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Welch Allyn® Hscribe™ Holter Analysis System

Clinician's Guide

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1. INTRODUCTION

Preface

This guide is intended for qualified health care professionals who want to learn more about the HScribe™ Holter system methods for analysis. It describes various aspects of the Welch Allyn VERITAS™ algorithm for Holter analysis. Contents of the HScribe final report are explained in detail for the interpreting physician's understanding. A "Quick Reference for the Holter Analyst" section contains representative ECG strips of commonly encountered rhythms and arrhythmias along with widely accepted medical definitions. This section also includes a description of how the HScribe analysis program interprets each event. This guide does not cover the user actions such as editing, review and results generation. These instructions are contained in the HScribe Holter Analysis System user manual.

Overview

HScribe is a high-speed, PC-based Holter scanner that performs analysis on continuous digital ECG data for up to 48 hours. The HScribe application provides full-disclosure data for arrhythmia analysis and incorporates Welch Allyn's exclusive VERITAS ECG algorithm for superior beat detection, QT/QTc analysis and ST segment analysis to acquired ECG data. The HScribe system is indicated for use in a clinical setting, by qualified medical professionals only, for patients requiring ambulatory (Holter) monitoring. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. The analysis software package includes detection and reporting features appropriate to the indications below:

- Evaluation of adult patients with symptoms suggesting arrhythmia
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of patient's response after resuming occupational or recreational activities (e.g. after myocardial infarction or cardiac surgery)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Clinical and epidemiological research studies
- Evaluation of ECGs from infants is limited to QRS detection and heart rate reporting, including infants weighing less than 10 kg (22 lbs) if supported by the Holter recorder device, see specific Holter recorder User Manual.

The HScribe analysis process consists of the following steps and components:

1. Reading the raw digital ECG data and then processing and storing the digital ECG data
2. Beat detection and creation of templates (QRS shapes) and their group types
3. Beat labeling and creation of navigable events within the following selections:
    - Strips
    - ECG
    - Summary
    - Templates
    - Histograms
    - Profile presentation with summary periods of data
    - Trend presentation in five-minute periods of data
4. Creation of summary data to provide totals for each beat and event type

Recording acquisition and the automatic computer analysis of a 24-hour or 48-hour recording is completed by the HScribe program in approximately one minute. Recalculation after an editing change is immediate.

Templates, beats, and events are navigable and can be edited during review. Holter ECG strips are added to the final report manually or automatically.

Holter results can be reported and exported in several different formats. The final report pages are numbered sequentially with examples explained in this guide.

2. PROCESSING THE ECG DATA

Accuracy of the Welch Allyn VERITAS analysis algorithm has been measured in accordance with the EC38 and EC57 standards published by the American National Standards Institute and the Association for the Advancement of Medical Instrumentation, as well as the international standard IEC 60601-2-47, who require sensitivity and positive predictivity of ECG analysis algorithms be reported for both QRS and ventricular ectopic beat detection. Tests were performed on all recordings excluding those with ventricular fibrillation and artificial pacemakers of two reference databases: AHA and MIT-BIH. Performance results show that the Welch Allyn HScribe Holter algorithm has 99.9% QRS detection accuracy, the best performance published by any company.

Note: Evaluation of ECGs from infants is limited to QRS detection and heart rate reporting, including infants weighing less than 10 kg (22 lbs) if supported by the Holter recorder device, see specific Holter recorder User Manual.

	AHA Database
Performance Measures	**Welch Allyn**
QRS Sensitivity %	99.88
QRS Positive Predictivity %	99.91
Ventricular Sensitivity %	93.73
Ventricular Positive Predictivity %	98.40
False Positive Rate %	0.15
	MIT-BIH Database
Performance Measures	**Welch Allyn**
QRS Sensitivity %	99.95
QRS Positive Predictivity %	99.87
Ventricular Sensitivity %	95.24
Ventricular Positive Predictivity %	97.05
False Positive Rate %	0.22

It is well-known that Holter ECG signals are subject to ambulatory noise and artifacts that can make the data difficult to analyze. Signal processing is performed to remove or lessen the types of noise and artifacts that occur during ambulatory recording such as baseline wander and shifts caused by high electrode impedance, 50/60 Hz AC interference, movement artifact, and muscular noise. The presence of noise and artifact in the recording can be minimized by using high-quality monitoring electrodes with proper skin preparation and electrode placement during patient hook up, explained in each device-specific user manual. Interactive review of the computer analyzed recording by a qualified clinician will ensure a highly accurate final report.

The results of EC 57 testing on the Noise Stress Database testify the resilience of the Veritas algorithm to noise up to twice the power of the ECG signal itself:

	NST Database
Performance Measures	**Welch Allyn**
QRS Sensitivity %	87.25
QRS Positive Predictivity %	89.44
Ventricular Sensitivity %	85.76
Ventricular Positive Predictivity %	72.42
False Positive Rate %	3.95

The HScribe analysis program applies a high pass filter to the data as it is acquired and read where appropriate for the recorder. Each sample is stored accompanied by a status field that contains indicators for diary events, no data, pacemaker spikes, and lead fail for each of the recorded channels.

Beat Detection

The analysis program checks the signal quality on each beat to determine the best quality channels to be used. Beat detection channels may change dynamically as the analysis progresses. Intermittent periods of lead fail or artifact will cause analysis channel switching to ensure accurate beat labeling. If required, the user can manually exclude channels from being used in the detection algorithm.

Templates and Beat Labeling

The analysis program groups beat in templates based on shape related information. Template groups such as Normal, Supraventricular*, Ventricular, Paced, and Unknown are then determined through evaluation of the dominant beat morphology, beat characteristics, prematurity and presence of any pacemaker spikes.

Templates with similar morphologies are merged during the final processing step based on the correlation between them.

Templates are presented in a total of 4 or 5 groups that may also contain other related beat types.

1. Normal
   - Supraventricular*
   - Bundle Branch Block
   - Aberrant*
2. Supraventricular*
   - Supraventricular*
   - Aberrant*
3. Ventricular
   - Fusion
   - R-On-T
     Once a beat is identified as being Ventricular, it is then compared to the previous beat. If the previous beat is not ventricular, its RR interval is less than 500 ms, and the beat is less than one-half of the previous beat's RR, it is declared an R-On-T beat by the analysis program.
   - Interpolated
   - Ventricular Escape
4. Paced
   - Atrial Paced
   - Ventricular paced
   - Dual Paced
5. Unknown

* When the user has selected **Enable Supraventricular Template Group**, all normal beats that meet the set SVPB prematurity percent criteria and manually labeled aberrant beats will be in the Supraventricular template group and not included in the Normal template group.

Each individual beat type is color-coded for rapid identification during review.

Automatically applied beat labels by the analysis program:	Manual beat labels:
Normal (N) Supraventricular (S) Ventricular (V) R on T (R) Ventricular Escape (E) Unknown (U) Atrial Paced (C) Ventricular Paced (P) Dual Paced (D)	Bundle Branch Block (B) Aberrant (T) Interpolated (I) Fusion (F) Delete Beat Artifact Note: Deleted beats and beats relabeled as artifact are removed

During review and editing, any applied beat label can be relabeled by the analyst with any one of the 13 beat labels. Additionally, the analyst may relabel a beat or region of the recording as Artifact to exclude data from being used for analysis, delete a beat or all beats within a template, and insert beat labels as desired. If an entire Template is relabeled Artifact, a short episode of recording containing each beat that is part of the template will be relabeled Artifact.

User-labeled Fusion and Interpolated beats will be classified as a ventricular beat type and used for ventricular calculations. User-labeled Bundle Branch Block beats will be classified as a normal beat type. Supraventricular beat types are identified by the program according to a user-defined prematurity percent setting and are contained within Normal templates or Supraventricular templates when enabled, as their QRS morphology is classified normal according to the dominant beat shape. Beats that are manually labeled as Normal or Supraventricular will not be relabeled on the basis of prematurity. User-labeled aberrant beats will also be classified as a supraventricular beat type.

Ectopic beats are grouped as "single" (one ectopic beat followed by a Normal beat), "couplets" or “pairs” (2 contiguous ectopic beats) and "Runs" (3 or more contiguous ectopic beats).

Event, Episode and Ectopy Presentation

Rhythm, QT and ST-segment analysis is performed using Welch Allyn's advanced VERITAS™ algorithm to determine isoelectric, Q, R, S and ST measurement points. The beat time, classification family, ST level, noise property,
Q onset and offset, QT interval, template number, and RR interval is analyzed for every beat and is processed by breaking down this information allowing the analyst to rapidly navigate to events and episodes through use of the HScribe Profile, Histograms, and Trends.

User-defined scan criteria settings can be modified on a per-study basis or set as a default for the following:

- Pacemaker analysis on/off and minimum pacemaker rate
- Automatic atrial fibrillation detection on or off
- Supraventricular prematurity percentage
- Pause duration in msec and if pauses are excluded from minimum HR calculation
- Pauses to use all beats or only normal to normal beats
- ST Segment Depression and Elevation thresholds in μV
- Tachycardia/Bradycardia heart rate thresholds and minimum duration
- Ventricular Tachycardia rate and number of consecutive beats
- Supraventricular Tachycardia rate and number of consecutive beats
- Heart Rate calculation on all beats, or only normal beats
- Heart Rate Variability calculation on normal beats only, or normal and supraventricular beats

The analysis program will identify ventricular bigeminy when the following pattern is present for at least 3 cycles: NVNVNV… Ventricular trigeminy is identified when the following pattern is present for at least three cycles: NNVNNVNNV… Navigation to these rhythm patterns is best performed in the Profile display.

The analysis program will identify supraventricular bigeminy when the following pattern is present for at least 3 cycles: NSNSNS… Supraventricular trigeminy is identified when the following pattern is present for at least three cycles: NNSNNSNNS… Navigation to these rhythm patterns is best performed in the Profile display.

Supraventricular or ventricular beats that occur during bigeminy and trigeminy episodes are included in the total ectopic beat count. The profile and summary statistics report the total number of beats that occurred during the bigeminy and trigeminy episodes (ventricular or supraventricular + Normal) in their respective columns.

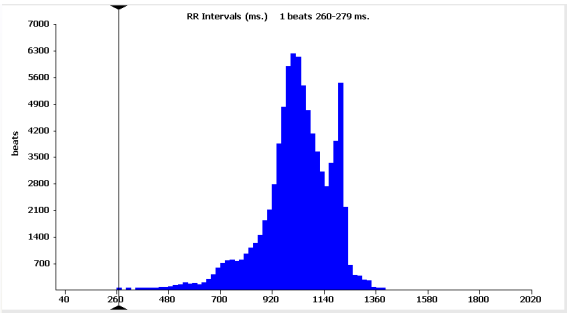
Periods of artifact that occur within a tachycardia or bradycardia episode will be considered to have the same heart rate and will be included in the duration of the event.

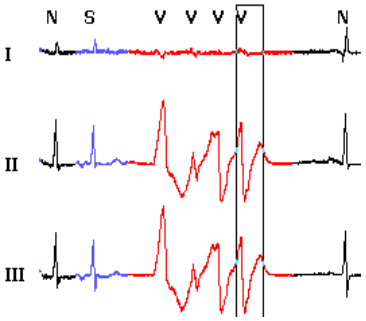
A colored Event Bar is selectable for display in the ECG view to indicate the start and end of an episode or event for the types listed below. Users may also define up to three custom event types per Holter study. Some event episodes may overlap and may not be visible. Event episodes are prioritized as follows:

- Exclusion (lead fail, artifact, user-removed)
- Atrial Fibrillation
- User-defined Event 1
- User-defined Event 2
- User-defined Event 3
- ST Depression
- ST Elevation

HScribe Profile information is broken into one-hour periods with calculated information presented for each period and a summary for the entire recording period.

HScribe RR Intervals Histogram information is created displaying the number of intervals that fall within 20 ms bins. This feature provides a graphical representation of the interval distribution allowing quick determination of frequency and density of intervals as well as navigation to the most extreme events.





HScribe Trend information is broken into five-minute periods presenting a minimum, average and maximum graphical representation of events and episodes.

Profile Events	Histogram Events	Trend Events
• Beat total • Min/Mean/Max Heart Rate • Bradycardia/Tachycardia • Bundle Branch Block Beats • Aberrant Beats • Interpolated Beats • Unknown Beats • Supraventricular • Atrial Fibrillation percent • Ventricular • Paced events and failures • Min/Max RR • Pauses • ST Elevation/Depression • RR variability calculations • Min/Mean/Max QT/QTc • User-defined episodes (3)	• RR Interval • Supraventricular Prematurity • Pace Spike→QRS • QRS→Pace Spike • Ventricular Run • Supraventricular Run	• Min/Mean/Max Heart Rate • Bundle Branch Block Beats • Aberrant Beats • Interpolated Beats • Unknown Beats • Supraventricular • Atrial Fibrillation percent • Ventricular • Paced events and failures • Min/Max RR • Pauses • ST Elevation/Depression • RR variability calculations • Min/Mean/Max QT/QTc • User-defined episodes (3)

Heart Rate Calculation

- Minimum and Maximum HR are calculated in a sliding window of 7.5-second intervals
- Mean HR is calculated on all beats within the time period (hourly, 5-minutes, 24-hours, etc.)

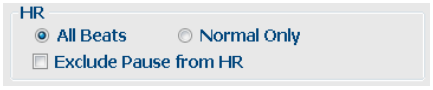
The analysis program calculates a heart rate for every beat based on the RR intervals in a 7.5-second window centered around the beat with a two interval minimum. The minimum and maximum (current) heart rate is then calculated using these heart rates in the defined profile period (e.g. one hour). The HScribe heart rate measurement range is 20 to 300 BPM.

Minimum and maximum heart rates consider all beats with a valid RR, unless configured to exclude RR intervals greater than the user-defined pause duration. The analysis program can also be configured to use only normal beats (Normal to Normal intervals) for heart rate calculation.

Mean heart rate is calculated on all beats with a valid RR interval within the recording period. This calculation can also be configured to use all beats or only normal beats.

There are two settings in the user defined Scan Criteria window that will affect heart rate calculation:

1) [Pause] Normal to Normal Only and 2) Exclude Pause from HR.



A pause is declared when the RR interval is greater than the user defined pause duration in the Scan Criteria window.

The heart rate RMS % error, as measured according to EC57 for the AHA, MIT-BIH and the Noise Stress Test databases are 2.69, 1.72 and 41.53 % respectively.

Atrial Fibrillation Detection

Atrial fibrillation episode detection is based on RR interval variability and P-wave analysis. Due to the nature of atrial fibrillation, detection is performed on episodes rather than beat-by-beat. The analysis program first divides the ECG into short sections of beats to compute the amount of variation in the RR interval of all beats with a normal morphology and the probability of P-wave presence prior to the QRS. When a criteria threshold is reached, the presence of atrial fibrillation is declared and the time of onset is established. Periods of artifact that occur within an atrial fibrillation episode will be considered to have the same average heart rate and will be included in the duration of the atrial fibrillation event.

In the interest of a high specificity, short (less than a minute) episodes of atrial fibrillation may not be seen by the automatic algorithm. These clinically less important episodes may be added by the user when encountered, usually during the review of supraventricular beats.

Regular (non-chaotic) variability, such as that which can be generated by occasional periods of supraventricular runs with regular rate or atrial flutter with constant AV-conduction, is specifically excluded by the detection algorithm. Irregular rhythm caused by sinus arrhythmia or frequent ectopic beats is also excluded in lieu of the presence of a P-wave in all or the majority of beats.

The analysis program does not automatically detect atrial flutter episodes which tend to present a regular rhythm that is not chaotic or random as well as a "P-wave" (flutter wave) correlated with the QRS complex. This episode type can be manually classified by the analyst by applying a user-defined event.

The percent of atrial fibrillation is summarized hourly and for the entire recording. An Atrial Fibrillation peak average heart rate value in the summary statistics reports the highest averaged heart rate of all of the atrial fibrillation episodes. This result may be useful when intermittent periods of atrial fibrillation are present.

	MIT-BIH Database
Performance Measures	**Welch Allyn**
Episode Sensitivity %	74
Episode Positive Predictivity %	76
Duration Sensitivity %	94
Duration Positive Predictivity %	78
Duration False Positive %	N/A
	NST Database
Performance Measures	**Welch Allyn**
Episode Sensitivity %	N/A
Episode Positive Predictivity %	0
Duration Sensitivity %	N/A
Duration Positive Predictivity %	0
Duration False Positive %	12.9

Performance has also been measured on the Physio net AFDB database (https://physionet.org/physiobank/database/afdb/), a database specifically collected to test the performance of atrial fibrillation algorithms. Results are as follows:

	AFDB Database
Performance Measures	**Welch Allyn**
Episode Sensitivity %	49
Episode Positive Predictivity %	95
Duration Sensitivity %	92
Duration Positive Predictivity %	99
Duration False Positive %	N/A

The AFDB database has also been used in a comparative study, using a slightly different way of measuring performance. The VERITAS results measured in the same way testifies the high specificity of the algorithm and are reported in the table below.

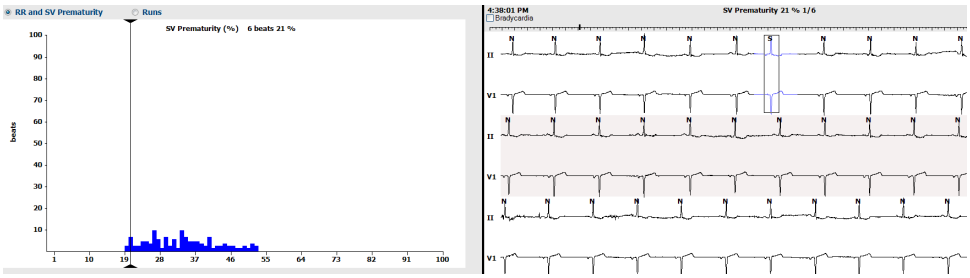
Comparison with 2011 Comparative Study

Algorithm	Method	Se (%)	Sp (%)	PPV (%)	Err (%)
VERITAS	RRI, AA	91.26	99.48	99.31	4.21
Moody et al.	RRI	87.54	95.14	92.29	7.88
Logan et al.	RRI	87.30	90.31	85.72	10.89
Linker et al.	RRI	97.64	85.55	81.81	9.61
Tatento et al.	RRI	91.20	96.08	90.32	5.32
Cerutti et al.	RRI	96.10	81.55	75.76	16.62
Slocum et al.	AA	62.80	77.46	64.90	28.39
Schmidt et al.	RRI, AA	89.20	94.58	91.62	7.57
Babaeizadeh et al.	RRI, AA	87.27	95.47	92.75	7.80
Couciero et al.	RRI, AA	96.58	82.66	78.76	11.77

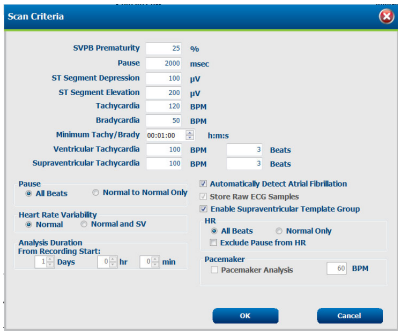
Larburu N, Lopetegi T, Romero I, "Comparative Study of Algorithms for Atrial Fibrillation Detection," *Comp. in Cardiol.* 2011; 38: 265-8. **RRI = RR Interval; AA = Atrial Activity**

Supraventricular Beat Identification

Supraventricular beats are shaped the same as normal beats, unless they are aberrantly conducted, and are included within the Normal templates and the Normal template group or the Supraventricular template group when the user has enabled it. The SV Prematurity (%) Histogram presents a graph of beats according to prematurity %. This offers a way to locate, review, and adjust prematurity percentage as needed.



The SV Prematurity % value is adjusted through selection of the menu bar Edit and Scan Criteria dialog. The clinician can change the SVPB prematurity percent to adjust when there are false calls. The default is 25%.

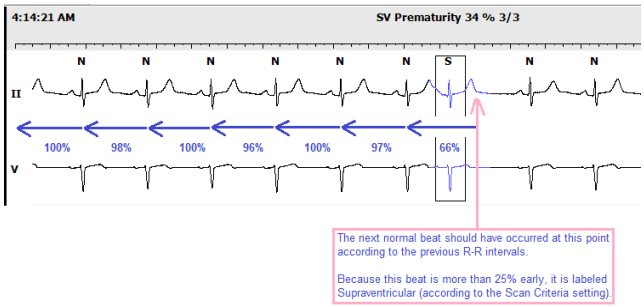


If SVEs are under called, the value can be decreased (20%, 15%, etc.).

If SV beats are overcalled, increase the value (30%, 40%, etc.).

The entire Holter recording is updated immediately after a change to the prematurity % value is made and the OK button is selected.

Supraventricular Prematurity Calculation: Supraventricular beat identification is based on the average R-to-R intervals from the previous Normal beats. Each beat is associated with an envelope of 16 preceding normal R-R intervals as demonstrated in the example below.



The Supraventricular template group, when enabled, and Supraventricular Ectopy columns within in the Profile tab and the Rhythm section are also helpful to quickly navigate to the system identified rhythm events.

Note: When a run of SVT approaches or exceeds 16 consecutive beats, the prematurity of the next R-R interval is likely to approach zero, since it is calculated compared to the previous 16 R-R intervals. Therefore, the next beat will be labeled normal (N) and the run is ended. In this case, the clinician may edit the beats of a long run when continuation of the run is determined. If, during a run of SVT, the next R-R interval is less than 400 ms (rate is greater than 150 bpm), it is always labeled supraventricular (S) independent of prematurity and the run is not ended.

ST Segment Analysis

During analysis, a per-beat measurement of ST level is determined at 60 msec post J for each "normal" beat. ST episode detection is performed by first processing all beats and then averaging the beat ST levels for each channel, excluding aVR, for each five-minute period in the recording.

An ST episode in a channel is found when the user-configured threshold is reached AND a 100 µV step occurred within one hour before the threshold was crossed, using the five-minute averages. Subsequently, the precise channel onset of the episode is found by determining where the individual beat measurements crossed the threshold. If a channel onset is found for more than one channel, the earliest of the channel onsets is used as the episode onset. Starting from the episode onset, the next twelve five-minute episodes (one hour) are evaluated for being below the threshold or showing a 100 µV step back. If the sum of these episodes in the next hour reaches a threshold, meaning that the ST-level has come back consistently, the offset of the episode is declared. This is done on all the channels where an onset was found, and the offset of the episode is determined where the last channel offset was found. The same process is then repeated backward in time, that is, from the last five-minute episode in the recording to the first, interchanging the offset and onset. Lastly, the ST-episodes found in the forward process are merged with those found in the backward process.

The same process is used for ST-depression and ST-elevation.

For each ST episode, the maximum ST values for each channel are calculated and the time at which each occurred is saved. The channel with the largest ST (average) value is labeled as the Primary channel, and the time of its maximum value is declared as the event time of the episode. The average ST value for each channel is calculated.

The ST-segment analysis performance of the VERITAS algorithm has been tested on the European STT database according to EC57. The results are depicted in the table below

	STT Database
Performance Measures	**Welch Allyn**
Discrepant measurements >100 µV %	7.3
Discrepant measurements >150 µV %	2.2
Discrepant measurements >200 µV %	0.8
Mean absolute error µV	49.1
Mean error µV	8.5
Standard deviation µV	66.1

QT/QTc Analysis

QT interval evaluation may be beneficial in detection of abnormal prolongation due to drug effects, electrolyte imbalance or genetic diseases, in order to evaluate the risk of serious ventricular arrhythmias that can lead to sudden cardiac death. The VERITAS™ algorithm automatically determines the QT from the interval between the earliest ventricular depolarization activity and the latest "end-of-T" point. This determination utilizes average beats as templates to reduce the effects of noise, but the actual QT interval determination is made on each single beat.

Each single QT value is corrected for previous heart rate (RR-intervals) by one of three formula's chosen by the user: Welch Allyn Linear, Bazett or Fridericia. These formulae correct the QT value for heart rates that differ from 60 bpm (RR intervals of 1 second). The following formulae are used where HR is expressed in beats per minute and QT, QTc and RR are expressed in seconds:

- Welch Allyn Linear: $QTcL = QT + (1-RR) * S$ (See Note below)
- Bazett: $QTcB = QT\ (HR/60)^{1/2} = QT\ (RR)^{-1/2}$
- Fridericia: $QTcF = QT\ (HR/60)^{1/3} = QT\ (RR)^{-1/3}$

There are three user selectable choices for the RR intervals to be used for QTc calculation:

RRprior	The previous RR interval in seconds; this method shows the immediate effect of the RR interval on the next QT value.
RR16	The sum of the previous 16 RR intervals; this method is most similar to how the QTc is calculated on a 10 second resting ECG.
RRc	A weighted average of the past 256 RR intervals; this method provides the optimal QT-RR correction according to current scientific insight, and is preferred for routine use.

