The Actiheart
USER MANUAL

Document Reference:	30207
Issue Version:	5.1.31
Issue Date:	30/6/22

This equipment must be configured and operated in accordance with these instructions and in conjunction with: ***'The Actiheart Guide to Getting Started'***

Regulatory Information

European Union

The Actiheart is NOT a Medical Device and is intended for the measurement of Energy Expenditure only. The Actiheart may be used for applications relating to Energy Expenditure and research related to HRV and is NOT indicated for use in clinical applications. Please contact CamNtech UK for advice on application if further clarification is required.

The CE mark is applied to the Actiheart to indicate conformity with the following Directives:

Electromagnetic Compatibility Directive 2014/30/EU.

RoHS2 Directive 2011/65/EU.

WEEE Directive 2012/19/EU.

Manufacturer:

For assistance with set-up, use or maintenance of the Actiheart or to report any unexpected operation or events, please contact CamNtech using the details below or contact your local representative.

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IMPORTANT SAFETY INFORMATION

WARNINGS

- Contains Lithium Battery – DO NOT ATTEMPT TO DISSASEMBLE: No user serviceable parts, danger of chemical hazard if battery is damaged.
- Do not connect the device to computer or charger while attached to the patient.
- Not Defibrillation proof.
- Not indicated for use on areas of broken, damaged or irritated skin.
- Remove ECG pads from skin if there is significant discomfort from skin irritation or reaction.
- Devices removed from subjects must be considered to be contaminated – see Section 6.

Device and Packaging Symbols and Markings:

MEANING	SYMBOL	DESCRIPTION
General Warning		Potential hazard -refer to the warnings in the instructions for use (i.e. this user guide).
Consult Instructions for Use		This symbol indicates that important operational information is contained in the user instructions (i.e. this user guide).
Ingress Protection Rating	IPX7	The Actiheart is suitable for temporary immersion in water (up to 1 hour at 1m).
Serial Number	SN	This number provides a unique identification for a particular device. Always quote this number when seeking technical assistance.
Catalogue Number	REF	This number identifies this particular variant of the product range.
Manufacturer and Date of Manufacture		This symbol is accompanied by a date in the format ***yyyy-mm*** which indicates when the device was manufactured. The symbol is also accompanied by the address and contact details of the manufacturer
Electrical Safety Classification		The Actiheart is a **TYPE B APPLIED PART**.

FOR FURTHER HANDLING & ENVIRONMENTAL INFORMATION PLEASE REFER TO SECTION 6

Contents

IMPORTANT BATTERY CARE INFORMATION!

The Actiheart device contains a miniature rechargeable battery which must be cared for correctly to maximise service life. Following any long recording, always ensure the battery is at least partly re-charged - do not leave it completely flat before storage. If the device is to be stored for an extended period then it should ideally be part-charged rather than left either completely fully or empty.

1 Actiheart Databases

The Actiheart uses two SQLite databases to store data and settings separately. Direct access to these is not required in order to record, read and analyse data. However if a user wishes to view the details of certain records which are not viewable through the user interface or if a user wishes to customise certain settings then these may be opened using any SQLite data viewer. For example, http://sqlitebrowser.org/ offer a browser for SQLite data.

The database(s) which hold the recorded data are created and named by the user and by default are saved in C:\Users\User Id\My Documents\Actiheart Data. The software is shipped with a database which contains demonstration files.

The Settings database is also shipped with the software and a copy placed in the AppData directory for each user during their first use.

1.1 Recordings Database

This database holds recorded data and has a number of tables containing recording, user and logging information. The two key tables are ReadInfo and Users.

1.1.1 ReadInfo Table

This is one of the most important tables in that it contains all the recording identifying data. Raw data is stored alongside in the ReadData table. This table is populated every time that the Actiheart is read. The following information is stored along with the raw data. Additional fields may be present.

- **Computer Name:** The Windows name of the computer used.
- **Computer User:** The current Windows login name.
- **Read Time:** Time at which the data was downloaded from the device to the computer. This is often the end time of the recording.
- **Start Time:** This is the time at which the recording started.
- **Serial No.:** The serial number of the recording Actiheart or other device.
- **Battery Voltage:** This is the battery voltage at the time the data was read.
- **User Id:** This is the User name which was used for the recording. If a Test Id was also used then the User Id field will be displayed as User Id_ Test Id e.g. 99934_ bike + treadmill.
- **Test type:** This is the recording mode, and is specific to the type of Actiheart or other device used for each recording.
- **Samples:** This is the raw recording data size in bytes.
- **Step Size:** This is the physical step height at which a test was conducted (in mm) and is very important reference information for the reasons given in ***Section 4.4***.

1.1.2 Users Table

This table contains User details many of which affect the calculation of energy expenditure. These are all entered from the Actiheart application and they are:

- **User ID:** Any ID may be used, either an actual name or ID number.
- **Height:** Always in metres, internally. Even when entered imperially.
- **Date of Birth**
- **Weight:** Always in kg, internally. This is used for many of the Energy Expenditure (EE) calculations.
- **Resting Heart Rate:** See ***Section 4.4.8.2*** for more details.
- **Measured RMR:** This is whichever value the user has opted for i.e. equation based or actually measured. See ***Section 4.4.8.1*** for more details.
- **HR max:** This is whichever the user has opted. i.e. equation based or user entered. See ***Section 4.4.8.3*** for more details.
- **VO2 max:** See ***Section 4.4.8.4*** for more details.

The table also contains individual Activity and Heart Rate calibration data obtained either from the built-in Step Test or from an external calibration.

The Step Test data is generated automatically when a Step Test is saved (see ***Section 4.5*** for more details). The data is contained in the fields labelled Energy20 to Energy280. The data is in Joules/min/kg.

Heart Rate calibration data is contained in the fields HRee20 to HRee280 and Activity Calibration data is contained in the fields ActEE50 to ActEE6400. This data is entered by the user. Please see ***Section 4.4.8*** on individual calibration for more details.

1.2 Settings Database

This database has a number of tables of which only two, paee and StepPAI are key operational tables. The paee table is described in more detail later. This table contains information about:

- Group calibration equations.
- Branched Model Discriminants and Weighting factors. See ***Appendix 2*** for more details.
- Compensation factors for recovered Heart Rate data and for stress (see ***Appendix 2***).
- Flags to enable individual calibration.

The group calibration equations shown in the table are the default ones supplied with the software but a user can specify his own. The branched model discriminants can also be varied at will. This information can be viewed directly from the application without having to open the database (see ***Sections 4.3.3 and 4.4.7***).

The StepPAI table contains the PAI-HRaS regression equation obtained from the Step Test (see Appendix 4).

StepPAI										
FAC										
1	2	3	4	5	6	7	8	9	10	11
2.9	1.1	2.9	1.3	-10	0	0	0	0	-75	0

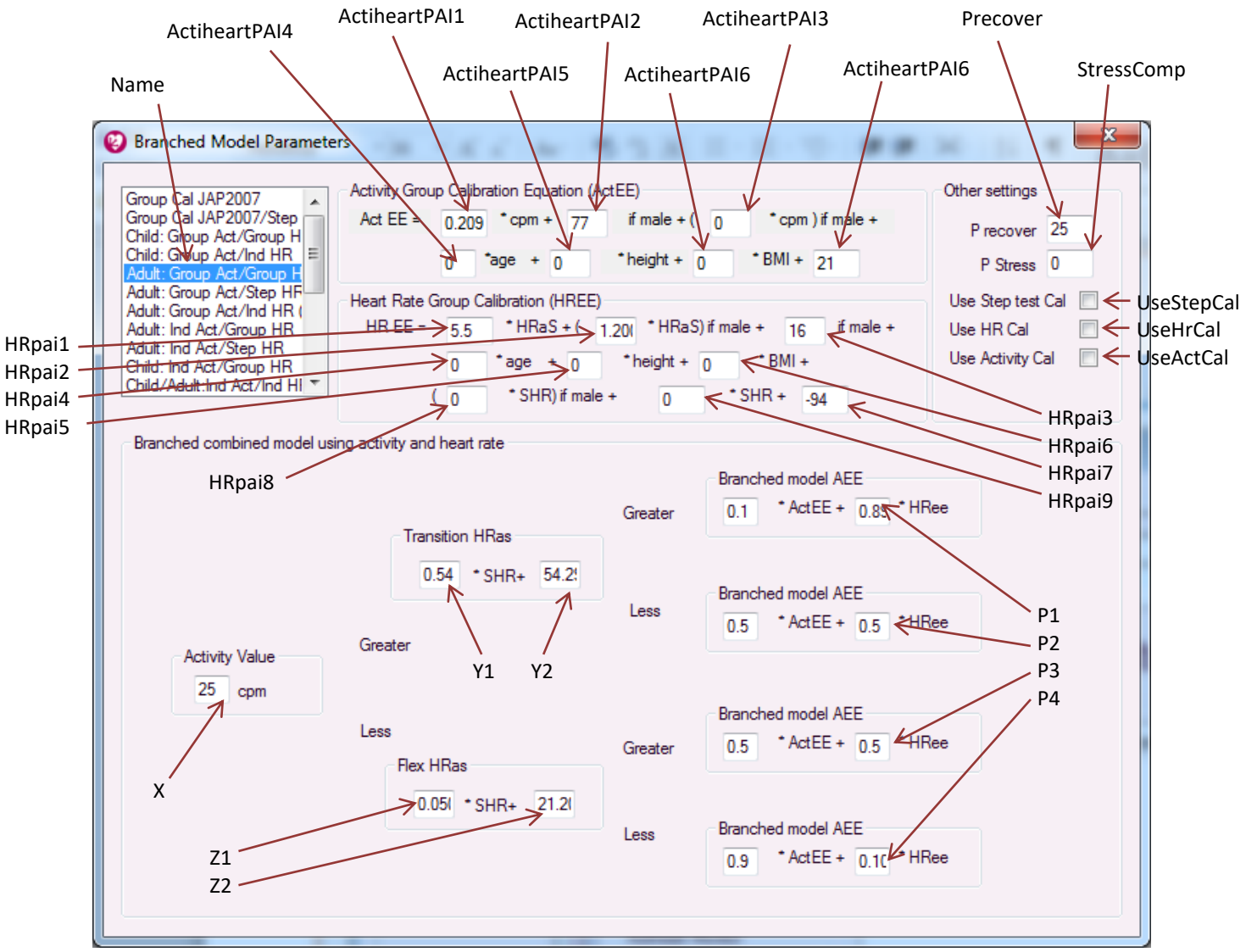
WARNING
When creating new equations or varying any of the branched model values do not replace any of the default values but create a new record in the database.

1.2.1 Energy Models

The different energy models available to analyse recordings are controlled by entries in the paee table of the settings database. If you wish to experiment with a new model or combinations of existing models, you may add new rows to this database. You should do this with some caution, and we can make no guarantee as to the energy expenditure results you will gain. You must not alter the existing rows.

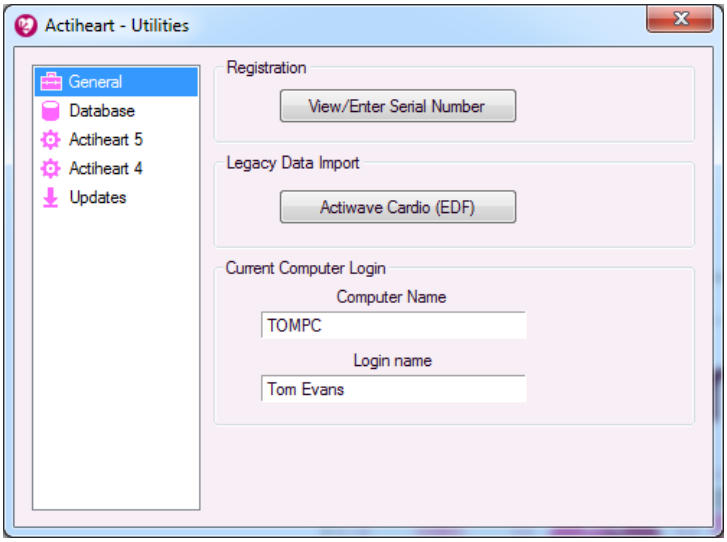
Each row added to the table will result in a new energy model being added to the list available within the software. Most of the columns needed for each entry are shown in the diagram on the following page, linked to the corresponding entries in the branched model parameters window. The remaining columns are explained immediately below:

- **ViewOrder:** This number determines the order in which the models will be displayed within the software. If adding a new model, simply choose a higher number, for example starting from 100.
- **ActiheartFlex:** This controls the “flex point” value of activity counts where the EE prediction switches between a linear projection from the origin to the Act EE equation.
- **HRflex:** This controls the “flex point” value of heart rate where the EE prediction switches between a linear projection from the origin to the HR EE equation.
- **Jap2007Activity:** This controls whether the piecewise linear activity to EE model from the JAP2007 paper will be used.
- **common:** This determines whether the model appears when “Show Common Models” is selected.


Name
ActiheartPAI4
ActiheartPAI1
ActiheartPAI2
ActiheartPAI3
ActiheartPAI5
ActiheartPAI6
ActiheartPAI6
Precover
StressComp
Branched Model Parameters
Group Cal JAP2007
Group Cal JAP2007/Step
Child: Group Act/Group H
Child: Group Act/Ind HR
Adult: Group Act/Group H
Adult: Group Act/Step HR
Adult: Group Act/Ind HR (
Adult: Ind Act/Group HR
Adult: Ind Act/Step HR
Child: Ind Act/Group HR
Child/Adult:Ind Act/Ind HI
Activity Group Calibration Equation (ActEE)
Act EE = 0.209 * cpm + 77 if male + (0 * cpm) if male +
0 * age + 0 * height + 0 * BMI + 21
Heart Rate Group Calibration (HREE)
HR EE = 5.5 * HRaS + (1.20 * HRaS) if male + 16 if male +
0 * age + 0 * height + 0 * BMI +
(0 * SHR) if male + 0 * SHR + -94
Other settings
P recover 25
P Stress 0
Use Step test Cal
Use HR Cal
Use Activity Cal
Branched combined model using activity and heart rate
Transition HRas
0.54 * SHR+ 54.2
Flex HRas
0.05 * SHR+ 21.2
Activity Value
25 cpm
Greater
Less
Greater
Less
Branched model AEE
0.1 * ActEE + 0.8 * HRee
Branched model AEE
0.5 * ActEE + 0.5 * HRee
Branched model AEE
0.5 * ActEE + 0.5 * HRee
Branched model AEE
0.9 * ActEE + 0.1 * HRee
HRpai1
HRpai2
HRpai4
HRpai5
HRpai8
HRpai3
HRpai6
HRpai7
HRpai9
UseStepCal
UseHrCal
UseActCal
P1
P2
P3
P4
Y1
Y2
X
Z1
Z2

2 Settings and Utilities

Clicking on the Utilities button from the main menu will display the Actiheart Utilities window as shown below.



The utilities are divided up using the sections on the left hand side of the window.

2.1 General

General settings relate to the software installation and user logging.

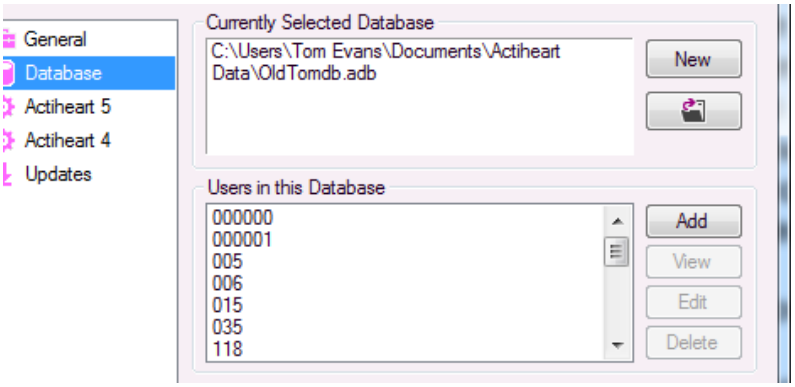
The View/Enter Serial Number function will allow you to enter a software serial number supplied by CamNtech to both register the software and enable full functionality.

The Legacy Data Import function allows a recording previously made with the Actiwave Cardio and saved as an .EDF file to be imported and converted for analysis with the Actiheart software.

The Current Computer Login information box shows the information automatically collected about the computer and user operating the software. Note that these will be captured each time a recording is made using the software to help reference and trace those recordings.

2.2 Database

The Database section of the Utilities window provides information and tools for the management of the current database of recordings and associated user information.



The currently selected database (and its location) are shown within the “Currently Selected Database” area. A listing of all users contained within this is shown in the “Users in this database” area.

2.2.1 Adding or Changing Databases

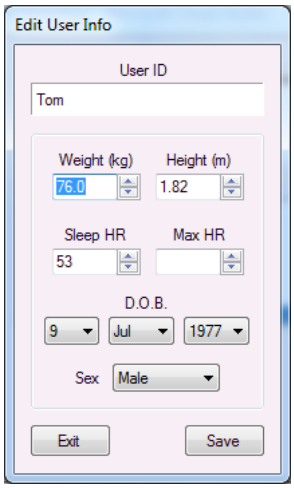
To add a new blank database (no users or records), click on the New button. A Windows file dialogue box will be displayed where you can supply the name and location of the new database before clicking Open to save the database.

To select a different existing database, click on the folder button. This will open a standard Windows file dialogue where it is then possible to locate and select the required existing database.

2.2.2 Managing User Information

It is possible to manage user information in the “Users in this database” area. This provides the following options:

- **Add:** This will invoke the “Add new user wizard” as described in the Guide to Getting Started.
- **View:** Click on any user in the list then click the View button to view details for that user.
- **Edit:** Click on a user in the list then click the Edit button to show the following screen:

  It is possible to change the following user details from this screen:

  - Weight
  - Height
  - Sleeping Heart Rate
  - Maximum Heart Rate

  When changes have been made, click Save to store the information.

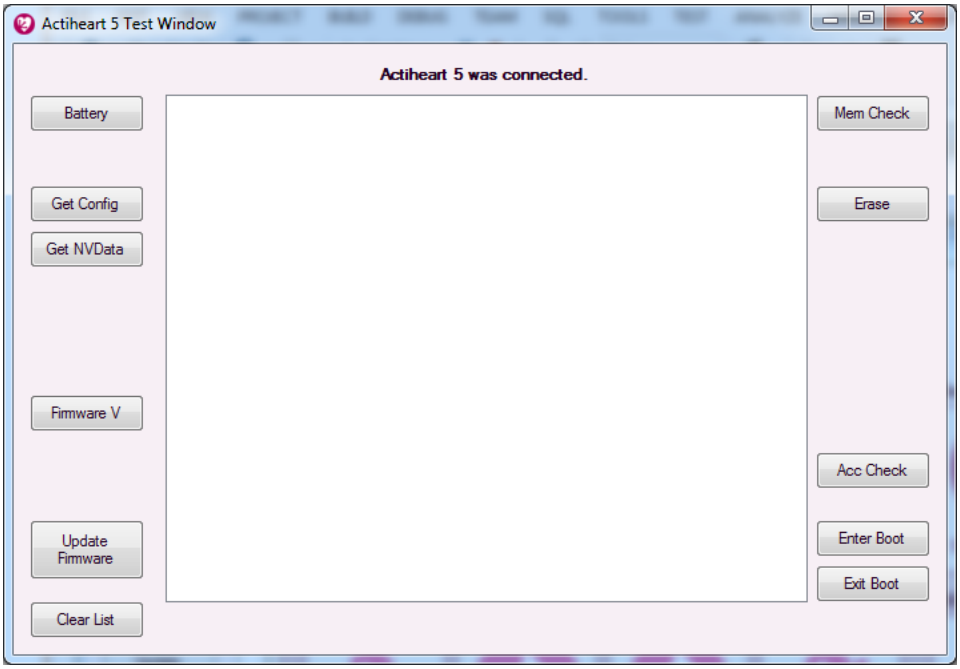
- **Delete:** If a user’s details are no longer required, click on a user in the list then click the “Delete” button to permanently erase the details.

2.3 Actiheart 5

Clicking the Actiheart 5 tabs brings a number of functions for monitoring or maintaining the Actiheart 5 device.

The “Read Actiheart” button will automatically attempt to read from the Actiheart connected, regardless of which section of the software the device was set up from. It can be used as an alternative to any of the individual specialist “Read” functions.

The “Test Actiheart” button will open the Actiheart 5 Test window, as shown below.



This test window is not needed in routine use, but will allow a number of diagnostics checks to be made if requested by CamNtech technical support. At the top of the window in the centre, the software will indicate whether an Actiheart 5 has been detected and whether it is in normal operating mode or “boot” mode only.

The functions available are explained below:

- **Battery:** This will send a query to the device to report on the estimated battery level. Note that the battery is charged continuously while the Actiheart is connected. There is no need to take any additional action to charge the Actiheart.
- **Get Config:** This will ask the Actiheart device to report back on its current configuration. That includes the recording mode details and recording / log size, but not the recording metadata.
- **Get NVData:** This function will show Non-Volatile data stored on the Actiheart, which includes both the current recording metadata (username and start date / time) and also any permanent stored data such as serial number and calibration values.
- **Firmware V:** The current firmware version will be reported here. Note that the bootloader and firmware have separate version numbers, so the value shown here will depend on whether the device has been moved into “boot” mode or not.

- **Update Firmware:** Clicking will open the firmware update window, allowing you to update the firmware of the currently attached device. Do not update the firmware of a device with a flat battery – allow it to charge partway first. Note that the software will apply a firmware update to the version packaged with your PC software. This can be either an “update” or “backdate” as you choose.
- **Clear List:** This will clear the large central list of diagnostic information which was collected by using the other functions.
- **Mem Check:** This is an internal CamNtech test to report on the memory chips of the device.
- **Erase:** This triggers a full erase of the device memory. It should only be performed if you are certain you wish to erase any recording data on the device. It is also performed automatically when you wish to set up for a new recording – there is no need to use this button.
- **Acc Check:** This is an internal CamNtech test to report on the accelerometer chips of the device.
- **Enter Boot:** The Actiheart connected will be asked to leave the normal firmware operating mode and enter “boot” mode. It is not necessary to perform this manually before a firmware update.
- **Exit Boot:** The Actiheart connected will be asked to leave the “boot” mode and enter its normal operating mode. This will normally happen automatically in use, but may be applied manually immediately after a battery charge, if the centre heading indicates that the device is in “boot” mode.

3 Activity and Heart Rate

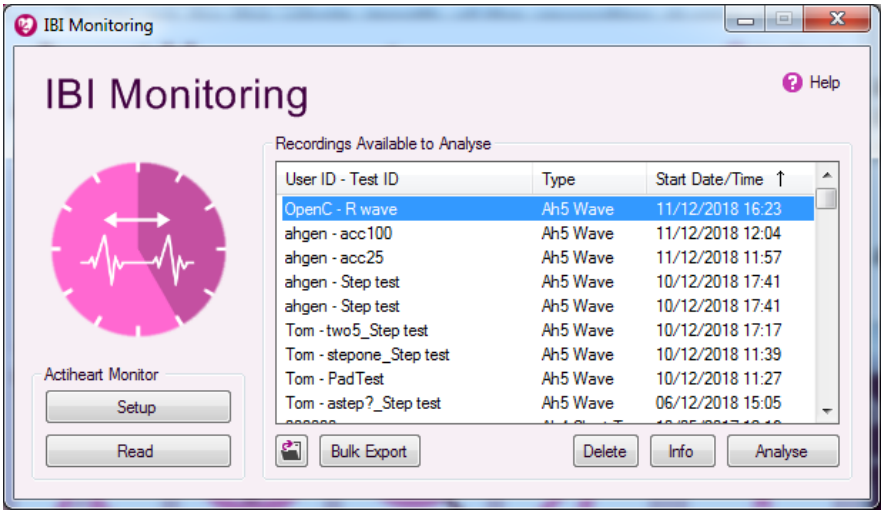
3.1 IBI Monitoring

3.1.1 Overview

The IBI Monitoring recording mode is designed for recording for up to two weeks, recording the timing of every single heartbeat and three-axis acceleration waveforms for that time. This recording mode allows for detailed heart rate variability (HRV) analysis.[1] Heart rate and activity counts are also computed and displayed for the whole length of the recording during analysis.

Recordings made using an Actiheart 5 in IBI Monitoring mode can also be used in the “Long Term” analysis function, and displayed in the “Full Waveform” analysis, albeit with only partial ECG information. They can furthermore be used in any of the Energy Expenditure monitoring functions.

Selecting the “IBI Monitoring” function in the main menu brings up the following window:



3.1.2 Setting Up an IBI Monitoring Recording

An IBI Monitoring recording is set up in the same way as a Signal Test recording by clicking on the Setup button then following the set-up wizard. For further details please see the Guide to Getting Started.

3.1.3 Delayed Start for IBI Monitoring Recording

Delayed Start allows the user time to set up an Actiheart or several Actihearts and for them to start recording at a time in the future. This can be useful, for example, when setting up a group of subjects together. The maximum start delay is 72 hours. The Actiheart will not begin recording until the start time is reached. All times are taken from the clock on the host PC.

