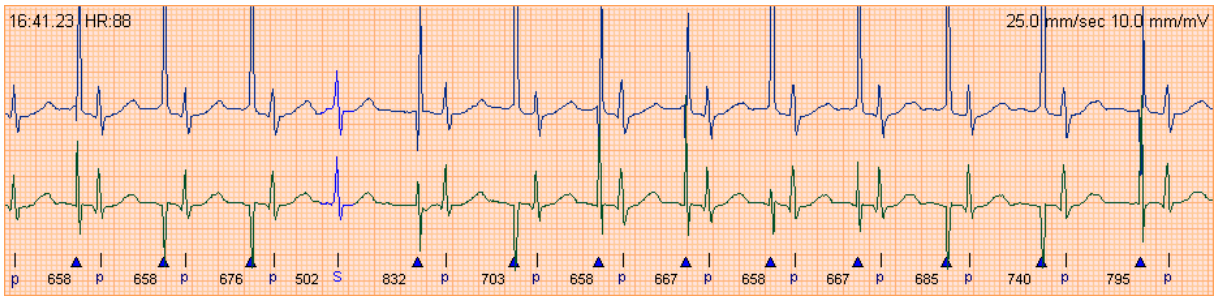

Figure 21.

The pacemaker analysis module's important job is to filter the pacemaker spikes from the ECG signal before R-detection, so the high amplitude spikes do not interfere with R-detector operation. During pacemaker analysis the program sorts the pacemaker spikes into 4 groups: ventricular, atrial, artefact originated, and unidentified.