Note: S is 0.143 (=1/7) if RRprior or RR16 is used and is 0.22 if RRc is used.
The use of RRc for QT correction in the ambulatory environment is recommended. The duration of the QT interval is influenced not only by the previous RR-interval, but depends on the history of the heart rate. This is also called QT-RR hysteresis. RRc takes this history into account. The weighting factors used have been calibrated to obtain the best average correction in a wide range of subjects and heart rate histories. It was found that the population average slope of the QT-RR relationship was higher than the traditional "Framingham" value when RRc was used, ranging from 0.19 in a young healthy population to 0.24 in a heart failure population. It should be noted, however, that significant individual differences exist.

The HScribe analysis program calculates an average QT and QTc duration in milliseconds of the normal beats in a 30-second window, centered on the time of interest. The Maximum, Minimum and Mean 30 second averages within a profile episode are displayed. The measurement of reliable QT/QTc values during ambulatory monitoring can be challenging and is dependent on recording quality. Proper assessment of periods of noise and the patient's ECG features are essential for correlation with any QT/QTc changes.

Time Domain RR Variability Calculation

During normal sinus rhythm, the heart rate varies from beat to beat. Heart rate variability, also known as RR variability, results from the dynamic interplay between the multiple physiologic mechanisms that regulate the spontaneous heart rate. Since short-term heart rate regulation is predominantly governed by sympathetic and parasympathetic neural activity, examination of heart rate fluctuations provides a window to observe the state and integrity of the autonomic nervous system.

Intervals used for RR variability calculations are those where the current, previous and second previous beats are Normal. The user may configure the program to use both Normal and Supraventricular beats. Intervals within an atrial fibrillation episode are excluded from analysis.

The HScribe RR Variability program calculates the following intervals in 5-minute periods from the start time of the Holter recording to the end: RMS SD, SDANN, SDNN index, and pNN50.

RMS SD, SDNN index, and pNN50 are calculated using all qualifying 5-minute intervals over the period of interest. In determining hour-by-hour statistics the program uses all qualifying 5-minute intervals for its analysis.

The HRV Triangular Index is calculated on the total number of RR intervals within the time period.

The SDANN value is calculated over a 24-hour period.

The following table contains definitions for each RR variability calculation:

pNN50	The percentage of Successive Differences in RR values greater than 50 ms (independent of sign) during the time period.
RMS SD	Root Mean Square of the Successive Differences in RR values during the time period. .
SDNN index	The average of five-minute period standard deviations of the RR intervals during the time period. Valid five minute periods are those that have at least two valid RR intervals. Also referred to as Magid SD.
SDANN	Standard Deviation of all five-minute average RR intervals during a 24-hour period. Valid five-minute periods are those that have at least two valid RR intervals. Also referred to as Kleiger SD.
HRV Triangular Index	Total number of RR intervals during the time period divided by the height of the histogram of all RR intervals measured on a discrete scale with bins of 7.8125 ms.

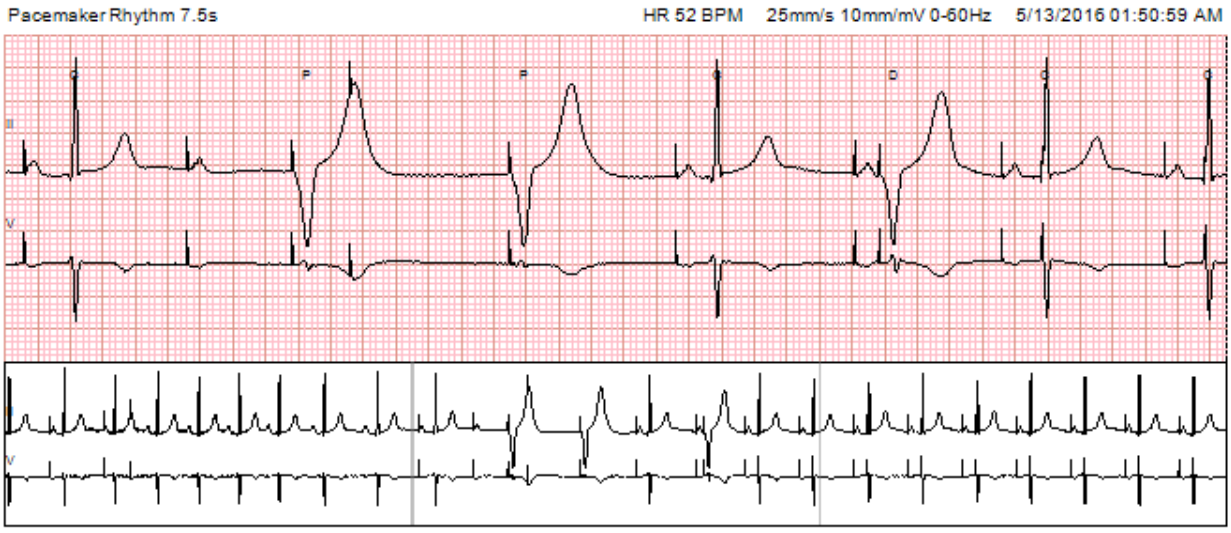
RR variability standard deviation, plotted as “Std” under the Trend tab and printed on the final report trend page is calculated using each 5-minute period representing the standard deviation of all RR intervals within the 5-minute period. This presents a statistical formula for variation.

The measurement of reliable RR variability calculations during ambulatory monitoring can be challenging and is dependent on recording quality. Proper assessment of periods of noise and the patient’s ECG features are essential for correlation with any RR variability changes.

Pacemaker Analysis

Pacemaker spikes are identified independently for each channel. Spikes that occur in channels with lead fail are ignored.

When pacemaker detection is enabled and pacing has been detected by the Holter analysis system, a spike marker at 500 µV amplitude will be present in the displayed waveform and in the final report ECG strips.



The analysis program will declare a beat is Atrial paced when the beat is normal and the pacer spike is within 250 to 125 msec before the beat detection point in any channel. Ventricular paced beats will be declared when the beat is paced and a pacemaker spike is within 60 msec before the beat detection point. Dual paced beats are declared when atrial and ventricular spikes are successive, the atrial spike is at least 60 msec before the ventricular spike and the beat is identified as paced.

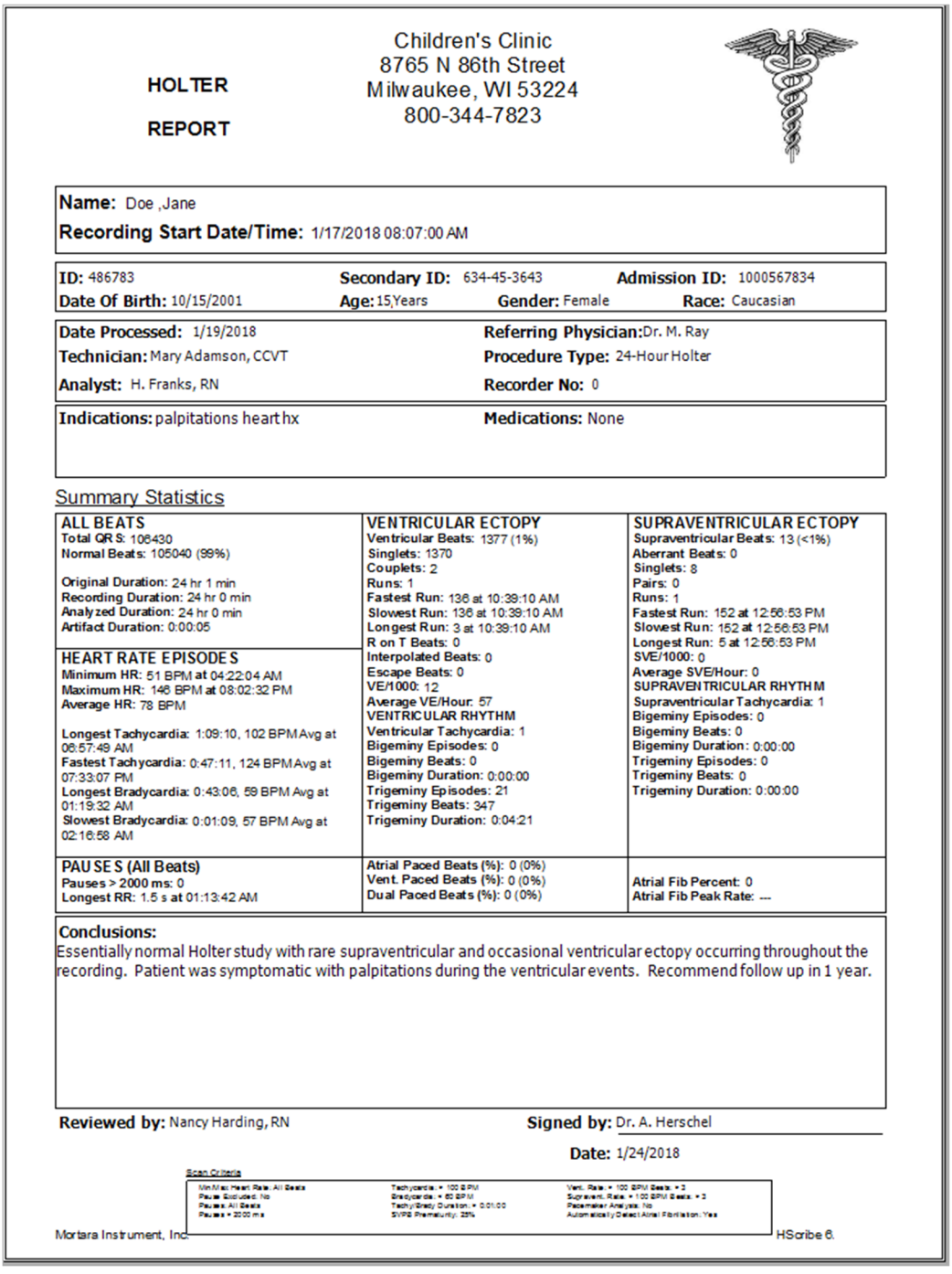
Pacemaker failures are identified as follows:

- Capture failure: a beat is not present after the pacer spike with an interval greater than 300 msec.
- Undersense: Pacer spike is earlier than expected and is less than one-third the time from its preceding beat.
- Oversense: The RR interval is greater than 1.2 times the expected paced interval after the beat; the minimum pacemaker rate is used to determine the expected paced interval.

3. FINAL REPORTS

Condensed Report Patient Information with Summary Statistics

The first report page contains patient demographic information, recording information, personnel information, summary statistical with tabular totals for recording events, and conclusions with an optional electronic signature with date signed. Scan criteria used for the recording is located at the bottom of the page. Institution contact information and a logo are customized by the administrative user.



HOLTER REPORT

Children's Clinic
8765 N 86th Street
Milwaukee, WI 53224
800-344-7823

Name: Doe ,Jane
Recording Start Date/Time: 1/17/2018 08:07:00 AM

ID: 486783 **Secondary ID:** 634-45-3643 **Admission ID:** 1000567834
Date Of Birth: 10/15/2001 **Age:** 15,Years **Gender:** Female **Race:** Caucasian

Date Processed: 1/19/2018 **Referring Physician:** Dr. M. Ray
Technician: Mary Adamson, CCVT **Procedure Type:** 24-Hour Holter
Analyst: H. Franks, RN **Recorder No:** 0

Indications: palpitations heart hx **Medications:** None

Summary Statistics

ALL BEATS
Total QRS: 106430
Normal Beats: 105040 (99%)

Original Duration: 24 hr 1 min
Recording Duration: 24 hr 0 min
Analyzed Duration: 24 hr 0 min
Artifact Duration: 0:00:05

HEART RATE EPISODES
Minimum HR: 51 BPM at 04:22:04 AM
Maximum HR: 146 BPM at 08:02:32 PM
Average HR: 78 BPM

Longest Tachycardia: 1:09:10, 102 BPM Avg at 06:57:49 AM
Fastest Tachycardia: 0:47:11, 124 BPM Avg at 07:33:07 PM
Longest Bradycardia: 0:43:06, 59 BPM Avg at 01:19:32 AM
Slowest Bradycardia: 0:01:09, 57 BPM Avg at 02:16:58 AM

PAUSES (All Beats)
Pauses > 2000 ms: 0
Longest RR: 1.5 s at 01:13:42 AM

VENTRICULAR ECTOPY
Ventricular Beats: 1377 (1%)
Singlets: 1370
Couplets: 2
Runs: 1
Fastest Run: 136 at 10:39:10 AM
Slowest Run: 136 at 10:39:10 AM
Longest Run: 3 at 10:39:10 AM
R on T Beats: 0
Interpolated Beats: 0
Escape Beats: 0
VE/1000: 12
Average VE/Hour: 57

VENTRICULAR RHYTHM
Ventricular Tachycardia: 1
Bigeminy Episodes: 0
Bigeminy Beats: 0
Bigeminy Duration: 0:00:00
Trigeminy Episodes: 21
Trigeminy Beats: 347
Trigeminy Duration: 0:04:21

Atrial Paced Beats (%): 0 (0%)
Vent. Paced Beats (%): 0 (0%)
Dual Paced Beats (%): 0 (0%)

SUPRAVENTRICULAR ECTOPY
Supraventricular Beats: 13 (<1%)
Aberrant Beats: 0
Singlets: 8
Pairs: 0
Runs: 1
Fastest Run: 152 at 12:56:53 PM
Slowest Run: 152 at 12:56:53 PM
Longest Run: 5 at 12:56:53 PM
SVE/1000: 0
Average SVE/Hour: 0

SUPRAVENTRICULAR RHYTHM
Supraventricular Tachycardia: 1
Bigeminy Episodes: 0
Bigeminy Beats: 0
Bigeminy Duration: 0:00:00
Trigeminy Episodes: 0
Trigeminy Beats: 0
Trigeminy Duration: 0:00:00

Atrial Fib Percent: 0
Atrial Fib Peak Rate: ---

Conclusions:
Essentially normal Holter study with rare supraventricular and occasional ventricular ectopy occurring throughout the recording. Patient was symptomatic with palpitations during the ventricular events. Recommend follow up in 1 year.

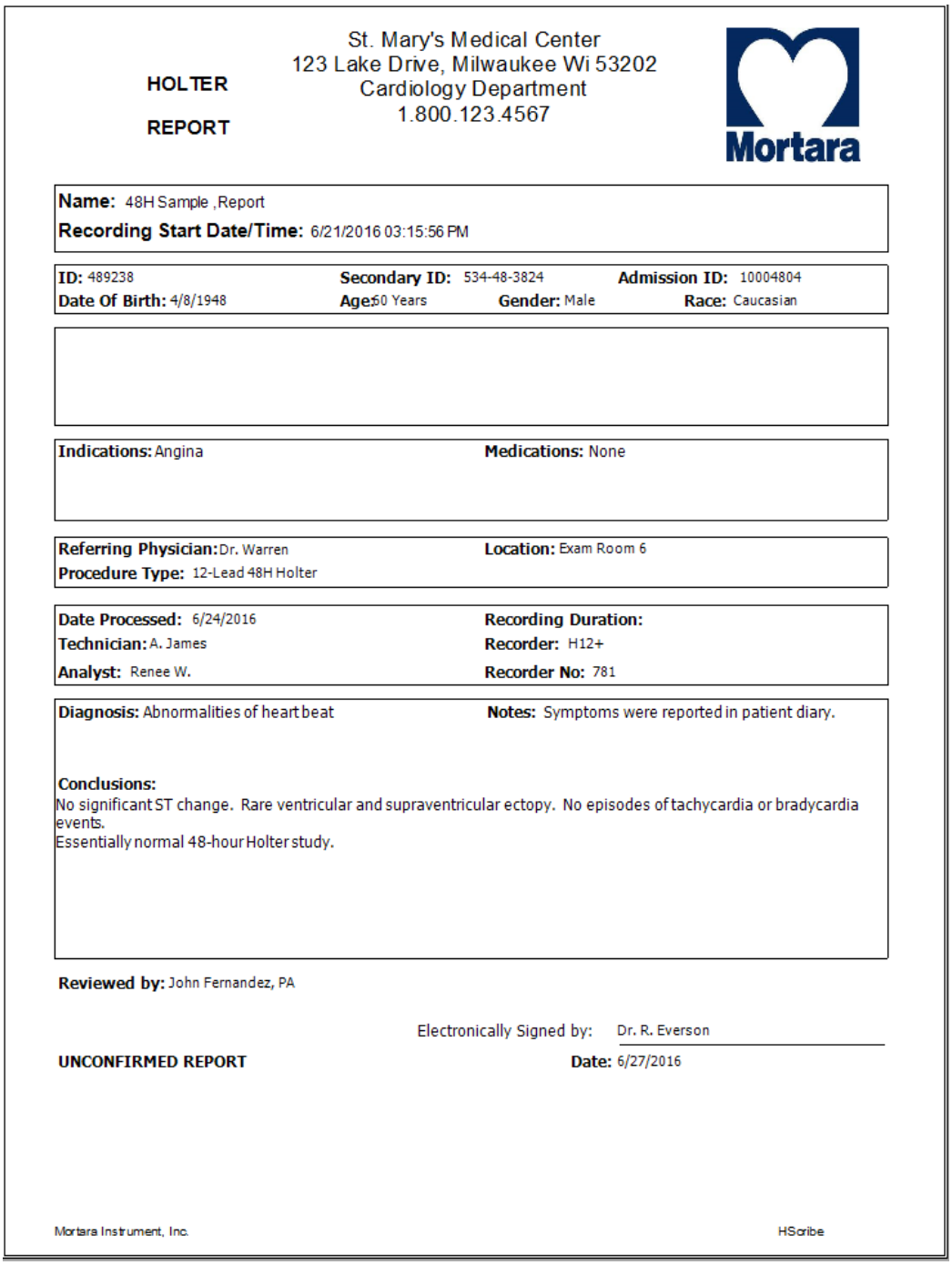
Reviewed by: Nancy Harding, RN **Signed by:** Dr. A. Herschel
Date: 1/24/2018

Scan Criteria

Mortara Instrument, Inc. HScribe 6.

Standard Report Patient Information

The first report page contains patient demographic information, recording information, personnel information and conclusions with an optional electronic signature with date signed. Institution contact information and a logo are customized by the administrative user. The layout of this page and the fields included can be customized by Welch Allyn Customer Service.



HOLTER

REPORT

St. Mary's Medical Center
123 Lake Drive, Milwaukee Wi 53202
Cardiology Department
1.800.123.4567

Mortara

Name: 48H Sample ,Report
Recording Start Date/Time: 6/21/2016 03:15:56 PM

ID: 489238 **Secondary ID:** 534-48-3824 **Admission ID:** 10004804
Date Of Birth: 4/8/1948 **Age:** 50 Years **Gender:** Male **Race:** Caucasian

Indications: Angina **Medications:** None

Referring Physician: Dr. Warren **Location:** Exam Room 6
Procedure Type: 12-Lead 48H Holter

Date Processed: 6/24/2016 **Recording Duration:**
Technician: A. James **Recorder:** H12+
Analyst: Renee W. **Recorder No:** 781

Diagnosis: Abnormalities of heart beat **Notes:** Symptoms were reported in patient diary.

Conclusions:
No significant ST change. Rare ventricular and supraventricular ectopy. No episodes of tachycardia or bradycardia events.
Essentially normal 48-hour Holter study.

Reviewed by: John Fernandez, PA

Electronically Signed by: Dr. R. Everson

UNCONFIRMED REPORT **Date:** 6/27/2016

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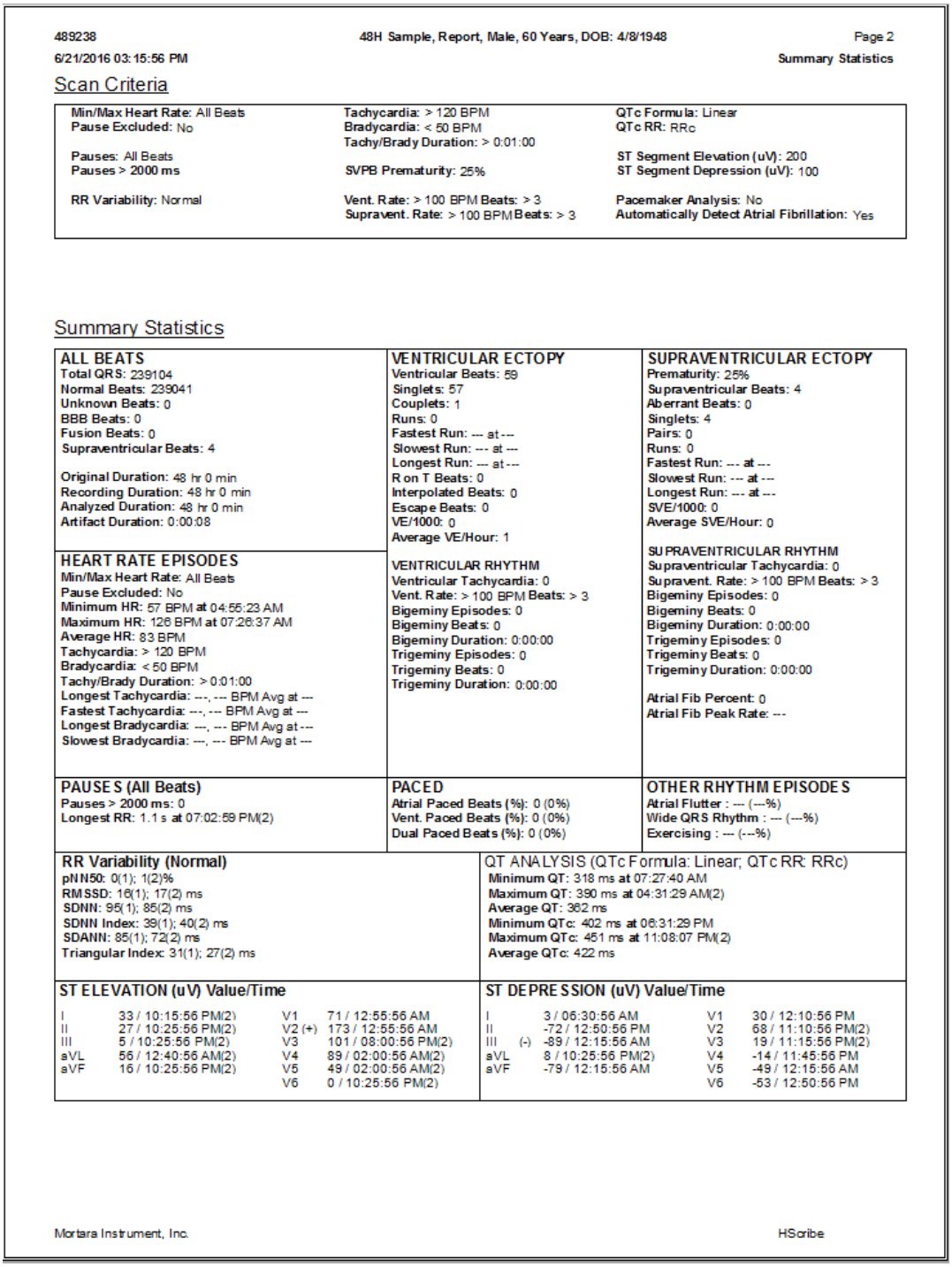
Standard Report Summary Statistics

The summary statistical page consists of scan criteria used for the recording at the top of the page and tabular totals for recording events. Page number and page type are printed on this and every following page.