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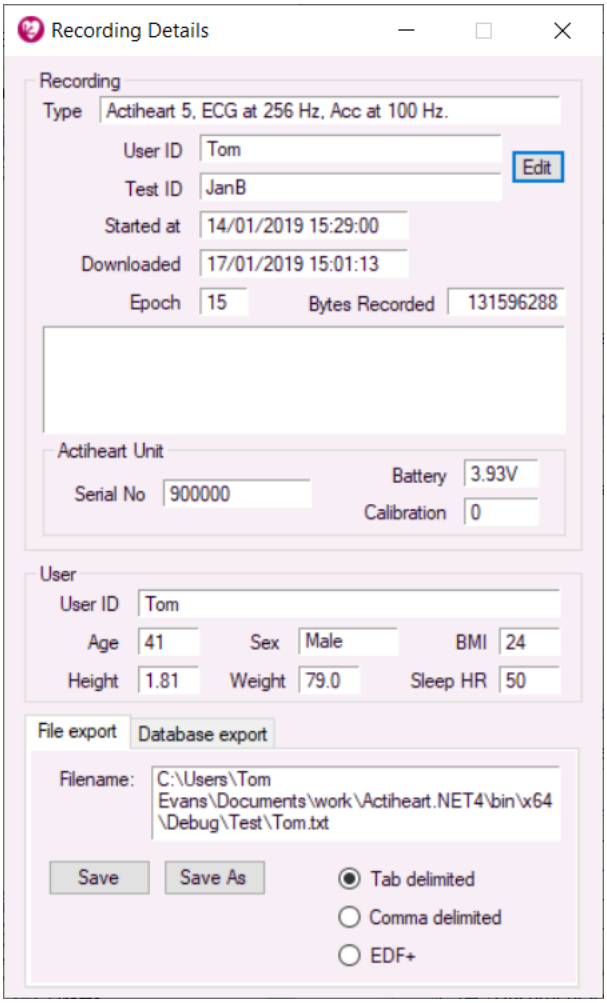
[1] *The term HRV is a generic term used in this manual to indicate the variability of the cardiac Interbeat Interval. The number of intervals available for analysis and the measure of variability used varies according to the application.*

3.1.4 Downloading IBI Monitoring Data from the Actiheart

Click on the Read button to download the data. This process is the same as for any other recording (for further details please see the Guide to Getting Started). The data is stored in the currently selected database ready for analysis.

3.1.5 Viewing Details of an IBI Monitoring Recording

Once the recording has been stored in the database, it is possible to view information about it. Highlight the required recording from the IBI Monitoring window and then click the Info button to produce the window shown below:



3.1.6 Database Export and File Export

It is possible to export a particular file or to export a user's data and experiment data from this field. This is done by selecting either the "File export" or "Database export" tab from the bottom of this screen.

- **Database Export:** Exports the full user details and experiment details to a target database which is selected by clicking on the "Export As…"

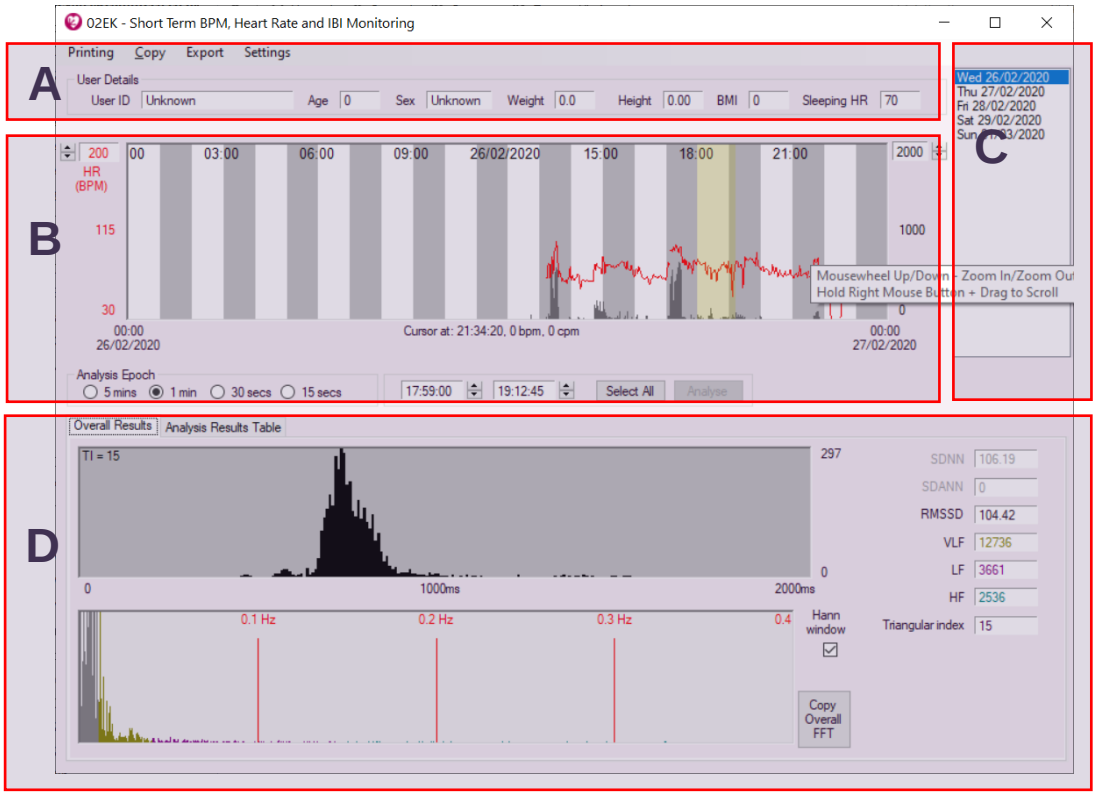
button. Click “Export” to export the database; when this is complete, a confirmation message is shown.

- **File export:** Exports a file in Tab or Comma Delimited text format, or in EDF+ data format for ECG analysis in external software. The default file name and location are shown and clicking Save will export the data. Alternatively, clicking “Save As” allows an alternative file name/folder location to be specified.

This export procedure is identical for all recording modes.

3.2 Analysing an IBI Monitoring Recording

The recording required for analysis can be selected by either double clicking on it, or highlighting it and clicking on Analyse. The IBI Monitoring analysis window will be shown, which is divided as shown below:



A. **User and Recording Details:** This area shows the parameters of the user logged for this recording – age, weight, etc.

B. **Heart Rate & Activity Graph:** This area shows a graph of activity data in black and heart rate data in red for the duration of the recording. Further details of the functions are provided below. It also allows you to zoom in and out, scroll through the data, select an analysis period, and choose the epoch for that analysis.

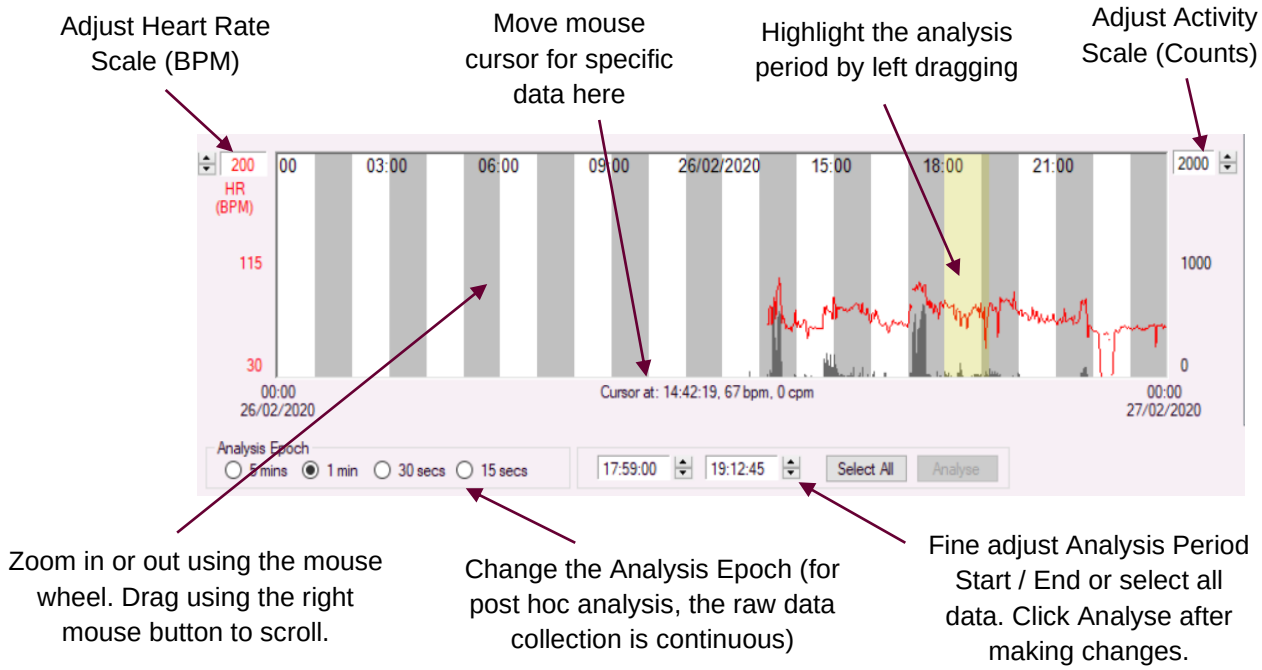
C. **Day Selection:** For a longer recording which spans multiple days, clicking the date in this list will cause the main heart rate and activity graph to shift to that day. A single click will shift to the day chosen whilst maintaining the current zoom and time-of-day position for the graph. A

double click will reset the graph to show the full 24 hours of the chosen day.

D. **Analysis Results:** Once a period has been selected for analysis, this area provides Overall Results with results in graphical and quantitative form of the entire period analysed as one, and an Analysis Results Table with epoch-by-epoch HRV measures.

3.2.1 Heart Rate & Activity Graph Controls

The Heart Rate & Activity graph has a number of controls and functions as described below:



Click and drag using the right mouse button to scroll through the data. Use your mouse wheel to zoom in and out on the time scale. Beyond a certain zoom level, the graph will begin to show IBI data in blue rather than only averaged heart rate in red. You may also use the controls to the left and right of the graph to change the vertical scale for activity (movement), HR and IBI.

3.2.2 Overall Results

It is possible to perform a detailed analysis of the IBI data recorded by highlighting the region of interest on the Activity and Heart rate graph as described above. The Overall Results tab will then present overall statistical results for the period alongside graphical illustrations. These results are described below.

- **VLF:** Very low frequency component of the IBI, derived using an FFT.
- **LF:** Low frequency component of the IBI, derived using an FFT.
- **HF:** High frequency component of the IBI derived using an FFT.
- **RMSSD:** Root mean square of the successive differences of the IBIs.
- **Triangular index:** The integral of the density distribution divided by the maximum interval. This is also shown on the histogram plot.

When the 5 minute analysis epoch is selected, the following further information is also displayed (otherwise these will be greyed out):

- **SDNN:** The standard deviation of the normal to normal intervals.
- **SDANN:** The standard deviation of the 5 minute average NN intervals.

Histogram Plot:

The upper graph of the Overall Results display shows a plot of the frequency of each IBI encountered over the analysed period. It may illustrate a well defined peak if a large amount of total time is spent around one heart rate, or a wider distribution where the data is more variable or encompasses a number of different activities.

Overall FFT Graph:

The lower graph of the Overall Results tab displays the results of a Fast Fourier Transform (FFT) of the entire period selected for analysis. The VLF, LF and HF bands are marked by colour. Data from the FFT can be exported using the Copy button to the right of the graph.

3.2.3 Analysis Results Table

Statistical information about the IBI data is shown in the Analysis Results Table. The detail that is shown here is dependent on the analysis epoch selected. Note that the analysis epoch is for ***post hoc*** analysis purposes only as the data is recorded on a continuous basis. The following data is shown for each analysis epoch:

- **Activity:** Activity counts (movement) in the analysis epoch
- **BPM:** The average heart rate in beats per minute for the epoch
- **IBI Ave:** Average Inter-beat Interval (IBI) for the analysis epoch
- **IBI Min:** Minimum IBI in the epoch
- **IBI Max:** Maximum IBI in the epoch
- **SD:** Standard Deviation of the IBI data
- **RMSSD:** The Root Mean Square of the Successive Differences of IBIs

If either a 1 minute or a 5 minute post hoc analysis epoch is selected then the following further information is also available:

- **LF:** The low frequency component of the IBI, derived using an FFT
- **HF:** The high frequency component of the IBI derived using an FFT
- **LF/HF:** The ratio of the LF component to the HF component of the IBIs

Additionally in the case of the 5 minute epoch the VLF (very low frequency) component of the IBI is also visible.

In addition to the above there is a column for “Used”, which is the fraction of time during each epoch during which IBI were available for the calculation. This is affected by the quality of data, but also by the use of the “Data-selective HRV” option, which only allows the inclusion of IBI considered “Valid”.

On each row of statistics, there will be a note if too few valid IBI points were found to analyse, along with missing results. This indicates that whilst the analysis can selectively use only valid IBI in the case of small amounts of missing data, it will not do so where 50% or more of the time period is missing.

Note: All time domain and frequency domain parameters are based on the definitions contained in “Heart Rate Variability, Standards of Measurement, Physiological Interpretation, and Clinical Use”. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology.

3.2.4 IBI Analysis Settings

The IBI Analysis window menu provides settings options for Data-selective HRV and HRV Bandwidth / Frequency.

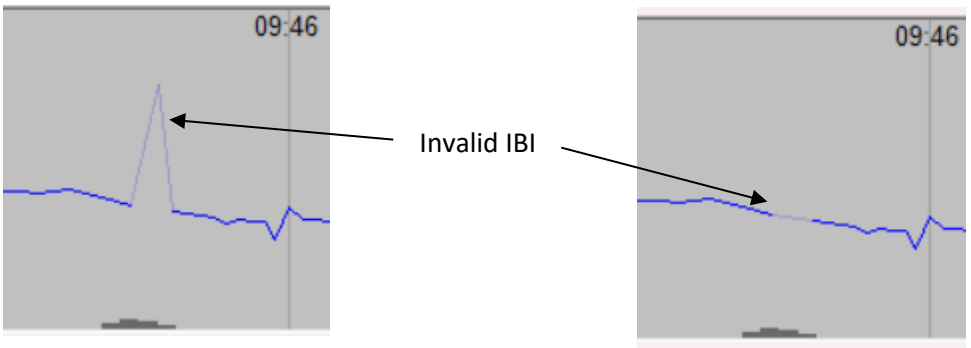
Data-selective HRV: This option (selected by default) allows the calculations of heart rate variability to attempt to use only those IBI which are considered likely to be valid by the ECG processing. IBI marked invalid will be excluded from the calculation.

It is very common in recorded ECG or IBI data to have sequences of “good” beat sequence data interspersed with a smaller number of “bad” data periods where reliable beat intervals could not be read. Most Heart Rate Variability (HRV) measures are very sensitive to this, and can produce disproportionately high output results from even small amounts of poor data. Note that this option must be consistently applied – results from “noisy” data processed with this option should be compared to other data processed with this option, not without.

For the IBI sequence based calculations (max IBI, min IBI, ave IBI, SD, RMSSD) the software will directly perform HRV calculations with invalid data points excluded. Successive differences will only be calculated on adjacent valid IBI.

For FFT based HRV calculations (LF, HF, etc), the software will perform a frequency analysis of the IBI signal with invalid data replaced with a straight-line segment to minimize variability from that period. However, variability magnitude is then adjusted to “scale-up” the remaining variability measures to the full period length. This will only be performed with over 50% of data valid, below which the software will not produce HRV measures.

When the heart rate & movement graph is zoomed in far enough to show IBI, the plot will also reflect the setting of this option:



No Data-selective HRV

Data-selective HRV

HRV Bandwidth / Frequency: This menu item allows the user to modify bandwidths used to calculate VLF, LF and HF frequency content from the IBI signal. The default values are those standardised for human study, but alternate frequency bands can be applied either for animal or human use.

3.2.5 Copying IBI Monitoring Data to the Clipboard

Data can be copied from the software for pasting into an external program of the user's choice. The selected data is exported to the clipboard and can then be pasted from there into, for example, Microsoft Excel. There are two options accessed from the Copy menu of the analysis screen:

Analysis IBI data: This function takes the analysed raw data and places it on the clipboard. The output provides a header containing information about the recording, the device and the User. Next is a listing of time stamped IBIs (in ms) for every beat in the analysis period. Note that all of these data are for the **selected analysis period** only.

Analysis Results: This function takes the information from the IBI statistics area and places it on the clipboard. The output provides a header containing information about the recording, the device and the User. This is followed by a listing of time stamped IBI analysis results as displayed on screen. Note that all of these data are for the **selected analysis period** only.

3.2.6 Exporting IBI Monitoring Data

It is possible to export the time stamped IBI data as a **text** file by selecting the required region (as described above) and clicking Export -> Time stamped IBI data from the menu. Take note of the confirmation message which contains the file name and folder for the data. The software uses the "Actiheart data" folder as the default folder and the file name has the following format:

IBI ddmmmyyyy hhmm.txt

Where ddmmmyyyy is the date of the export and hhmm is the time of the export.

3.2.7 Editing IBI Data.

In some circumstances, IBI data may be noisy or contain periods of missed beats. If this is the case then the recording should be opened in the "Full Waveform" window to examine the period in greater resolution. This can be performed both with Full Waveform and Actiheart 5 IBI recordings, and will save modified IBI data which will then be used within re-opening the IBI Analysis window.

3.2.8 Legacy IBI Analysis Function

The Actiheart 4 HRV System was constrained by the limits of the Actiheart 4's internal data collection. This was limited to a maximum of 2000ms IBI, and carried no evaluation of whether each individual recorded ECG peak was likely correct on incorrect in relation to recorded beat sequence. Actiheart 5 IBI and Full Waveform recordings are not subject to these restrictions. In contrast, they

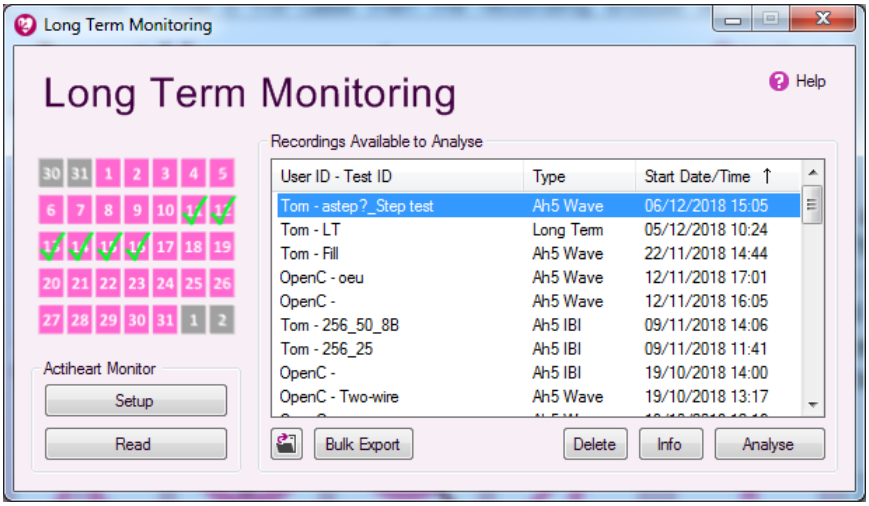
have no intrinsic upper IBI limit, and the system can estimate post-recording whether each recorded inter-beat-interval is likely correct or not based on the magnitude and timing consistency of surrounding peaks.

As a result, IBI data recorded using an Actiheart 4 will be opened using a legacy version of the IBI analysis function. This contains many of the same functions as the current version, but with the 2000ms limitation, and no ability to ignore specific noisy IBI samples within an otherwise good analysis epoch.

It is also possible to open Actiheart 5 recordings using the legacy analysis function by selecting the option to do so from within the Utilities window. This is not recommended for normal use, but may be useful to maintain consistency with a project which has already begun.

3.3 Long Term Recording

The long term recording mode is optimised for lower-resolution analysis of longer time periods of a week or more. When the Actiheart 5 is set up from here, it will track every single IBI and the acceleration waveforms as for IBI Monitoring mode, only the focus of the analysis window is different. Data collected from "Long Term" mode may be freely used in IBI Monitoring or any of the energy Expenditure functions. It may also be opened in the Full Waveform analysis window, but the ECG form available will be limited.



3.3.1 Setting up a Long Term Recording

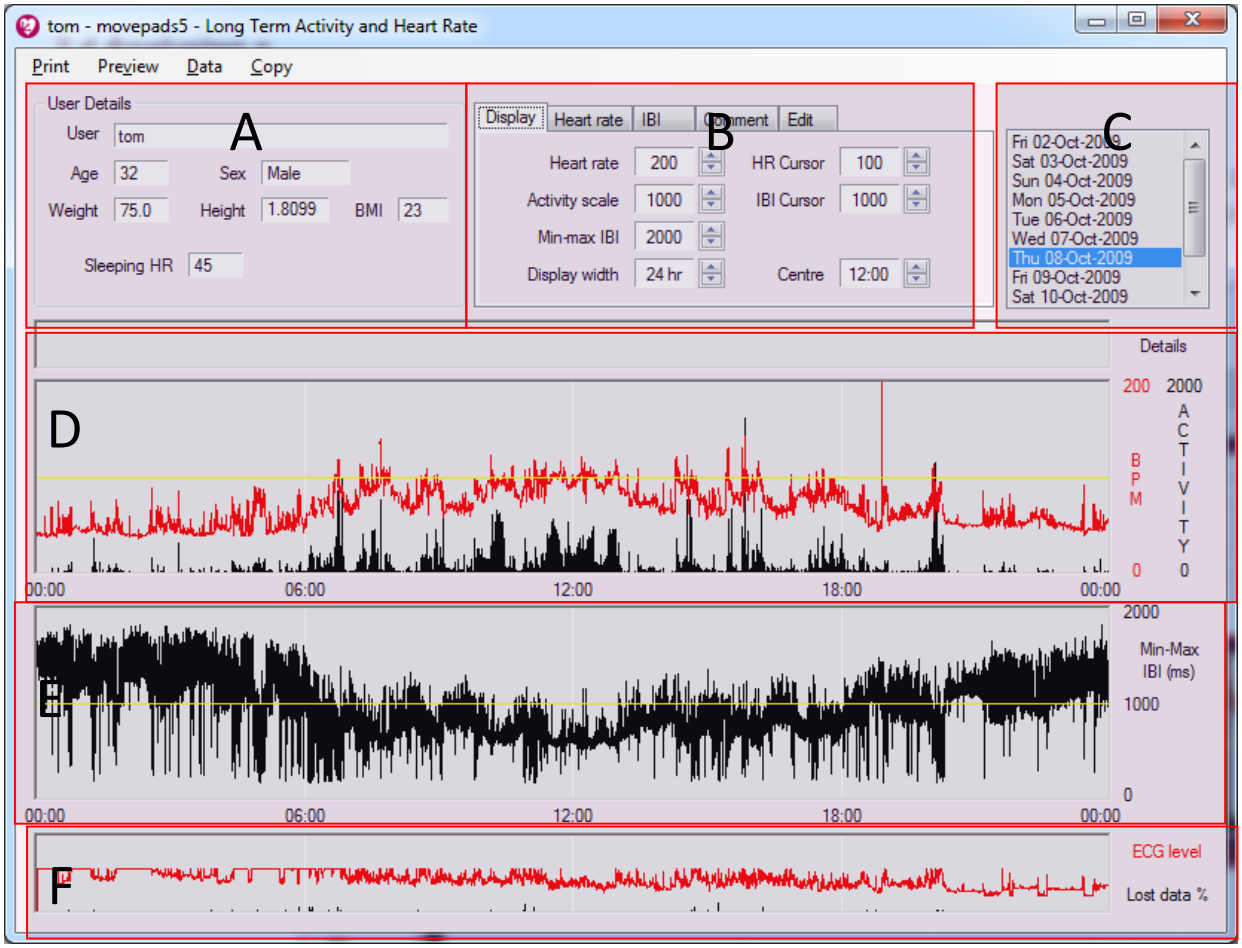
A recording is set up using the Setup button in the bottom-left of the window. For further details, please see the Guide to Getting Started. If the user is not yet set up in the database, please set up a new user as described in that guide also.

3.3.4 Reading Long Term Data from the Actiheart

Downloading a long term recording is the same as any other recording, using the Read button above. For further details please see the Guide to Getting Started. The data is stored in the selected database for analysis.

3.4 Analysing a Long Term Recording

The recording required for analysis can be selected by either double clicking on it or highlighting it and then clicking on Analyse. This will produce the following window:



The main screen is divided into 6 main regions as shown above:

A. **User details:** Information about the user to which the recording relates.

B. **Tools Tabs:** Displays analysis information and provides analysis tools.

C. **Day Selector:** Allows the analysis day to be quickly selected.

D. **Activity and Heart rate data:** Shows the activity and heart rate data for a section of the recording. The heart rate data is shown in red and the activity data in black.

E. **IBI Min and Max data:** Shows the IBI min and max data (the average of the two lowest IBI figures and the two highest IBI figures per epoch respectively) for the recording displayed for each 15 second epoch.