489238 48H Sample, Report, Male, 60 Years, DOB: 4/8/1948 Page 2

6/21/2016 03:15:56 PM Summary Statistics

Scan Criteria

Min/Max Heart Rate: All Beats	**Tachycardia:** > 120 BPM	**QTc Formula:** Linear
Pause Excluded: No	**Bradycardia:** < 50 BPM	**QTc RR:** RRc
	Tachy/Brady Duration: > 0:01:00	
Pauses: All Beats		**ST Segment Elevation (uV):** 200
Pauses > 2000 ms	**SVPB Prematurity:** 25%	**ST Segment Depression (uV):** 100
RR Variability: Normal	**Vent. Rate:** > 100 BPM **Beats:** > 3	**Pacemaker Analysis:** No
	Supravent. Rate: > 100 BPM **Beats:** > 3	**Automatically Detect Atrial Fibrillation:** Yes

Summary Statistics

ALL BEATS
Total QRS: 239104
Normal Beats: 239041
Unknown Beats: 0
BBB Beats: 0
Fusion Beats: 0
Supraventricular Beats: 4

Original Duration: 48 hr 0 min
Recording Duration: 48 hr 0 min
Analyzed Duration: 48 hr 0 min
Artifact Duration: 0:00:08

HEART RATE EPISODES
Min/Max Heart Rate: All Beats
Pause Excluded: No
Minimum HR: 57 BPM **at** 04:55:23 AM
Maximum HR: 126 BPM **at** 07:26:37 AM
Average HR: 83 BPM
Tachycardia: > 120 BPM
Bradycardia: < 50 BPM
Tachy/Brady Duration: > 0:01:00
Longest Tachycardia: ---, --- BPM Avg at ---
Fastest Tachycardia: ---, --- BPM Avg at ---
Longest Bradycardia: ---, --- BPM Avg at ---
Slowest Bradycardia: ---, --- BPM Avg at ---

VENTRICULAR ECTOPY
Ventricular Beats: 59
Singlets: 57
Couplets: 1
Runs: 0
Fastest Run: --- at ---
Slowest Run: --- at ---
Longest Run: --- at ---
R on T Beats: 0
Interpolated Beats: 0
Escape Beats: 0
VE/1000: 0
Average VE/Hour: 1

VENTRICULAR RHYTHM
Ventricular Tachycardia: 0
Vent. Rate: > 100 BPM **Beats:** > 3
Bigeminy Episodes: 0
Bigeminy Beats: 0
Bigeminy Duration: 0:00:00
Trigeminy Episodes: 0
Trigeminy Beats: 0
Trigeminy Duration: 0:00:00

SUPRAVENTRICULAR ECTOPY
Prematurity: 25%
Supraventricular Beats: 4
Aberrant Beats: 0
Singlets: 4
Pairs: 0
Runs: 0
Fastest Run: --- at ---
Slowest Run: --- at ---
Longest Run: --- at ---
SVE/1000: 0
Average SVE/Hour: 0

SUPRAVENTRICULAR RHYTHM
Supraventricular Tachycardia: 0
Supravent. Rate: > 100 BPM **Beats:** > 3
Bigeminy Episodes: 0
Bigeminy Beats: 0
Bigeminy Duration: 0:00:00
Trigeminy Episodes: 0
Trigeminy Beats: 0
Trigeminy Duration: 0:00:00

Atrial Fib Percent: 0
Atrial Fib Peak Rate: ---

PAUSES (All Beats)
Pauses > 2000 ms: 0
Longest RR: 1.1 s **at** 07:02:59 PM(2)

PACED
Atrial Paced Beats (%): 0 (0%)
Vent. Paced Beats (%): 0 (0%)
Dual Paced Beats (%): 0 (0%)

OTHER RHYTHM EPISODES
Atrial Flutter : --- (---%)
Wide QRS Rhythm : --- (---%)
Exercising : --- (---%)

RR Variability (Normal)
pNN50: 0(1); 1(2)%
RMSSD: 16(1); 17(2) ms
SDNN: 95(1); 85(2) ms
SDNN Index: 39(1); 40(2) ms
SDANN: 85(1); 72(2) ms
Triangular Index: 31(1); 27(2) ms

QT ANALYSIS (QTc Formula: Linear; QTc RR: RRc)
Minimum QT: 318 ms **at** 07:27:40 AM
Maximum QT: 390 ms **at** 04:31:29 AM(2)
Average QT: 362 ms
Minimum QTc: 402 ms **at** 06:31:29 PM
Maximum QTc: 451 ms **at** 11:08:07 PM(2)
Average QTc: 422 ms

ST ELEVATION (uV) Value/Time

I	33 / 10:15:56 PM(2)	V1	71 / 12:55:56 AM
II	27 / 10:25:56 PM(2)	V2 (+)	173 / 12:55:56 AM
III	5 / 10:25:56 PM(2)	V3	101 / 08:00:56 PM(2)
aVL	56 / 12:40:56 AM(2)	V4	89 / 02:00:56 AM(2)
aVF	16 / 10:25:56 PM(2)	V5	49 / 02:00:56 AM(2)
		V6	0 / 10:25:56 PM(2)

ST DEPRESSION (uV) Value/Time

I	3 / 06:30:56 AM	V1	30 / 12:10:56 PM
II	-72 / 12:50:56 PM	V2	68 / 11:10:56 PM(2)
III (-)	-89 / 12:15:56 AM	V3	19 / 11:15:56 PM(2)
aVL	8 / 10:25:56 PM(2)	V4	-14 / 11:45:56 PM
aVF	-79 / 12:15:56 AM	V5	-49 / 12:15:56 AM
		V6	-53 / 12:50:56 PM

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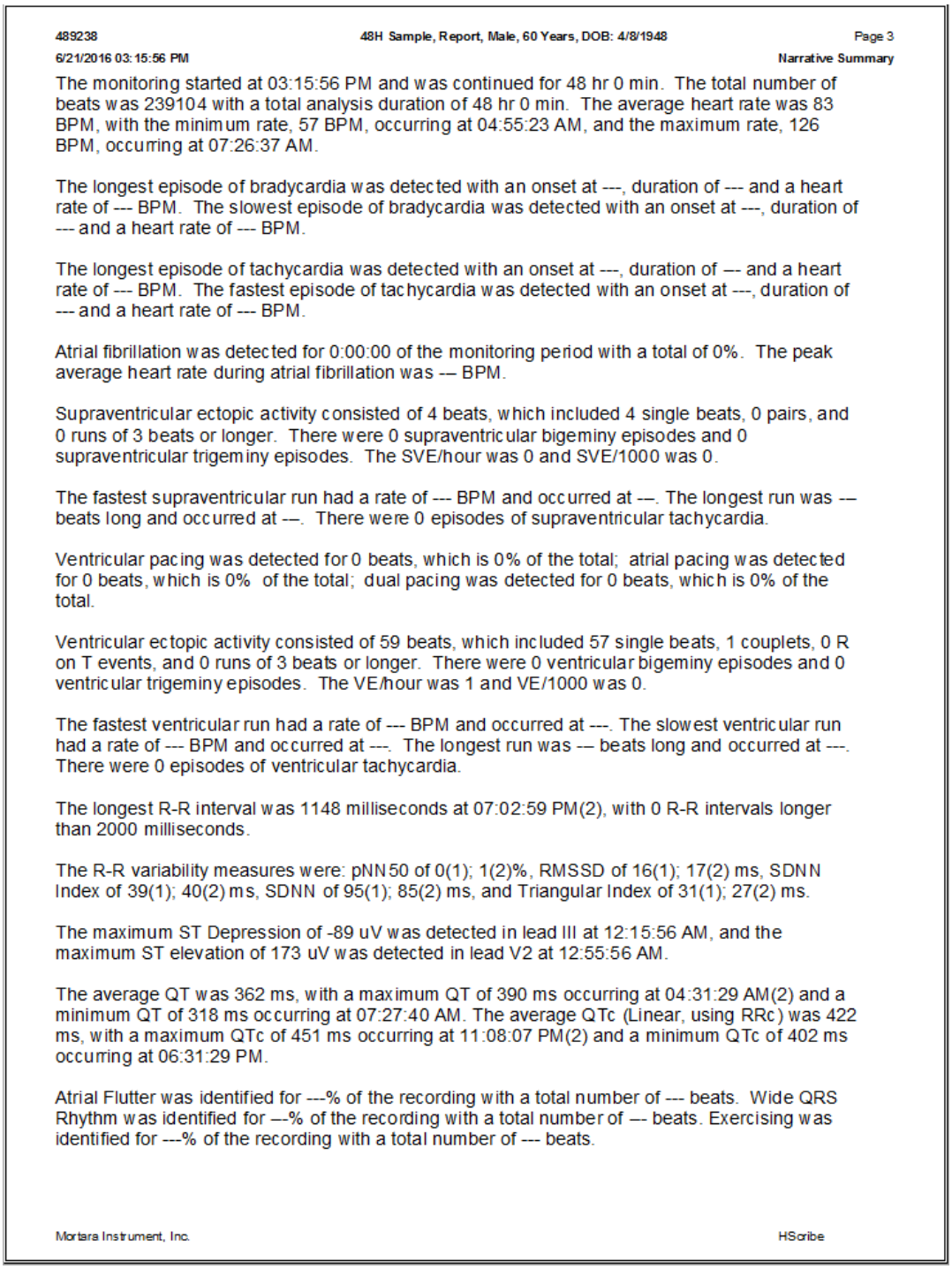
Narrative Summary

The narrative page repeats the tabular information in a narrative fashion. This page can be customized through use of the Report Configuration Tool.



489238 48H Sample, Report, Male, 60 Years, DOB: 4/8/1948 Page 3

6/21/2016 03:15:56 PM Narrative Summary

The monitoring started at 03:15:56 PM and was continued for 48 hr 0 min. The total number of beats was 239104 with a total analysis duration of 48 hr 0 min. The average heart rate was 83 BPM, with the minimum rate, 57 BPM, occurring at 04:55:23 AM, and the maximum rate, 126 BPM, occurring at 07:26:37 AM.

The longest episode of bradycardia was detected with an onset at ---, duration of --- and a heart rate of --- BPM. The slowest episode of bradycardia was detected with an onset at ---, duration of --- and a heart rate of --- BPM.

The longest episode of tachycardia was detected with an onset at ---, duration of --- and a heart rate of --- BPM. The fastest episode of tachycardia was detected with an onset at ---, duration of --- and a heart rate of --- BPM.

Atrial fibrillation was detected for 0:00:00 of the monitoring period with a total of 0%. The peak average heart rate during atrial fibrillation was --- BPM.

Supraventricular ectopic activity consisted of 4 beats, which included 4 single beats, 0 pairs, and 0 runs of 3 beats or longer. There were 0 supraventricular bigeminy episodes and 0 supraventricular trigeminy episodes. The SVE/hour was 0 and SVE/1000 was 0.

The fastest supraventricular run had a rate of --- BPM and occurred at ---. The longest run was --- beats long and occurred at ---. There were 0 episodes of supraventricular tachycardia.

Ventricular pacing was detected for 0 beats, which is 0% of the total; atrial pacing was detected for 0 beats, which is 0% of the total; dual pacing was detected for 0 beats, which is 0% of the total.

Ventricular ectopic activity consisted of 59 beats, which included 57 single beats, 1 couplets, 0 R on T events, and 0 runs of 3 beats or longer. There were 0 ventricular bigeminy episodes and 0 ventricular trigeminy episodes. The VE/hour was 1 and VE/1000 was 0.

The fastest ventricular run had a rate of --- BPM and occurred at ---. The slowest ventricular run had a rate of --- BPM and occurred at ---. The longest run was --- beats long and occurred at ---. There were 0 episodes of ventricular tachycardia.

The longest R-R interval was 1148 milliseconds at 07:02:59 PM(2), with 0 R-R intervals longer than 2000 milliseconds.

The R-R variability measures were: pNN50 of 0(1); 1(2)%, RMSSD of 16(1); 17(2) ms, SDNN Index of 39(1); 40(2) ms, SDNN of 95(1); 85(2) ms, and Triangular Index of 31(1); 27(2) ms.

The maximum ST Depression of -89 uV was detected in lead III at 12:15:56 AM, and the maximum ST elevation of 173 uV was detected in lead V2 at 12:55:56 AM.

The average QT was 362 ms, with a maximum QT of 390 ms occurring at 04:31:29 AM(2) and a minimum QT of 318 ms occurring at 07:27:40 AM. The average QTc (Linear, using RRc) was 422 ms, with a maximum QTc of 451 ms occurring at 11:08:07 PM(2) and a minimum QTc of 402 ms occurring at 06:31:29 PM.

Atrial Flutter was identified for ---% of the recording with a total number of --- beats. Wide QRS Rhythm was identified for ---% of the recording with a total number of --- beats. Exercising was identified for ---% of the recording with a total number of --- beats.

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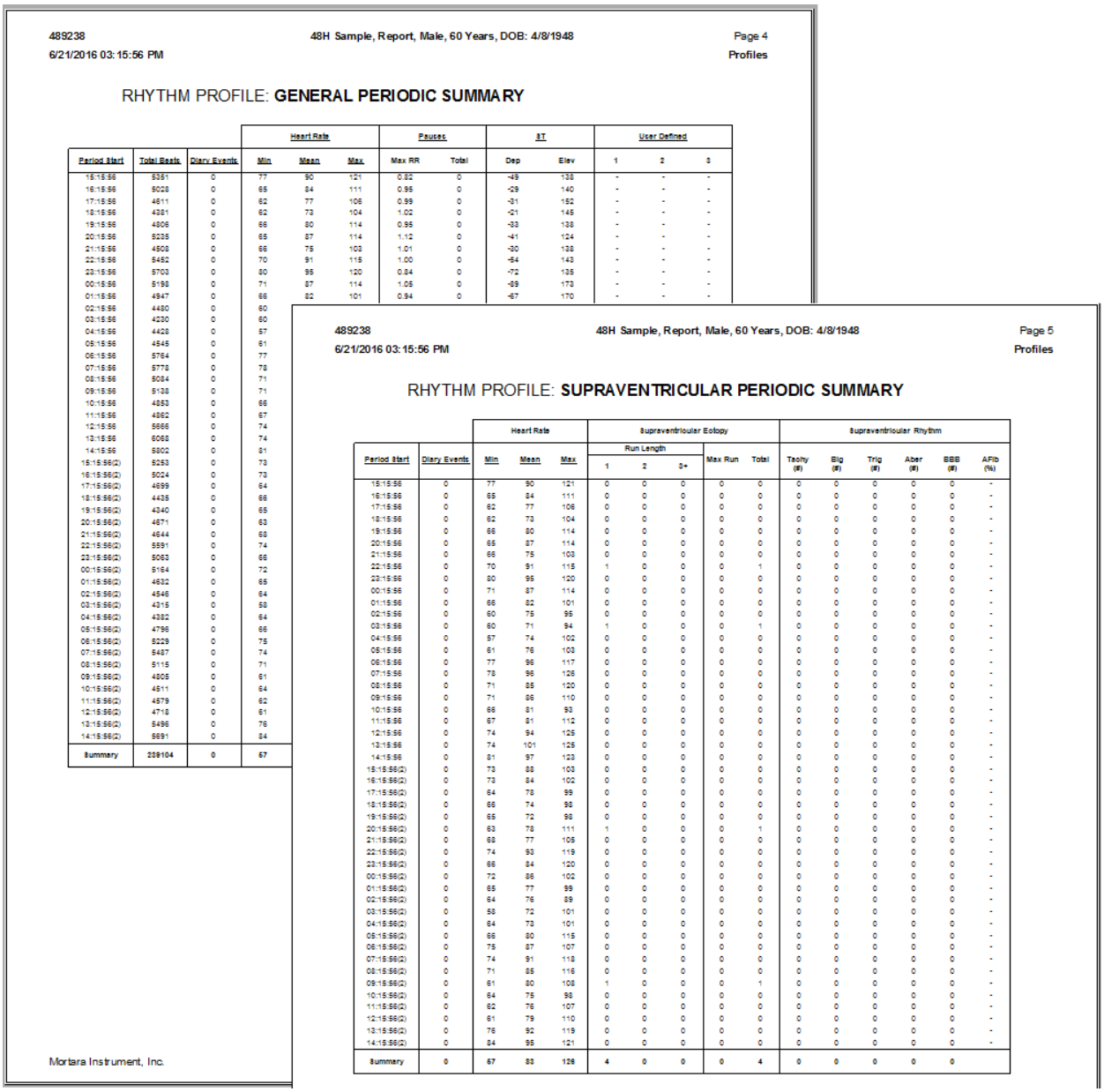
Profiles

Profile pages provide hour-by-hour statistics with a summary of the entire recording in the bottom row.



489238 48H Sample, Report, Male, 60 Years, DOB: 4/8/1948 Page 4
6/21/2016 03:15:56 PM Profiles

RHYTHM PROFILE: **GENERAL PERIODIC SUMMARY**

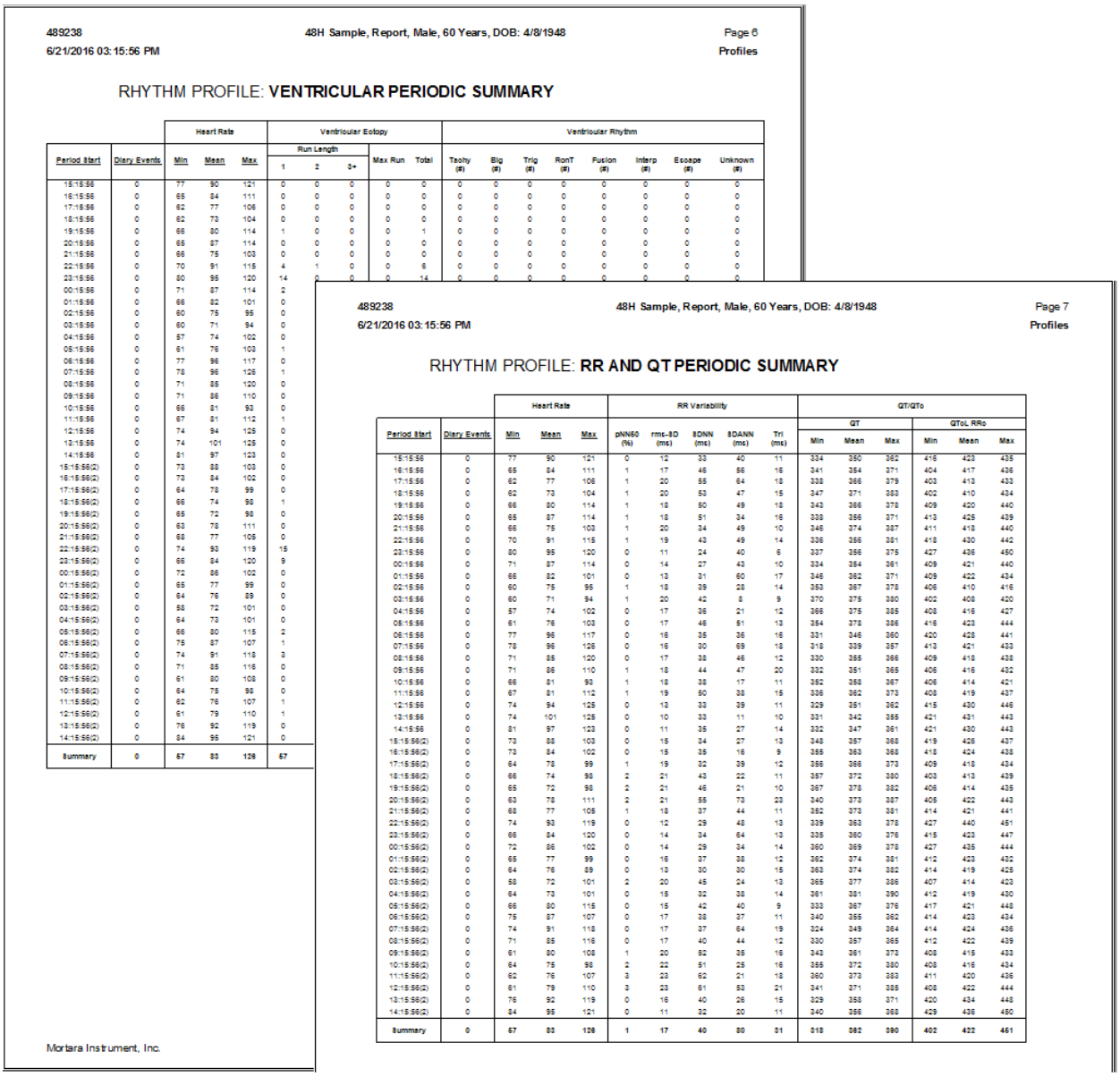
			Heart Rate			Pauses		ST		User Defined		
Period Start	Total Beats	Diary Events	Min	Mean	Max	Max RR	Total	Dep	Elev	1	2	3
15:15:56	5351	0	77	90	121	0.82	0	-49	138	-	-	-
16:15:56	5028	0	65	84	111	0.95	0	-29	140	-	-	-
17:15:56	4611	0	62	77	106	0.99	0	-31	152	-	-	-
18:15:56	4381	0	62	73	104	1.02	0	-21	145	-	-	-
19:15:56	4806	0	66	80	114	0.95	0	-33	138	-	-	-
20:15:56	5235	0	65	87	114	1.12	0	-41	124	-	-	-
21:15:56	4508	0	66	75	103	1.01	0	-30	138	-	-	-
22:15:56	5452	0	70	91	115	1.00	0	-54	142	-	-	-
23:15:56	5703	0	80	95	120	0.84	0	-72	138	-	-	-
00:15:56	5198	0	71	87	114	1.05	0	-69	173	-	-	-
01:15:56	4947	0	66	82	101	0.94	0	-67	170	-	-	-
02:15:56	4480	0	60									
03:15:56	4230	0	60									
04:15:56	4428	0	57									
05:15:56	4545	0	61									
06:15:56	5784	0	77									
07:15:56	5778	0	78									
08:15:56	5084	0	71									
09:15:56	5138	0	71									
10:15:56	4853	0	66									
11:15:56	4862	0	67									
12:15:56	5666	0	74									
13:15:56	6068	0	74									
14:15:56	5802	0	81									
15:15:56(2)	5253	0	73									
16:15:56(2)	5024	0	73									
17:15:56(2)	4699	0	64									
18:15:56(2)	4435	0	66									
19:15:56(2)	4340	0	65									
20:15:56(2)	4671	0	63									
21:15:56(2)	4644	0	68									
22:15:56(2)	5591	0	74									
23:15:56(2)	5063	0	66									
00:15:56(2)	5164	0	72									
01:15:56(2)	4632	0	65									
02:15:56(2)	4546	0	64									
03:15:56(2)	4215	0	58									
04:15:56(2)	4382	0	64									
05:15:56(2)	4796	0	66									
06:15:56(2)	5229	0	75									
07:15:56(2)	5487	0	74									
08:15:56(2)	5115	0	71									
09:15:56(2)	4805	0	61									
10:15:56(2)	4511	0	64									
11:15:56(2)	4579	0	62									
12:15:56(2)	4718	0	61									
13:15:56(2)	5496	0	76									
14:15:56(2)	5691	0	84									
Summary	239104	0	57									

Mortara Instrument, Inc.

489238 48H Sample, Report, Male, 60 Years, DOB: 4/8/1948 Page 5
6/21/2016 03:15:56 PM Profiles

RHYTHM PROFILE: **SUPRAVENTRICULAR PERIODIC SUMMARY**

		Heart Rate			Supraventricular Ectopy					Supraventricular Rhythm					
					Run Length										
Period Start	Diary Events	Min	Mean	Max	1	2	3+	Max Run	Total	Tachy (#)	Big (#)	Trig (#)	Aber (#)	BBB (#)	AFib (%)
15:15:56	0	77	90	121	0	0	0	0	0	0	0	0	0	0	-
16:15:56	0	65	84	111	0	0	0	0	0	0	0	0	0	0	-
17:15:56	0	62	77	106	0	0	0	0	0	0	0	0	0	0	-
18:15:56	0	62	73	104	0	0	0	0	0	0	0	0	0	0	-
19:15:56	0	66	80	114	0	0	0	0	0	0	0	0	0	0	-
20:15:56	0	65	87	114	0	0	0	0	0	0	0	0	0	0	-
21:15:56	0	66	75	103	0	0	0	0	0	0	0	0	0	0	-
22:15:56	0	70	91	115	1	0	0	0	1	0	0	0	0	0	-
23:15:56	0	80	95	120	0	0	0	0	0	0	0	0	0	0	-
00:15:56	0	71	87	114	0	0	0	0	0	0	0	0	0	0	-
01:15:56	0	66	82	101	0	0	0	0	0	0	0	0	0	0	-
02:15:56	0	60	75	95	0	0	0	0	0	0	0	0	0	0	-
03:15:56	0	60	71	94	1	0	0	0	1	0	0	0	0	0	-
04:15:56	0	57	74	102	0	0	0	0	0	0	0	0	0	0	-
05:15:56	0	61	76	103	0	0	0	0	0	0	0	0	0	0	-
06:15:56	0	77	96	117	0	0	0	0	0	0	0	0	0	0	-
07:15:56	0	78	96	126	0	0	0	0	0	0	0	0	0	0	-
08:15:56	0	71	85	120	0	0	0	0	0	0	0	0	0	0	-
09:15:56	0	71	86	110	0	0	0	0	0	0	0	0	0	0	-
10:15:56	0	66	81	93	0	0	0	0	0	0	0	0	0	0	-
11:15:56	0	67	81	112	0	0	0	0	0	0	0	0	0	0	-
12:15:56	0	74	94	125	0	0	0	0	0	0	0	0	0	0	-
13:15:56	0	74	101	125	0	0	0	0	0	0	0	0	0	0	-
14:15:56	0	81	97	123	0	0	0	0	0	0	0	0	0	0	-
15:15:56(2)	0	73	88	103	0	0	0	0	0	0	0	0	0	0	-
16:15:56(2)	0	73	84	102	0	0	0	0	0	0	0	0	0	0	-
17:15:56(2)	0	64	78	99	0	0	0	0	0	0	0	0	0	0	-
18:15:56(2)	0	66	74	93	0	0	0	0	0	0	0	0	0	0	-
19:15:56(2)	0	65	72	93	0	0	0	0	0	0	0	0	0	0	-
20:15:56(2)	0	63	78	111	1	0	0	0	1	0	0	0	0	0	-
21:15:56(2)	0	68	77	105	0	0	0	0	0	0	0	0	0	0	-
22:15:56(2)	0	74	93	119	0	0	0	0	0	0	0	0	0	0	-
23:15:56(2)	0	66	84	120	0	0	0	0	0	0	0	0	0	0	-
00:15:56(2)	0	72	86	102	0	0	0	0	0	0	0	0	0	0	-
01:15:56(2)	0	65	77	99	0	0	0	0	0	0	0	0	0	0	-
02:15:56(2)	0	64	76	89	0	0	0	0	0	0	0	0	0	0	-
03:15:56(2)	0	58	72	101	0	0	0	0	0	0	0	0	0	0	-
04:15:56(2)	0	64	73	101	0	0	0	0	0	0	0	0	0	0	-
05:15:56(2)	0	66	80	115	0	0	0	0	0	0	0	0	0	0	-
06:15:56(2)	0	75	87	107	0	0	0	0	0	0	0	0	0	0	-
07:15:56(2)	0	74	91	118	0	0	0	0	0	0	0	0	0	0	-
08:15:56(2)	0	71	85	116	0	0	0	0	0	0	0	0	0	0	-
09:15:56(2)	0	61	80	108	1	0	0	0	1	0	0	0	0	0	-
10:15:56(2)	0	64	75	98	0	0	0	0	0	0	0	0	0	0	-
11:15:56(2)	0	62	76	107	0	0	0	0	0	0	0	0	0	0	-
12:15:56(2)	0	61	79	110	0	0	0	0	0	0	0	0	0	0	-
13:15:56(2)	0	76	92	119	0	0	0	0	0	0	0	0	0	0	-
14:15:56(2)	0	84	95	121	0	0	0	0	0	0	0	0	0	0	-
Summary	0	57	83	126	4	0	0	0	4	0	0	0	0	0	



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RHYTHM PROFILE: **VENTRICULAR PERIODIC SUMMARY**

		Heart Rate			Ventricular Ectopy					Ventricular Rhythm							
					Run Length												
Period Start	Diary Events	Min	Mean	Max	1	2	3+	Max Run	Total	Tachy (#)	Big (#)	Trig (#)	RonT (#)	Fusion (#)	Interp (#)	Escape (#)	Unknown (#)
15:15:56	0	77	90	121	0	0	0	0	0	0	0	0	0	0	0	0	0
16:15:56	0	65	84	111	0	0	0	0	0	0	0	0	0	0	0	0	0
17:15:56	0	62	77	106	0	0	0	0	0	0	0	0	0	0	0	0	0
18:15:56	0	62	73	104	0	0	0	0	0	0	0	0	0	0	0	0	0
19:15:56	0	66	80	114	1	0	0	0	1	0	0	0	0	0	0	0	0
20:15:56	0	65	87	114	0	0	0	0	0	0	0	0	0	0	0	0	0
21:15:56	0	66	75	103	0	0	0	0	0	0	0	0	0	0	0	0	0
22:15:56	0	70	91	115	4	1	0	0	6	0	0	0	0	0	0	0	0
23:15:56	0	80	95	120	14	0	0	0	14	0	0	0	0	0	0	0	0
00:15:56	0	71	87	114	2												
01:15:56	0	66	82	101	0												
02:15:56	0	60	75	95	0												
03:15:56	0	60	71	94	0												
04:15:56	0	57	74	102	0												
05:15:56	0	61	76	103	1												
06:15:56	0	77	96	117	0												
07:15:56	0	78	96	126	1												
08:15:56	0	71	85	120	0												
09:15:56	0	71	86	110	0												
10:15:56	0	66	81	93	0												
11:15:56	0	67	81	112	1												
12:15:56	0	74	94	125	0												
13:15:56	0	74	101	125	0												
14:15:56	0	81	97	123	0												
15:15:56(2)	0	73	88	103	0												
16:15:56(2)	0	73	84	102	0												
17:15:56(2)	0	64	78	99	0												
18:15:56(2)	0	66	74	98	1												
19:15:56(2)	0	65	72	98	0												
20:15:56(2)	0	63	78	111	0												
21:15:56(2)	0	68	77	105	0												
22:15:56(2)	0	74	93	119	15												
23:15:56(2)	0	66	84	120	9												
00:15:56(2)	0	72	86	102	0												
01:15:56(2)	0	65	77	99	0												
02:15:56(2)	0	64	76	89	0												
03:15:56(2)	0	58	72	101	0												
04:15:56(2)	0	64	73	101	0												
05:15:56(2)	0	66	80	115	2												
06:15:56(2)	0	75	87	107	1												
07:15:56(2)	0	74	91	118	3												
08:15:56(2)	0	71	85	116	0												
09:15:56(2)	0	61	80	108	0												
10:15:56(2)	0	64	75	98	0												
11:15:56(2)	0	62	76	107	1												
12:15:56(2)	0	61	79	110	1												
13:15:56(2)	0	76	92	119	0												
14:15:56(2)	0	84	95	121	0												
Summary	0	57	83	126	57												

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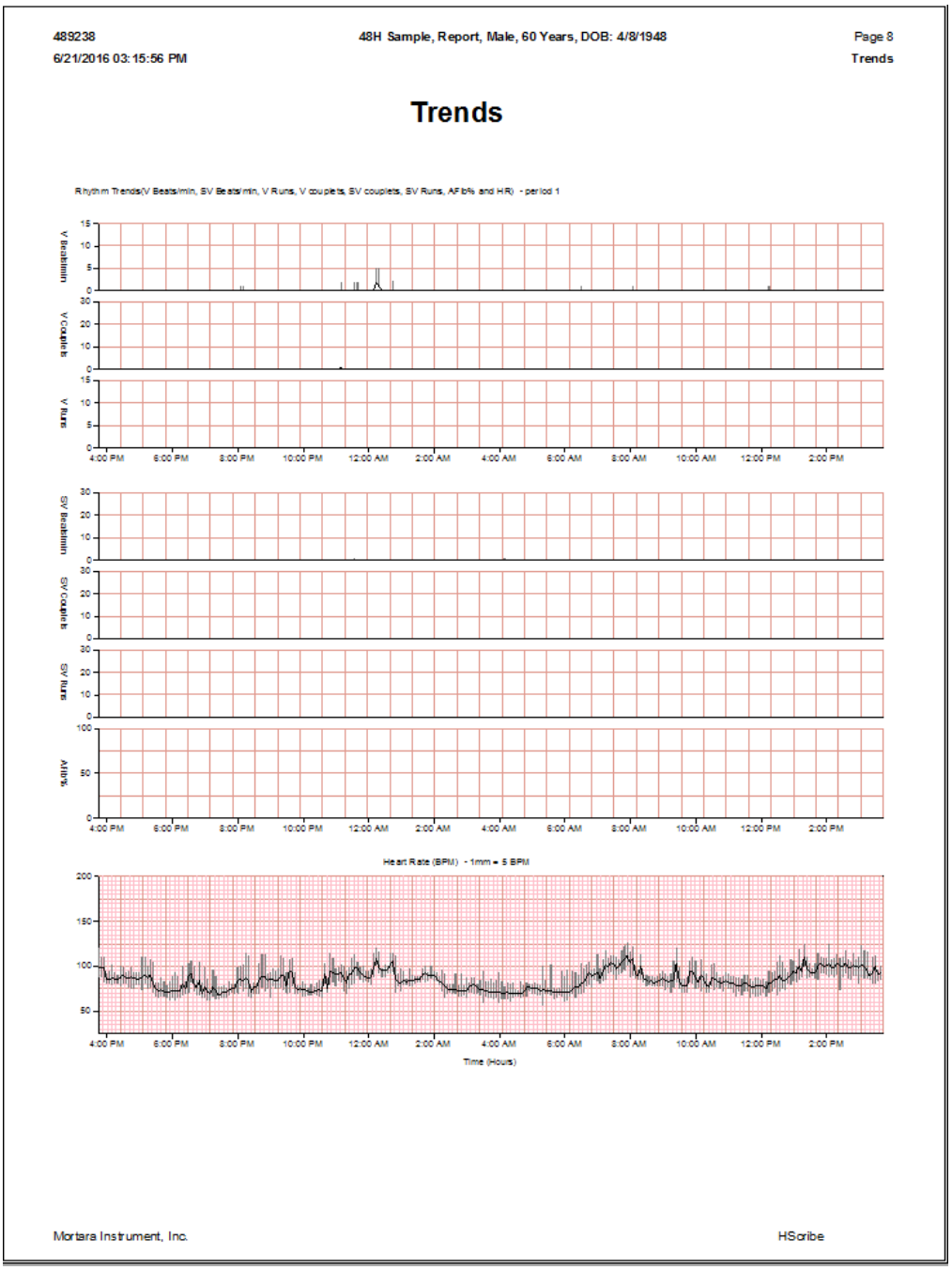
RHYTHM PROFILE: **RR AND QT PERIODIC SUMMARY**

		Heart Rate			RR Variability					QT/QTc					
										QT			QTcL RRc		
Period Start	Diary Events	Min	Mean	Max	pNN50 (%)	rmsSD (ms)	SDNN (ms)	SDANN (ms)	Tri (ms)	Min	Mean	Max	Min	Mean	Max
15:15:56	0	77	90	121	0	12	33	40	11	334	350	362	416	423	435
16:15:56	0	65	84	111	1	17	46	56	16	341	354	371	404	417	426
17:15:56	0	62	77	106	1	20	55	64	18	338	366	379	403	413	433
18:15:56	0	62	73	104	1	20	53	47	15	347	371	383	402	410	434
19:15:56	0	66	80	114	1	18	50	49	18	343	366	378	409	420	440
20:15:56	0	65	87	114	1	18	51	34	16	338	366	371	413	425	439
21:15:56	0	66	75	103	1	20	34	49	10	346	374	387	411	418	440
22:15:56	0	70	91	115	1	19	43	49	14	336	356	381	418	430	442
23:15:56	0	80	95	120	0	11	24	40	6	337	356	375	427	436	450
00:15:56	0	71	87	114	0	14	27	43	10	334	354	361	409	421	440
01:15:56	0	66	82	101	0	13	31	60	17	346	362	371	409	422	434
02:15:56	0	60	75	95	1	18	39	28	14	353	367	378	406	410	416
03:15:56	0	60	71	94	1	20	42	8	9	370	375	380	402	408	420
04:15:56	0	57	74	102	0	17	36	21	12	366	375	385	408	416	427
05:15:56	0	61	76	103	0	17	46	51	13	354	378	386	416	423	444
06:15:56	0	77	96	117	0	16	35	36	16	331	346	360	420	428	441
07:15:56	0	78	96	126	0	16	30	69	18	318	339	357	413	421	433
08:15:56	0	71	85	120	0	17	38	46	12	330	355	366	409	418	438
09:15:56	0	71	86	110	1	18	44	47	20	332	351	365	406	416	432
10:15:56	0	66	81	93	1	18	38	17	11	352	358	367	406	414	421
11:15:56	0	67	81	112	1	19	50	38	15	336	362	373	408	419	437
12:15:56	0	74	94	125	0	13	33	39	11	329	351	362	415	430	446
13:15:56	0	74	101	125	0	10	33	11	10	331	342	355	421	431	443
14:15:56	0	81	97	123	0	11	35	27	14	332	347	361	421	430	443
15:15:56(2)	0	73	88	103	0	15	34	27	13	348	357	368	419	426	437
16:15:56(2)	0	73	84	102	0	15	35	16	9	355	363	368	418	424	438
17:15:56(2)	0	64	78	99	1	19	32	39	12	356	366	373	409	418	434
18:15:56(2)	0	66	74	98	2	21	43	22	11	367	372	380	403	413	439
19:15:56(2)	0	65	72	98	2	21	46	21	10	367	378	382	406	414	435
20:15:56(2)	0	63	78	111	2	21	55	73	23	340	373	387	405	422	443
21:15:56(2)	0	68	77	105	1	18	37	44	11	352	373	381	414	421	441
22:15:56(2)	0	74	93	119	0	12	29	48	13	339	363	378	427	440	451
23:15:56(2)	0	66	84	120	0	14	34	64	13	335	360	376	415	423	447
00:15:56(2)	0	72	86	102	0	14	29	34	14	360	369	378	427	435	444
01:15:56(2)	0	65	77	99	0	16	37	38	12	362	374	381	412	423	432
02:15:56(2)	0	64	76	89	0	13	30	30	15	363	374	382	414	419	425
03:15:56(2)	0	58	72	101	2	20	45	24	13	365	377	386	407	414	423
04:15:56(2)	0	64	73	101	0	15	32	38	14	361	381	390	412	419	430
05:15:56(2)	0	66	80	115	0	15	42	40	9	333	367	376	417	421	448
06:15:56(2)	0	75	87	107	0	17	38	37	11	340	355	362	414	423	434
07:15:56(2)	0	74	91	118	0	17	37	64	19	324	349	364	414	424	436
08:15:56(2)	0	71	85	116	0	17	40	44	12	330	357	365	412	422	439
09:15:56(2)	0	61	80	108	1	20	52	35	16	343	361	373	408	415	433
10:15:56(2)	0	64	75	98	2	22	51	25	16	355	372	380	408	416	434
11:15:56(2)	0	62	76	107	3	23	62	21	18	360	373	383	411	420	436
12:15:56(2)	0	61	79	110	3	23	61	53	21	341	371	385	408	422	444
13:15:56(2)	0	76	92	119	0	16	40	26	15	329	358	371	420	434	448
14:15:56(2)	0	84	95	121	0	11	32	20	11	340	356	368	429	436	450
Summary	0	57	83	126	1	17	40	80	31	318	362	390	402	422	461

Trends

The trends pages consist of 5-minute rhythm trends, QT trends, RR variability trends, and ST trends. Episodes of ST elevation and ST depression will be listed on the ST trends page. The heart rate trend is repeated in each trend for correlation. When the recording duration is between 24 and 48 hours, each trend page will represent a 24-hour period.



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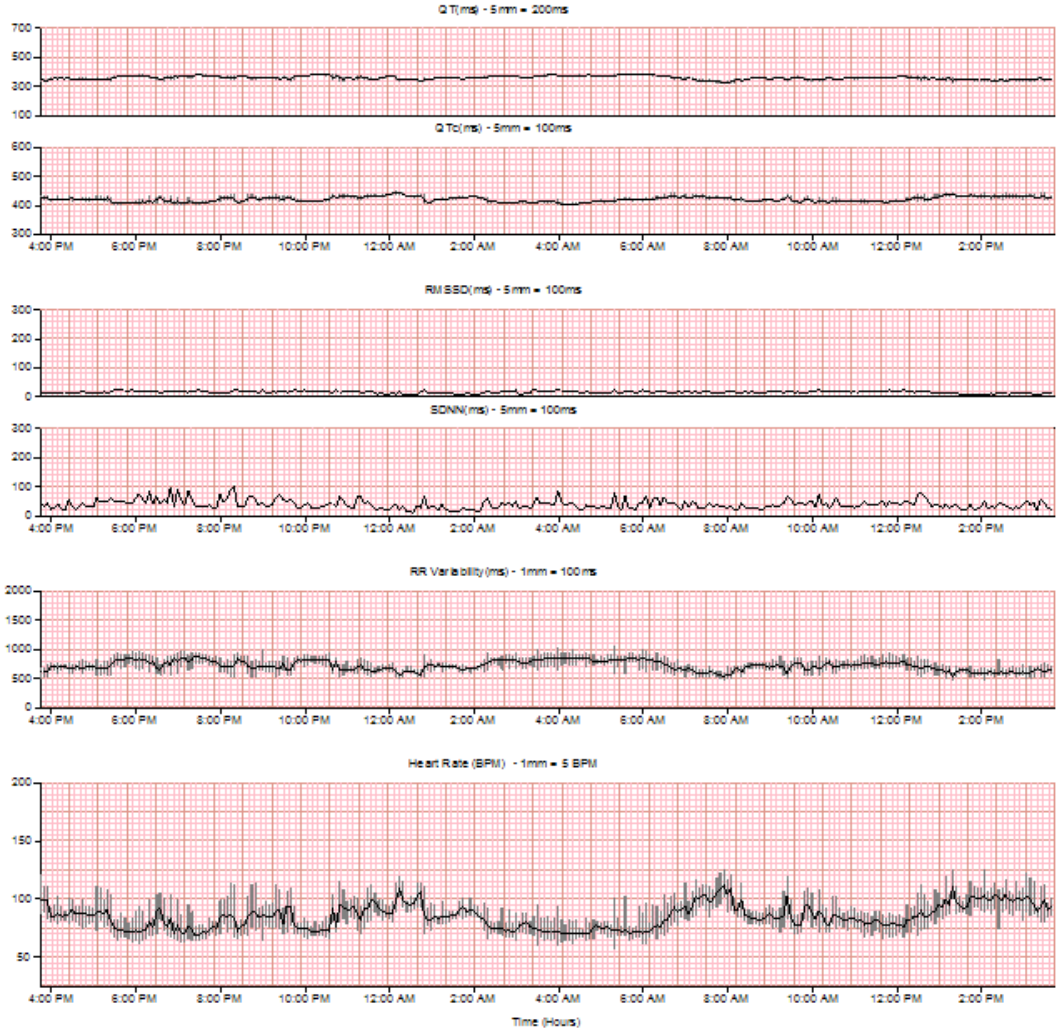
6/21/2016 03:15:56 PM Trends

QT Trends (QT, QTcL RRc, RMSSD, SDNN, RR Variability and HR) - period 1



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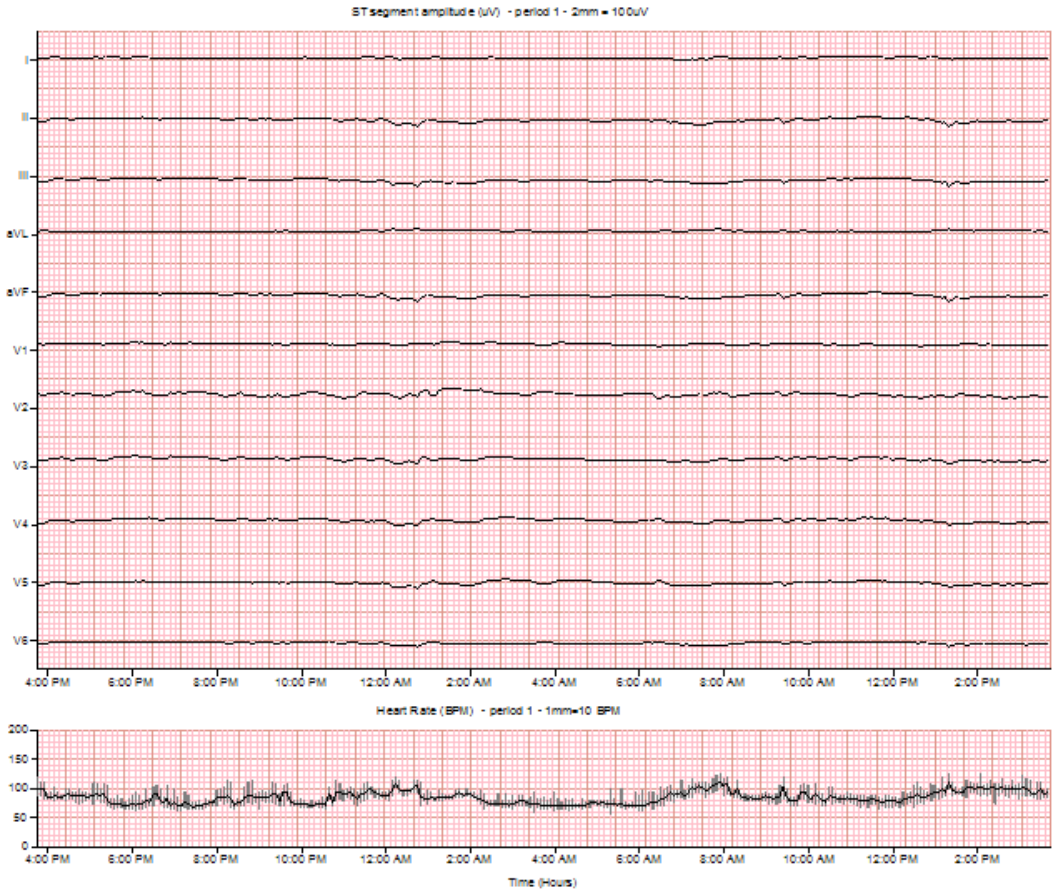
6/21/2016 03:15:56 PM Trends