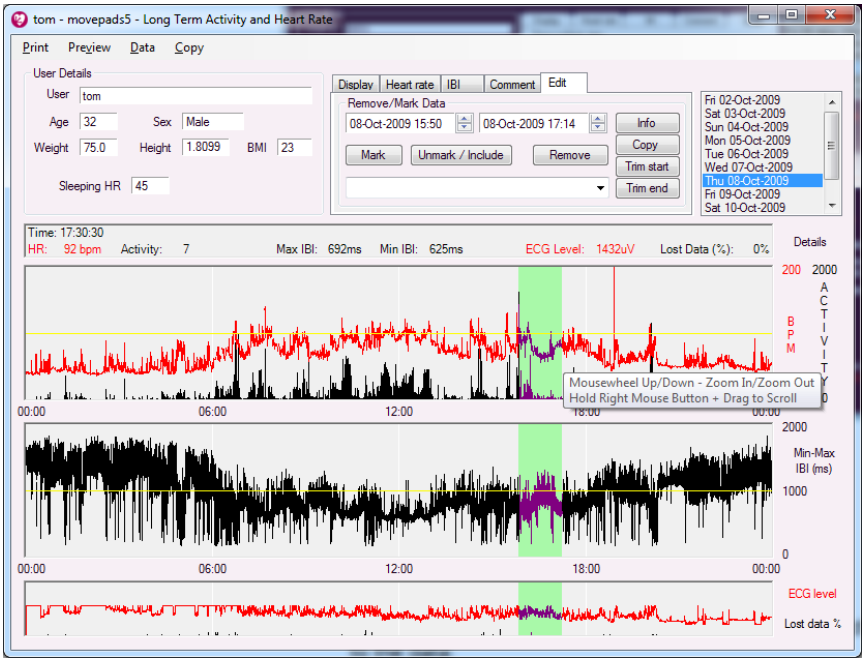
F. **Lost data and ECG level:** The level of ECG signal and the % of lost signal per epoch.

The central Actiheart and Heart Rate graph can be navigated using the mouse wheel to zoom in and out, and right-dragging to scroll through the data. Details of the other controls, tools and graphs are provided in the following sections.

3.4.1 Long Term Tools Tabs & Controls

The tools section [B] contains 5 tabs with the following functions:

- **The Display Tab:** Allows the user to adjust the following parameters:
  - Heart Rate scale
  - Activity scale
  - Min Max IBI scale
  - Display width (adjustable down to 1 hour)
  - Heart Rate cursor (shown on the screen in yellow)
  - IBI cursor (shown on the screen in yellow)
  - Display centre – also manipulated by right-dragging the data
- **The Heart Rate Tab:** allows the user to view the following information:
  - The average, minimum, and maximum heart rate for the selected day of the recording.
  - The average, minimum and maximum heart rate for all days of the recording.
- **The IBI Tab:** This tab shows the average and distribution of IBI's for both the currently selected day and for all days of the study.
- **The Comments Tab:** This tab allows a comment to be stored with the recording. This could be, for example, the type of pads used in the study or information about the type of activity or exercise being done.
- **The Edit Tab:** The user is able to mark, remove, unmark/include, trim and copy sections of the data. To manipulate a section of the data, the required section first has to be highlighted. This is done by left mouse clicking at the start of the data and then dragging across until the desired end point is reached. For fine adjustment of this period, the sliders in the middle of the edit box can be used. The screenshot below shows a highlighted area of data on the selected day:



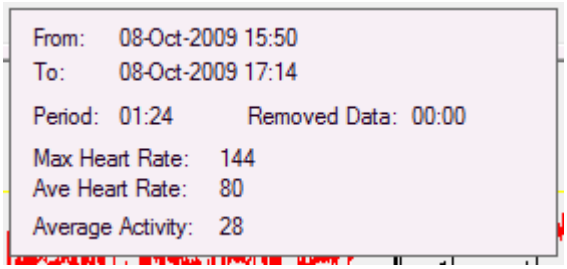
Having selected the required period, the following functions may applied to the data:

- **Mark:** Selecting this function will cause the area highlighted to be marked. A comment associated with the marked area can be added. There are some stored comments which can be accessed via the drop down menu, or a user can enter a comment of choice. Comments recorded will be displayed in the bottom section of the screen when the cursor is passed over the marked area of data.
- **Remove:** This function enables the user to remove a section of the heart rate and activity data.
- **Unmark/include:** This is the opposite of the Mark and Remove functions, and unmarks or re-includes previously marked or removed data.

Marked data is highlighted in grey whilst removed data is highlighted in blue.

Removing data does not alter the raw data. A mask is applied to the data and a note to that effect is stored in the recordings database.

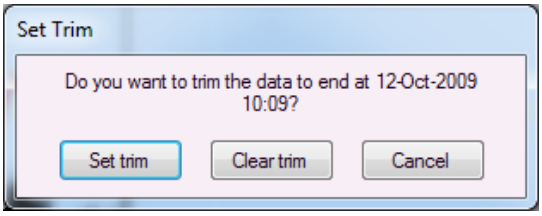
- **Info:** Selecting Info with an area of the data marked shows the information below:



Information on the period selected is shown, including the times of the marked period, the average heart rate, maximum heart rate and average activity levels.

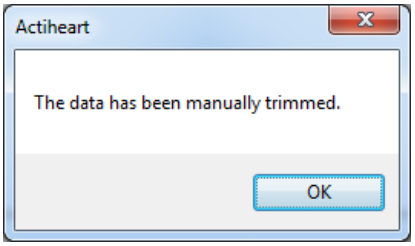
- **Copy:** Selecting the copy function will export the marked data to the clipboard from where it can be pasted into an external program e.g. Excel for further analysis. Removed data is copied as zero in the “Edited Activity” and “Edited BPM” columns respectively and the comments column will say “Removed”. If the data has been cleaned then the comments column will say either “Interpolated” or “Recovered”. Moreover if following cleaning the Edited BPM is zero the “Comments” column will say “Lost” and if the unit has not been worn a “Not Worn” comment will be shown. If the data has not been cleaned the Comments column will say “Uncleaned”.

- **Trim:** The trim function allows the user to remove all of the data after a given point. Clicking on the point after which all data is to be removed gives the following message:



Selecting Yes will remove all data after the date and time given. Note, this is reversible by reselecting Trim and then “Clear trim”.

After a file has been trimmed the following message is displayed every time that file is opened for analysis:



This message is also shown when a trimmed file is first selected from the list of available recordings in the long term recording mode.

3.5 Previewing & Printing Long Term Data

There are three printed report options that may previewed on the screen (preview menu) or printed as a hard copy (print menu):

- **Preview/Print Days:** Provides an 8-day graphical report of Heart Rate and Activity data starting from the currently selected day.
- **Preview/Print Circadian Review:** Provides a 7 day report of double plotted heart rate graphs with an average/SD graph for the period starting from the currently selected day.
- **Preview/Print Window Data:** Provides a detailed graphical report for the currently selected day.

3.6 Auto Clean

The Auto Clean option may be accessed from the Data menu. This is intended for data from older recording devices. Actiheart 5 recording data is already processed to the best result during first opening and analysis.

3.7 Estimate Sleeping HR

This function may be used to automatically determine the sleeping heart rate for the wearer. The software will determine the average sleeping heart rate for each 24 hour period of the recording and then provide an overall average for all days. It is possible to select/de-select which day averages are included in the overall average. The sleeping heart rate may then be saved with the user data.

Using this function is normally the simplest and most accurate method of collecting sleeping heart rate data. We do not recommend attempting to create resting HR results from any other method unless a sleep recording is not possible for some reason.

3.8 Select Day

This option may be selected from the Data menu and provides a quick means for selecting the full day of data (from midnight to midnight) for analysis.

3.9 Copying data to the clipboard

There are two copy functions available from the ‘Copy’ menu:

3.9.1 Copy all data

This function provides an epoch-by-epoch export for all days of data and includes time stamped Activity, ECG (µV), BPM, and IBI min-max information.

3.9.2 Copy Circadian Components

This function provides estimates of the 24-hour components in the heart rate and activity waveforms. Note that the auto clean function as described above must be applied first to ensure that any unworn periods do not skew the data.

4 Energy Expenditure Analysis

4.1 Overview

The Actiheart system is designed to calculate Activity Energy Expenditure (AEE) using recorded heart rate and activity levels. Recordings as described in the previous chapters can be analysed using the Daily EE or Advanced EE windows. These energy expenditure windows' Setup functions can also be used to begin recordings for subsequent analysis. The Step Test application serves a different purpose – to create an individual calibration for the user – and is described fully in ***Section 4.5***.

4.1.1 Differences between the two Applications

When using an Actiheart, any recording can be analysed using either Daily Energy Expenditure or Advanced Energy Expenditure. The "Setup" button in either may be used to start an IBI Mode recording using the Actiheart, which will maximise available recording time by recording every IBI rather than the full ECG waveform.

The difference between Daily and Advanced Energy Expenditure is mostly one of emphasis. Daily EE will allow you to proceed with minimal options, and present a relatively simple summary of day-by-day energy expenditure without further breakdown or options. Advanced EE allows more options and hence considerably more potential for confusion or need to understand the processing. A few of the detailed differences are listed below.

- Individual calibration data can only be viewed and edited using Advanced Energy Expenditure
- Sleeping HR for a user can only be set using Advanced Energy Expenditure
- HR max can only be set using Advanced Energy Expenditure
- REE can only be set using Advanced Energy Expenditure
- Using Advanced Energy Expenditure, the energy calculation mode is selectable, i.e. *Branched*, *HR only*, *Activity only* (for further details see ***Appendix 2***).

4.2: Factors Affecting the Calculation of Energy Expenditure

4.2.1 The Branched Model Settings

The calculation of AEE is done using the Branched Model which is described in ***Appendix 2***. The software contains certain default settings (group calibration coefficients and branch parameters) based on validation data. However it is possible to customise these settings in order to create other variants of the model. These settings reside in the Settings database where they can be edited if necessary using an external SQLite browser. However they can be viewed and applied from either the Advanced Energy Expenditure or the Daily Energy Expenditure applications (see ***Sections 4.3.3*** ***&*** ***4.4.7***)

4.2.2 Branched Model Adjustment in the Presence of Recovered Data

See **Appendix 2**.

4.2.3 Branched Model Adjustment in the Presence of Stress

See **Appendix 2**.

4.2.4 Individual Calibration

Individual calibration data can be used in the calculation of AEE instead of a group calibration. The individual calibration can be applied from either Daily Energy Expenditure or Advanced Energy Expenditure. However the calibration data itself for each user (i.e. Activity, HR, PAI) can only be viewed in Advanced Energy Expenditure (see ***Section 4.4.8***).

4.2.5 Resting Energy Expenditure (REE)

This is required in order to calculate the Total EE. By default the program uses the REE estimated from the Schofield equations. However it is possible to replace this value with a measured value of REE. To do this the User information needs to be opened using the Advanced Energy Expenditure part of the software. For further details please see ***Section 4.4.8.1*** on measured RMR.

4.2.6 Sleeping Heart Rate (SHR)

This is required in order to calculate AEE. The program will use in the first instance the value of SHR if entered with the user details during setup. This may be replaced with a measured value from an overnight recording or another value which is more accurate than the original.

We would normally recommend using the “Set Sleeping Heart Rate” function in either the Long Term window or Advanced EE to set it directly from an overnight recording.

The SHR however also be changed manually by entering numbers from one of two locations: go to the “Utilities” window and then “Database” tab and edit a user, or go to the Advanced EE window and press “View/Edit” to bring up the “Individual Calibration” information window (see ***Section 4.4.8***).

4.2.7 Lost Heart Rate Data

Lost or corrupt HR data will affect the calculation of AEE. Therefore whenever a file is viewed in either Advanced or Daily EE an attempt is made to recover any

lost data. In those epochs where recovery fails the AEE is solely based on Activity.

There are three steps in the cleaning process:

STEP 1: Cleaning

This involves setting suspect values to zero according to the following criteria:

- If HR < 30 or
- If HR > 30 and the rate of change of heart rate is > 100, 132 & 160 BPM/Min for a 1 min, 30 sec & 15 second epoch respectively.

STEP 2: Removing Spurious signals from the cleaned data

The cleaned data is analysed minute-by-minute and if the cleaned HR at any data point is >1.75 * Filtered HR then the cleaned HR is set to zero. Filtered HR is the average of the HR over the 4 minutes preceding the data point being analysed. Between 4 and 16 HR values will be averaged depending on the epoch.

STEP 3: Replacing Removed Data

a) Recovery

For each minute where the HR has been set to zero each stored IBI minimum and maximum (there will be minimum of sixteen, if the epoch is 15 sec) is used to calculate a HR (60,000/ms) which is then compared with the previous valid heart rate. The calculated HR which is closest to the valid heart rate and within 30 BPM's of it is used to replace the zero values. This is termed "Recovered Data". If the difference is > 30 BPM the calculated HR is not used to replaced the zero value.

b) Interpolation

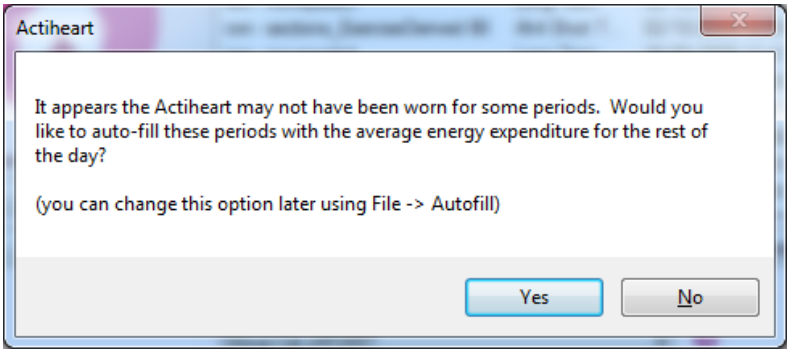
Following the recovery process any remaining zero value gaps of < 5 minutes are filled by interpolation (straight line join). If the gap is greater than 5 minutes the value is left at zero.

If there are gaps in the data (see below) due to the unit not being worn the cleaning is disabled in the gaps.

4.2.8 Gaps in the Data

Whenever a file is opened from the Advanced EE or Daily EE screen an attempt is made to identify gaps in the data in each day due to the unit not being worn and the user is offered the option of filling these gaps with an average of the

day's AEE excluding the gaps. If selected the "Auto Fill" is automatically applied to all the days in the recording.



In order to decide whether the Actiheart has not been worn the software searches for continuous periods of 2 hours or more of zero Activity.

This auto-fill from average energy expenditure is intended for periods when you have no knowledge of the real activity of the intended wearer during that period. If instead you know that they were sedentary, for example having a nap or an overnight sleep, it would be more appropriate to select "No" and leave the Activity EE at zero for these periods.

4.3 Daily Energy Expenditure

Selecting the "Daily EE" button from the main screen will bring up the Daily Energy Expenditure window as shown below. Note that an Energy Model must be selected in order to view any recordings, because some models require more individual information about users in order to be able to calculate them and some do not.

To quickly view some data, you may select the topmost group model – but don't proceed to use the data from this in any critical way without understanding the available models later.

4.3.1 Steps in Performing an Analysis

- Set up, record and download the data as described in the Guide to Getting Started
- Choose the desired Energy Model (see ***Section 4.3.2***).
- Set Sleeping Heart Rate (only possible from 'Advanced Energy Expenditure' tab). See ***Section 4.4.8.2*** for more details.
- [optional] Set Resting Energy Expenditure (only possible from 'Advanced Energy Expenditure' tab). See ***Section 4.4.8.1*** for more details.
- Analyse as described below.

4.3.2 Selecting an Energy Model

Before you can view a recording and analyse it, you first need to select the "Energy Model" that you wish to apply to the analysis from the drop-down list. If you select one of the group calibration models then all recordings will be displayed. However, if you select an individual calibration model e.g. "Step-test HR" or "Individual HR Cal" then only the recordings that contain an individual calibration will be displayed. The energy expenditure calculation will then be based on the selected variant.

The available energy models are split into two groups - the four common models, which will be appropriate for most new users, and other modes which are provided either for backwards compatibility or more specialised uses. The common modes are:

Group Cal JAP2007: This model uses a group calibration for heart rate and activity. We recommend it for any new analysis work on adults, where you do not wish to perform a step test on each participant.

Group Cal Jap2007/Step HR: This model uses the individual users' step test results to calibrate for heart rate, but the same group calibration for movement as above. We recommend this for greater absolute accuracy, where it is possible to perform a step test on each participant. Note that the step test is not used for movement calibration, because this is very variable per-activity and adjusting based on a step test alone would be inadvisable.

Child: Group Act/Group HR: This model uses group calibration measurements from a test performed on children. We recommend it for any new analysis work on children, and it does not require individual testing for each participant.

Child: Group Act/Ind HR: This model uses group calibration measurements from children for movement, but the individual calibration table for relating HR to EE for that user. We recommend this for analysis of children where you have the capability to perform HR to EE calibration measurements for relevant activities on each child.

Note that regardless of the energy model used, per-user information such as weight, sex, age, height and sleeping heart rate must still be entered accurately.

The other modes visible when "Show All Models" are selected are a combination

of options. The meaning of options are described below:

Adult ... (old): This describes models created from an earlier group calibration than the JAP2007 group above. These models are provided for backwards compatibility, but not recommended for new studies.

Group Act *vs* Ind Act: Most models are provided with an activity calibration based on group measurements. It is also possible to enter a table of individual Activity to EE values from measurements, though it is difficult to do so accurately across a range of activities. The "Ind Act" models will use the provided table of Activity to EE values for each user. Note that the branched model will favour EE estimates based on HR for higher intensity, so this table will mostly affect lower intensity results.

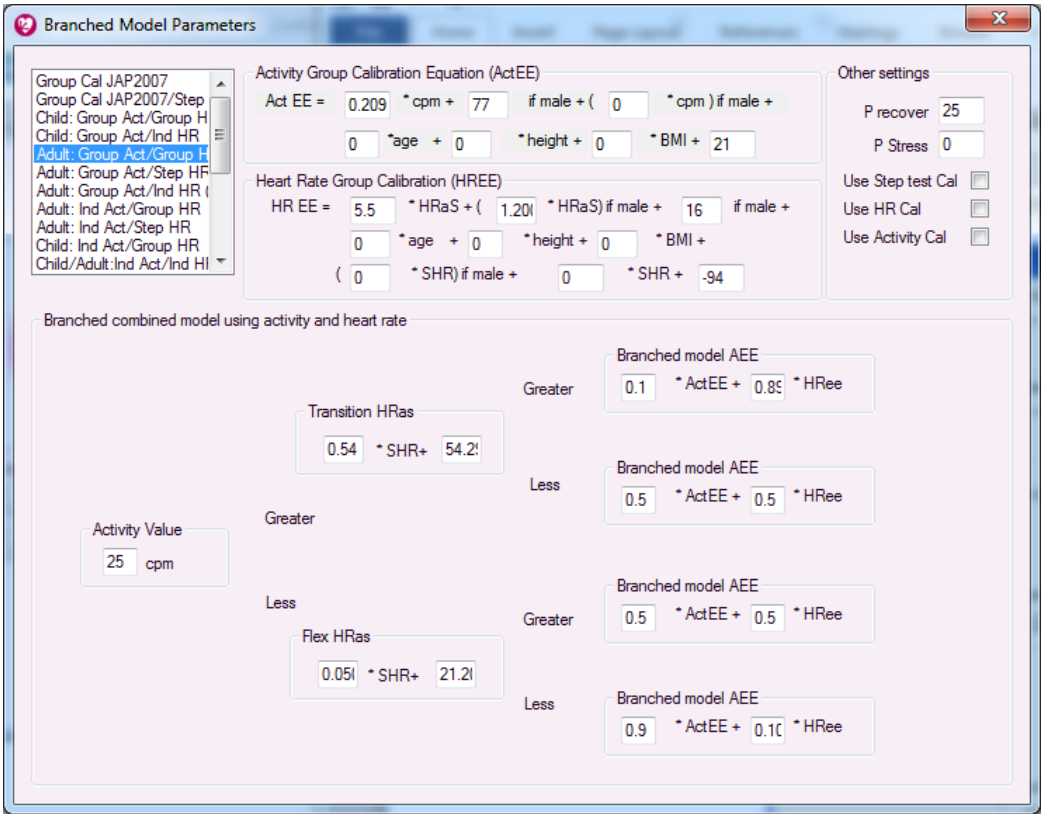
Group HR *vs* Step HR *vs* Ind HR: The relationship between heart rate and EE can be provided from a group calibration, or from the saved results of a step test for each user, or from a user-provided table of HR to EE measurements for each user. Models with each of these in the name will use the relevant source for relating heart rate to energy expenditure.

Child: Models beginning with "Child" are using a group calibration from measurements made to a group of children, and so are likely to be more accurate when used on children than the Adult group measurements.

Child/Adult: Some models do not use a group calibration, so have no inherent bias to adults or children. All of the calibration information must be provided individually for these.

+stress: Some occupations may be particularly prone to raising heart rate without associated physical activity, and hence associated energy expenditure. The "+stress" models will attempt to detect this and minimise the errors. The correction cannot be applied perfectly so it is recommended for simplicity that the model is not used unless there is believed to be a particular problem with stress in the group targeted.

In order to view the available models stored in the Settings database, click on the “Branched Model Parameters...” button within the “Energy Model” box, the following window will be displayed:



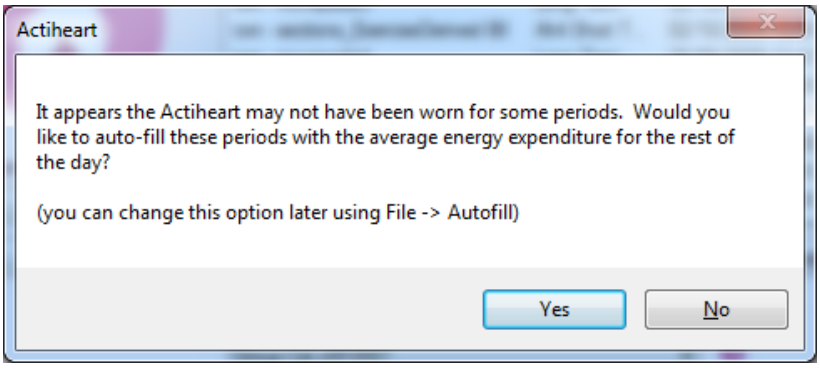
The screen above allows the settings to be viewed. The top left hand window contains a list of all the variants of the model furnished with the software as standard. The components of each variant (calibration coefficients and branch parameters) can be viewed by highlighting that variant in the window.

4.3.4 Individual Calibration

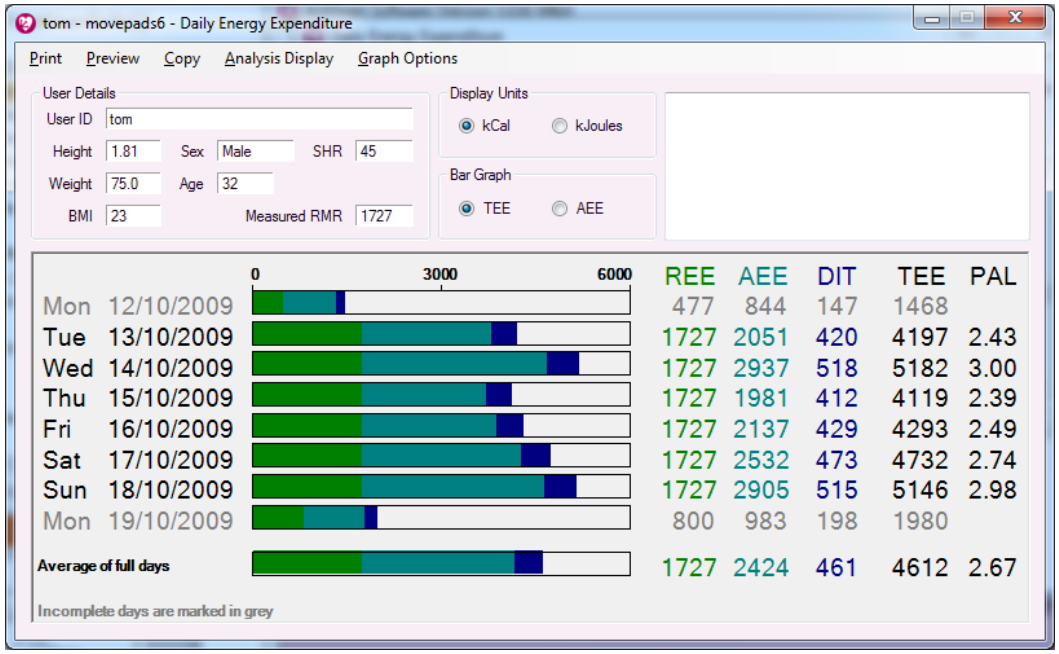
To view and select an individual calibration go to the Advanced Energy Expenditure application and proceed in the manner described in ***Section 4.4.8***.

4.3.5 Analysing a recording

A recording is selected either by double clicking on it, or highlighting it and selecting Analyse. The message shown below may then be displayed if there are gaps in the Actiheart recording:



Selecting Yes (to auto-fill) or No will lead to the daily overview window:



The top region of the screen provides the user details and allows the selection of display units in kCal or kJoules. It is also possible to select just to view the AEE component of energy expenditure rather than viewing all of the components.

The lower section of the display shows the components of energy expenditure day by day.

These are shown graphically and numerically with both being colour coded. Total Energy Expenditure (TEE) is derived by adding to the calculated AEE a component for Resting Energy Expenditure (REE) and a component for Diet Induced Thermogenesis (DIT). The physical activity level (PAL) is also shown and this is a ratio of daily TEE to REE. The REE can either be estimated using the Schofield equations or can be specified by the user (see ***Appendix 3*** and ***Section 4.4.8.1*** respectively).

For details of how the AEE and REE values are calculated during incomplete days and /or when the monitor is not worn please see **Appendix 5.**

A PAL figure is only shown for complete days with the figures for an incomplete day being shown in grey.

4.3.6 Gaps in the Data

Please see **Section 4.2.8**.

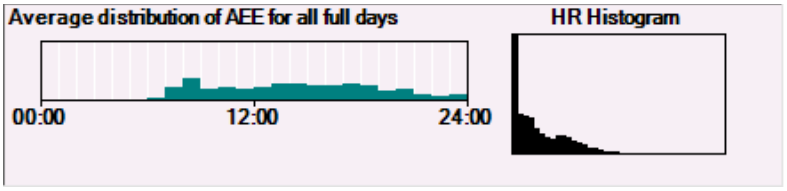
4.3.7 The Distribution of AEE

It is possible by right clicking on the appropriate bar graph to view the distribution of the AEE component of energy expenditure for each day and for all days. Other information can be viewed along with the AEE. There are 4 possible viewing options for the analysis:

- Mets
- HR info

- HR limits
- HR histogram

To move between these, they can either be selected from the drop down menu “Analysis display” at the top of the screen, or they can be scrolled through by repeatedly right clicking on the required day in the bar graph. An example of the HR displayed data is shown below:



This example shows the average distribution of AEE for all full days together with the HR histogram option.

4.3.8 Previewing & Printing Data

It is possible to preview and/or print the data from the daily living screen. There are two options for preview/print which may be selected from the relevant menus:

Preview/Print Energy Summary: This provides a hard copy of the on-screen data with the addition of a graph showing the average distribution for all days. This report also provides average daily times for MET levels.

Preview/Print Activity & Heart Rate Data: This report provides graphs for all days showing the BPM (red) and Activity (Black) with daily HR statistics.

4.3.9 Copying Data

There are 5 possible options for copying data to the clipboard for importation and analysis into an external program such as Excel:

1. **Copy Summary Row:** Provides an export with header information of the average values for all full days in the report.

2. **Copy Daily Data:** Provides an export with header information and detailed statistics for each individual day.

3. **Copy Activity & HR Data:** Provides an export with header information and an epoch-by-epoch, time stamped listing of activity and Heart Rate data.

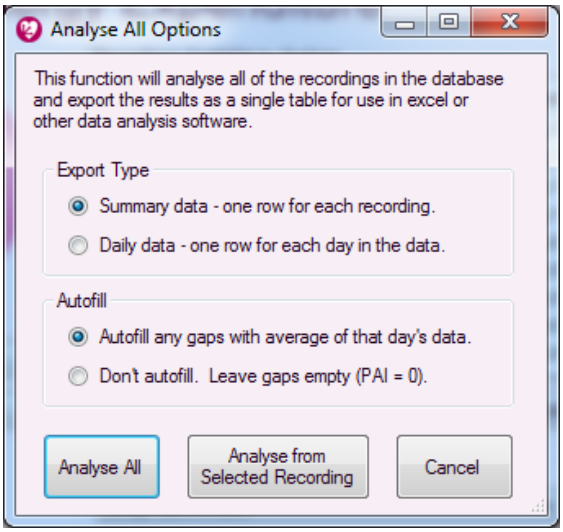
4. **Copy MET Data:** Provides an export with header information and an epoch-by-epoch, time stamped listing of activity and Heart Rate data with MET values.

5. **Copy Full Data and Analysis:** Provides an export with header information and an epoch-by-epoch, time stamped listing of all data from the analysis [Note that this is a very large export and may take some time to copy depending upon the speed of the computer].

6. **Copy Hourly Energy Expenditure:** Provides an export with header information and a breakdown of the energy expenditure into each day and furthermore into columns for each hour of each day.

4.3.10 Analyse All

This is a batch processing function which appears on the main Daily Energy Expenditure screen. It will analyse all of the recordings in the database and place all of the analysed data onto the clipboard. The following prompt shows the available export options.



In the Summary Data, calculated values are the average of all full days.

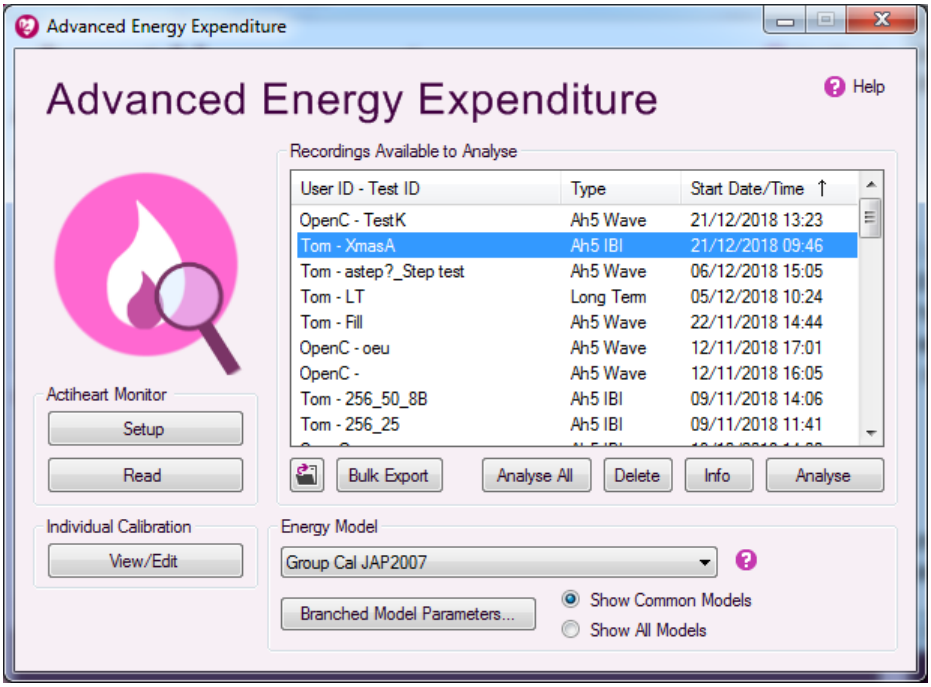
The option to begin analysis from only the currently selected recording may be useful if only a subset of a large group is required. Note that the list can be sorted differently by clicking on column headings.

4.4 Advanced Energy Expenditure

The Advanced EE window provides the same branched model of energy expenditure based on heart rate and movement as Daily, but with many more options to adjust the calculation method, and a breakdown to epoch-by-epoch contributions of energy expenditure. This higher resolution EE result is both shown graphically and fully available for export.

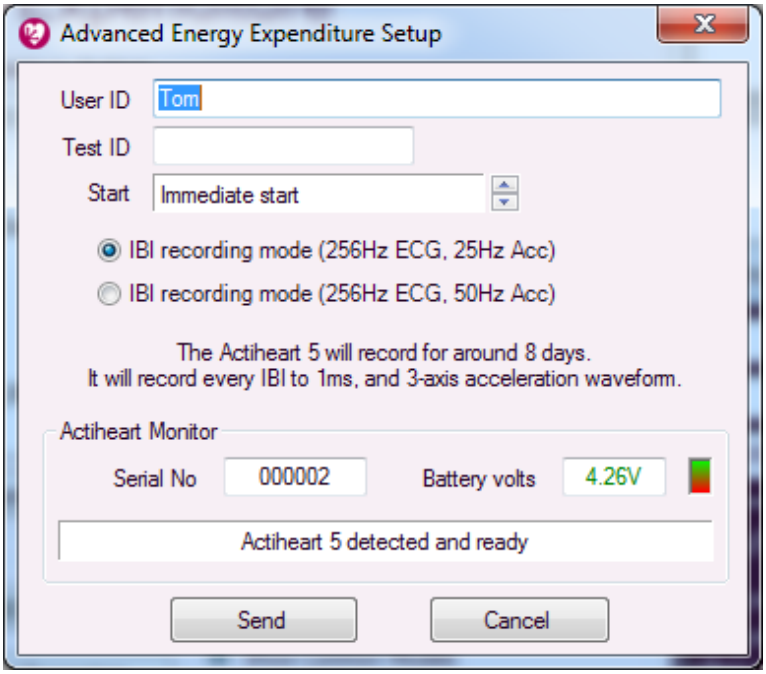
4.4.2 Setting up a Recording

Clicking the “Advanced Energy Expenditure” button on the main menu produces the following recordings window:



The user can view all available recordings which can be analysed with the currently selected Energy Model. The list can be sorted by any column to assist in finding the right recordings for analysis.

A recording and user are set up in the same way as previously documented. For further details please see ***Section 7*** of the Guide to Getting Started. When the user is set up and the parameters are ready to be sent to the Actiheart, the screen on the following page is shown:



This screen allows the user to select the required recording type. The maximum guaranteed recording time is around 8 days with 50Hz acceleration data, or 14 days with 25Hz acceleration, but the precise length achieved will depend on both the heart rate and amount of continuous movement during the recording period. Recording at 25Hz for acceleration capture instead of 50Hz will allow a quicker download and longer recording, but please ensure the battery is maximally

charged for the case of 2 week recordings. Both modes can be used for any Energy Expenditure analysis.

4.4.3 Setting up a Recording – Delayed Start

For details on setting up a delayed start recording please see ***Section 3.1.3***.

4.4.4 Downloading an Advanced EE Recording

Downloading an Advanced EE recording is the same as any other recording, described in The Guide to Getting Started. If the correct database is already selected, simply click on the “Read” button.

4.4.5 Viewing Details of an Advanced EE Recording

For details on how to view information on a long term recording, please see ***Section 3.1.5***.

4.4.6 Database Export and File Export

For further details please see ***Section 3.1.6***.

4.4.7 Selecting an Energy Model

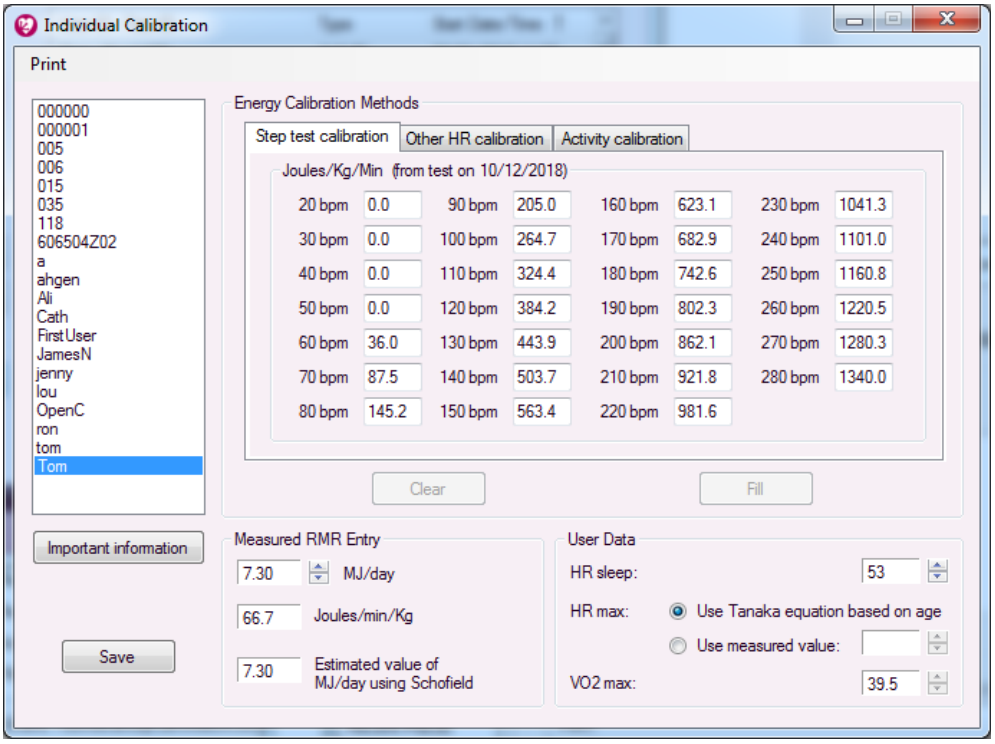
Before you can view a recording and analyse it, you first need to select the “Energy Model” that you wish to apply to the analysis from the drop-down list. If you select one of the group calibration models then all recordings will be displayed. However, if you select an individual calibration model e.g. “Step-test HR” or “Individual HR Cal” then only the recordings that contain an individual calibration will be displayed. The energy expenditure calculation will then be based on the selected variant.

The meaning of the common models is described in ***Section 4.3.3***.

In order to view the available models stored in the Settings database, click on the “Branched Model Parameters…” button within the “Energy Model” box. The screen displayed there is described in the section for Daily EE.

4.4.8 Individual Calibration

This display is accessed by clicking the “View/Edit” button on the Advanced Energy Expenditure screen.



The individual calibration serves the following purposes:

a. It allows an individual calibration for a given user to be saved in the database from where it will be called by the energy model and used as a basis for the calculation of energy expenditure instead of the group calibration. There are three possible sources of calibration data:

i. Step test calibration. If a user has performed a Step Test (for more details see later section on the Step Test) and saved the result, then the software will automatically fill this table with the parameters generated by the Step Test.

ii. Other HR calibration. If a calibration has been performed by some other means the data generated by this can then be entered here. **Read the Important Information before doing this.**

iii. Activity calibration. If a calibration has been performed by some other means the data generated by this then can be entered here.

b. It is also possible to enter other parameters in the individual calibration screen which have a bearing on the calculation of energy expenditure and are described below.

4.4.8.1 Measured RMR

As mentioned previously, the RMR is normally estimated from the Schofield equations. If however there is a measured RMR for the user this can be inserted here. To revert to the Schofield value, at any time double click in the “Measured RMR” box.

4.4.8.2 Sleeping Heart Rate

It is possible to enter a value for measured sleeping heart rate in this screen. Once saved this will overwrite whatever value was entered for that user in the database when the user was created. If required, the software can calculate this from an overnight recording and save that directly. This is the recommended method (see ***Section 4.4.15***).

4.4.8.3 Maximum Heart Rate

An estimate of HR max may have been entered into the database when a user was created. This screen allows one to alter the initial value, or to use the Tanaka equation as an estimate[2]. This is 208 – (0.7 x n) where n = age of the subject. Selecting the 'Tanaka' option will allow the estimate to be generated separately for each recording, using the subject's age at the time of each recording.

Note that the maximum heart rate is not used for Energy Expenditure calculations, only for producing an estimate of VO2 max.

4.4.8.4 VO2 Max

This parameter is a measure of an individual's fitness. It is calculated automatically when a Step Test is performed. See ***Appendix 4*** for details of how this is calculated.

VO2 max is calculated from the value of PAI when the heart rate is equal to HR max. To calculate proceed as follows:

- Select the calibration curve i.e. Step Test or Other HR
- Ensure that any calibration data extends to the end of the table. If real data
- is not available use the Fill function which will extrapolate in a linear manner.
- Ensure that the HR max field has a value.
- Double click on the VO2 max. This brings up a confirmation message to continue the calculation with the currently selected tab for HR-EE calibration.

Selecting Yes will input a value into the VO2 box.

The VO2 max value is stored with the user information in the database. This is the last value calculated either from the Step Test or from the Individual Calibration. Only one value can be accommodated.

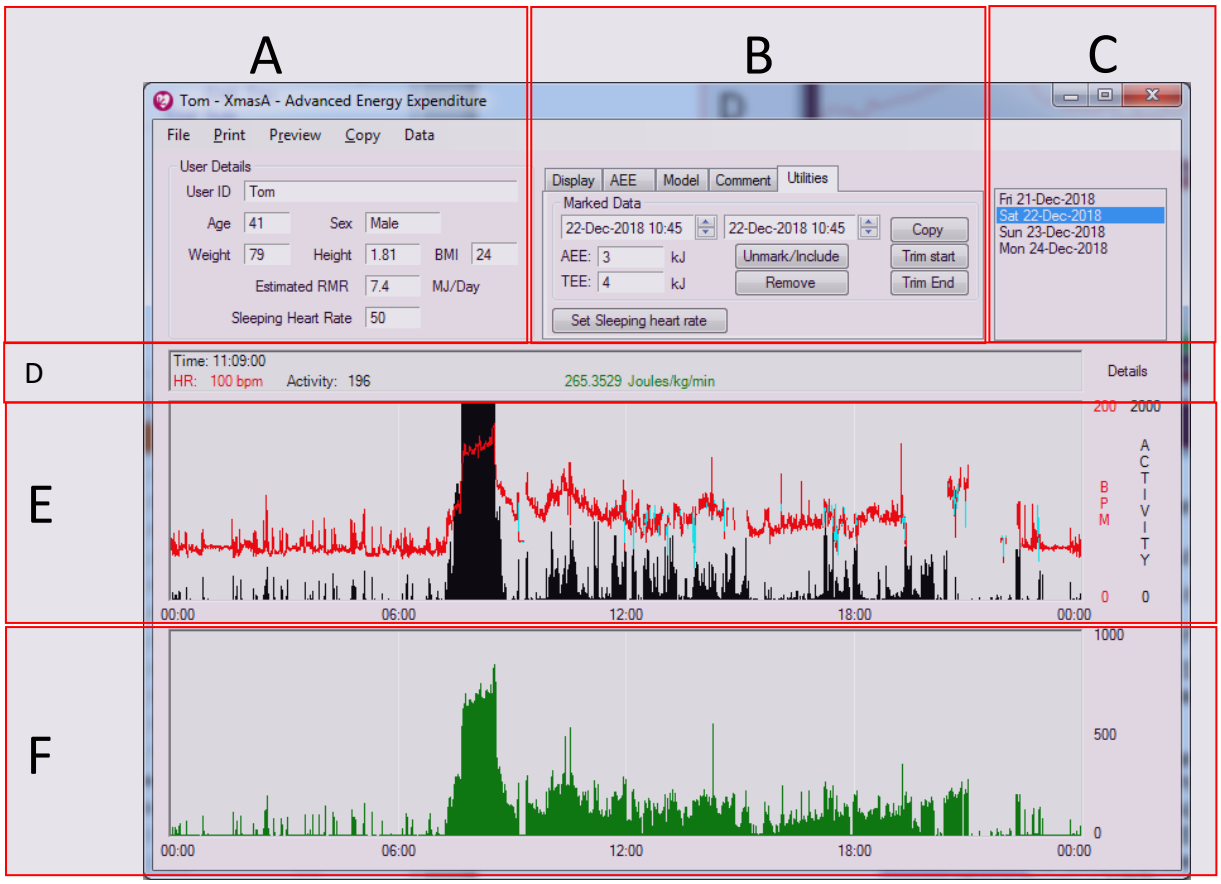
When entering a table of values for the EE calibration, all boxes must be filled either directly or using the Fill function after a few key points are entered. If the tables' values doe not increase monotonically with each box, the software will refuse to save it as the calibration cannot be applied regularly.

[2] Tanaka H, Monahan KD, Seals DR. Age-predicted maximal heart rate revisited. J `Am.Coll.Cardiol. 2001; 37(1):153-56.

Once all of the required parameters have been input into the individual calibration screen, clicking on Save will save these parameters for that user into the database.

4.4.9 Analysing an Advanced Energy Expenditure Recording

Having selected the desired energy model and individual calibration data, if applicable, select the required recording for analysis from the list of available recordings, double clicking on the recording or highlighting it and selecting Analyse brings up the following screen (note you may see a message asking if you wish to auto-fill data for unworn periods; select yes or no):



The screen is divided up into six primary regions as follows:

A. **User details:** Information about the user to which the recording relates.

B. **Tools Tabs:** displays analysis information and provides analysis tools.

C. **Day Selector:** Allows the analysis day to be quickly selected.

D. **Cursor Details:** Displays the HR, Activity and EE details of the exact moment as the mouse cursor is moved across one of the data graphs.

E. **Activity and Heart rate data:** Shows the activity and heart rate data for a section of the recording. The heart rate data is shown in red and the activity data in black.

F. **Energy Expenditure:** Shows an epoch by epoch plot of either Activity Energy Expenditure (AEE) or Physical Activity Intensity (PAI) in the units chosen or the Total Intensity (AEE + REE)/(REE) in METS. For the

purpose of this calculation, REE is based on the Schofield equation. See ***Section 4.4.11*** for details of the available measures and units. When METs are selected, this display will be colour-coded as follows:

1-3 METS	Green
3-6 METS	Orange
> 6 METS	Red

NOTE:

During periods where the unit is not worn the display will show only 1 MET based on AEE = 0.

4.4.10 Viewing a Specific Point

It is possible to view the data values at any given point on screen. This is done by moving the mouse across the data graphs, and reading from section D above. This shows the time, heart rate in beats per minute in red, activity level in counts in black and Energy Expenditure in green (as for the graph elements).

Moving along the recording will display the data epoch by epoch. To review individual high resolution epochs, e.g. 15 seconds, it will be necessary to reduce the display width to allow more epochs to be resolved on screen.

4.4.11 The Display Tab

The Display tab is used to select the measure and units of AEE. The following options are available for AEE measure:

- /kg/min
- /min
- /kg
- /epoch
- MET

For AEE units:

- Joules
- KJoules
- Calories
- KCalories

It is also possible to alter the following parameters from the Display tab:

- Heart rate scale
- Activity scale
- Display width
- Display centre

4.4.12 The AEE Tab

The AEE tab shows the average and maximum AEE for each day of the study and the average for the whole study. Epochs that have been removed are excluded from this calculation. “Not worn” epochs are included provided auto-fill has been chosen. In epochs with no HR, the AEE is calculated using only

activity. It is also used to select whether the branches are visible in both the colour shading of the EE graph and the cursor's detailed information bar (D).

4.4.13 The Model Tab

This tab is used to select the model used in the AEE calculation. It is possible to select the branched model or either just activity or just heart rate from this tab. The selected energy model is also shown here. The selection process is described in ***Section 4.4.7***.

4.4.14 The Comments Tab

This tab allows a comment to be stored with the recording. This could be, for example, the type of pads used in the study or information about the type of activity or exercise being done.

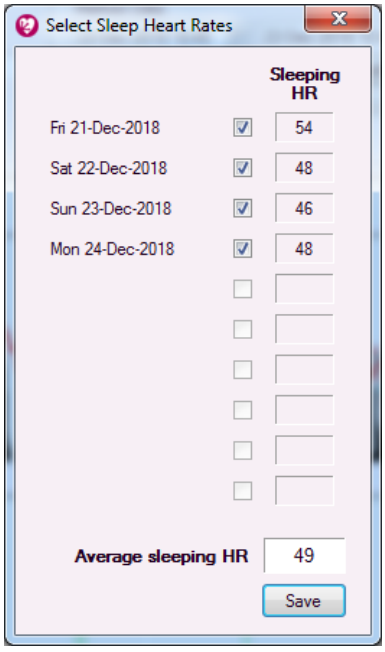
4.4.15 The Utilities Tab

This tab has a number of functions:

Remove, Copy, Unmark/Include and Trim: these are described in **Section 3.4.1**.

AEE and TEE: These boxes display the values of AEE and TEE in the highlighted period. If the monitor has not been worn for part of this period then the AEE = 0 unless auto-fill has been selected. The TEE value includes REE.

Set Sleeping Heart Rate: It is possible from the Utilities tab to set the sleeping heart rate for a user. This is done using "Set Sleeping heart rate". The following screen is displayed:



To calculate SHR the Actiheart must be worn for at least one complete night. The SHR is set at the highest value of the thirty lowest minutes of HR readings during a 24 hr day.

More than one night of recording will both allow the software to average over the multiple nights, and also allow you to untick the contribution from any nights which appear inconsistent.

The Sleeping Heart rate can also be entered manually from the "Individual Calibration" screen (see ***Section 4.4.8***).

4.4.16 Printing and Previewing Data

This is covered in ***Section 3.5***.

4.4.17 Copying all Days

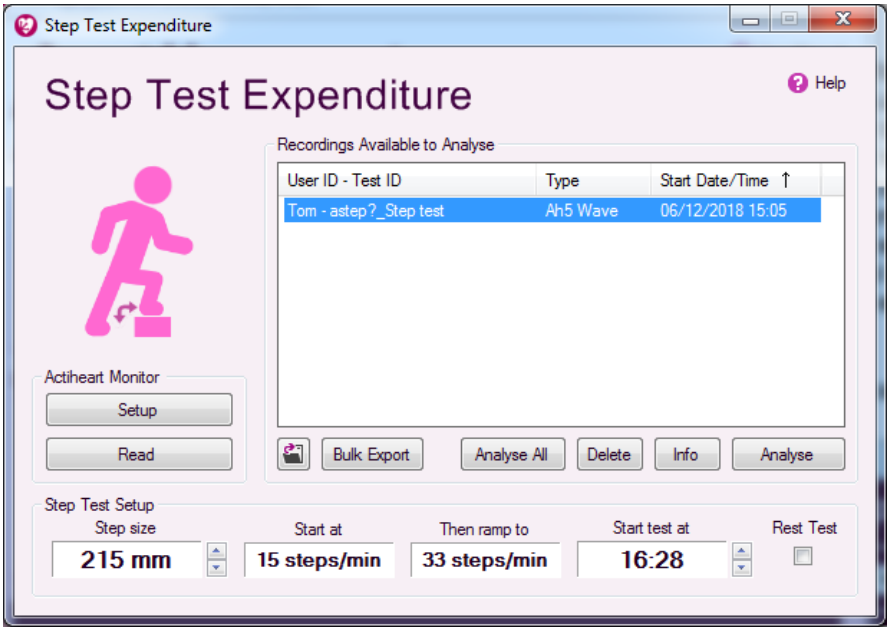
The “Copy -> All Data” option on the menu bar copies all of the recorded data to the clipboard, including a row for every 15 second epoch of the recording.

4.5 The Step Test

4.5.1 Overview

The Step Test is a built-in function of the Actiheart software enabling an individual HR calibration to be carried out easily without needing a laboratory or an oxygen analyser. For details of how the calibration curve is derived, please see ***Appendix 4***. The data obtained by the Step Test is also used to provide an estimated figure for VO2 max, for assessing a subject’s level of aerobic fitness. The test lasts for 8 minutes and the stepping speed ramps linearly from 15 step cycles (1 step cycle is “up, up, down, down”) per minute to begin with up to 33 step cycles per minute at the end. The stepping speed is dictated either by a drum rhythm or by voice commands. The user can select whether the vocal prompt or drum beat is used in a given test.