ST Summary and Trends

ST Analysis Criteria = 200 uV ST segment elevation; 100 uV ST segment depression



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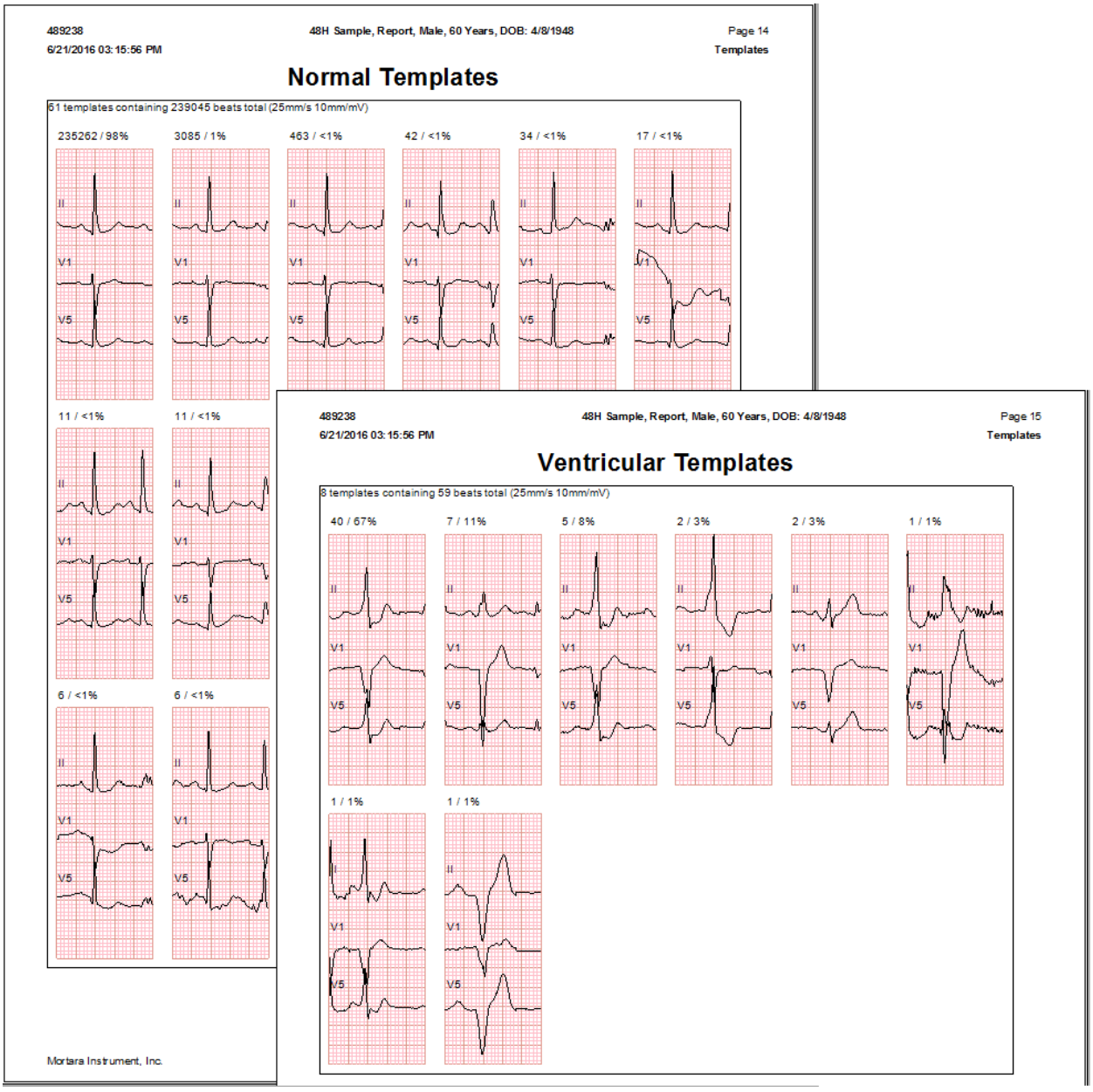
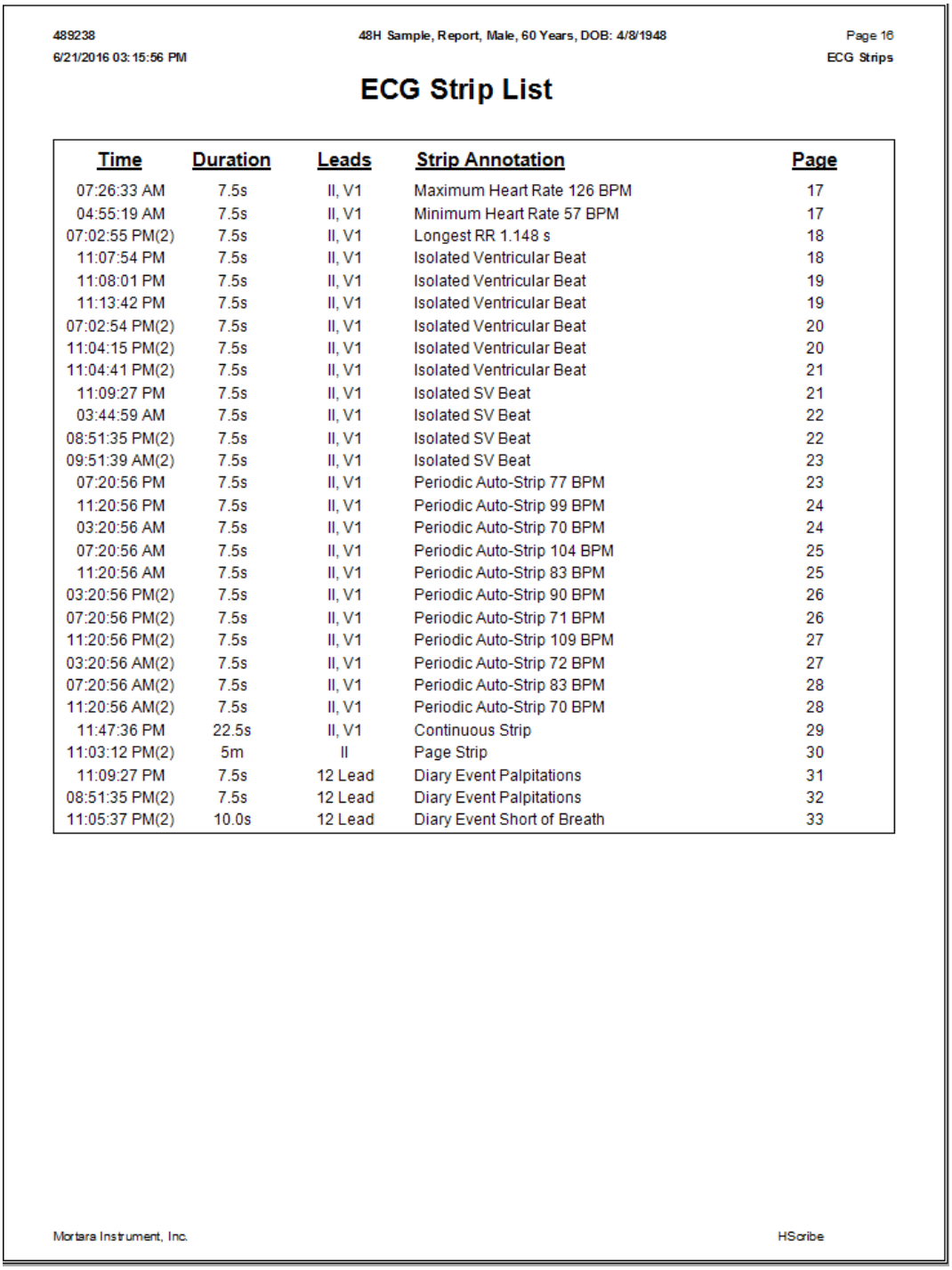
Templates

Templates pages consist of one page for each template group present within the recording. Each beat shape shows the total number of matched beats and the percent of that beat shape within the template group.



ECG Strip List and ECG Strips

An index of all included strips in the final report shows duration of each strip, ECG leads, annotations and page numbers precedes the actual strips. Beginning after the initial 24-hours, each following 24-hour period is numbered and enclosed in parentheses.



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6/21/2016 03:15:56 PM ECG Strips

ECG Strip List

Time	Duration	Leads	Strip Annotation	Page
07:26:33 AM	7.5s	II, V1	Maximum Heart Rate 126 BPM	17
04:55:19 AM	7.5s	II, V1	Minimum Heart Rate 57 BPM	17
07:02:55 PM(2)	7.5s	II, V1	Longest RR 1.148 s	18
11:07:54 PM	7.5s	II, V1	Isolated Ventricular Beat	18
11:08:01 PM	7.5s	II, V1	Isolated Ventricular Beat	19
11:13:42 PM	7.5s	II, V1	Isolated Ventricular Beat	19
07:02:54 PM(2)	7.5s	II, V1	Isolated Ventricular Beat	20
11:04:15 PM(2)	7.5s	II, V1	Isolated Ventricular Beat	20
11:04:41 PM(2)	7.5s	II, V1	Isolated Ventricular Beat	21
11:09:27 PM	7.5s	II, V1	Isolated SV Beat	21
03:44:59 AM	7.5s	II, V1	Isolated SV Beat	22
08:51:35 PM(2)	7.5s	II, V1	Isolated SV Beat	22
09:51:39 AM(2)	7.5s	II, V1	Isolated SV Beat	23
07:20:56 PM	7.5s	II, V1	Periodic Auto-Strip 77 BPM	23
11:20:56 PM	7.5s	II, V1	Periodic Auto-Strip 99 BPM	24
03:20:56 AM	7.5s	II, V1	Periodic Auto-Strip 70 BPM	24
07:20:56 AM	7.5s	II, V1	Periodic Auto-Strip 104 BPM	25
11:20:56 AM	7.5s	II, V1	Periodic Auto-Strip 83 BPM	25
03:20:56 PM(2)	7.5s	II, V1	Periodic Auto-Strip 90 BPM	26
07:20:56 PM(2)	7.5s	II, V1	Periodic Auto-Strip 71 BPM	26
11:20:56 PM(2)	7.5s	II, V1	Periodic Auto-Strip 109 BPM	27
03:20:56 AM(2)	7.5s	II, V1	Periodic Auto-Strip 72 BPM	27
07:20:56 AM(2)	7.5s	II, V1	Periodic Auto-Strip 83 BPM	28
11:20:56 AM(2)	7.5s	II, V1	Periodic Auto-Strip 70 BPM	28
11:47:36 PM	22.5s	II, V1	Continuous Strip	29
11:03:12 PM(2)	5m	II	Page Strip	30
11:09:27 PM	7.5s	12 Lead	Diary Event Palpitations	31
08:51:35 PM(2)	7.5s	12 Lead	Diary Event Palpitations	32
11:05:37 PM(2)	10.0s	12 Lead	Diary Event Short of Breath	33

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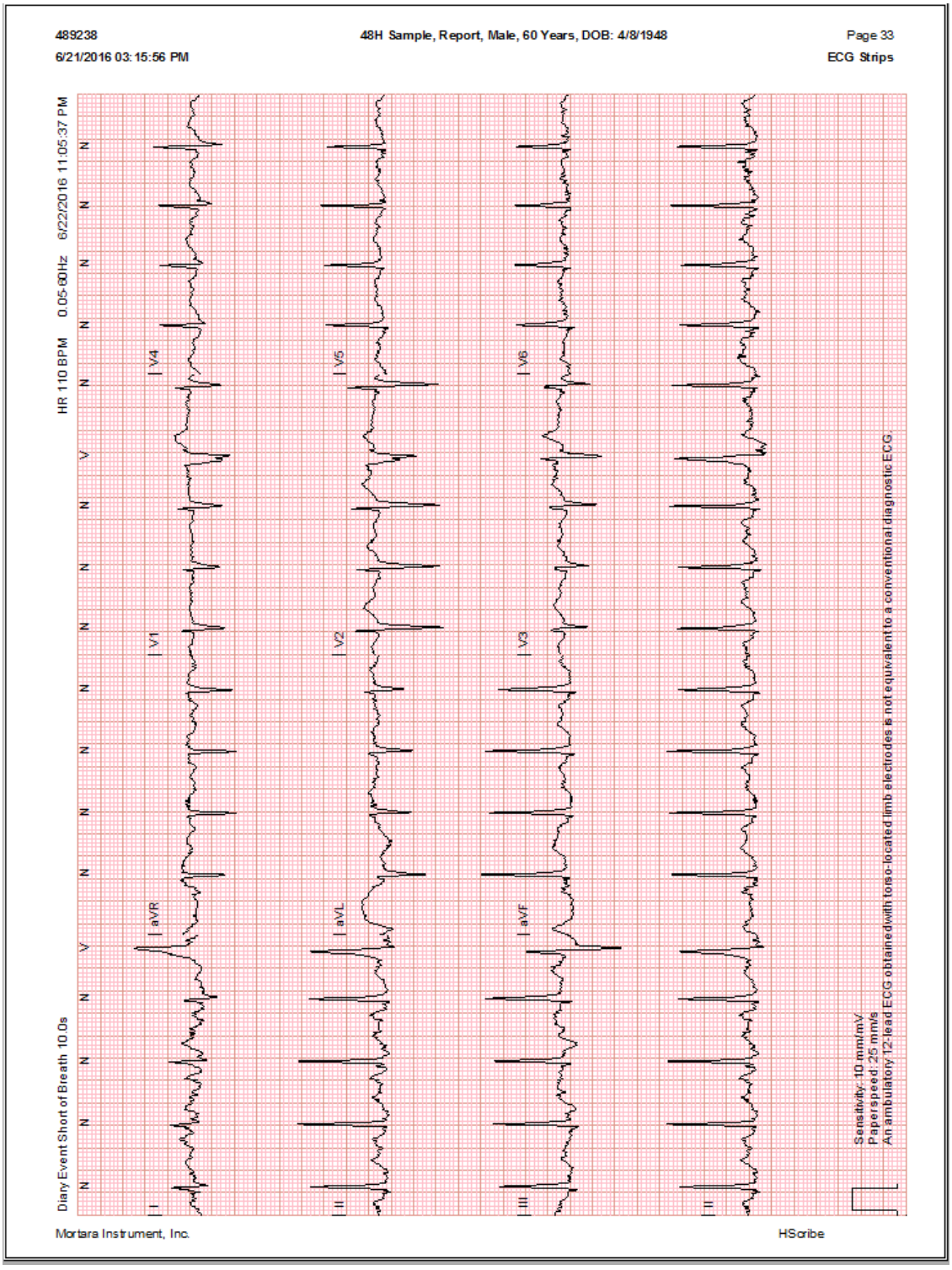
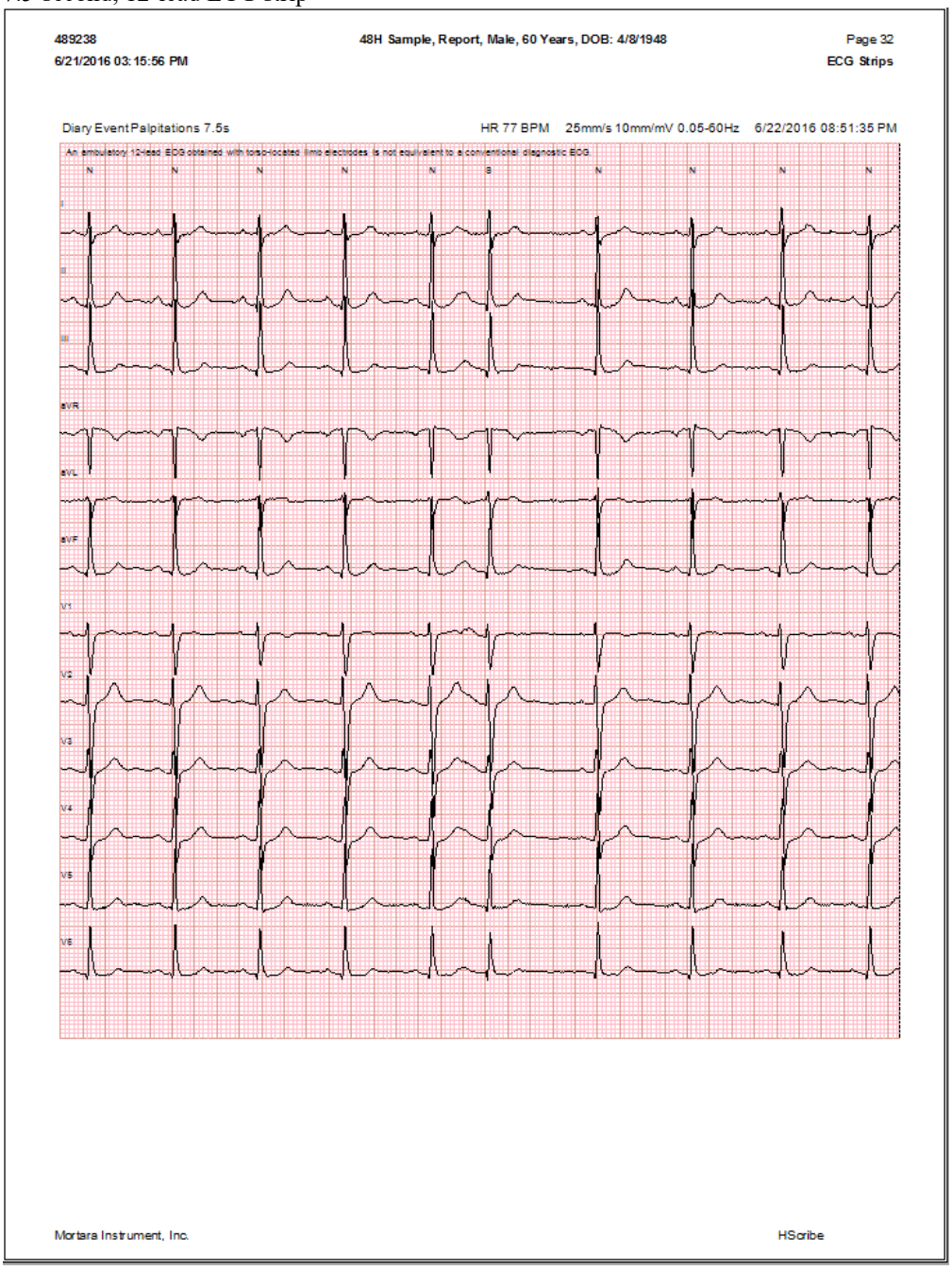
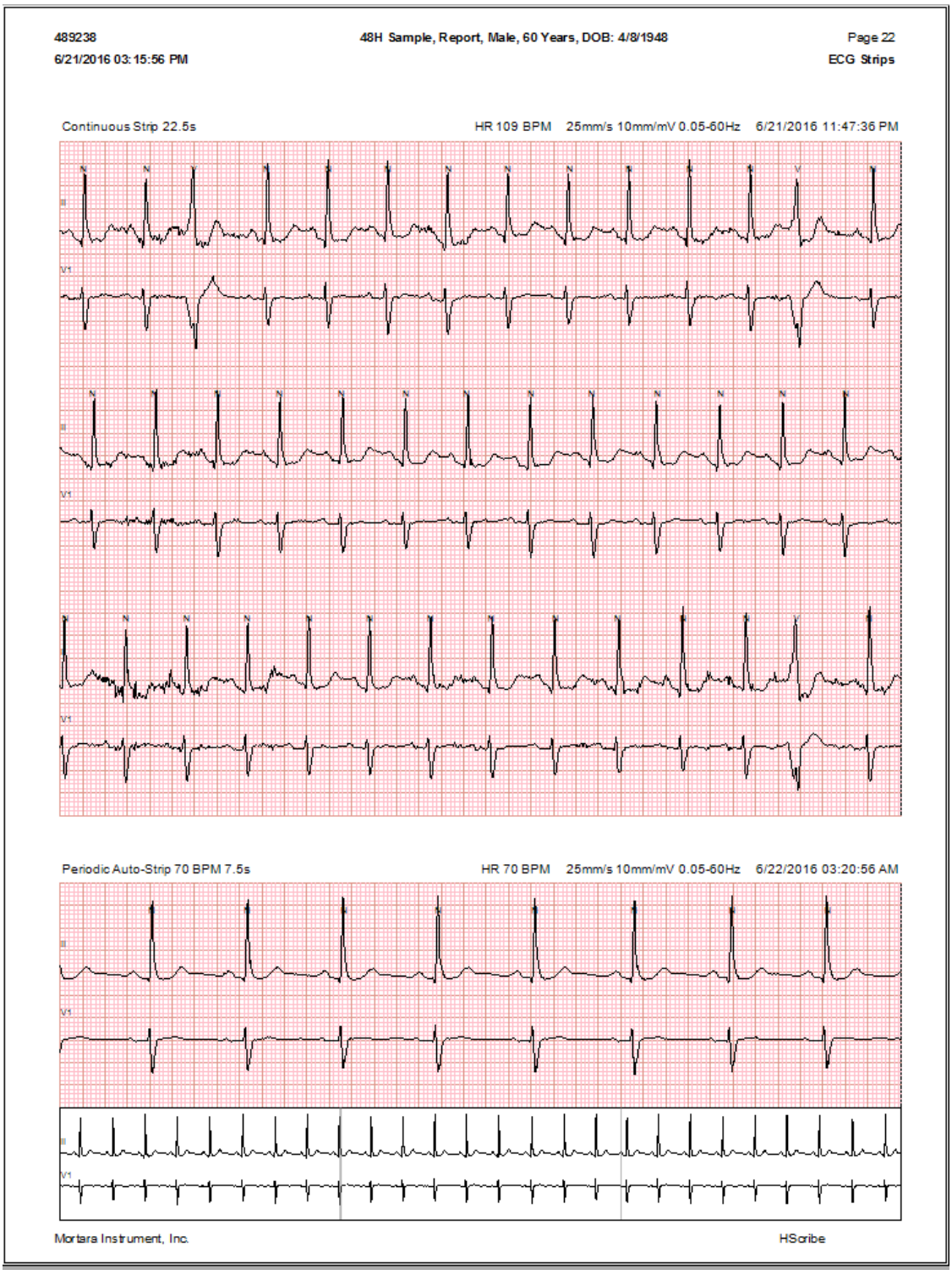
10-second, 12-lead ECG strip


489238
48H Sample, Report, Male, 60 Years, DOB: 4/8/1948
Page 33
6/21/2016 03:15:56 PM
ECG Strips
HR 110 BPM 0.05-80Hz 6/22/2016 11:05:37 PM
Diary Event Short of Breath 10.0s
I
aVR
V1
V4
II
aVL
V2
V5
III
aVF
V3
V6
II
Sensitivity: 10 mm/mV
Paperspeed: 25 mm/s
An ambulatory 12-lead ECG obtained with torso-located limb electrodes is not equivalent to a conventional diagnostic ECG.
Mortara Instrument, Inc.
HScribe

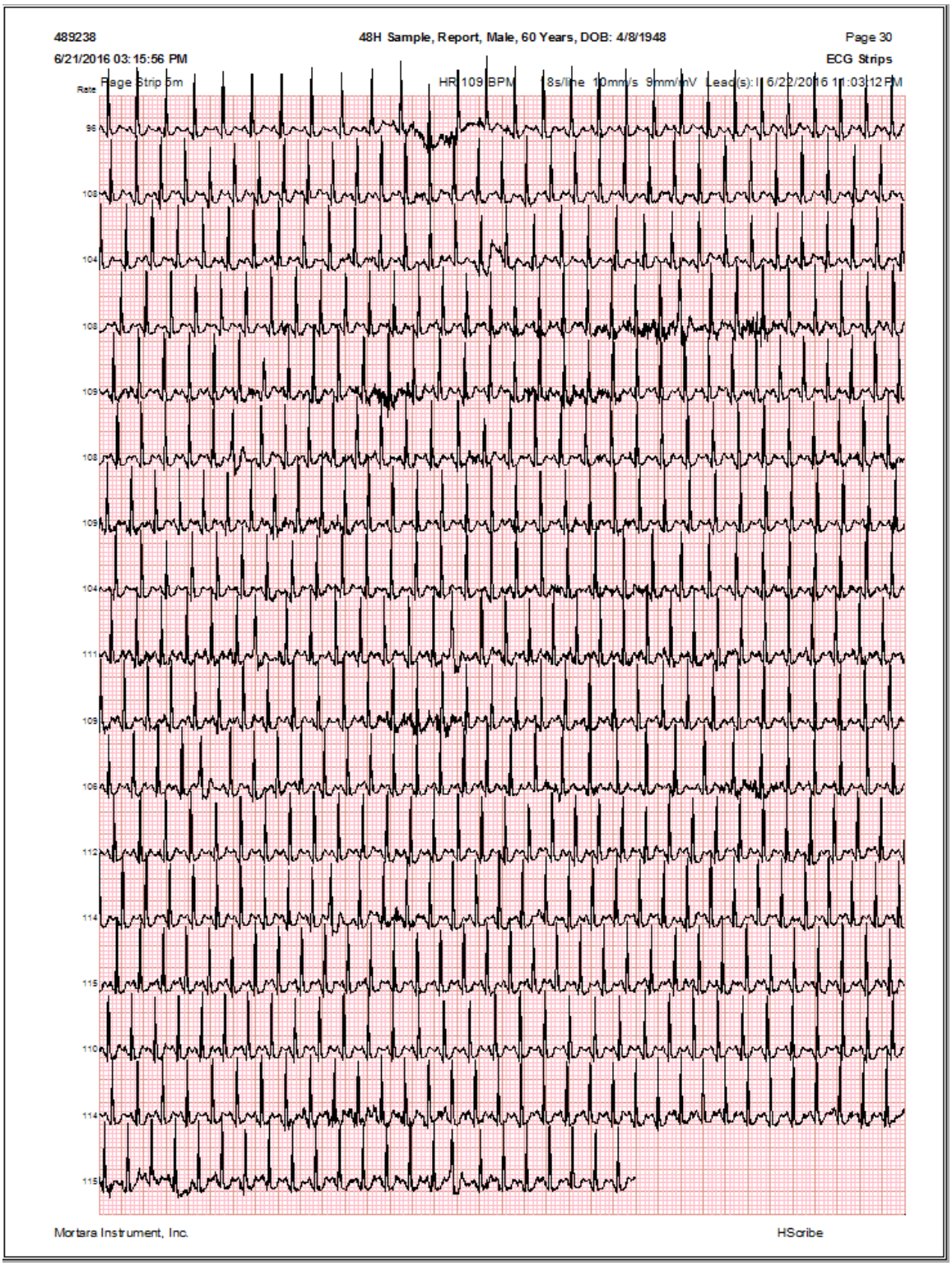
7.5-second, 12-lead ECG strip



Continuous 22.5-second strip followed by a 7.5-second, 2-channel ECG strip.