Clicking the “Step Test” button brings up the following window:



4.5.2 Setting-Up a Step Test

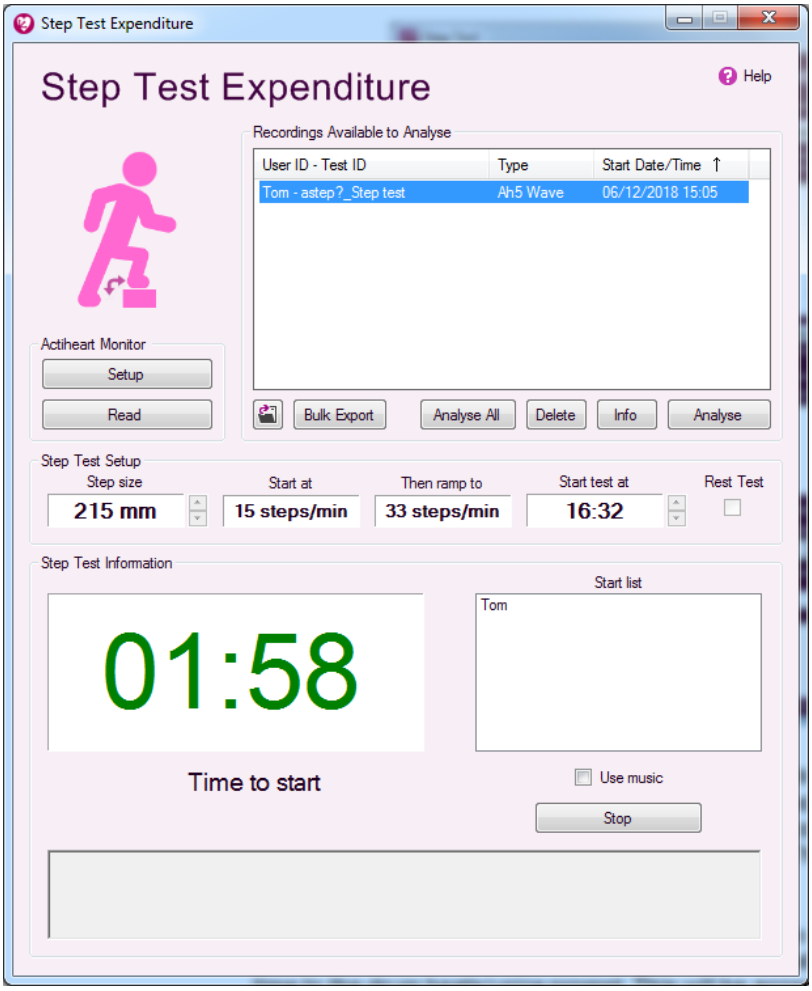
A user is set up in the same way as previously documented. For further details please see Section 6 of the Guide to Getting Started. Unless a measured value of HR Max is known for the user, leave the HR Max field blank. The application will then use the Tanaka equation by default.

During setup, you may choose to configure the Actiheart in Live Display mode, if your Actiheart was ordered with a Bluetooth module fitted for this purpose. This will allow monitoring of ECG and heart rate in real time during the step test. See the Guide to Getting Started for instructions in using the Live Display mode. After

the end of the test, you must plug the Actiheart in to USB and download the recording in order to analyse the result for calibration.

Once the chosen parameters have been inserted and sent to the Actiheart, the screen below will be shown.

Warning: If Step Test data for a particular user already exists then take care if recording an additional step test, even with a different Test ID. It is possible to save calibration data for the user from either test. Subsequent analysis using the step calibration will use whichever Step Test was analysed and saved most recently beforehand.



The software will count down from at least 90 seconds to allow time to put the Actiheart on the user. After the Actiheart has been placed on the user, they should stand still in front of the step until the test starts. The default audio instruction is to step “up”, “up”, “down”, “down” repeatedly. It is also possible to select a drum beat using the “Use music” checkbox if preferred, but take care not to step at twice the necessary rate if using this.

At the end of the countdown the last five seconds will be a vocal prompt “five, four, three, two, one” and then the software will start the test. The user should step in time to the drum beats or voice prompt. This will be accompanied by colour prompts at the bottom of the window signifying that the user should step.

At the end of the test, the software will count down a two minute rest period during which time the user should stand still with the Actiheart still fitted. At the end of this two minute period a message will be displayed telling the user that the

Actiheart is ready for reading. If at any time the user feels uncomfortable with the test, they should stop immediately and rest with the Actiheart on until the end of the test. The test can be stopped at any time by pressing the stop key. Pressing the Stop key twice will allow the unit to be read without waiting for the two minute count-down period.

4.5.3 Downloading Step Test Data from the Actiheart

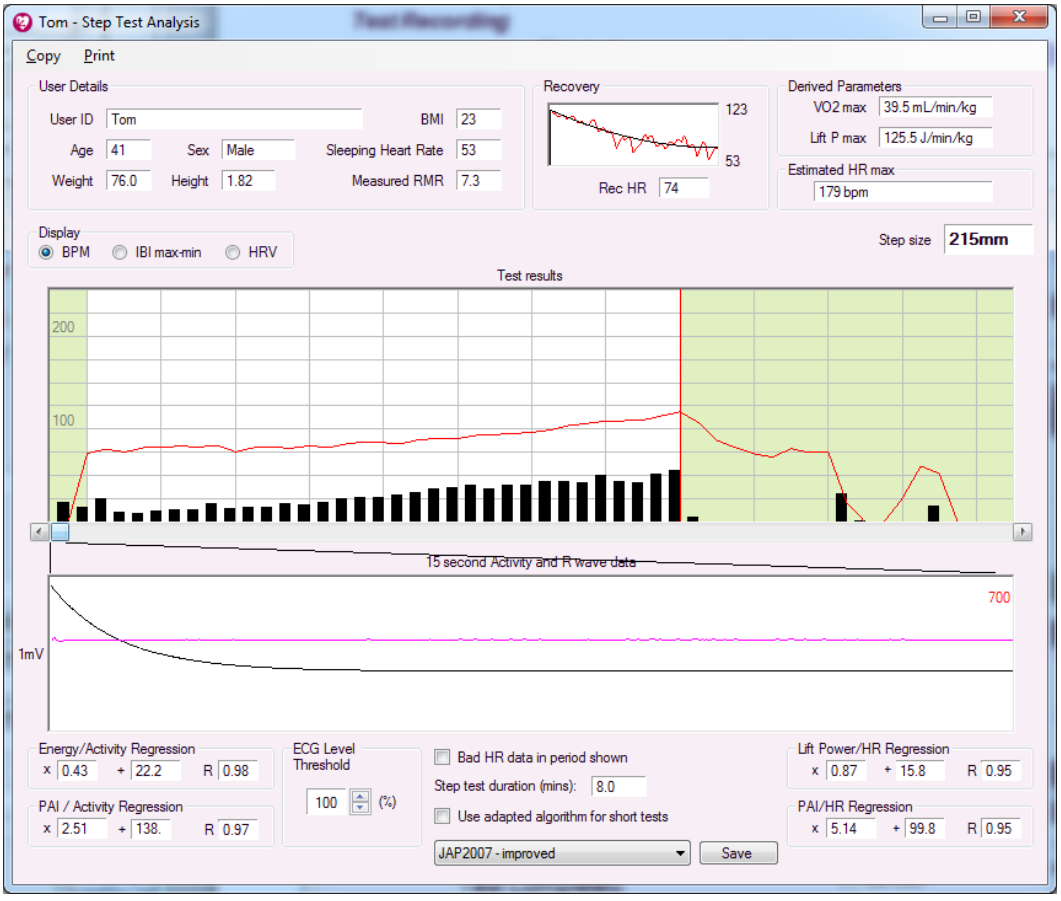
Downloading a Step Test recording is the same as any other recording, but is normally performed directly using the “Read” button on the window above.

4.5.4 Viewing Details of a Step Test Recording

This is the same as for other recordings; please see ***Section 3.1.5***.

4.5.6 Analysing a Step Test Recording

A recording is selected either by double clicking on it, or highlighting it and selecting Analyse. The following screen is then shown:



The display is divided into three regions. The top region shows the user details such as ID, age, weight and sex of the individual. Also shown is a value of Recovery heart rate, which is effectively a noise-filtered estimate of the heart rate after 60 seconds of recovery from the end of the test. This is calculated from a polynomial fit on the whole period, evaluated at the 60 second point. On the right

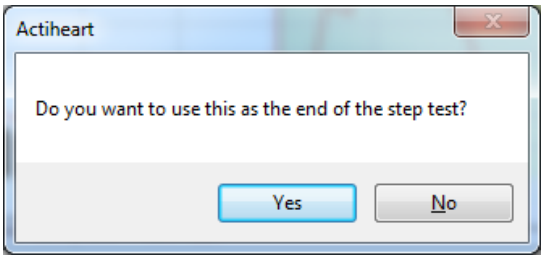
are shown derived values of VO2 max. The HR max is obtained from the P max which is the maximum power that can be produced by stepping. The step size which is used in the calculations is shown just underneath these values.

The central region of the screen shows the activity data as 15 second black blocks derived from the Actiheart accelerometer. The additional red line in the display is by default heart rate in BPM, but can also be selected to show the Heart Rate Variability per 15 second interval displayed either as max-min or the Root Mean Square of the beat to beat interval. Any 15 second segment of this data can be selected with the left mouse button, and viewed in the bottom region of the screen where ECG is shown along with activity waveform. A segment can be selected by using the scroll bar or by clicking on the upper graph. The IBI is accurately derived to within one millisecond using an algorithm to remove noisy and spurious beats. The actual data values in each 15 second epoch can be displayed by pressing and holding down the right mouse button whilst scrolling in the top graph. All the data can be copied to the clipboard.

The lower region of the display shows a summary of the analysis results and certain options for controlling the calculation of energy expenditure from the step test results. The meaning of these are discussed further below in Section 4.5.7.

IMPORTANT

If the subjected stopped stepping earlier than the full 8 minutes, the end point of the test (which is important for the calculation of the recovery) is sometimes detected incorrectly by the software. It is possible to set the end point manually to the nearest second in the following manner. Right click in the bottom third of the screen until only the movement waveform is visible. Then double-click on the point where the activity ceases; the following message will appear:



Clicking on the Yes option will cause the step test calculation to be updated with the new end point marked. This end point is marked by a vertical red line on the main plot, and a blue line in the detailed zoom below when the relevant portion is selected.

4.5.7 The Energy Regression Equations

The Step Test has a linearly increasing step rate from 15 to 33 step cycles per minute after the first minute. As the weight and step height are constant, the energy needed by the user is proportional to the step rate so the energy expended is also linear during the test. A straight line can therefore be fitted to the rising portion of the data.

The resulting regression equations are shown at the bottom of the screen. They are of the form BX+A and these values are displayed along with the R value of the data. An R value of 1 shows a completely straight line fit of the data. For details of how the regression equations are arrived at please see ***Appendix 4.***

There are a number of options for controlling the calculation of energy expenditure calibration from the step test observations. These are selectable options above the “Save” button. We recommend that for new projects the “JAP2007 – improved” option is chosen. The “Original” option refers to the calibration included with the first version of the Step test software. It should only be chosen by those who need to continue with backwards-compatible work. The “JAP2007” option refers to a calibration using improved information from the paper referenced in Appendix 2. The “JAP2007 – improved” option is from the same results, but with validated scaling for varying step height and step tests where the user has stopped well before the eight minute mark.

The activity equation is provided solely for information. It is not used to derive an individual calibration based on activity and therefore it has no effect on the calculation of energy expenditure. The heart rate equation on the other hand forms the basis of the derivation of a PAI-HR calibration equation which can be used in the branched model in lieu of the group equations.

4.5.8 Setting-Up Multiple Users

It is possible set up more than one user to do the Step Test simultaneously. This is achieved by setting up the required number of Actihearts individually and setting them all to a synchronous start time. Multiple physical steps will be required.

4.5.9 Marking Bad HR data

When manually reviewing the R wave graph and regions of bad signal are found, it is possible to manually mark a 15 second block as bad data if you do not wish it to be included in the analysis. This may be achieved by using the ‘Bad HR data’ checkbox below the R wave graph; a large red ‘X’ will appear on the graph to show it is marked as bad data. A small ‘X’ will also appear at the top of the upper graph. It is possible to select/de-select each of these marked blocks by double-clicking on the small red ‘X’ on the upper graph.

4.5.10 Copying Data for a User

There are 2 possible options for copying data to the clipboard for importation and analysis into an external program such as Excel:

1. **Copy Detailed Data:** Provides an export with header information and an epoch-by-epoch, time stamped listing of activity and Heart Rate data with IBI and HRV values.
2. **Copy Summary Row:** Provides a single row export of the results for the current analysis.

4.5.11 Printing and Previewing

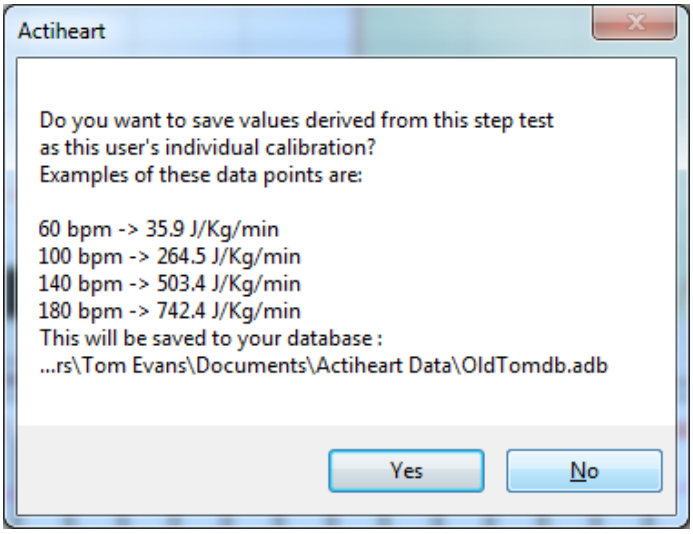
It is possible to preview or print the step test report which contains a results summary and graphs of the activity and HR, a graph of the ECG for the currently selected 15 second block, a graph of the Activity for the currently selected 15 second block and a graph of the Heart rate and Activity Energy Expenditure. Select preview to view the report on screen, select print to send the report to the printer.

4.5.12 Analyse All

This is a batch processing function which places on the clipboard a summary row for all the step tests in the selected database. This function also provides the option of saving the individual calibration of each user.

4.5.13 Saving an Individual Calibration

The results of the Step Test are not saved in the database unless the Save button in the right hand corner of the Step Test analysis screen is pressed. Pressing this button produces the following screen:



Clicking Yes will save the results of the test for this user into the currently selected database.

WARNING

If any of the anthropomorphic variables such as HR max, Sleeping Heart Rate and weight are altered for a completed test then the results will alter accordingly on screen and if Save is pressed the original Step Test calibration data held in the database will be overwritten.

If a Step Test for a subject is performed at a later date or time and possibly with a different step height but with the same user ID as previously, it will be logged as a separate test in recordings database. However, when the results are saved, the earlier calibration data held in the database for this user will be overwritten. Subsequent analysis using the step calibration will use whichever Step Test was analysed and saved most recently beforehand.

4.5.14 Correcting the Step Height of a Completed Test

If following completion of a test it is found that the entered height during set-up was incorrect the value can be changed by editing the Step Size in the ReadInfo table of the Recordings Database (see ***Section 1.1.1***).

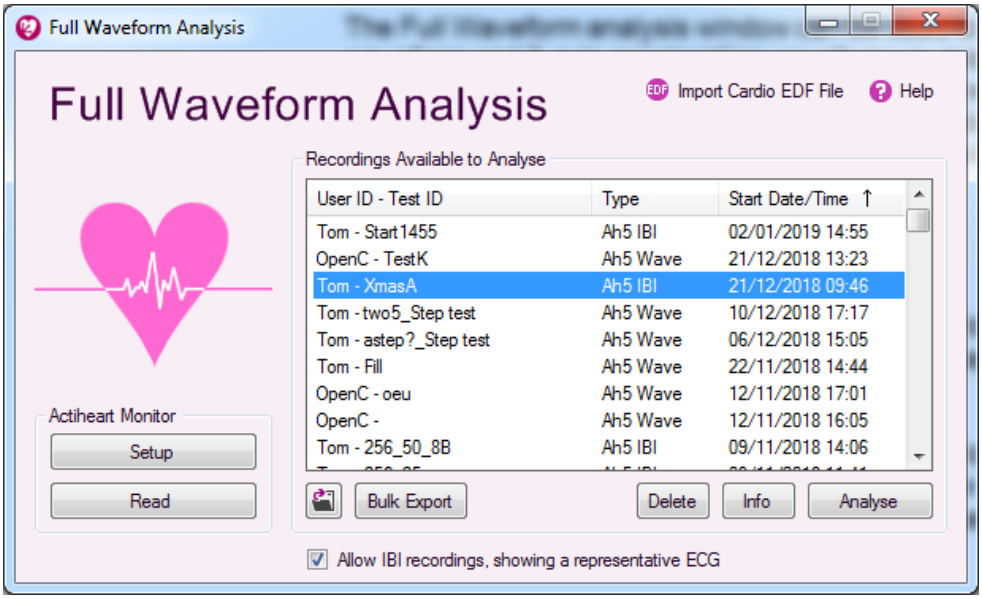
5 Full Waveform Analysis

The Full Waveform analysis window is designed to examine the ECG and 3-axis acceleration waveforms in detail. After initial loading and processing, fast navigation is supported for scrolling and zooming throughout the recording using the mouse. This allows a detailed overview of the full recording's heart rate and movement together with rapid zoom and scrolling of the detailed high-resolution waveform.

Note that if your Actiheart was ordered with a Bluetooth module fitted for this purpose, then when setting up an Actiheart from the Waveform Analysis section, it is also possible to specify the Live Display recording mode. This will both enable the live broadcast of data for viewing (as described in the Guide to Getting Started), and capture the full waveform recording to internal storage for later download via USB.

5.1 Selecting a Recording

Use the "Full Waveform" button in the main menu to open the recordings list window shown below.



This shows a list of all recordings eligible for the waveform analysis window, including those from Actiheart and legacy devices. Additionally, if the checkbox to "Allow IBI recordings, showing a representative ECG" is selected, Actiheart 5 IBI Mode recordings will be shown. These are represented with a sequence of correctly timed and sized ECG spikes showing all the detail captured from the ECG signal in those recordings.

After double-clicking on a recording, or selecting and using the "Analyse" button, the recording will begin opening. Because the full loading may take some time, it will display gradually until all data is processed. The ECG is always re-sampled to 1024Hz – a cubic spline is carried out to interpolate and smooth the data for original sample rates below 1024Hz. The resulting ECG is analysed for IBI data if being opened for the first time, and all other channels shown.

5.2 Waveform Viewer

This window graphically shows all of the raw waveform data captured by the device, in addition to summary data such as heart rate and movement. Initially we describe the contents of the “Waveform Viewer” tab which is used to explore the data.

The view can be navigated either using the “Step Through” buttons and “View Size” options, or by using the mouse and scroll wheel. To zoom in and out of the data you can move the mouse across a point of interest and then roll the scroll wheel to zoom in our out. Once zoomed in, you can use the right mouse button and drag the time to left or right as an alternative to the << and >> buttons.

The data channels shown in the plot are calculated as follows:

- **ECG:** The full recorded ECG waveform is graphed. When zoomed out, this will mostly show the outer envelope of the signal which gives a quick indication of periods of good or bad ECG electrode pickup. When zoomed in, the individual heart beats are marked in light blue together with a horizontal line linking them where an IBI interval is judged definitely correct by the software.

- **ECG Peaks:** This is shown for an Actiheart 5 IBI Mode recording. It is shown as a flat line with vertical peaks drawn at the timings and magnitudes of ECG signal peaks recorded by the Actiheart 5. Note that it includes not just the QRS complexes identified by light blue lines as heart beats, but also a number of smaller noise peaks in order to allow more robust analysis and detection of the IBI and heart rate.

- **Accel XYZ:** The acceleration is shown for all 3 measured axes. The X-axis is left-right on the body, Y is up-down, and Z is back-front oriented. These channels will typically consist of long regions of relatively “flat” data as the wearer is inactive, interspersed with much higher magnitude movement periods, then more “flat” data but with changed levels as a new inactive period with different overall orientation has been assumed by the wearer.

The above data channels all relate to original raw data recorded by the device. Channels below are summary results derived from that raw data:

- **BPM:** The heart rate (Beats Per Minute) data is derived once per second regardless of the heart rate and is displayed in red. The rate is averaged over several seconds to give a better indication of overall heart rate rather than individual beat changes. It is shown as zero where there is considered to be any break in the reliability of the signal available.

- **IBI:** The Inter-Beat-Interval (IBI) data is displayed in orange. This shows the time interval between every single beat, rather than an averaged rate of heart beats. This graph often better illustrates the changes of heart rate variability in its upper and lower envelope during different activities than the BPM graph does.

- **Movement:** This is a measure of the amount of overall movement in each second. It is calculated in the same manner as activity counts from all other analysis screens. It provides a good quick overview of when and how much physical movement has occurred.

- **Rotation / Upright:** The orientation of the user is shown with a black bar representing the standing / laying down position on the Upright data row. The rotation of the body when not vertical is shown using a red/green bar, where red denotes the left should and green the right. This allows you to see clearly which side the wearer was lying on, particularly when asleep. These orientation diagrams are not available when the wearer was moving.

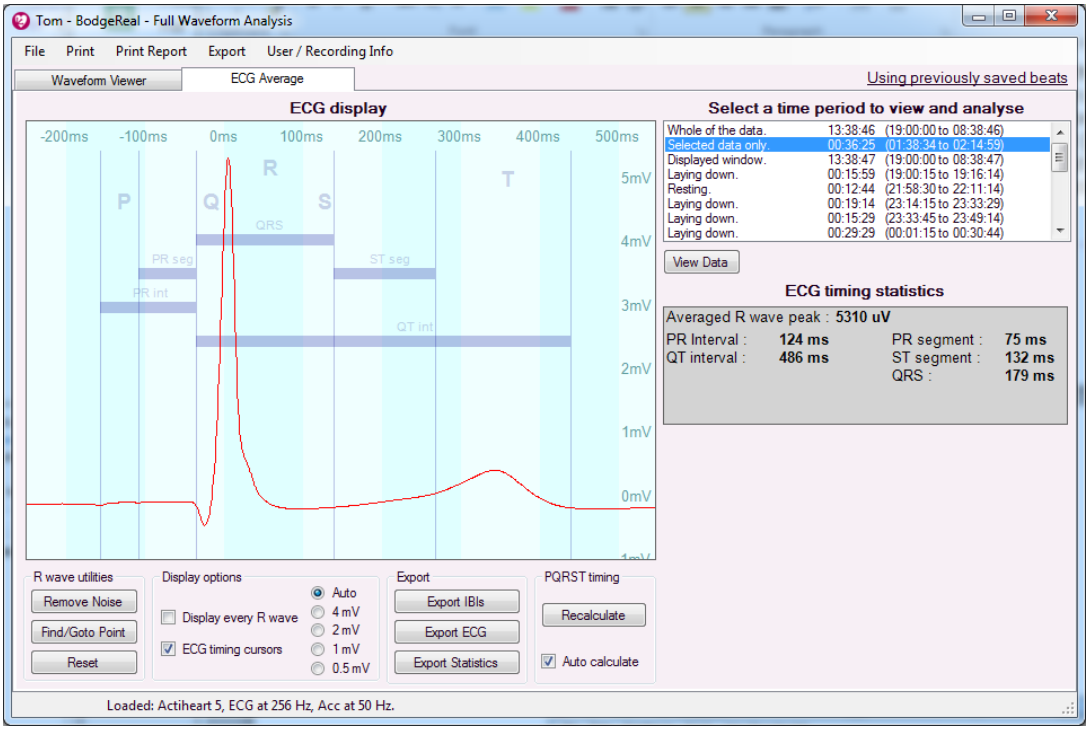
- **Active / Resting / Laying:** Using the Actimetry and the orientation data, the user’s status is shown as Active, Resting or Laying down. This status is used later for HRV analysis.

The left mouse button allows you to quickly select a region either to zoom in to that data, or to concentrate on that period in the “ECG Average” tab. Once selected, the period is highlighted on the display and the start and end times given in the “Selection start / end” boxes towards the bottom of the window. Selection start and end times can be dragged using the mouse without re-setting the entire selection period. The selected period can then be zoomed exactly using the “View Selection” button, and also becomes one of the analysis periods available on the second tab “ECG Average”.

The Export menu provides spreadsheet-suitable export of the data visible in the Waveform Viewer. This is broken down into the heart rate & movement derived data, which is on a simple one second basis, and the acceleration data which contains many more samples. Note that ECG data for a selected period is available from the ECG Average tab. Raw ECG data for the whole recording is also available through the Info button from the recordings list window rather than an analysis window.

5.3 ECG Average

The ECG Average function is reached through the tab near the top of the window, and allows the user to view the averaged ECG from a particular section of data for purposes of measurement. The average ECG waveform from a number of beats is then computed and displayed, along with [optionally] a faint trace of every ECG beat during that period which contributed to the average. The software will also automatically attempt to find the PQRST points on the averaged trace and display their measurements.



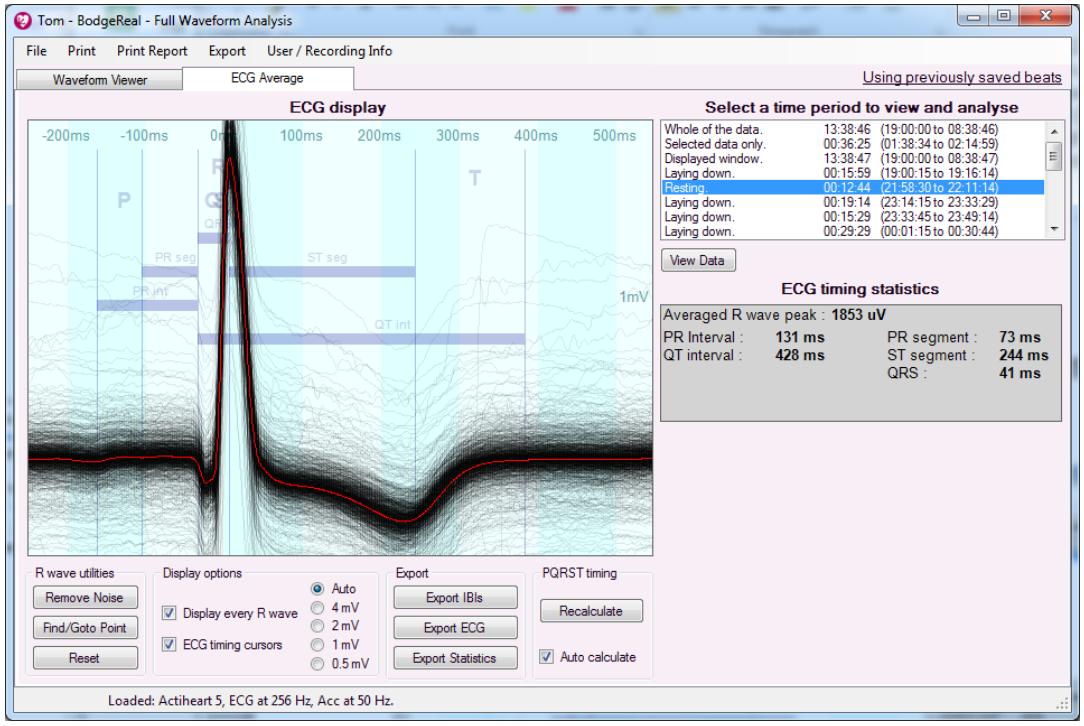
The data above shows a selected period of the recording. A period of essentially no movement has been selected because only under these conditions will the ECG waveform be sufficiently repeatable for the average ECG to be meaningful. A different analysis period may be selected using the list available in the upper right of the window.

The main graph shows a red line of the average of all ECG heart-beat tracings during the selected period. The automatically derived PQRST measurements are both shown on the graph and numerically in the statistics box to the right. The average ECG is analysed to get the PQRST timings, although the algorithm may be upset by noise and irregular waveforms. The ECG may not always contain all the classic ECG elements so the user must always check and adjust the PQRST cursors if necessary. This is done simply by clicking and dragging the relevant vertical line on the display graph.

Export: The three export buttons each provide a spreadsheet-suitable summary of the information for the currently displayed time period. These include the IBI timing sequence, the actual ECG waveform as consecutive samples, and the timing statistics currently shown onscreen.

Display options: This function group has options to vary the scale of the graph vertically in order to better view unusually large or small features. You can also enable or disable the PQRST timing cursors in order to view the data more clearly. In addition, it allows you to display every single R wave, which may be useful either to view the variation in the signal or to highlight any potential

outliers. This should normally only be enabled for a short selected period for performance reasons. An example viewing is shown below.



Once selected, faint black lines are shown for every one of the ECG traces making up the average red line. This creates an overall visual impression of where the most commonly encountered waveform lies. It also highlights individual traces which were affected by movement or unusual timing in some way. Those may be investigated using the “R wave utilities” described below.

Find/Goto Point: This function may be employed to trace unusual ECG lines in the context of the full recording. To use it, first click the button, and then click the crosshair on a single faint line in the ECG display. This will cause the software to jump to the corresponding point in the Waveform Viewer window, which may make it clear why that waveform has arisen.

Remove Noise: This function allows a group of ECG traces to be excluded from the analysis based on their graphical location. To use it, first click the button, then drag across a region of the ECG display to exclude every ECG trace which crosses that region. This might be used for example on the lines well above or below the average (darker region & red line) of the plot.

Reset: Use this button to re-include all of the time period’s heart beats for the ECG Average calculation. This removes the effect of the two functions above.

6.0 Sleep Analysis [Research Only]

6.1 Overview

The Actiheart for Sleep software can be used for analyses to aid the detection of Obstructive Sleep Apnoea (OSA) and to identify the sleep stages. **Note that this is an optional software module for research purposes only. It is not verified or guaranteed in any manner and all results should be treated with caution**. Because of this, the function must first be enabled by entering the Utilities menu of the software and selecting the "Enable Sleep Analysis" check-box.

Two techniques are utilised in the Actiheart for OSA screening. The first[1] (***Section 6.5***) relies solely on the use of Heart Rate Variability (HRV) analysis. This technique does not attempt to identify specific apnoeic episodes. The second technique (***Section 6.6***) attempts to pinpoint individual apnoeic occurrences through the use of either HRV alone[2] or HRV combined with ECG – Derived Respiration[3] (EDR).

EDR is an indirect method of monitoring respiration. It is not as accurate as direct methods that measure airflow directly. ECGs recorded from the surface of the chest are influenced by the motion of the electrodes with respect to the heart due to expansion and contraction of the chest during breathing. The ECG is also affected by changes in the electrical impedance of the thoracic cavity due to the filling and emptying of the lungs. These physical influences result in amplitude variations in the ECG waveform which is inversely correlated with respiration, i.e higher amplitude ECG corresponds to a lower EDR amplitude.

Sleep stage identification in the Actiheart employs HRV analysis based on the findings of Vaughn[4] and others but also uses the movement data captured by the accelerometer in the Actiheart. The algorithm used is described in more detail in ***Section 6.4***.

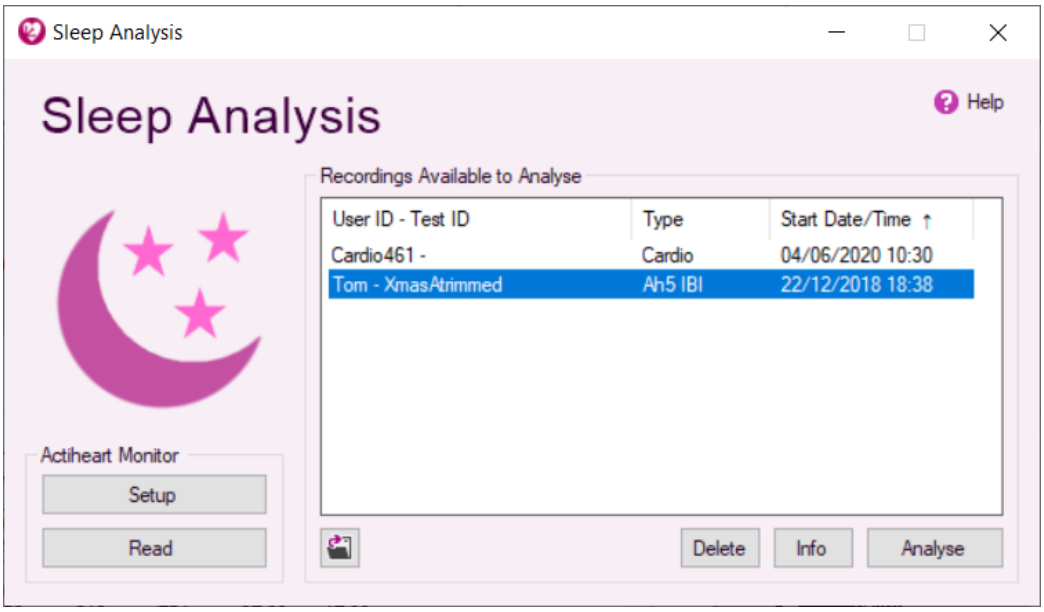
6.1.1 Choosing an Application for Making a Recording

Any Actiheart 5 recording can be used for Sleep Analysis. If the user is interested in conducting a sleep analysis, then it is easiest to set-up the Actiheart from the 'Sleep analysis' screen to ensure an appropriate recording mode (even if using earlier Actiheart or Actiwave devices).

1 *See Frederic Roche et al., Cardiac Interbeat Interval Increment for the Identification of Obstructive Sleep Apnoea, Journal of Pacing and Clinical Electrophysiology, Vol. 25, No. 8, August 2002.*
2 *See Th. Penzel et al., Systematic comparison of different algorithms for apnoea detection based on electrocardiogram recordings, Med. Biol. Eng. Comp., 40, 2002.*
3 *See George .B Moody et al., Derivation of Respiratory Signals from Multi-lead ECGs, Computers in Cardiology, Vol. 12, 1985.*
4 *See B. V. Vaughn et al., Heart period variability in sleep, Electroencephalography and Clinical Neurophysiology, 94, 1995.*

6.2 Sleep Analysis

Clicking on the 'Sleep Analysis' button on the main screen produces the screen below:



From this window, the user can set up a new recording, read recorded data from an Actiheart or view a recording from the database.

6.2.1 Setting up a Sleep Recording

This is the same as the process previously described for other recording types. Please see ***Section 7*** of the Guide to Getting Started for more details.

For details on setting up a delayed start recording, please see ***Section 3.1.3***.

Downloading a Sleep Analysis recording is the same as any other recording. For further details, please see ***Section 7*** of the Guide to Getting Started.

6.3 Analysing a Sleep Analysis Recording

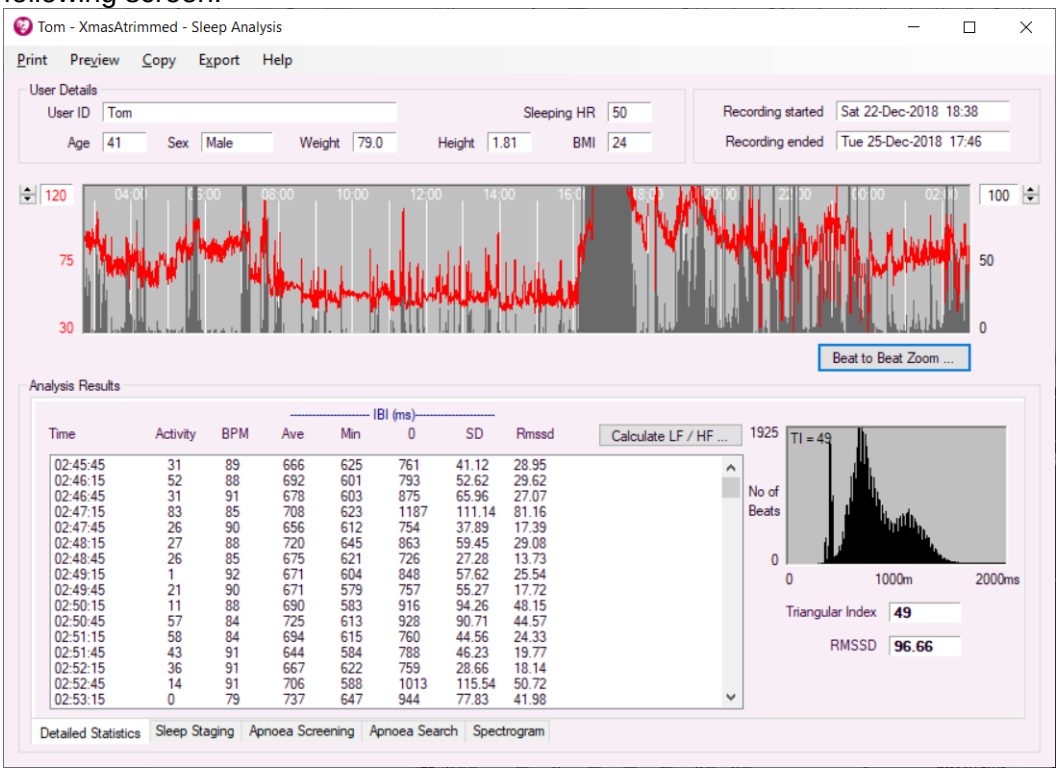
The recorded data can be accessed from the listing on the main Sleep Analysis screen (see **Section 6.2** above). The data can be used for:

- A detailed statistical analysis of the IBI data
- Identifying the Sleep Stages
- Apnoea Screening
- Searching for occurrences of apnoeic events

- Calculating a Spectrogram of the heart rate signal

When you first attempt to open a multi-day Actiheart recording, the software will show a summary graph of the entire recording and prompt you to select a single 24-hour period from it. This allows the analysis window to then focus on a single night of sleep without the full length of recording.

Highlighting a recording of interest and clicking on ‘Analyse’ produces the following screen:



This screen is divided into three regions:

Top region. This shows the parameters of the chosen recording, namely those for the user and those for the start and finish times of the recording.

Second region. This shows the activity data in black and the heart rate data in red for the duration of the recording. The scale of these can be adjusted using the sliders to either side of this display.

Third region. This section shows the analysis results for the complete recording in 30 sec. analysis epochs:

- **Activity** The total number of counts in the analysis epoch
- **BPM** The average heart rate in beats per minute for the analysis epoch
- **IBI Ave** Average Interbeat Interval (IBI) for the analysis epoch
- **IBI Min** Minimum IBI in the epoch
- **IBI Max** Maximum IBI in the epoch

Time-domain heart rate variability data:

- **SD** Standard Deviation of the IBI data

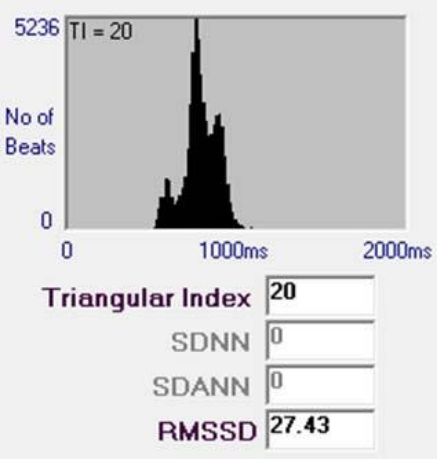
- **RMSSD** The root mean square of the successive differences of the IBI's

Clicking on 'Calculate LF/HF' calculates and displays the following frequency-domain parameters:

- **LF** The low frequency component of the IBI, derived using an FFT
- **HF** The high frequency component of the IBI derived using an FFT
- **LF/HF** The ratio of the LF component to the HF component of the IBIs

To the right of the analysis results are the histogram window and some further general statistics. The histogram shows a time domain frequency plot of the analysed IBIs. The statistics give the following data:

- **Triangular index** This is the integral of the density distribution divided by the maximum interval. This is also shown on the histogram plot.
- **RMSSD** This is the root mean square of the successive differences of the IBI's.



Note: All time domain and frequency domain parameters are based on the definitions contained in "Heart Rate Variability, Standards of Measurement, Physiological Interpretation, and Clinical Use". Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology.

6.3.1 Viewing a Specific Data Point

It is possible to view the data at any given point on screen. This is done by right mouse clicking on the data at the point of interest. The readout is shown on the screen below, showing the time in black, heart rate in red and activity counts in black.

6.3.2 Beat to Beat Zoom

Double-clicking on a section of the recording highlights an area around the selected data point in blue and causes the beat to beat zoom window to appear as shown in the screen below:

By left clicking on the screen and dragging left or right, it is possible to scroll through the recording. The default functionality of the left mouse button can be changed by clicking on the 'Paints Marker' radio button. This will allow areas of interest to be labelled.

6.3.3 Previewing Data

It is possible to preview the window and beat to beat zoom data for the recording. This is done by selecting 'Preview' from the drop down menu. This produces a report which contains a graph of the full analysis period showing Activity and HR, a zoomed activity and HR graph and the histogram, triangular index and RMSSD:

6.3.4 Printing Data

It is possible to print out the window data, the histogram, and the general statistics of the recording. This is done by selecting print from the drop down menu at the top of the screen.

6.3.5 Copying Data

Data can be copied from the software for pasting into an external program of the user's choice. The selected data is exported to the clipboard and can then be pasted from there into, e.g. Microsoft Excel. There are three options:

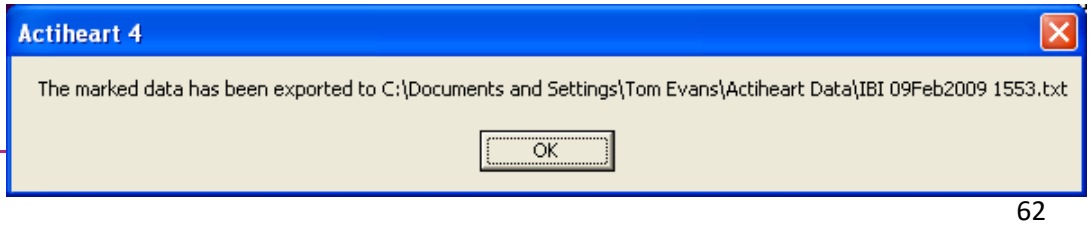
1. **Copy raw data.** This takes the raw activity, heart rate, and IBI data and puts it on the clipboard.
2. **Copy Detailed Statistics.** Provides an export with header information and an epoch-by-epoch, time stamped listing of activity and Heart Rate data with IBI, SD and RMSSD data.
3. **Copy Marker Summary.** This is to copy areas of interest that may have been labelled in the beat to beat zoom window.

6.3.6 Exporting Data

It is possible to export data for further analysis in other programs. There are two options:

1. **Export time-stamped IBI data**. This is done by selecting 'Export' and then 'Time-stamped IBI data' from the menu.
2. **Export HRV Analysis.** This is done by selecting 'Export' and then 'HRV Analysis' from the menu

The following message will be produced, showing the file path to which the data has been exported:



6.4 Sleep Staging

The software performs a two-stage analysis of the sleep record. The first stage involves measuring various characteristics of the heart beat record and uses them to derive an empirical measure of ‘sleep depth’ at 30 second intervals. In the second stage this measure is combined with the movement record to produce an approximate estimate of sleep stage.

The empirical ‘sleep depth’ measurement is calculated from:
* Absolute heart rate - a lower heart rate implies greater sleep depth
* Size of breathing peak in HRV spectrum - larger implies greater sleep depth
* Total of all HRV - smaller implies greater sleep depth

The absolute heart rate refers to the average rate during the interval. The breathing peak is a prominent peak in the HRV spectrum (normally around 0.2-0.3Hz) generated as a consequence of heart rate varying slightly with breathing. Slowing and deepening of breathing will amplify the magnitude of the peak. Faster and shallower breathing will have the opposite effect. The total HRV measure includes a wide band of HRV in addition to the breathing peak. Additional HRV outside the breathing peak tends to reduce during deep sleep.

After the sleep depth measure has been calculated for the whole night, the movement record is used to identify periods of waking, and a combination of thresholding and hysteresis is applied to identify the different sleep stages.

The two-stage calculation is necessary because the thresholds vary from individual to individual as a consequence of normal heart rate and HRV variation, and so must be derived from the night’s data as a whole.

Clicking on the ‘Sleep Staging’ tab at the bottom of the analysis screen produces the following screen:

Moving the ‘To Bed’ and ‘Get Up’ sliders to the respective bed times and get up times and clicking on the white area produces the following result:

The ‘Estimated Sleep stage’ window now contains the sleep stages for the period, with light sleep displayed in yellow, deep sleep displayed in green, and REM sleep in red. The time spent awake during the night is shown in black.

The ‘Sleep Statistics’ window now contains the selected bed and get up times as well as the following calculated sleep parameters:

- Time in Bed
- Sleep Start
- Sleep End
- Sleep Time
- Sleep Latency
- Time Awake
- Sleep Efficiency

6.4.1 Previewing Data

There are two ways of previewing data:

a. **Previewing General Statistics**. This displays the window and beat to beat zoom data (if selected) as well as the histogram, triangular index and RMSSD for the recording, and is done by selecting first ‘Preview’ and then ‘General Statistics’ from the drop down menu.

b. **Previewing Sleep Staging**. This is done by first selecting ‘Preview’ and then ‘Sleep Staging’ from the drop down menu.

6.4.2 Printing Data

There are two options for printing data:

a. **Print General Statistics**. This prints out the window data, the beat to beat zoom (if it has been selected), the histogram, and the general statistics of the recording, and is done by selecting first ‘Print’ and then ‘General Statistics’ from the drop down menu at the top of the screen.

b. **Print Sleep Staging**. This prints out the window data, the calculated estimated sleep stages, a hypnogram of the sleep stages, and the sleep statistics, and is done by selecting first ‘Print’ and then ‘Sleep Staging’ from the drop down menu at the top of the screen.

6.4.3 Copying Data

Data can be copied from the software for pasting into an external program of the user’s choice. The selected data is exported to the clipboard and can then be pasted from there into, e.g. Microsoft Excel. There are three options:

a. **Copy raw data**. This takes the raw activity, heart rate, and IBI data and puts it on the clipboard. This is done by selecting first ‘Copy’ and then ‘Raw Data’ from the drop down menu at the top of the screen.

b. **Copy Detailed Statistics**. This is done by selecting first ‘Copy’ and then ‘Detailed Statistics’ from the drop down menu at the top of the screen. Provides a report with epoch-by-epoch time stamped data containing Activity, BPM, IBI, Sleep stage and comments.

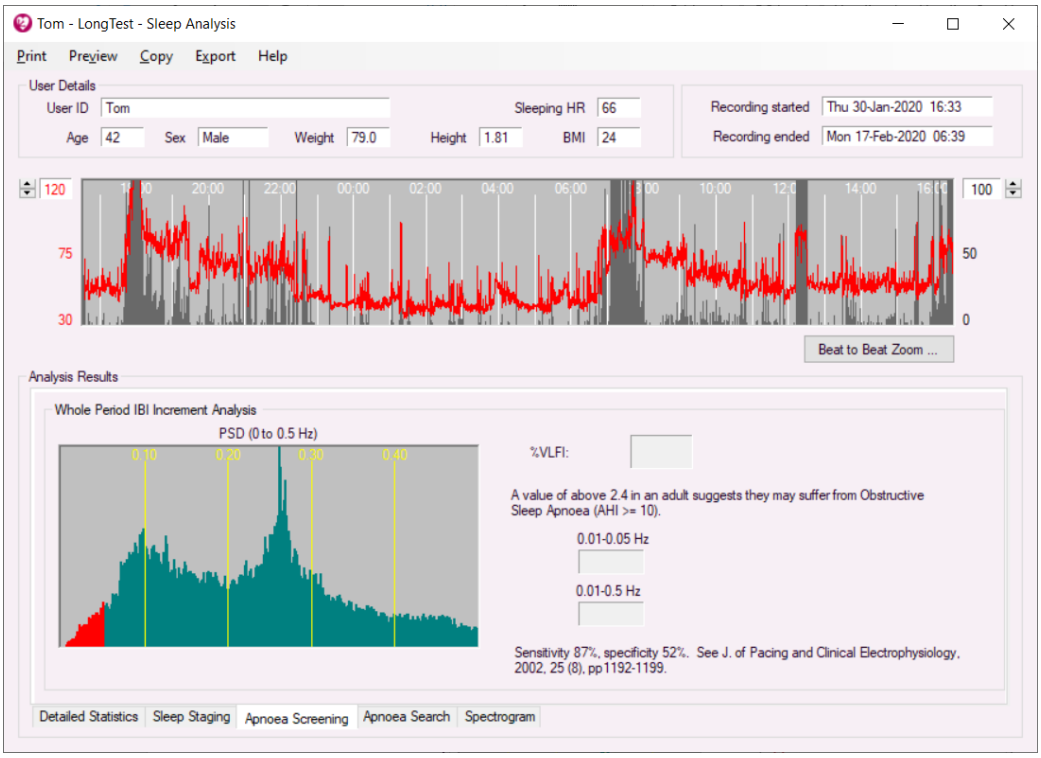
c. **Copy marker summary**. This is to copies areas of interest that may have been labelled in the beat to beat zoom window.

6.4.4 Exporting Data

It is possible to export data for further analysis in other programs. Please refer to ***Section 6.3.6*** for further details.

6.5 Apnoea Screening

Clicking on the 'Apnoea Screening' tab automatically performs a frequency domain analysis of the cardiac inter-beat interval increment of the recording. This analysis extracts the Very Low Frequency components of the IBI as shown in the results below:



The Apnoea screen is divided into three sections:

a. **Top section.** This shows the parameters of the chosen recording namely those for the user and those for the start and finish times of the recording.

b. **Second section.** This shows the activity data in black and the heart rate data in red for the duration of the recording. The scale of these can be adjusted using the sliders to either side of this display.

c. **Third section**. The 'Analysis Results' window shows a power spectral analysis of the heart rate variability data, with the Very Low Frequency component highlighted in red and the low and high frequency in light blue. The %VLFI is the percentage of very low frequency power spectral density on the total power spectral spectral density, which has been identified as a well-suited variable for screening patients with obstructive sleep apnoea.*

***** For further details, see Frederic Roche et al., *Cardiac Interbeat Interval Increment for the Identification of Obstructive Sleep Apnoea*, Journal of Pacing and Clinical Electrophysiology, Vol. 25, No. 8, August 2002, pp. 1192-1199.

6.5.1 Previewing Data

It is possible to preview the window and beat to beat zoom data for the recording. This is done by selecting ‘Preview’ from the drop down menu.

6.5.2 Printing Data

It is possible to print out the window data, the histogram, and the general statistics of the recording. This is done by selecting print from the drop down menu at the top of the screen.