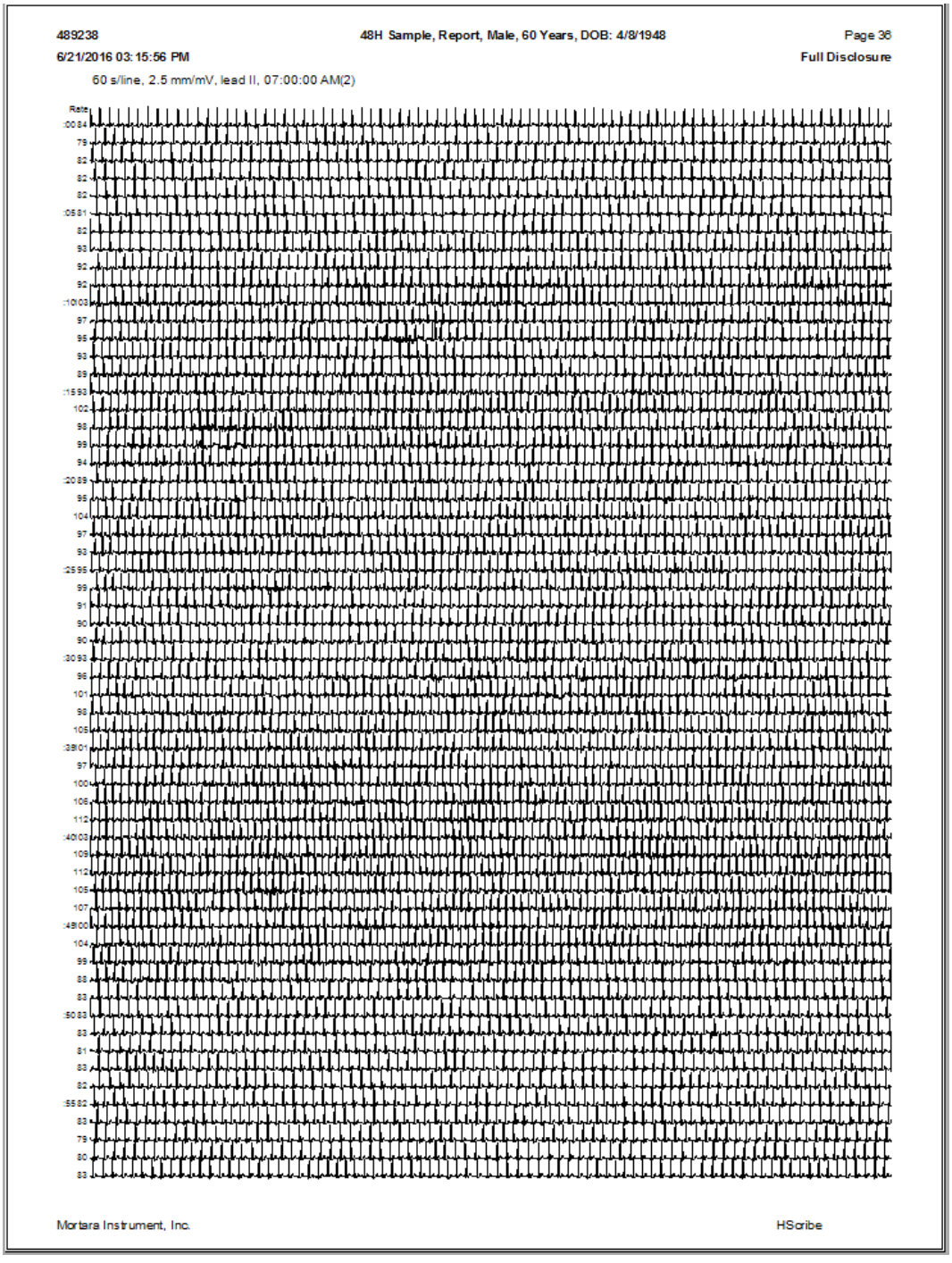


5-minute, single-channel page strip



Full Disclosure

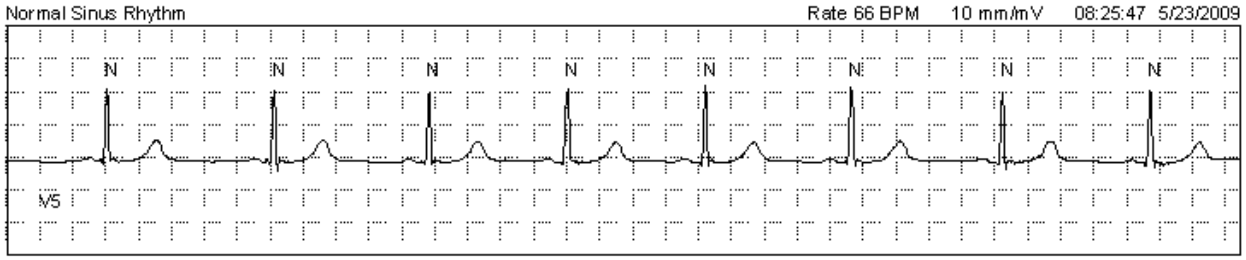
Each full disclosure page contains 60 minutes of miniature ECG at 2.5 mm/mV



4. QUICK REFERENCE FOR THE HOLTER ANALYST

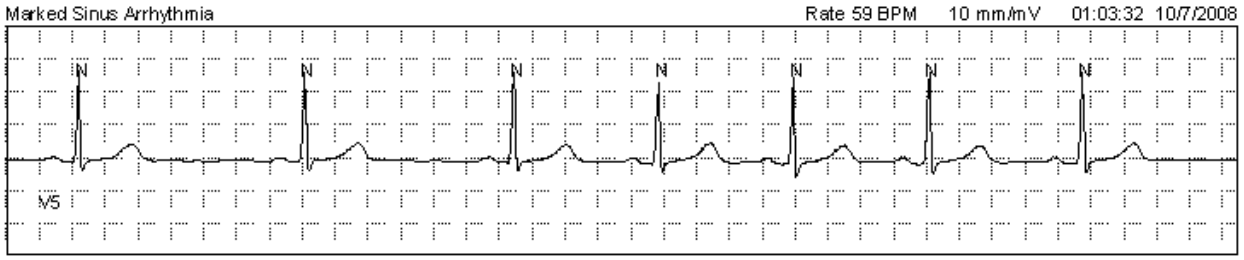
Rhythm and Conduction

<u>Normal Sinus Rhythm</u> – Sinus Rhythm consists of an electrical impulse originating in the Sino-atrial (SA) node and radiating through both atria, traveling through the Atrio-ventricular (AV) node, continuing through the Bundle of His, both the left and right bundle branches, the Purkinje fibers and finally depolarizing the ventricular myocardium. When the SA node paces the heart at a rate between 60 and 100 BPM, the rhythm is called NORMAL SINUS RHYTHM; at a rate of 100 BPM or more, SINUS TACHYCARDIA; at a rate below 60 BPM, SINUS BRADYCARDIA.



HScribe Approach – Our system chooses the predominant rhythm to be that patient's "normal". The analyst simply allows the underlying rhythm to be identified as "Normal". The highest HR and the lowest HR ECG times are reported automatically. The analyst may add and annotate these strips as Sinus Tachycardia or Sinus Bradycardia as desired.

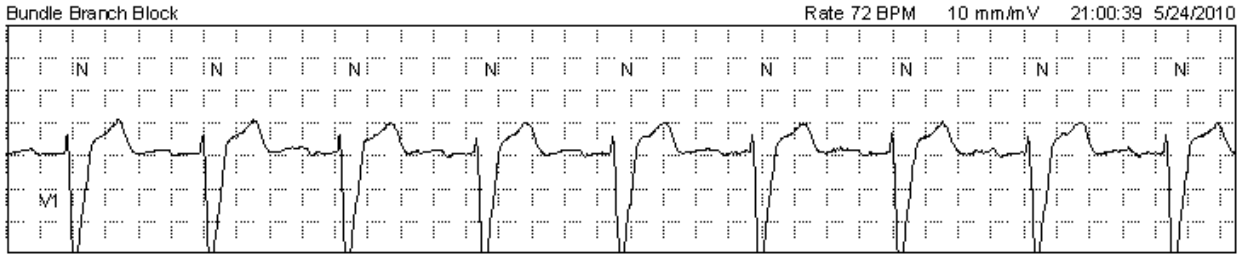
<u>Sinus Arrhythmia</u> – When the SA Node paces the heart irregularly, typically a rhythmic increase and decrease in rate that corresponds to respiration, the rhythm is called Sinus Arrhythmia. This is typically a normal rhythm and shows that there is a good balance between the parasympathetic and sympathetic nervous system (reflected in heart rate variability calculations).



HScribe Approach – When the sinus arrhythmia is pronounced (or marked), some beats may be incorrectly identified as supraventricular when the prematurity percentage is set at 25, which is appropriate for most recordings. It is recommended that the percent value be increased to prevent false SVPB calls.

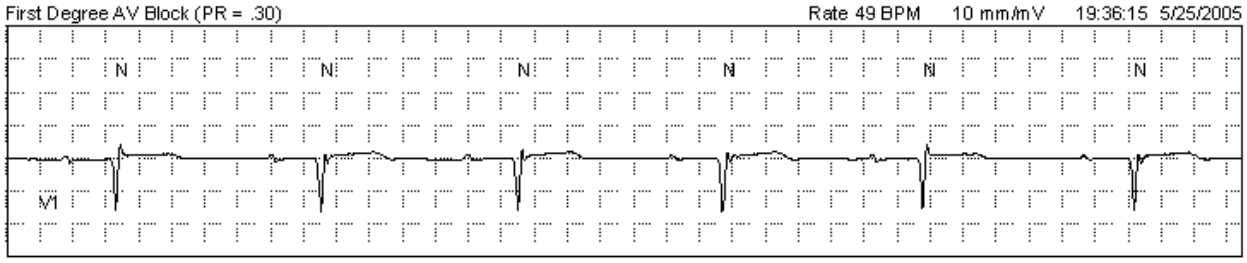
You may first try 30% to see if beat labels are adequate and if not, increase the value in 5% steps until labeling is satisfactory.

<u>Bundle Branch Block (BBB) or Intraventricular Conduction Defect (IVCD)</u> – When a block exists along either of the bundle branch pathways, the electrical impulse travels through the right or left bundle branch to stimulate one ventricle and then through the septum to stimulate the other ventricle. The P-wave and PR interval are normal, but because one ventricle is stimulated later than the other, the QRS complex is wider than normal and is usually 0.12 seconds in duration or more. BBB or IVCD may also occur intermittently during the recording.



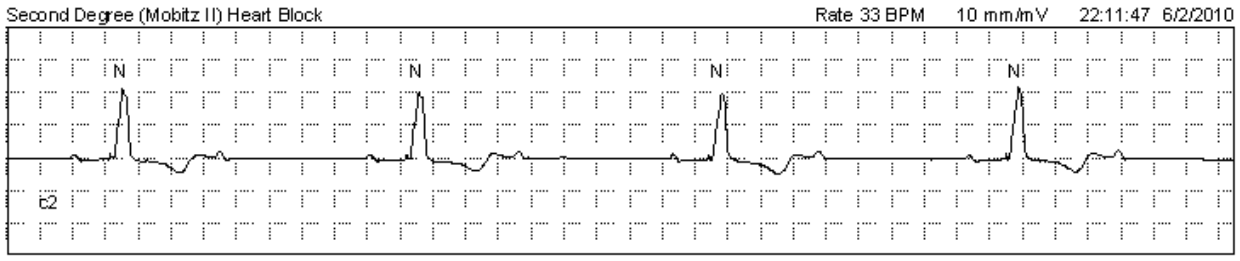
HScribe Approach – The template corresponding to the QRS can be identified as normal or Bundle Branch Block so the HScribe analysis program will consider any properly-timed QRS of this morphology in normal beat calculations. Because HScribe updates the predominant morphology, any conduction changes will be reflected in the Template view as well as the ECG and superimposition views.

<u>First Degree AV Block</u> – If a block exists in the AV node so that the electrical impulse is held for a longer than normal period of time, the rhythm is called FIRST DEGREE AV BLOCK. This rhythm is characterized by a PR interval prolonged to greater than 0.20 seconds.



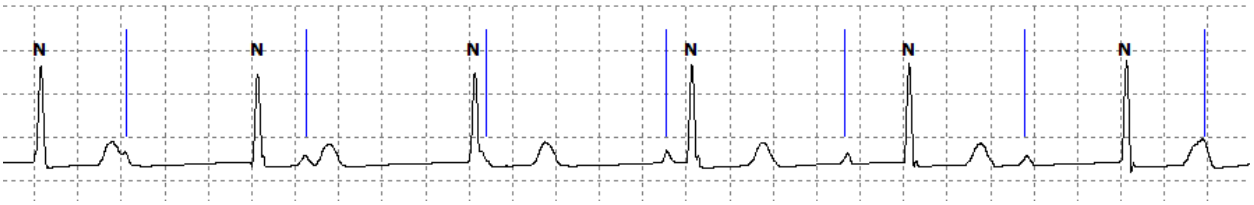
HScribe Approach – Since the HScribe analysis program detects only the QRS, no lengthening of the PR interval will be detected by the system alone. The Superimposition display allows easy detection of changes in the PR interval. A PR interval within the normal range will be superimposed with the P-wave preceding the QRS, while the onset of a first degree block causes the P-wave to slide farther to the left side of the superimposition display.

<u>Second Degree AV Block</u> – Two types of SECOND DEGREE AV BLOCK are caused by blocks in the AV node with only some of the electrical impulses from the atria conducting through to the ventricles. MOBITZ I, also called WENCKEBACH, holds the impulse within the AV node for longer than the preceding electrical impulse until the electrical impulse does not conduct through the AV node at all. This block is characterized by a gradual prolongation of the PR interval followed by a non-conducted P wave. MOBITZ II blocks impulses intermittently and PR intervals with conduction are normal. When a beat is dropped, a normally timed P-wave occurs and is not followed by a QRS.



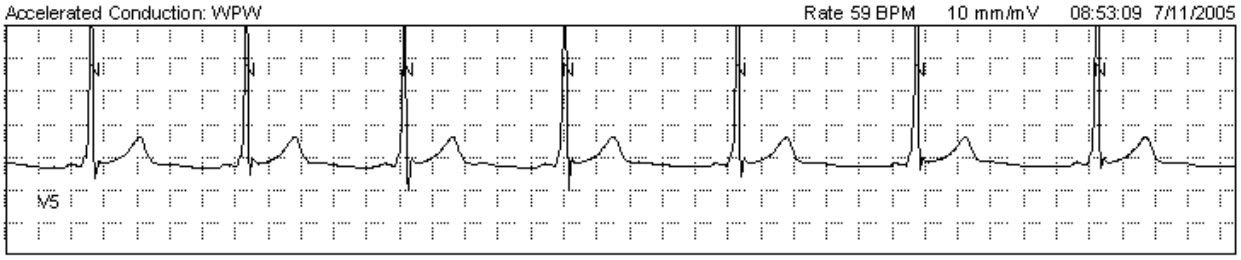
HScribe Approach – Our system will report the RR interval of the dropped beat in the Profile display as a long RR interval or as a pause if it exceeds the set criteria. The RR interval histogram will show a characteristic shape of more than one peak depending on frequency of the blocked beats.

<u>Third Degree (Complete) AV Block</u> – When none of the atrial impulses are conducted through the AV node, the rhythm is called a COMPLETE AV BLOCK. Typically, a lower portion of the AV node or a ventricular site takes over pacing function at a slow BPM rate. This is referred to as an "Escape Rhythm". The atria and ventricles will pace independently and there is no relationship between the P waves and the QRS complexes.



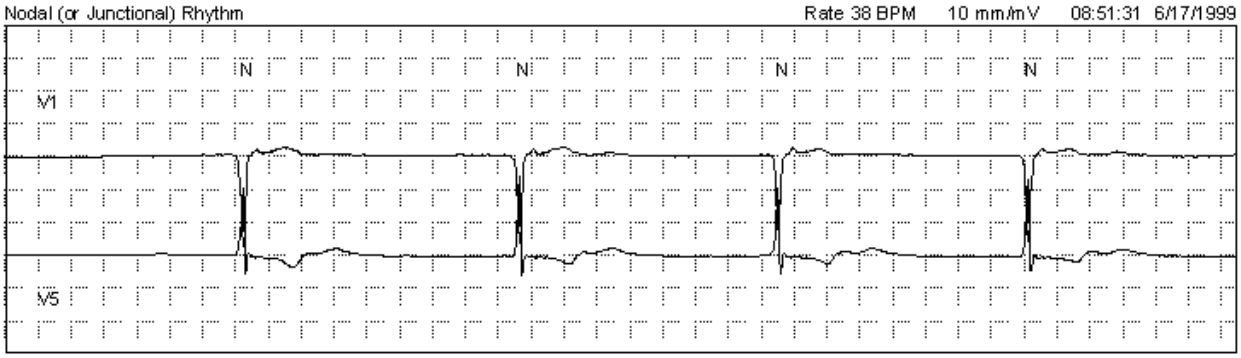
HScribe Approach – Whether the escape rhythm is nodal (sometimes called junctional) or ventricular in origin, the analysis program will identify the predominant rhythm as "Normal" with a slow heart rate. Intermittent episodes will be found in the Profile (Min HR, Bradycardia episodes, Max RR, or Pauses), the RR interval Histogram with a wide distribution, and can be observed in the superimposition display characterized by P-waves that appear to float forward or backward relative to the QRS. Users can "march out" the calipers for assistance in the identification of hidden P-waves as shown in the example above.

<u>Accelerated Conduction</u> – Wolf-Parkinson-White (WPW) and Lown-Ganong-Levine (LGL) are both types of accelerated conduction defects. Rather than the electrical impulse being delayed in the AV node, there is pre-excitation of the ventricles by mean of abnormal conduction fibers that parallel and bypass the normal conduction pathway. LGL presents as a shorter than normal PR interval (< 0.08 seconds). WPW presents a slurring of the onset of the QRS making it appear wider than normal; this slurring is called a delta-wave. Accelerated conduction defects may lead to re-entry tachycardia, sometimes mimicking ventricular tachycardia.



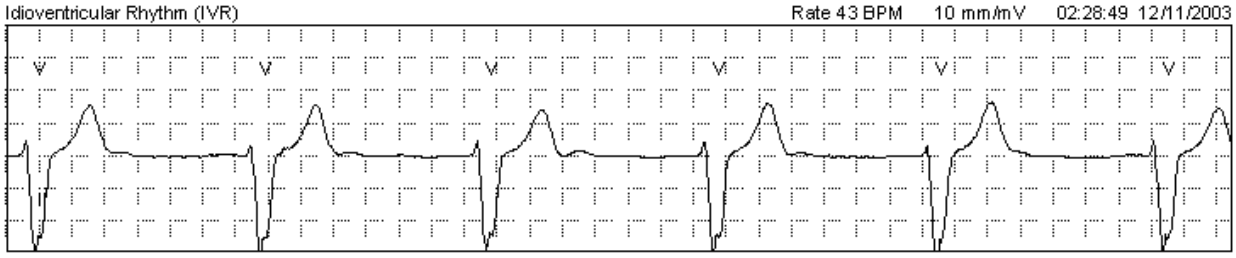
HScribe Approach – These abnormalities can be easily detected by routine measurements of the PR interval using the on-screen caliper tool. Intermittent changes will be apparent in the Superimposition scanning mode.

<u>Nodal or Junctional Rhythm</u> – When the predominant pacemaker is the AV node rather than the SA node, the rhythm is called nodal or junctional. This rhythm is characterized by normal conduction and an inverted P-wave, sometimes seen after the QRS complex or the absence of a P-wave altogether. The ventricular rate is typically 40 – 50 BPM, but can be accelerated with a faster rate.



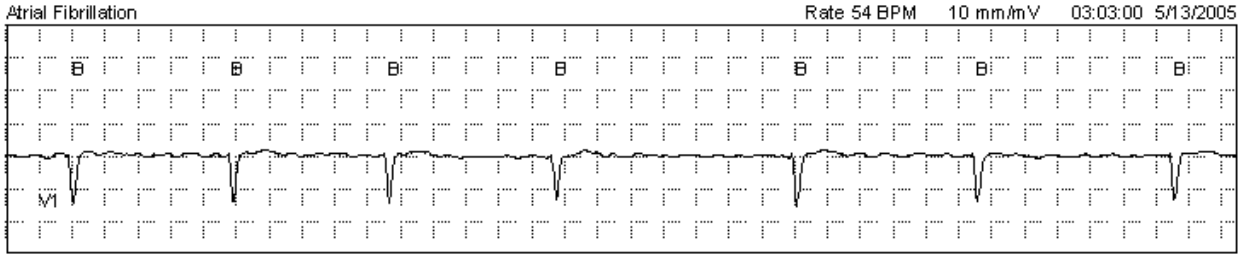
HScribe Approach – A change or absence of the P-wave is easily observed in the superimposition display. Onset of this rhythm is seen as either the appearance of a negative P-wave or the disappearance of the P-wave. Intermittent episodes may be found in the Profile under minimum HR.

<u>Idioventricular Rhythm (IVR) and Accelerated Idioventricular Rhythm (AIVR)</u> – When the predominant pacemaker is ventricular in origin, rather that the SA node or another supraventricular focus, the rhythm is considered IVR if the rate is 50 BPM or less. AIVR is called if the rate is 50 to 100 BPM. These rhythms are characterized by the absence of P-wave and a QRS of ventricular morphology.



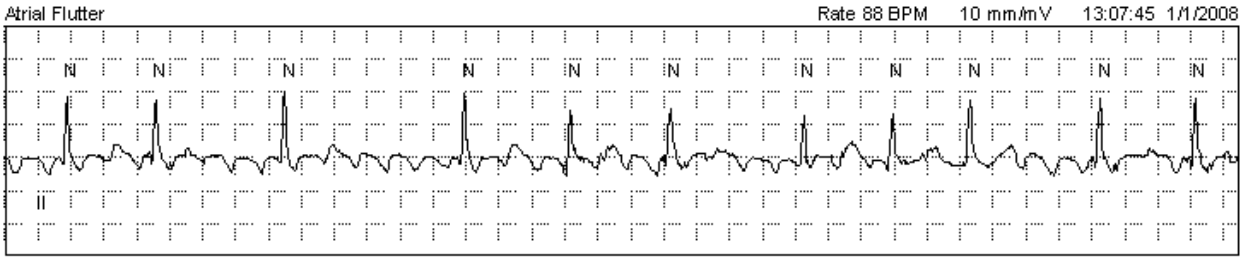
HScribe Approach – When a ventricular focus is the predominant rhythm, the rhythm will be identified as "Normal". If the ventricular rhythm is transient, the episodes will be quantified in the ventricular run length summary and can easily be found in the Profile view. Since the HScribe cannot distinguish between a sinus rhythm with Bundle Branch Block and Idioventricular Rhythm, the user should inspect the Normal templates and rename templates with Idioventricular Rhythm to "Ventricular".

<u>Atrial Fibrillation</u> – When the electrical activity in the atria is chaotic and many ectopic foci are firing erratically, the atria are said to be "fibrillating". Some impulses conduct through the AV node and stimulate the ventricles. This rhythm is characterized by a chaotic baseline with no distinct P-wave and highly irregular RR intervals.