6.5.3 Copying Data

Data can be copied from the software for pasting into an external program of the user’s choice. The selected data is exported to the clipboard and can then be pasted from there into, e.g. Microsoft Excel. There are three options:

a. **Copy raw data**. This takes the raw activity, heart rate, and IBI data and puts it on the clipboard. This is done by selecting first ‘Copy’ and then ‘Raw Data’ from the drop down menu at the top of the screen.
b. **Copy Detailed Statistics**. This is done by selecting first ‘Copy’ and then ‘Detailed Statistics’ from the drop down menu at the top of the screen. Provides a report with epoch-by-epoch time stamped data containing Activity, BPM, IBI, Sleep stage and comments.
c. **Copy marker summary**. This is to copies areas of interest that may have been labelled in the beat to beat zoom window.

6.5.4 Exporting Data

It is possible to export data for further analysis in other programs. Please refer to ***Section 6.3.6*** for further details.

6.6 Apnoea Search

Clicking on the ‘Apnoea Search’ tab produces the following screen:

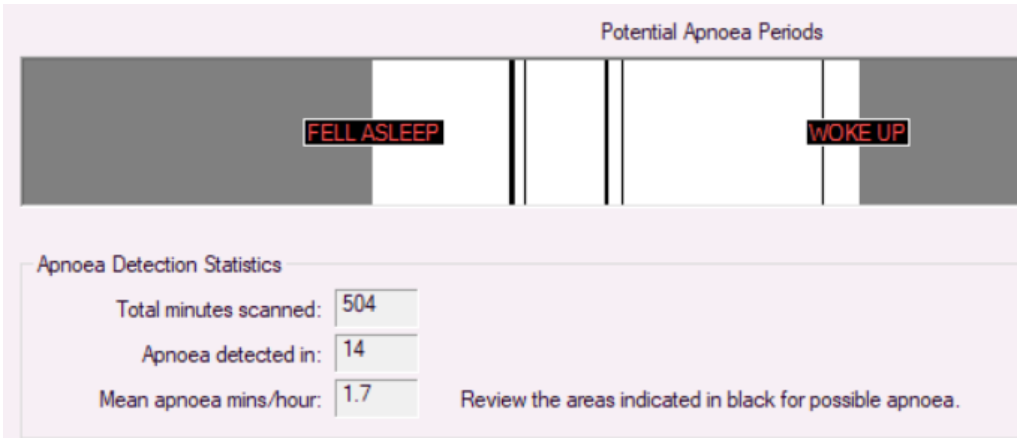
This screen is divided into three sections:

a. **Top section.** This shows the parameters of the chosen recording namely those for the user and those for the start and finish times of the recording.

b. **Second section.** This shows the activity data in black and the heart rate data in red for the duration of the recording. The scale of these can be adjusted using the sliders to either side of this display.

c. **Third section**. The ‘Analysis Results’ window is used to display potential occurrences of sleep apnoea and some statistics.

Moving the ‘Fell Asleep’ and ‘Woke Up’ sliders to the respective times and clicking on the white area begins the analysis, and produces the following screen:



The black vertical bars are estimated apnoeic periods during the night. By expanding the window with the beat to beat zoom, the periods identified as possible apnoeic events can be reviewed. An example of the zoom window with possible apnoeic events marked in black underneath the heart rate and activity data is shown below:

6.6.1 Previewing Data

It is possible to preview the window and beat to beat zoom data for the recording. This is done by selecting ‘Preview’ from the drop down menu.

6.6.2 Printing Data

It is possible to print out the window data, the histogram, and the general statistics of the recording. This is done by selecting print from the drop down menu at the top of the screen.

6.6.3 Copying Data

Data can be copied from the software for pasting into an external program of the user’s choice. The selected data is exported to the clipboard and can then be pasted from there into, e.g. Microsoft Excel. There are three options:

a. **Copy raw data**. This takes the raw activity, heart rate, and IBI data and puts it on the clipboard. This is done by selecting first ‘Copy’ and then ‘Raw Data’ from the drop down menu at the top of the screen.

b. **Copy Detailed Statistics**. This is done by selecting first ‘Copy’ and then ‘Detailed Statistics’ from the drop down menu at the top of the screen. Provides a report with epoch-by-epoch time stamped data containing Activity, BPM, IBI, Sleep stage and comments.

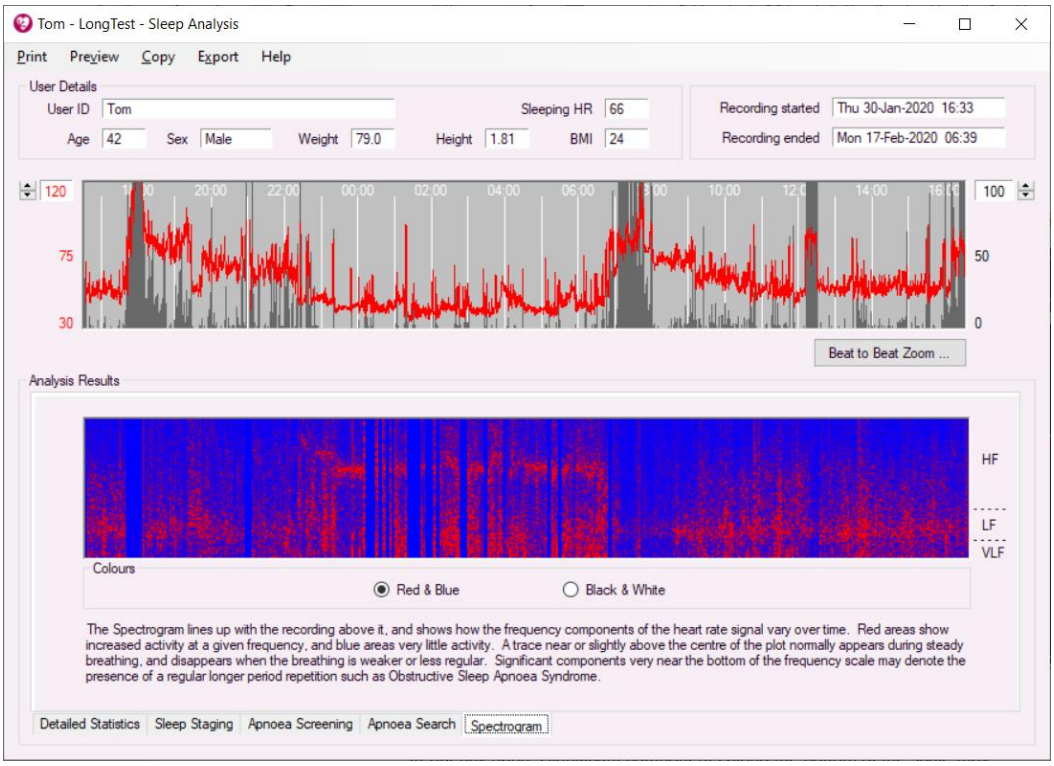
c. **Copy marker summary**. This is to copies areas of interest that may have been labelled in the beat to beat zoom window.

6.6.4 Exporting Data

It is possible to export data for further analysis in other programs. Please refer to ***Section 6.3.6*** for further details.

6.7 Spectro-gram

Clicking on the ‘Spectrogram’ tab, automatically performs a calculation of the frequency spectrum of the heart rate signal as shown below:



The resulting spectrogram as shown in the screen below lines up with the heart rate recording above it and shows how the frequency components of the heart rate signal vary over time. The red areas show increased activity in a given frequency band. Significant components along the bottom of the scale may indicate the presence of sleep apnoea.

6.7.1 Previewing Data

It is possible to preview the window and beat to beat zoom data for the recording. This is done by selecting ‘Preview’ from the drop down menu.

6.7.2 Printing Data

It is possible to print out the window data, the histogram, and the general statistics of the recording. This is done by selecting print from the drop down menu at the top of the screen.

6.7.3 Copying Data

Data can be copied from the software for pasting into an external program of the user's choice. The selected data is exported to the clipboard and can then be pasted from there into, e.g. Microsoft Excel. There are three options:

a. **Copy raw data**. This takes the raw activity, heart rate, and IBI data and puts it on the clipboard. This is done by selecting first 'Copy' and then 'Raw Data' from the drop down menu at the top of the screen.
b. **Copy Detailed Statistics**. This is done by selecting first 'Copy' and then 'Detailed Statistics' from the drop down menu at the top of the screen. Provides a report with epoch-by-epoch time stamped data containing Activity, BPM, IBI, Sleep stage and comments.
c. **Copy marker summary**. This is to copies areas of interest that may have been labelled in the beat to beat zoom window.

6.7.4 Exporting Data

It is possible to export data for further analysis in other programs. Please refer to ***Section 6.3.6*** for further details.

7 Safety and Handling Information

7.1 Decontamination

- Devices removed from subjects must be considered to be contaminated.
- The operator must use gloves to handle such devices before and during de-contamination.
- The Actiheart casing, cable and clip must be carefully cleaned to minimise any potential contamination. CamNtech recommend the use of aqua based disinfection products and our recommended products are Clinell® Universal Wipes or Spray. These products do not contain chemicals known to cause deterioration of plastics.
- Do not use products containing Glutaraldehyde, Glucoprotamin, Isopropyl, ethyl, or methyl alcohols, hydrogen peroxide, or bleach products. Do not use plasma sterilization or ethylene oxide sterilization procedures. Do not autoclave.
- Take care not to place excessive stress on the cable assembly during cleaning.

7.2 Battery

- The device is INTERNALLY POWERED and operates at voltages below 5VDC; there is hence no risk from electric shock (equipment Type B).
- The battery is **NOT** user replaceable – **no attempt should be made to open the device casing**.
- If the battery may have been run completely flat, the device will no longer connect fully to the PC using USB. In this case, plug it in to charge for several hours, then disconnect and re-plug to USB again. This should restore a basic charge level and correct USB connection.
- The battery is re-chargeable; to maximise the service life of the battery:-
  - Following any large download of data, always at least partially re-charge the Actiheart by leaving it connected.
  - Do not leave the battery completely flat before long-term storage.
  - As with all rechargeable batteries the capacity of the Actiheart battery will deteriorate with time/usage.

7.3 Disposal

Waste Electrical & Electronic Equipment (WEEE) The EU requires, under the Waste Electrical and Electronic Equipment Directive 2012/19/EU, that manufacturers and/or distributors of Electronic and/or Electrical Equipment manage and pay for the collection and further handling of WEEE products, as well as provide WEEE-related information to their customers.

CamNtech has taken the following approach to complying with this Directive:

- CamNtech has registered with an approved producer compliance scheme (PCS) in accordance with the requirements of the WEEE Directive.
- CamNtech will provide free recycling for all of its WEEE products when returned to them.
- CamNtech WEEE products will be designed with recycling, reuse and waste management as a consideration.
- CamNtech WEEE products will be labelled or stamped with the WEEE marking in accordance with European Standard EN 50419

7.4 EMC Declaration and Guidance

The following tables provide a declaration of compliance and user guidance regarding Electromagnetic compatibility of the Actiheart system.

Electromagnetic Emissions

Guidance and Manufacturers Declaration – Electromagnetic emissions		
The Actiheart is intended for use in the electromagnetic environment specified below. The customer or the user of the Actiheart should assure that it is used in such an environment.		
Emissions Tests	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The Actiheart uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Actiheart is suitable for use in professional healthcare and home healthcare environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The Actiheart has not been tested for use in the following special environments: Military areas. Heavy Industrial Areas. Medical treatment areas with high powered ME equipment. Inside the shielded room of an MRI system.
Harmonic Emissions EN61000-3-2	Not Applicable	
Voltage Fluctuations / flicker emissions EN61000-3-3	Not Applicable	

Essential Performance

If periods of EM disturbance are experienced by the device, increased background noise may be present upon the ECG signal. Any such noise will be below the threshold for detection as beats. In severe cases of EM disturbance, the Actiheart may be reset and may require intervention within the software to restart. Recorded data will not be affected. Patient safety is not affected.

Adjacent Equipment

The Actiheart normal mode of operation is typically well spaced from other devices or equipment. The device should not be operated close to potential sources of EM disturbance (e.g. a mobile phone in a breast pocket).

Connecting Cables

The Actiheart is supplied with a Micro USB cable of length 1.8m. Cables exceeding 1.8m are not recommended.
The Actiheart patient lead is tested as part of the system and should not be modified or extended.
WARNING: Use of cables and/or accessories other than those specified by CamNtech may result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.

Use adjacent to Portable RF Communications equipment

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Actiheart, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Immunity

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The Actiheart is intended for use in the electromagnetic environment specified below. The customer or the user of the Actiheart should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Radiated Field Immunity	IEC61000-4-3 IEC61000-4-3	10 V/m 80-2700 MHz 1 kHz 80% am 9-28 V/m 385-6000 MH pulse mode	
Conducted RF Immunity	IEC61000-4-6 IEC61000-4-6	3 Vrms 0.15-80 MHz 1 kHz 80% am 6 Vrms 0.15-80 MHz 1 kHz 80% am ISM/amateur radio band	
Electrostatic Discharge (ESD) IEC 61000-4-2	IEC 61000-4-2 IEC 61000-4-2	+/-8kV Contact +/-15kV Air	

The Actiheart is not mains powered hence no ac power line tests are applicable.

Appendix 1: Technical Specifications of the Actiheart 5

Accelerometer Specification

Range:	+/- 8g
Resolution:	12 Bit
Sampling rate:	25, 50 or 100 Hz
Frequency range:	0Hz - ½ sampling rate

Acceleration Measurement

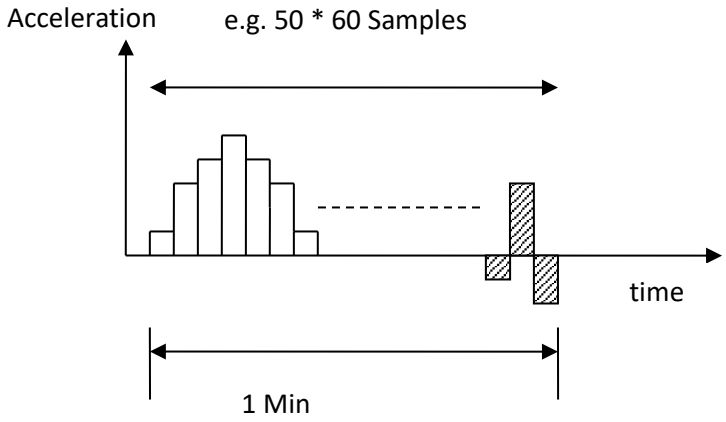
Acceleration is measured using an integrated 3-axis MicroElectroMechanical System (MEMS) accelerometer. This uses the displacement of a polysilicon structure to respond to acceleration in each axis, together with capacitive sensing of that displacement and associated electronics to create a 12-bit digital output.

The digital output of this accelerometer is stored using lossless compression in the Actiheart 5. This means that where there is little movement and the signal is very steady, the output will be stored as a long sequence of small values, taking up less space. When the wearer is moving violently and the signal is large, the full value may need to be stored for each sample, taking up greater storage space. Hence the exact recording time available will depend on the movements experienced during recording. Typical results are quoted for recording times.

Note that “lossless” compression means that the data will never be affected – the original is stored and re-used exactly. The only consequence is that compression is only achieved when the signal is steady and predictable. But this is normally the case.

Activity Counts

For the purposes of visualisation, Energy Expenditure calculations, and simple quantitative summary of acceleration data, activity counts are used. These are essentially an empirical measure of the amount of movement encountered during an epoch. The value is normally given in counts, and accumulates over time so that the total of two 15 second epochs would be equivalent to that of a single 30 second epoch. So, for standardisation these are often quoted in counts per minute (cpm).
To determine activity counts, the raw acceleration signal is first filtered to remove the lowest frequency components and then summed up over each second of the recording. The results of this are scaled during factory calibration to provide 2000 counts per minute on a rotating jig spinning at 180rpm. This provides a measure from the area under the curve in the schematic diagram below.



For activity counts, the accelerometer is designed to detect vertical movement with the person upright. It is therefore important for maximum consistency of activity counts and also processing of the complete 3-axis acceleration waveform that the Actiheart be positioned on the chest so that the sensor is as horizontal as possible. See the Guide to Getting Started for further details on positioning the Actiheart.

ECG Specification

Range:	10 mV p-p
Resolution:	10 Bit
Sampling rate:	128 – 1024 Hz
Bandwidth:	0.05 – 55 Hz
IBI Mode sampling:	256 Hz
IBI Mode resolution:	1 ms, by interpolation

ECG Derived Measurements

In IBI Mode, the Actiheart 5 records the timing and magnitude of peaks in the ECG signal 2nd derivative. These are recorded with a threshold sufficiently low to capture all likely QRS complexes, but high enough to record more compactly than a full ECG waveform. Around 5 peaks per second will be recorded, varying dynamically with the input signal. These peaks are processed by the PC software to identify the most likely IBI sequence amongst any noise registered, in a more robust manner than can be achieved in real-time on the recording hardware.

Heart rate is calculated as a moving average from the IBI sequence recorded. This may be “filled” or cleaned for uses of HR such as Energy Expenditure where a small gap in exact HR is of little consequence. However, the full IBI sequence is required for HRV calculations, so that may not be cleaned in the same manner.

Actiheart Recording Times

Because the acceleration waveform is captured using a lossless compression as described previously, and the IBI Mode may record varying amounts of data dependent on the signal quality and heart rate, predicted recording time limits are not exact.

Setting	Length
IBI Mode, 25Hz Acc	14 days
IBI Mode, 50Hz Acc	8 days
128Hz ECG, 25Hz Acc	6d, 2h
128Hz ECG, 50Hz Acc	4d, 11h
256Hz ECG, 25Hz Acc	3d, 18h
256Hz ECG, 50Hz Acc	3d, 1h
256Hz ECG, 100Hz Acc	2d, 5h
512Hz ECG, 50Hz Acc	1d, 21h
512Hz ECG, 100Hz Acc	1d, 12h
1024Hz ECG, 100Hz Acc	0d, 22h

Sensor Calibration and Reproducibility

All Actiheart units are tested and calibrated for both ECG and acceleration before they leave CamNtech. This involves both the application of a small calibration factor adjustment, and also ensuring that the raw calibration is within controlled limits.

Note that inherent variation in positioning and mounting movement of Actiheart units means that it is not possible in practice to place two recording devices on a subject and record identical outputs.

Time Keeping

The Actiheart time is set by the PC clock and elapsed time is marked in each unit by means of a crystal oscillator. This system is also used when any delays in the starting of recording are set.

Waterproof Case

The Actiheart is waterproof. However, please see the Guide to Getting Started for further details regarding use of the Actiheart in water.

Service Life

The Actiheart and Reader have an expected service life of at least 5 years.

Appendix 2: The Branched Model, Calibration Equations and Other Equations

Estimating Energy Expenditure (EE) from Activity and Heart Rate

Activity monitors use motion sensors (accelerometers) to provide an objective indicator of total body movement. They can be used to assess the frequency, intensity, duration and EE of physical activity. A well described limitation of activity monitors typically worn on the hip is the inability to assess upper body activities such as throwing, catching, carrying or lifting and lower body activity such as cycling. Moreover they are unable to differentiate between walking on the flat versus up or down hills or stairs. Studies have documented that activity monitors significantly underestimate EE of common daily activities in adults for all of the above reasons.

Heart rate (HR) monitors provide an objective indicator of physiological effect of physical activity. They too can be used to assess frequency, intensity, duration and EE of physical activity. HR has been shown to be linearly related to VO2 and EE during physical activity. However the relationship between HR and VO2 depends on the amount of upper body work that is taking place. HR will be higher for any given VO2 during arm activity in comparison with leg activity or combined arm and leg activity. This is primarily because of the smaller amount of muscle mass involved with arm-only activity. Therefore HR alone will lead to an overestimation of EE. For reliable results the HR-VO2 relationship needs to be derived for a specific individual. Numerous other factors that influence HR under resting conditions e.g. stress contribute additional error when HR monitors are used for extended periods of monitoring of daily activities.

Studies (1) & (2) (and others before them) have demonstrated that use of HR along with motion data can improve prediction of energy expenditure for lifestyle activities.

Techniques used for Estimating Energy Expenditure from Activity and Heart Rate

The techniques used for estimating EE from either activity or heart rate alone involve establishing calibration curves of activity vs VO2 and HR vs VO2. This is done in a laboratory usually on a treadmill or a bike (for lower body activity).

If using a treadmill, subjects walk at a variety of incremental speeds and gradients and HR or activity counts are measured and plotted against oxygen consumption (VO2). A curve is fitted to the data using linear regression and the resulting regression equation is used to predict VO2 and hence EE. 1litre of Oxygen = 4.8 kcal= 20kJ. EE is often expressed as an average intensity in terms of metabolic units or METS which represent multiples of resting metabolic rate. 1 MET = 3.5 ml/kg/min or 0.017Kcal/kg/min. HR Calibration curves are unique to

an individual, due to physiological variations (stroke volume haemoglobin content etc.).

Calibration curves of activity vary due to biomechanical factors and possibly to the activity mode too. It is more economical in terms of participant and researcher workload to use a group regression equation although individualized regression equations are more accurate.

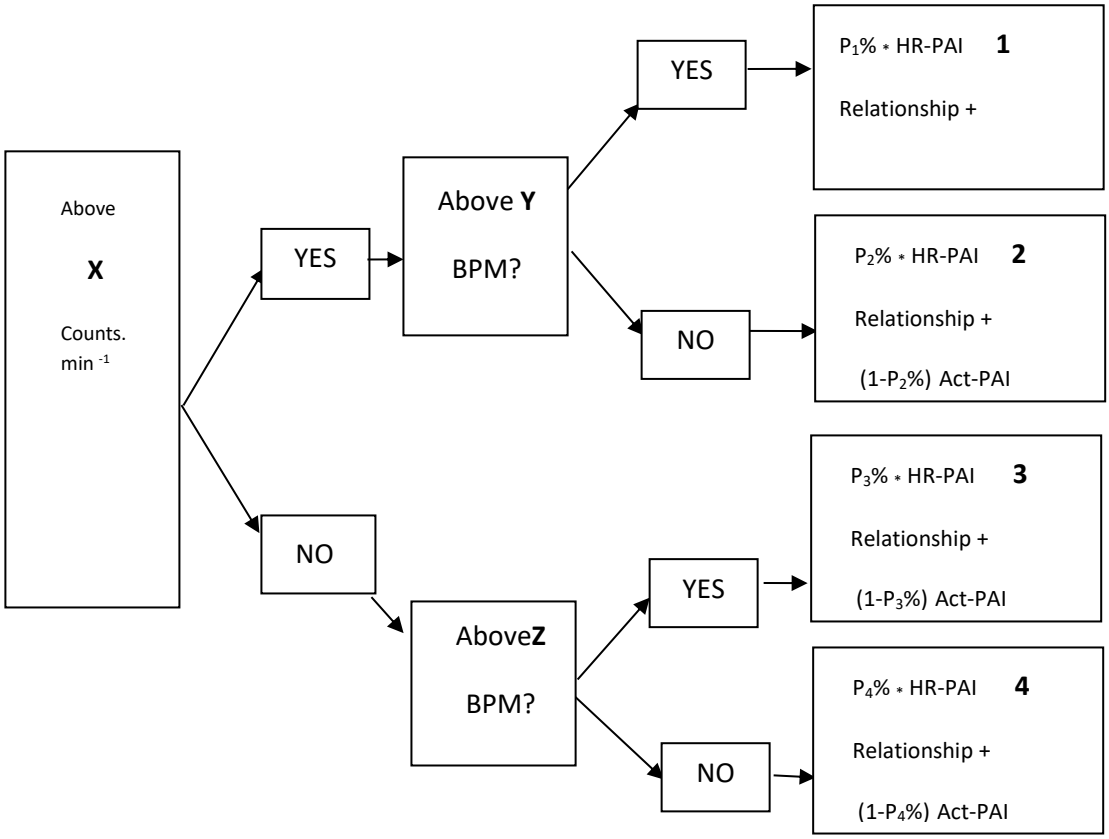
In the case of both activity counts and HR there is a point below which the linear relationship no longer holds. This is referred to as the Flex Point and it has been used to demarcate resting energy expenditure (REE) from energy expended during physical activity (AEE). The flex point is required when HR alone is used to estimate EE. This is commonly referred to as the Flex HR method and it has been thoroughly validated elsewhere. The Flex HR was first defined as the average of the highest HR during rest and the lowest HR during incremental exercise in a treadmill test. If HR is below an individual's Flex HR point AEE is normally assumed to be zero, the only energy expended being resting energy expenditure (REE). For HR values above FlexHR EE is predicted using a regression line. The AEE is set to zero in the classical HR-only model to avoid overestimation of EE in daily living. This does not apply to the model below due to the low weighting given to HR compared with activity in daily living.

Where HR and activity are combined the derivation of the regression line is the same is similar. A multi-linear regression (MLR) equation is derived and expressed in terms of both activity counts and HR. Flex HR is normally not used in such an equation.

The Branched Equation Model for Estimating AEE from Simultaneous Activity and HR

The above techniques rely heavily on individual calibration and have to date been shown to be effective for selected field-based activities and for estimating AEE in free living. Branched modelling proposed by Brage (4) uses movement data quantitatively and has the following aims:

a. To achieve better estimates of AEE than those obtained using MLR.
b. To interpret simultaneous HR and accelerometry data into minute by minute Physical Activity PAI.
c. To minimize the need for individual calibration.
d. To establish a framework that can be used for estimating more accurately AEE in free living.