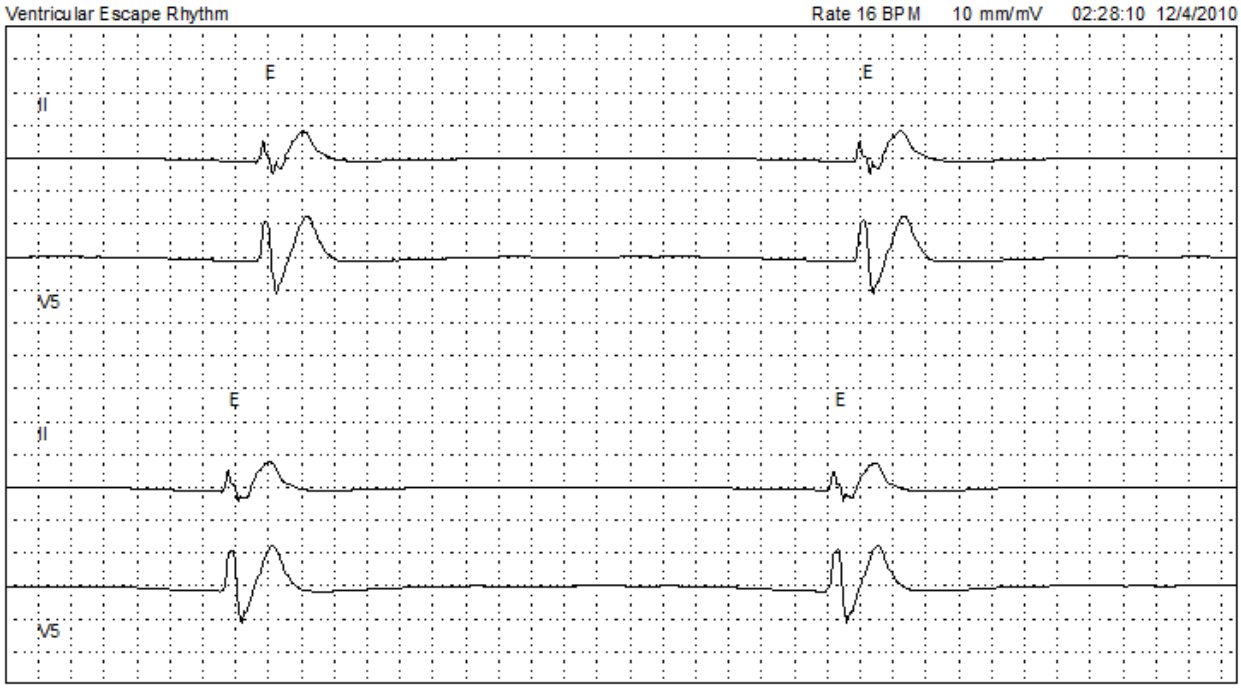
HScribe Approach – Atrial fibrillation (Afib) is detected by irregular RR intervals and will be identified automatically when "Detect Atrial Fibrillation" has been enabled. When intermittent, Afib episodes can be navigated in the Profile display and by episode bars in the ECG view.

<u>Atrial Flutter</u> – When one atrial focus fires repeatedly and regularly at a rate between 220 and 350 BPM, the rhythm is called atrial flutter. Not all of the atrial impulses are conducted through the AV node so the ventricular rate is typically much lower. The baseline appears "saw-toothed" and the RR intervals can be regular or irregular, dependant on the variability of blocked impulses.



HScribe Approach – Atrial flutter is not automatically detected by the HScribe analysis program. This rhythm is easily detected in the Superimposition display and will likely be seen when reviewing Min/Max HR, Min/Max RR interval, and Pause ECG strips. Often the RR-histogram shows distinct peaks.

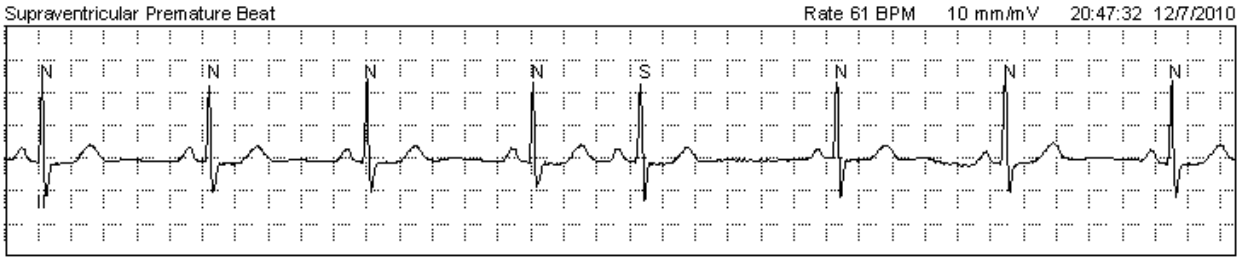
<u>Escape Rhythms</u> – Nodal and ventricular myocardial cells of the heart have inherent pacemaking ability with a different intrinsic rate. Normal nodal foci fire between 40 and 60 beats per minute (BPM), normal ventricular foci at 40 and lower BPM. These foci may provide an "escape rhythm" should the SA node fail to pace. Escape rhythms are not infrequent in trained athletes during sleep; single escape beats also occur after a sinus or AV block.



HScribe Approach – Any escape mechanism following an RR interval will most likely be seen when reviewing minimum HR, maximum RR, and Pause events in the Profile display.

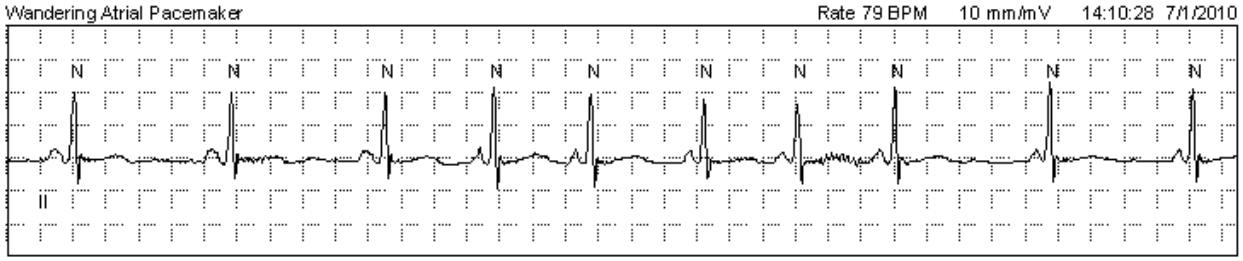
Premature Beats

<u>Supraventricular Premature Beats (SVPB)</u> – SVPB is a beat initiated by an irritable focus in one of the atria. The beat looks normal in morphology with a slight difference in the P-wave morphology, occurs early compared to the normal sinus rhythm preceding it, and resets the SA node so that the next beat is slightly later than the normal sinus rate.



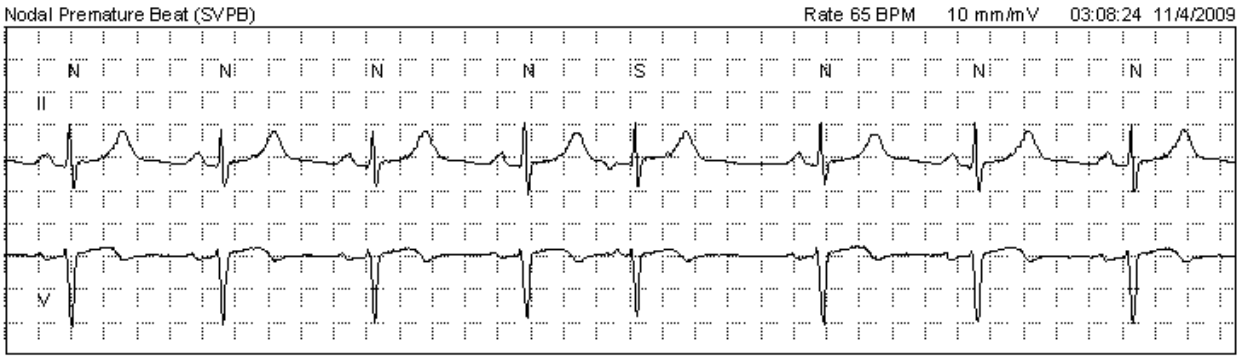
HScribe Approach – An early beat (at least 10% early compared to the preceding rhythm) that is either normal in morphology or matches a morphology that the analyst has determined is supraventricular in origin will be labeled an SVPB. The SVPB prematurity % criterion is typically set to 25 and can be adjusted by the analyst depending on the prematurity of the supraventricular ectopy and regularity of the rhythm. SVPBs are best found in the Profile display and are presented as isolated, in pairs and runs with the longest and fastest run reported in the summary. When the Supraventricular template group has been enabled in the Scan Criteria dialog, beats identified as supraventricular are quickly reviewed and can be edited as necessary.

<u>Wandering Atrial Pacemaker</u> – When the predominant atrial pacemaker is not limited to the SA node, but instead varies from one atrial focus to another, the phenomenon is called wandering atrial pacemaker. The PR intervals and conduction are usually normal with slightly irregular RR intervals and slightly varying P-wave shapes.



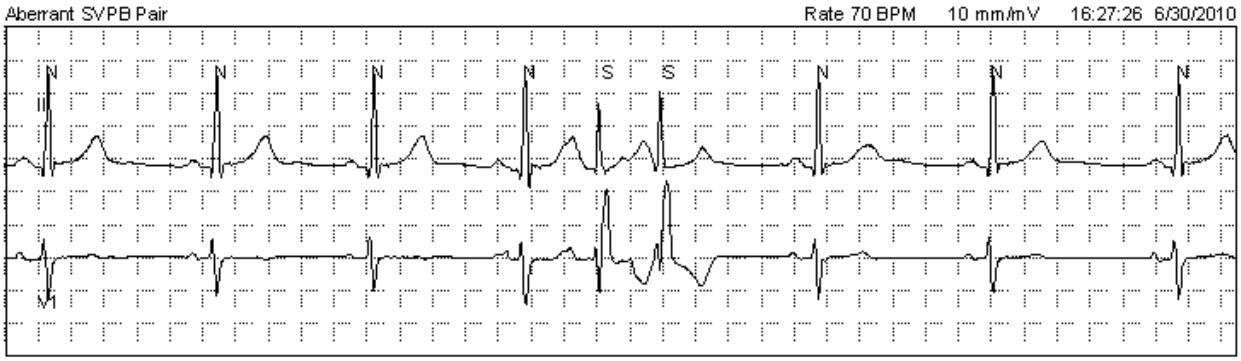
HScribe Approach – Changes of the primary pacemaker are easily detected in the superimposition display as varying P-wave morphologies. The RR Histogram may be used to find irregularity.

<u>Nodal or Junctional Premature Beat (SVPB)</u> – When an irritable site in the tissue surrounding the AV node fires prematurely, the conducted beat is normal in morphology except for the P-wave. An inverted P-wave preceding the QRS implies that the site is high-nodal; if the P-wave follows the QRS, the site is low-nodal; the absence of a P-wave indicates that atrial depolarization is occurring during the QRS and that the site is mid-nodal.



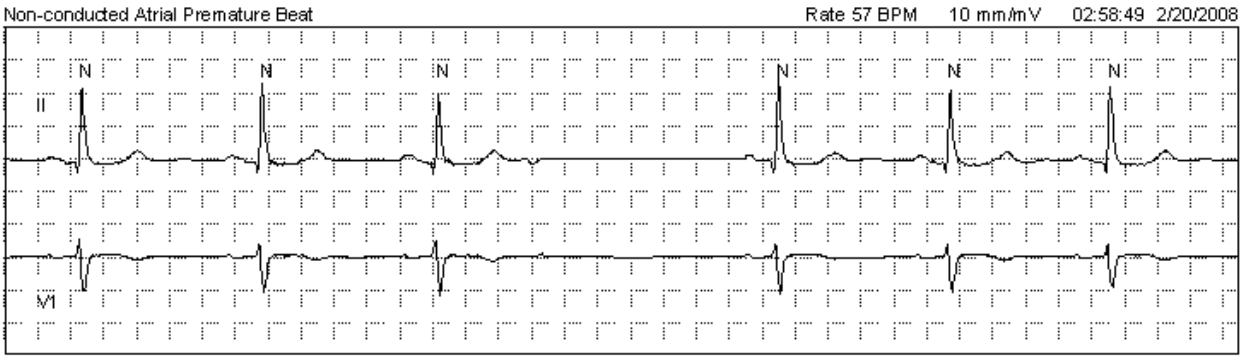
HScribe Approach – Our analysis program determines that the QRS is normal in morphology and early. The analyst must determine that the P-wave is either non-existent or retrograde and can annotate the sample strip precisely.

<u>Aberrant Supraventricular Premature Beat (SVPB)</u> – When an irritable supraventricular site fires early enough that the connective tissue is still partially refractory (has not completely repolarized), conduction is abnormal and the beat is called an aberrant SVPB. This is characterized by an early P-wave followed by a normal PR interval and a wide QRS.



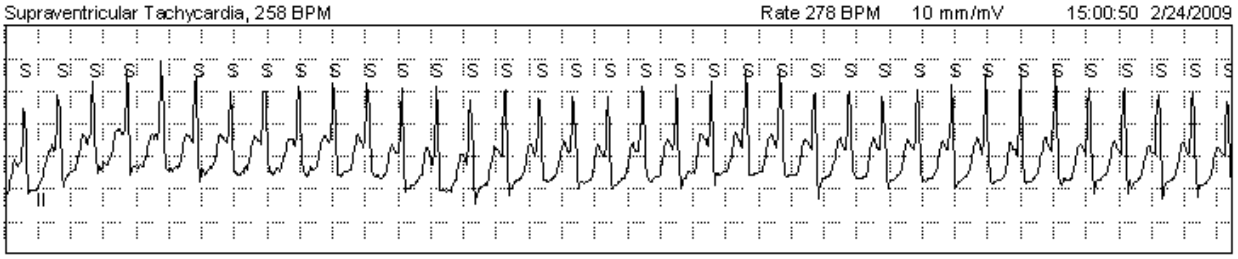
HScribe Approach – Our analysis program will likely identify an aberrant SVPB as a ventricular premature beat because of the different QRS morphology between normal and the aberrancy. If the analyst determines that the beat is an aberrant supraventricular premature beat because a P-wave can be seen, the beat can be relabeled "Aberrant" and will be included in Supraventricular calculations.

<u>Non-Conducted Atrial Premature Beat (APB)</u> – When an irritable atrial focus fires early and the electrical impulse does not conduct through the AV node because the conduction system is still completely refractory, the missing beat is called a non-conducted APB. This is characterized by the presence of an early P-wave without a subsequent QRS resulting in a longer than normal RR interval.



HScribe Approach – Any long RR intervals will be seen when reviewing maximum RR and Pause events in the Profile and the RR Histogram displays. On-screen calipers can be used to see if the sinus rhythm is reset after the long RR interval.

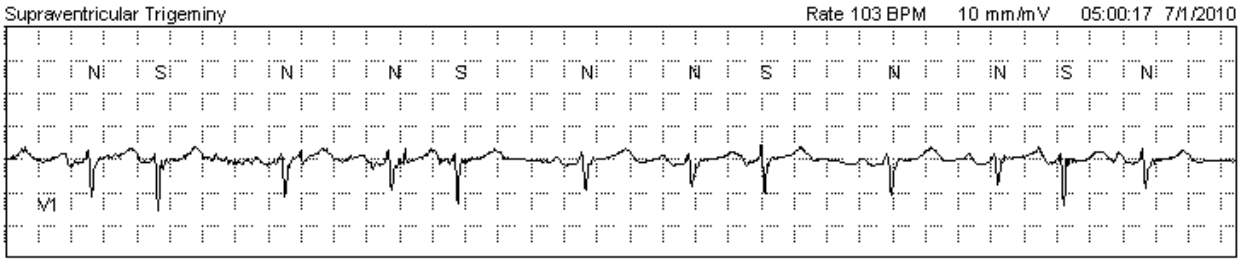
<u>Supraventricular Tachycardia (SVT) and Runs</u> – When one or more supraventricular foci fire in succession (three or more beats) and the impulses conduct through to the ventricles, the ectopic event is called SVT when it occurs at a heart rate of 100 BPM or more and is called a supraventricular run when it occurs at a heart rate of less than 100 BPM. SVT can be sub-divided into Paroxysmal Atrial Tachycardia (PAT), when only one focus is firing and the RR intervals are regular, and Multifocal Atrial Tachycardia (MAT) when more than one focus is firing and the RR intervals are irregular.



HScribe Approach – Any run of three or more supraventricular premature beats is identified by the analysis program as a supraventricular run that can be navigated through use of the Profile display. The analyst may choose to annotate the Supraventricular runs with a rate of greater than 100 BPM as SVT, PAT or MAT.

Note: When a run of SVT approaches or exceeds 16 consecutive beats, the prematurity of the next R-R interval is likely to approach zero, since it is calculated compared to the previous 16 R-R intervals. Therefore, the next beat will be labeled normal (N) and the run is ended. In this case, the clinician may edit the beats of a long run when continuation of the run is determined. If, during a run of SVT, the next R-R interval is less than 400 ms (rate is greater than 150 bpm), it is always labeled supraventricular (S) independent of prematurity and the run is not ended.

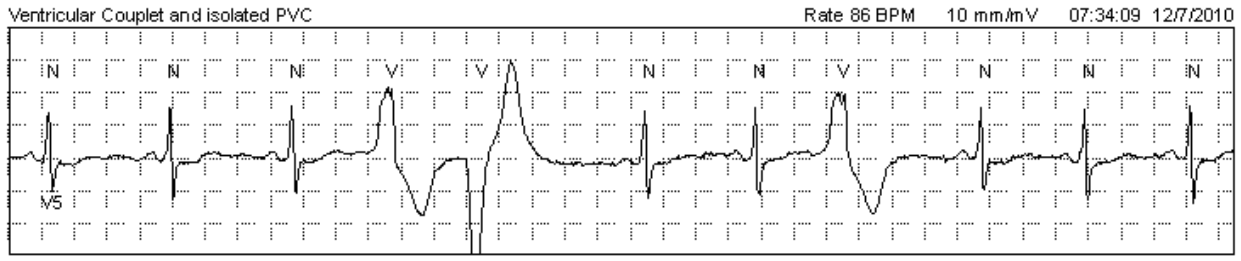
<u>Supraventricular Bigeminy and Trigeminy</u> – When supraventricular premature beats occur alternating with normal beats so that every other beat is a supraventricular beat, the rhythm is called bigeminy. When every third beat, the rhythm is trigeminy.

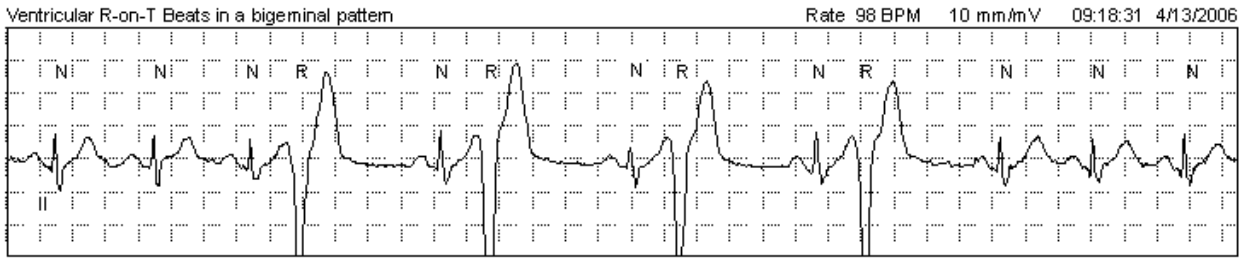


HScribe Approach – The analysis program will identify bigeminy when the following pattern is present for at least 3 cycles: NSNSNS… Trigeminy is identified when the following pattern is present for at least three cycles: NNSNNSNNS… Navigation to these rhythm patterns is best performed in the Profile display.

<u>Ventricular Premature Beat or Premature Ventricular Complex (VPB or PVC)</u> – An irritable ventricular focus that fires prematurely are called a VPB or PVC. It is characterized by the absence of a P-wave, a QRS that is wide and bizarre in morphology, and typically is followed by a full compensatory pause (does not reset the SA node). These beats can occur as single isolated beats, in couplets (or pairs), or in runs of 3 or more. An R-On-T is a very early VPB that occurs on, or near, the peak of the T-wave of the previous beat, a very vulnerable period during repolarization, that could initiate ventricular tachycardia and other lethal arrhythmias.

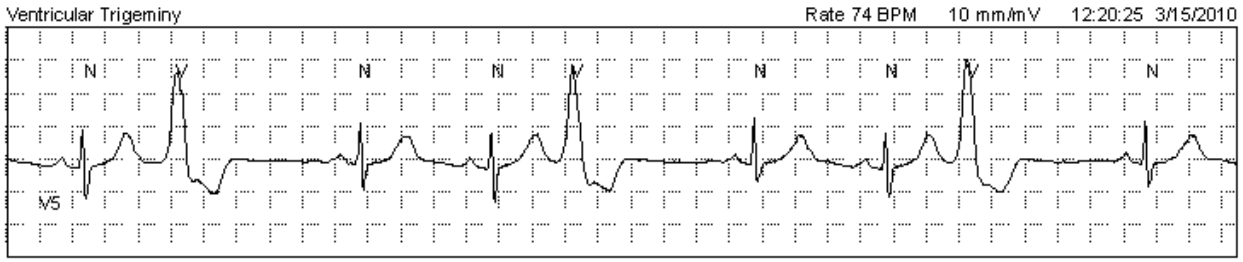
Clinicians may quantify VPB frequency on a per hour basis or per 1,000 beats (average number of VPBs per 1,000 normal beats) to classify occurrence as rare, occasional or frequent during the Holter monitoring period. The Lown classification scale from 0 to 5 may also be used. This quantification may be helpful to gauge effects of antiarrhythmic drugs.





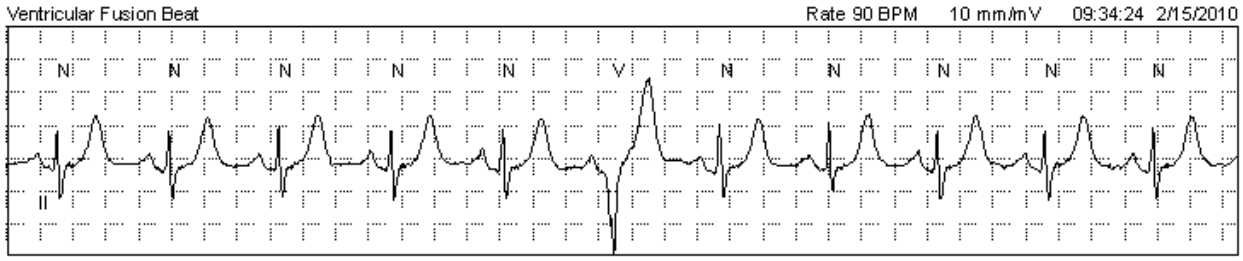
HScribe Approach – The analysis program will identify an abnormal beat that does not match the dominant beat shape and is not paced as a Ventricular beat type. When this beat type exceeds a prematurity threshold as compared to the preceding rhythm, the beat is identified as an R-On-T beat. These beats and runs are easily navigable in the Profile display.

<u>Ventricular Bigeminy, Trigeminy</u> – When ventricular beats occur alternating with normal beats so that every other beat is from the same ventricular focus, the rhythm is called bigeminy. When every third beat is ventricular, the rhythm is trigeminy.



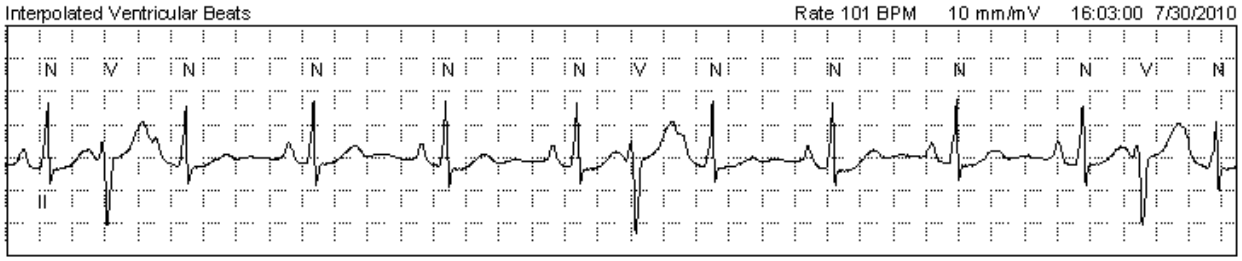
HScribe Approach – The analysis program will identify bigeminy when the following pattern is present for at least 3 cycles: NVNVNV… Trigeminy is identified when the following pattern is present for at least three cycles: NNVNNVNNV… Navigation to these rhythm patterns is best performed in the Profile display.

<u>Fusion Beat</u> – When a ventricular focus fires after the SA node has fired but before the impulse has been conducted through to the ventricles, a fusion beat occurs. Its morphology is a combination of the normal and ventricular morphologies with a normally-timed P-wave and a shortened PR interval.



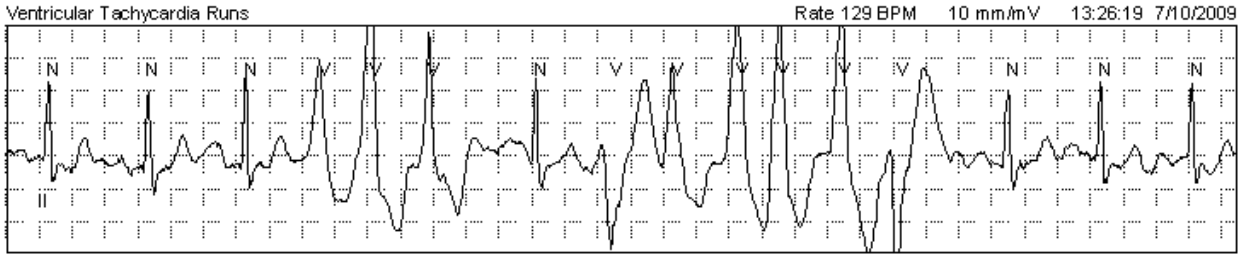
HScribe Approach – The analysis program will identify the fused sinus and ventricular beats as ventricular if the morphology is different enough from the dominant normal morphology. The analyst can relabel the fused beat templates or individual beats as “Fusion” and they will be included in ventricular calculations.

<u>Interpolated VPB</u> – When a VPB occurs early enough that the normally-timed impulse from the SA node conducts through to the ventricles immediately following the VPB, the VPB is called "interpolated". Rather than replacing the normal QRS, the VPB occurs between two normally-timed sinus beats and is not followed by a compensatory pause.



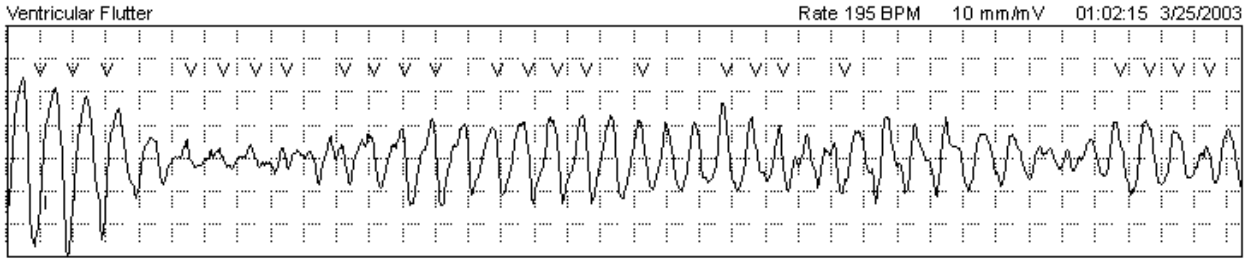
HScribe Approach – The analysis program will identify ventricular beats as usual and they will be found in the Ventricular templates and in the Profile display. The analyst can relabel these ventricular beats individually as "Interpolated" and they will be included in ventricular calculations.

<u>Ventricular Tachycardia (VT, VTAC, or VTach) and Ventricular Runs</u> – When one or more ventricular foci fire in succession (three or more beats), the ectopic event is called VT when it occurs at a heart rate of 100 BPM or more and is referred to as an idioventricular or accelerated ventricular rhythm when it occurs at a heart rate of less than 100 BPM.



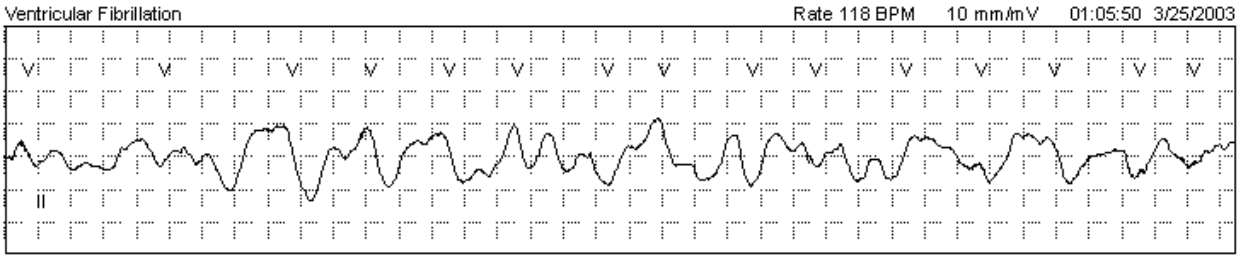
HScribe Approach – Three or more consecutive ventricular beats will be identified by the analysis program as a ventricular run that can be navigated through use of the Profile display. The analyst may choose to annotate the ventricular runs with a rate of greater than 100 BPM as VT; with a rate of less than 100 BPM as IVR or AIVR.

<u>Ventricular Flutter (VFlut)</u> – When a single ventricular focus fires repeatedly and rapidly enough to prevent even a reduced cardiac output, the event is call ventricular flutter. Rather than having the distinct QRS morphology of VT, VFlut is identified by its sinusoidal appearance.



HScribe Approach – Ventricular runs that degenerate into ventricular flutter will continue to be identified as a ventricular run with most flutter waves counted as ventricular beats if the amplitude is large enough, otherwise a pause will be detected.

<u>Ventricular Fibrillation (VFib)</u> – When many ventricular foci are firing in rapid succession, the electrical activity in the ventricles is chaotic and the myocardium is twitching rather than contracting, the heart is in ventricular fibrillation. There is no cardiac output. The ECG waveform is distinctively chaotic.



HScribe Approach – The electrical impulses of VFib will continue to be identified as ventricular runs if the system can find any possible QRS complexes or will be identified as a pause according to the set pause criteria. An entire event showing the onset of VT and degeneration into VFlut and VFib can be documented and annotated with continuous strips.

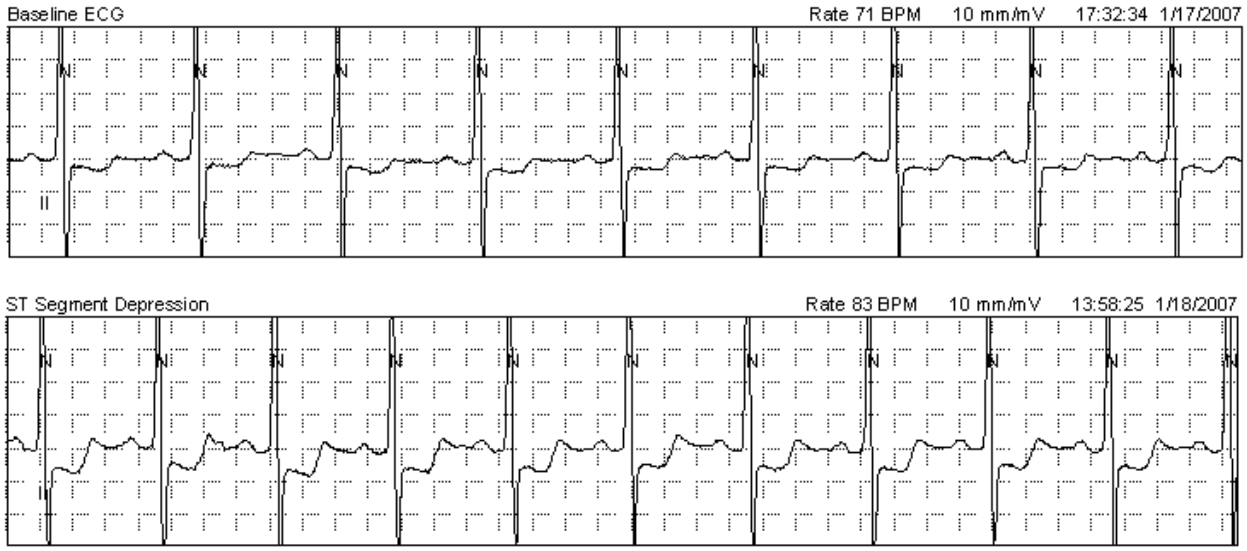
ST Segment Analysis

An analysis of the ST segment is used in the diagnosis of ischemia, an inadequate supply of oxygen to the ventricular myocardium. Ischemia, whether accompanied by pain or not (termed "silent ischemia"), is indicated when the ST segment voltage change at the J-point is typically greater than or equal to 100 µV and the morphology of the ST segment is either flat or downsloping, rather than steeply upsloping. ST elevation can be attributed to early repolarization, pericarditis, acute injury, and acute infarction. Holter monitoring records ST segment changes in an ambulatory setting where episodes may occur with a variety of causes. 12-lead Holter analysis is a benefit for increased sensitivity for ST segment elevation or depression episodes to assist in the identification of patterns indicating cardiac ischemia or injury.

<u>ST Baseline</u> – ST segment analysis can be performed on any Holter recording. The change in voltage of the ST segment should be measured relative to the normal ECG baseline; normal is defined as the stable voltage measurement relative to isoelectric before the onset of the possible ST depression or elevation event.

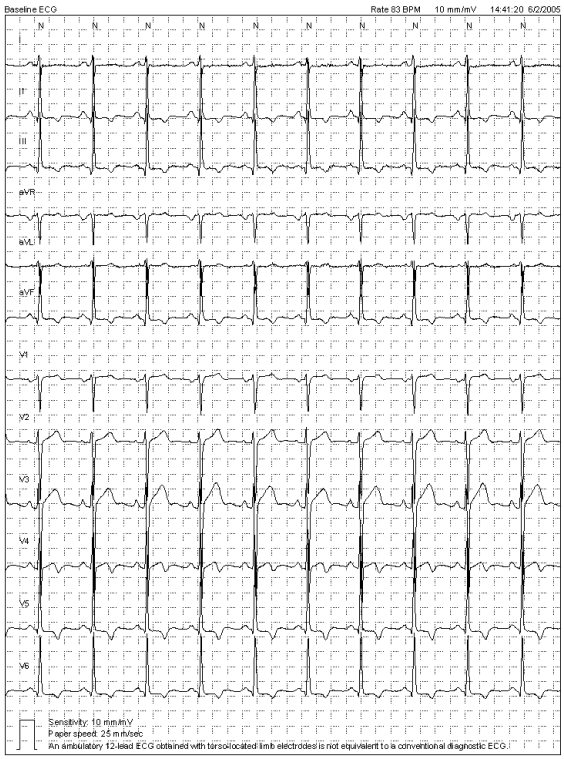
HScribe Approach – The analysis program performs a per-beat measurement of ST offset determined at 60 msec post J. ST depression and elevation episodes are declared by locating a persisting ST level that is beyond the user-configured threshold and following a change of at least 100 µV. Only beats identified as "Normal" are used for this analysis.

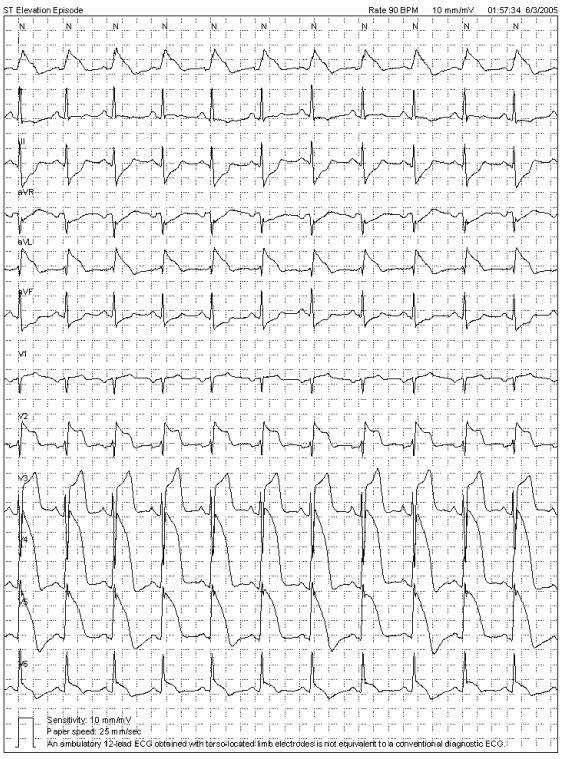
<u>ST Depression</u> – ST segment depression is typically defined as 1 millimeter (100 µV) or more of negative change from the baseline ST segment. To be considered ischemic, the slope of the ST segment usually must be flat or downsloping.



HScribe Approach – After eliminating artifact and ensuring all ectopic beats are labeled appropriately, the analysis program measures the ST segment for each normal beat and averages the measurements. The Profile and Trend displays will show any change in ST segments and depression episode onset, offset and durations will be reported according to user-defined thresholds.

<u>ST Elevation</u> – ST segment elevation is typically defined as 1 millimeter (100 µV) or more of positive change from the baseline ST segment.





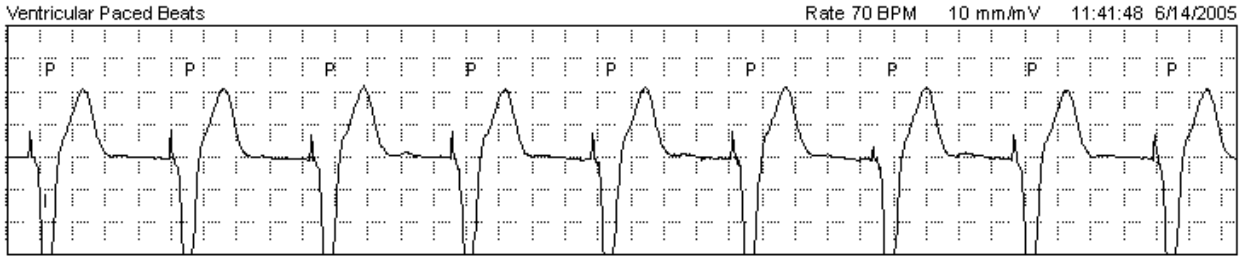
In the examples above, a baseline ECG is selected for comparison. Notice that there is elevation is some channels and depression in others, referred to as reciprocal change. Also notice that ST change is not apparent in all 12 leads. The ST episode lasted for a period of approximately 2 minutes that may have been missed if only lead II had been observed and the patient were asymptomatic.

HScribe Approach – After eliminating artifact and ensuring all ectopic beats are labeled appropriately, the analysis program measures the ST segment for each normal beat and averages the measurements. The Profile and Trend displays will show any change in ST segments and elevation episode onset, offset and durations will be reported according to user-defined thresholds.

Pacemaker Analysis

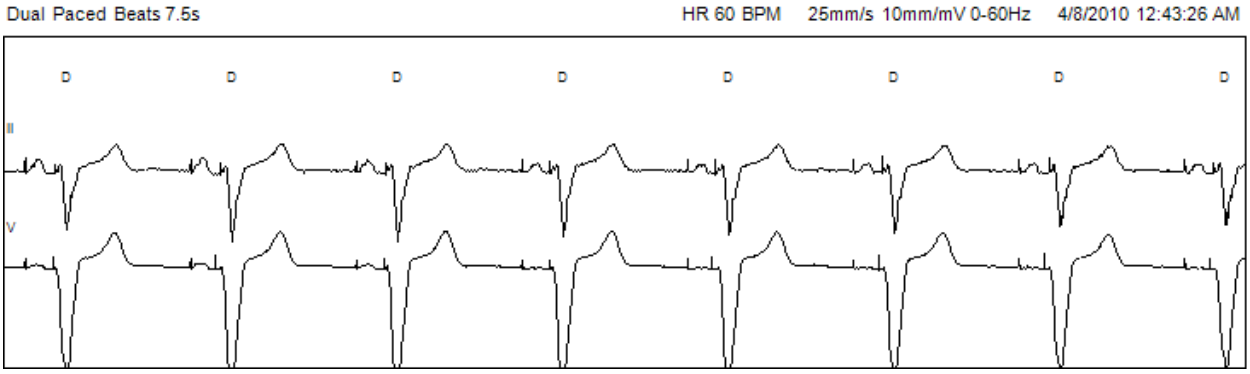
Pacemakers fall into categories that are identified by three-letter abbreviations that describe their pacing, sensing, and response mechanisms. The first letter identifies the location of the pacing electrode(s); the choices are "A" for atrial, "V" for ventricular, and "D" for dual (both atrial and ventricular). The second letter identifies the location of the sensing electrode(s); again the choices are "A", "V", and "D". The third letter identifies the appropriate response of the pacing electrode(s): the choices are "I" for inhibited, "T" for triggered, and "D" for dual (both inhibited and triggered).

<u>Ventricular Demand Pacemaker (VVI)</u> – A VVI pacemaker senses in and paces only the ventricles. Pacing of the ventricles is inhibited when the pacemaker senses ventricular activity. When the pacemaker senses that no ventricular activity has occurred in a certain pre-defined time period (for example one second, corresponding to 60 beats per minute), it will fire to initiate a beat. This results in a paced escape rhythm whenever the patient's intrinsic rate drops below the rate of the pacemaker.



HScribe Approach – When pacemaker detection is turned on, ventricular paced beats are declared when the beat is paced and a pacemaker spike is immediately before the beat.

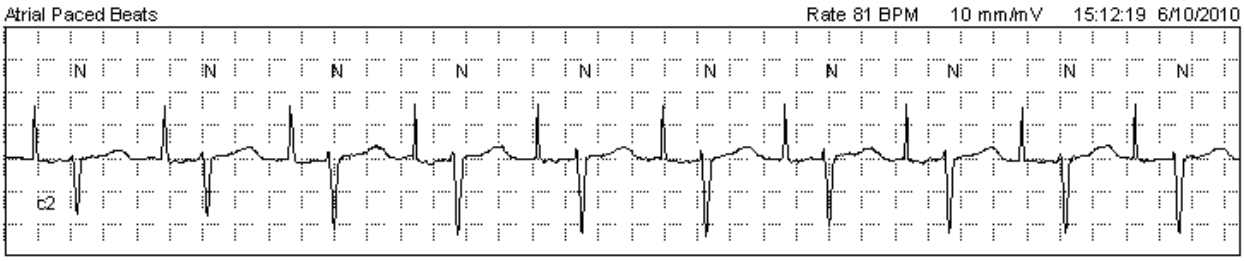
<u>AV Sequential Pacemaker (DVI)</u> – A DVI pacemaker paces both atrial and ventricular chambers whenever it does not sense ventricular activity during a certain pre-defined time period. Functionality is similar to that of a VVI, but the patient has a higher cardiac output by also pacing the atria.



HScribe Approach – When pacemaker detection is turned on, the analysis program will declare a beat is Atrial paced when the beat is normal and the pacer spike precedes the beat. Ventricular paced beats (P) are declared when the beat is paced and a pacemaker spike is immediately before the beat. Dual paced beats (D) are declared when atrial and ventricular spikes are successive and the beat is identified as paced.

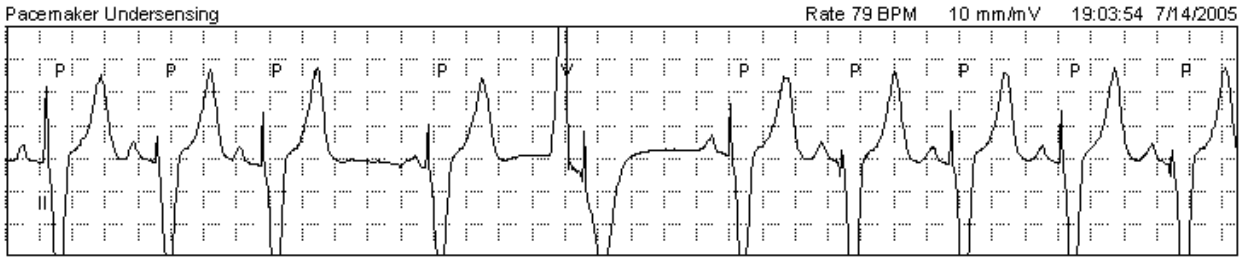
<u>Dual Demand Pacemaker (DDD)</u> – A DDD pacemaker independently paces and senses in both atrial and ventricular chambers. This results in three different modes of pacing:

1. **Atrial pacing by sensing no atrial or ventricular activity has occurred. If conduction is normal, the impulse travels through the ventricles;**
2. **Atrial tracking by sensing atrial activity but no ventricular response, the pacemaker initiates electrical activity at the ventricular lead;**
3. **Dual-chambered pacing by sensing no atrial or ventricular activity, the pacemaker initiates electrical activity at the atrial lead. If the impulse does not conduct through normally and there is no ventricular response, the ventricular lead initiates the electrical impulse in the ventricles.**



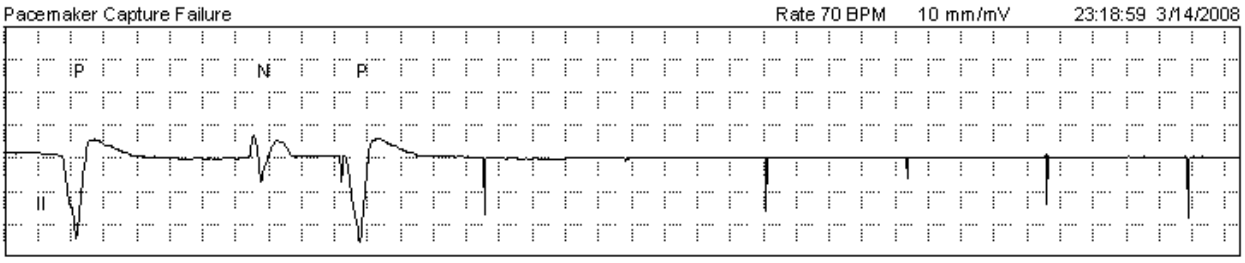
HScribe Approach – When pacemaker detection is turned on, the analysis program will declare a beat is Atrial paced when the beat is normal and the pacer spike precedes the beat. Ventricular paced beats are declared when the beat is paced and a pacemaker spike is immediately before the beat. Dual paced beats are declared when atrial and ventricular spikes are successive and the beat is identified as paced.

<u>Pacemaker Failure to Sense</u> – If either an atrial or a ventricular sensing electrode does not sense either a P-wave or a QRS complex that occurs, the failure is called a "sense failure". This is sometimes also referred to as undersensing. Failure of the ventricular-inhibited lead to sense a QRS results in an early paced beat. Failure of an atrial-triggered lead to sense a P-wave results in a non-tracked P-wave.



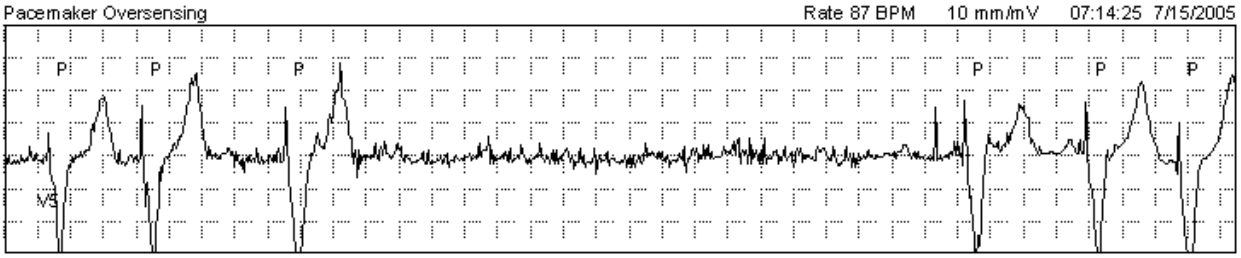
HScribe Approach – The analysis program will identify when a pacer spike is earlier than expected and is less than one-third the time from its preceding beat. This failure can be found in the Pacer Profile display.

<u>Pacemaker Failure to Capture</u> – When any pacing electrode fires and fails to initiate depolarization, the failure is called a "capture failure". This is characterized by either an atrial or a ventricular spike not followed by a subsequent P-wave or QRS complex.



HScribe Approach – The analysis program will identify when a beat is not present after the pacer spike with an interval greater than 300 msec. This failure can be found in the Pacer Profile display.

<u>Pacemaker Oversensing</u> – When either an atrial or a ventricular sensing electrode senses a P-wave or a QRS complex that does not occur, the failure is called inappropriate inhibition or "oversensing". If a ventricular-inhibited lead senses inappropriately and fails to fire, the result is a longer than programmed RR interval; oversensing often happens during exercise and may be caused by sensing of the muscle activity.



HScribe Approach – The analysis algorithm will identify when the RR interval is greater than 1.2 times the expected paced interval after the beat. This failure can be found in the Pacer Profile display and also under maximum RR/Pause events.