P1 – P4 are weighting factors. X is used to discriminate between activity and "no activity". Y and Z are used to apply HR thresholds in the presence and absence of activity respectively Y is used to discriminate between walking and running. At running speeds HR is a very reliable measure of EE whereas activity as measured by vertical acceleration is less reliable since during running the latter does not increase linearly with speed. This is reflected by the weighting in Box 1 where P1 is high.

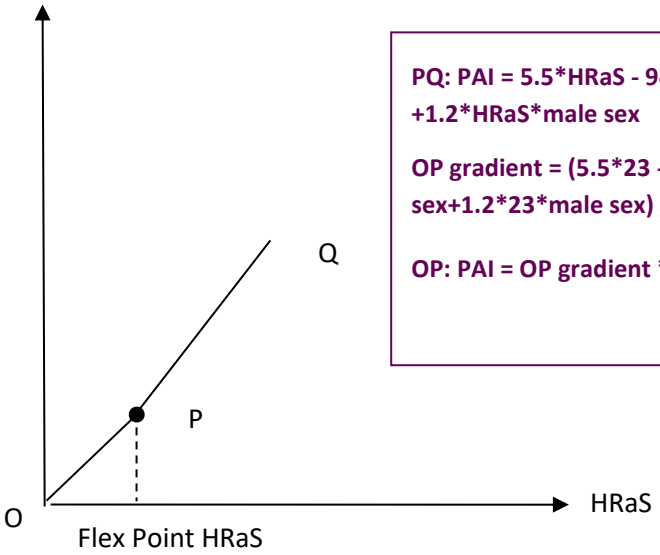
At the other end of the spectrum HR is a poor measure of intensity whereas movement registration is more reliable and this is reflected by a relatively low weighting of the HR-EE relationship i.e. P4 is low. Z is used to discriminate between raised HR due to some true activity in the presence of "no activity" (as set by X) and raised HR due to other factors. In boxes 2 and 3 movement and HR are equally weighted.

The HR-PAI relationship and the Activity–PAI relationships are given by the group calibration regression equations shown below for adults and children respectively. These have been derived by walking and running on a treadmill in studies conducted with the Actiheart (5) (6) (7) and are included in the Actiheart EE analysis.

The equations below the flex points are derived using the flex point itself and the regression line above it. The HR is not set to zero at the Flex point as is normal for the reasons mentioned previously.

The movement flex point is a relatively new concept (4) which serves to interpolate the intensity curve of activity in the region between rest (0, 0) and the slowest walking speed.
HRaS = Heart rate above sleeping heart rate

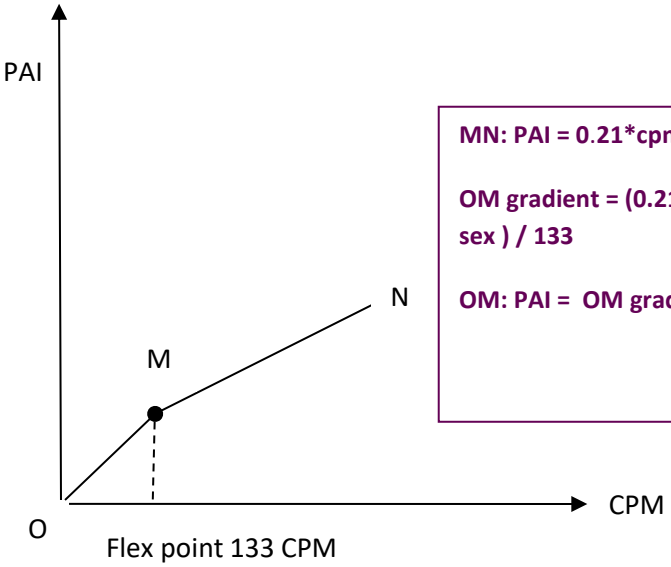
ADULTS Based on references (5) & (7)



PQ: PAI = 5.5*HRaS - 94 + 16*male sex +1.2*HRaS*male sex

OP gradient = (5.5*23 -94 + 16*male sex+1.2*23*male sex) / 23

OP: PAI = OP gradient * HRaS

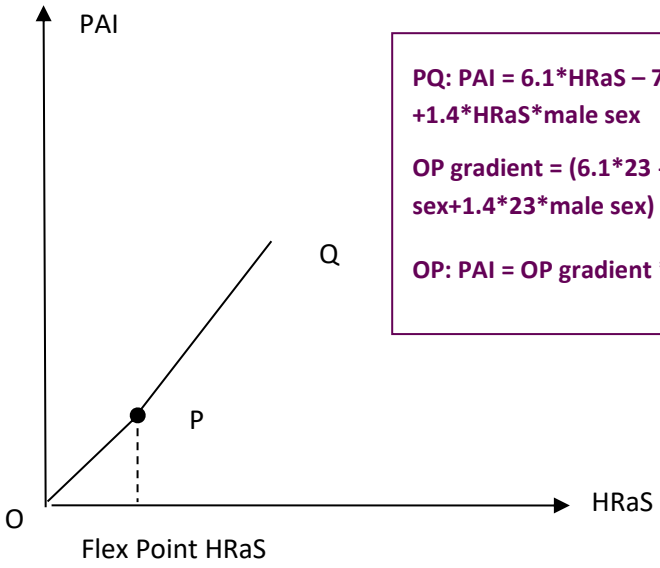


MN: PAI = 0.21*cpm +21+ 77* male sex

OM gradient = (0.21*133+21 +77*male sex) / 133

OM: PAI = OM gradient * cpm

CHILDREN Based on reference (6)

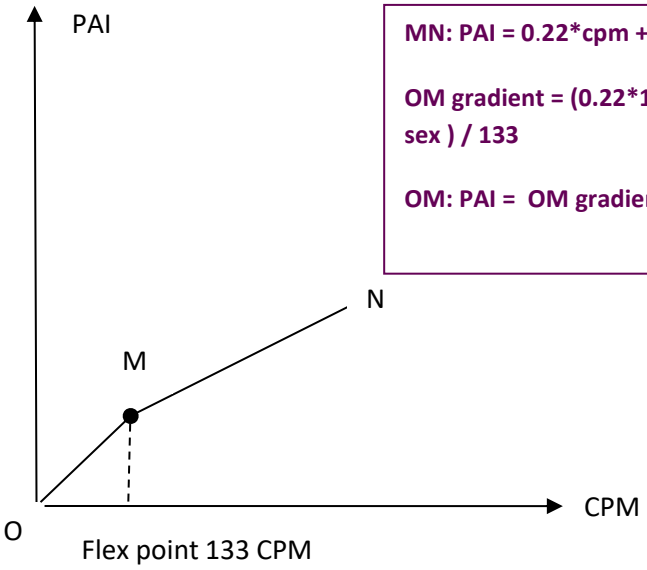


PQ: PAI = 6.1*HRaS – 73.1 - 20.7*male sex +1.4*HRaS*male sex

OP gradient = (6.1*23 -73.1 - 20.7*male sex+1.4*23*male sex) / 23

OP: PAI = OP gradient * HRaS

Above equation is based on that in (6) but modified for use with Sleeping HR instead of Resting HR.



MN: PAI = 0.22*cpm +144.3+ 29.3* male sex

OM gradient = (0.22*133+144.3 +29.3*male sex) / 133

OM: PAI = OM gradient * cpm

Default Parameter Values for the Branched Model.

The values below have been validated for walking and running and are believed to be reasonably valid for free living conditions. Formal validation of the values for the latter conditions is in progress. Therefore the values below are subject to minor changes as the branched model evolves and is validated for other activities.

1. **Flex HRaS**

   Flex HRaS is defined as the average above sleep of the highest HR during rest and the lowest HR during incremental exercise during the treadmill test. In (5) RHRaS at is 10 BPM and the HRaS at 3.2 kph is 36 BPM. Thus the Flex HR is set to 23.6bpm.

2. **Transition HRaS**

   This is the average between the highest walking and slowest jogging HRaS. See (5) i.e. 80.4 BPM.

3. **X value**

   Since cycling intensity is best quantified by HR (when using walking/running calibration equations), the value of X is chosen so that observations end up in one of the two top boxes (1 or 2). So a value of X has been chosen which is exceeded in cycling but at the same time is high enough to ensure that “no movement” (including noise) will be quantified by the two lower boxes (P3 or P4).

4. **Y value**

   This is set to TransHRaS

5. **Z value**

   A value equal to FlexHRaS has been chosen as a starting point. However Z is independent of FlexHRaS need not be equal to FlexHRaS.

a. **P1 value**

   0.9

b. **P2 value**

   0.5

c. **P3 value**

   0.5

d. **P4 value.**

   0.1

Activity Only or Heart Rate Only Mode

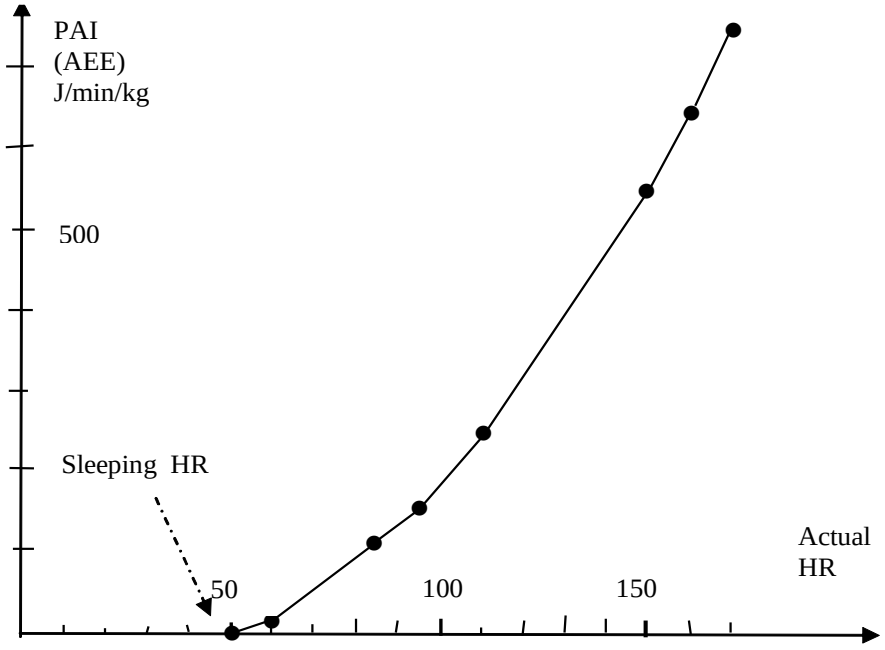
This is a special case of the Branched Model where EE is estimated using either the Activity data or the HR data. In this case the regression equations relating only to Act (PAI-Act) or only to HR (PAI-HR) are used. The weighting (P1, P2, P3 and P4) for the various modes is as follows:

	P1	P2	P3	P4
Act	0	0	0	**0**
HR	1(100%)	1	1	**1**
Act + HR	**0.9**	**0.5**	**0.5**	**0.1**

NB: HR only mode is useful for any activity, not just walking and running, where the intensity is such that the HR is above the Flex HR

Individual Calibration

Group calibration is an approximation for a range of individual fitness levels. Heart Rate above sleep HRaS based on individual sleeping HR is used to reduce error but individual calibration is more accurate. Individual calibration equations may be used in the Actiheart instead of the default group calibration ones. The user may derive these values in the usual way by means of a treadmill test as described previously. A typical calibration curve is shown below.



For convenience the AH includes a built-in step–test protocol which can be used for deriving the individual HR-PAI relationship in the field. The Step Test also provides an estimate of VO2 max. Please see ***Appendix 4*** for more information about the Step Test.

Customising the Equations and the Model

All of the calibration equations and the discriminants and the weighting factors of the Branched Model are held in a database and can be altered by a user. For a description of how to do this please refer to ***Chapter 1*** of this manual.

Branched Model Adjustment in the Presence of Recovered Data

Normally in the branched model the contribution to energy expenditure from activity and heart rate is weighted epoch by epoch according to certain activity and HR thresholds. However since the recovered HR data is obviously less reliable than bona fide recorded data, it may be desirable to override the branched model default weighting factors with another factor which reduces the HR contribution. A “Recovered” factor of 25 means that wherever there is “recovered” data a 25/75 weighting will be applied to the HR/Act respectively in preference to the default weighting for that epoch.

The Recovery factor must be set in the Settings database to a value between zero and 100. If no value is entered in the database the program will set a default value of 25.

Example

In an epoch which falls into Branch 1 the HR would normally be weighted by 90% and the Activity by 10%. However if the HR data within the epoch is “Recovered” data and the “Recovered” factor is set to 15 then the HR within that epoch will be weighted by 15% and the activity by 85%.

Branched Model Adjustment in the Presence of Stress

This allows the normal HR data weighting to be reduced where there is a raised HR in the absence of sufficient activity. This compensation works in a similar way to the Recovery factor. Again this stress factor overrides the default weighting. The following criterion is used for deciding whether the raised HR in an epoch is likely to be due to stress. If the activity in the previous three minutes of activity is < 25 counts per minute then the stress correction factor is applied. 25 is equal to the value of X in the Branched Model.

If an epoch where stress is detected has recovered data which has had a Recovery Factor applied to it then the stress factor will override the recovery factor.

The stress factor is set in the Settings database. If the box is left empty then the stress compensation is disabled.

Example

In an epoch with good HR data which falls into Branch 1 the HR would normally be weighted by 90% and the Activity by 10%. However if the stress factor is set to 0.1 then the HR /Act weighting which is applied will be 10%/90%.

In an epoch with recovered data which has a Recovery factor of 25 applied to it the HR would be weighted by 25% and the Activity by 75%. However if that epoch is identified as a “stress” epoch and the stress factor is .2 then the weighting applied to HR/Activity will be 20% / 80%

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2. ***Strath SJ, Bassett DR, Jr., Swartz AM and Thompson DL****. Simultaneous heart rate-motion sensor technique to estimate energy expenditure. Med Sci Sports Exerc 33: 2118-2123, 2001.*
3. ***Strath SJ, Bassett DR, Jr., Thompson DL and Swartz AM****. Validity of the simultaneous heart rate-motion sensor technique for measuring energy expenditure. Med Sci Sports Exerc 34: 888-894, 2002.*
4. ***Søren Brage, Niels Brage, Paul W. Franks, Ulf Ekelund, Man-Yu Wong, Lars Bo Andersen, Karsten Froberg, & Nicholas J. Wareham*** *Branched equation modelling of simultaneous accelerometry and heart rate monitoring improves estimate of directly measured physical activity energy expenditure. J Appl Physiol 96: 343–351, 2004.First published September 12, 2003; 10.1152/japplphysiol.00703.2003.*
5. ***Søren Brage, Niels Brage, Paul Franks, Ulf Ekelund, Nicholas J Wareham Karsten Froburg*** *Cross Validation of Intensity Prediction equations for treadmill walking and running . The combined heart rate and motion sensor , Actiheart Institute of Public Health, University of Cambridge, UK, and 2 Institute of Sport Science & Clinical Biomechanics, University of Southern Denmark, Odense, DK****.*** *Poster.*
6. ***Kirsten Corder, Søren Brage, Nicholas J Wareham, Ulf Ekelund*** *Comparison of PAEE from Combined and Separate Heart Rate and Movement Models in Children, American College of Sports Medicine 2005, pp 1761-1767*
7. ***Søren Brage, Niels Brage, Paul Franks, Ulf Ekelund, Nicholas J Wareham*** *Reliability and validity of the combined heart rate and movement sensor Actiheart Institute of Public Health, University of Cambridge, UK, and 2 Institute of Sport Science & Clinical Biomechanics, University of Southern Denmark, Odense, DK****. European Journal of Clinical Nutrition 2005***
8. ***Søren Brage, Ulf Ekelund, Niels Brage, Mark A Hennings, Karsten Froberg, Paul W Franks, Nicholas J Wareham*** *Hierarchy of individual calibration levels for heart rate and accelerometry to measure physical activity. Journal of Applied Physiology 103: 682-692, 2007.*

Appendix 3: The Schofield Equations

Schofield Equations

Children and Adolescents

Age	Male	Female
<3	0.167W+1517.4H-617.6	**16.252W+1023.2H-413.5**
3-10	19.59W+130.3H+414.9	**16.969W+161.8H+371.2**
10-18	**16.25W+137.2H+515.5**	**8.36W+465H+200**

Wt = Kg; H = metres; RMR = kcal/day

Adults

Age	Male	Female
18-30	(0.063 x wt) + 2.896	**(0.062 x wt) + 2.036**
30-60	(0.048 x wt) + 3.653	**(0.034 x wt) + 3.538**
Over 60	**(0.049 x wt) + 2.459**	**(0.038 x wt) + 2.755**

Wt = Kg; RMR = MJ/day. To convert to kcal multiply by 238.846

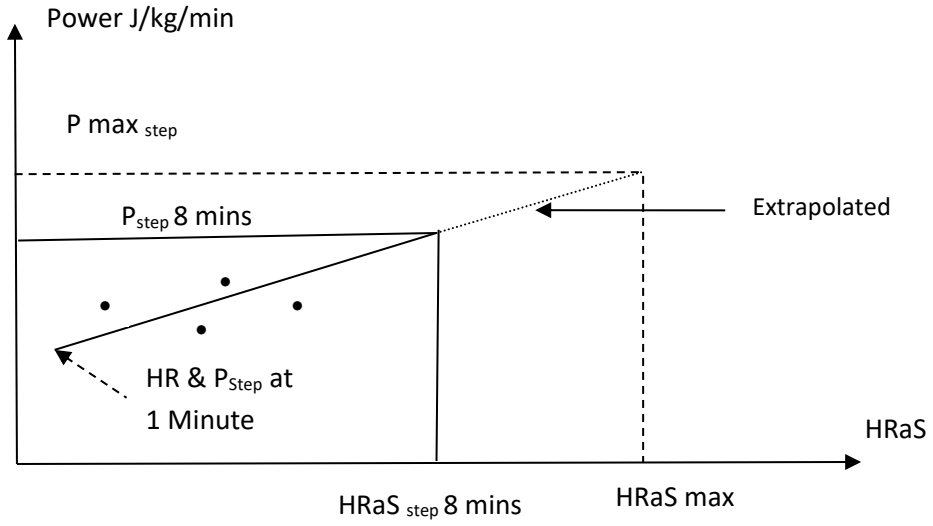
Appendix 4: The Step Test Calculations

HR Calibration

The built –in step can be used to derive an individual HR calibration equation without needing access to a laboratory and an oxygen analyser. Derivation of the Physical Activity Intensity (PAI) – HR calibration equation is a 4-step process.

1. The recovery HR τ is measured
2. The power P_{step} generated during stepping in Joules/min/kg is calculated as follows:

   Joules/kg/min = Vertical distance (m) x steps /min
3. P_{step} and HR_{step} values are plotted and a straight line is fitted to the data



Slope = β_HRaS $_{step}$ J/kg/beat

Intercept = α_HRaS $_{step}$ J/min/Kg

4. PAI vs HRaS is then established a function of HRaS, τ , β_HRaS step, α_HRaS step:

PAI = 2.9·HRaS + 1.1·HRaS·male sex + 2.9·HRaS·βstep + 1.3·αstep - 10·male sex + zero* τ + zero* τ ·HRaS + zero *age + zero *height -75 + zero* BMI

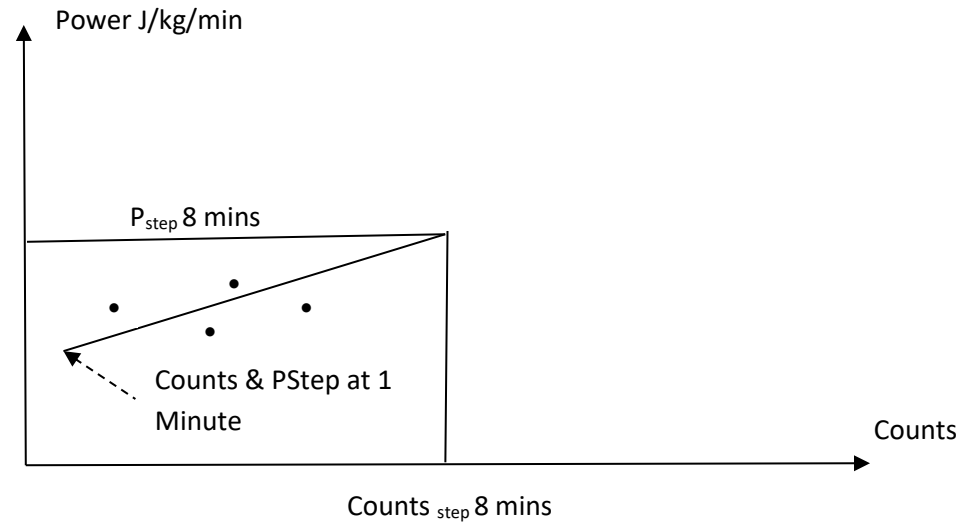
This equation is valid for adults and is referred to in ***Reference No. 7 in Appendix 2***. There 'zero' multiplier terms in the equation are not being used, so mean literally zero. They were inserted into the software for future flexibility if those parameters are found to increase accuracy, but are not currently used.

The resulting PAI - HR line thus obtained for an individual is then extrapolated to the assumed HR max for the person's age. The predicted VO_2 max in ml /kg /min is then equal to PAI max in J /kg.min divided by 20.35 J /ml O2.

HRaSmax =HRmax-SHR. The maximum HR for an individual is predicted from age (HR max =208-0.7*age) and is based on a meta-analysis done by Tanaka et al:* *Tanaka H, Monahan KD, Seals DR. Age-predicted maximal heart rate revisited. J `Am.Coll.Cardiol. 2001; 37(1):153-56.

If individual calibration is based not on Step Test data but on measured HR and VO2 data e.g. in a laboratory the external data can be imported into the Actiheart analysis software.

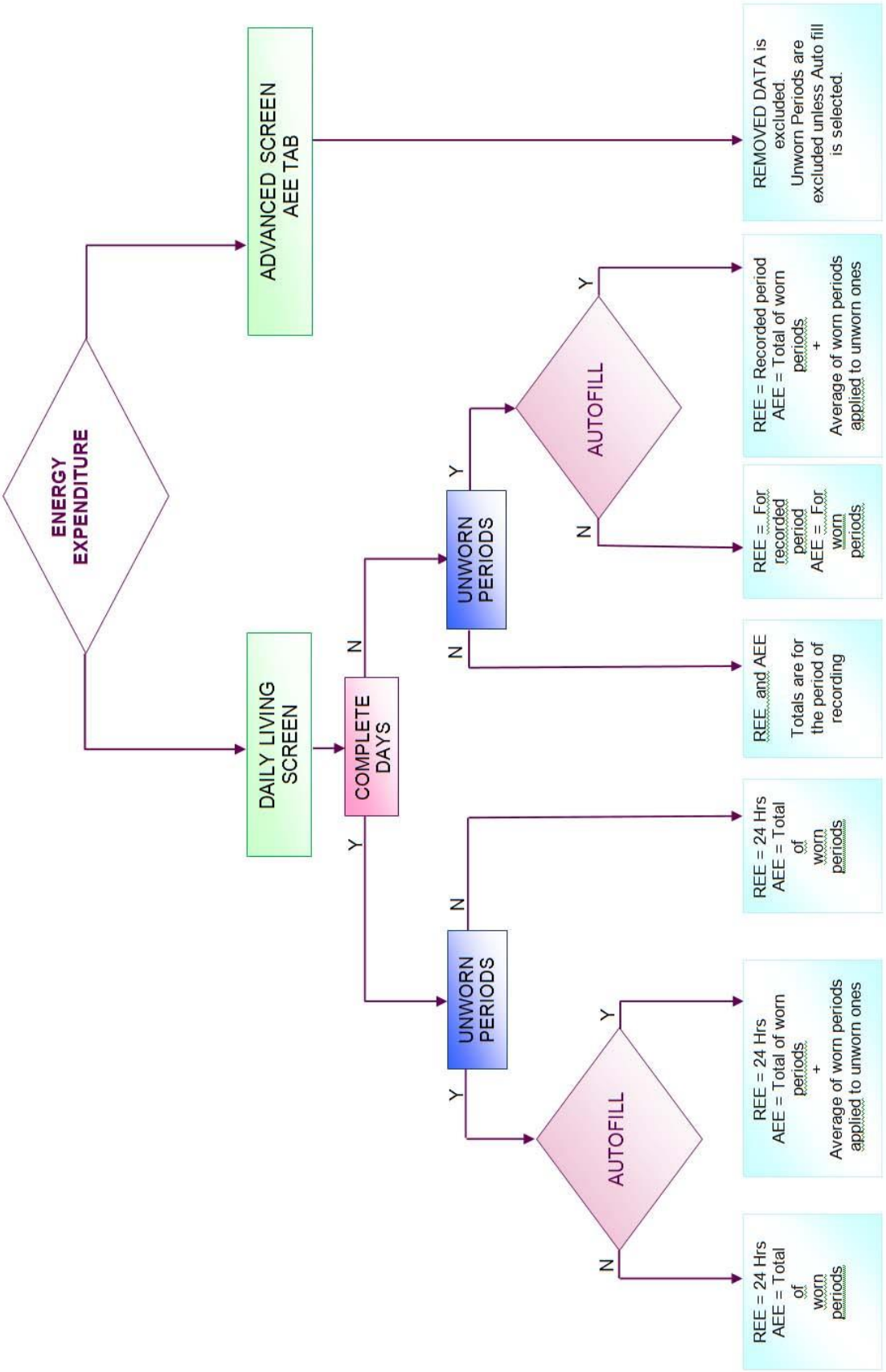
Activity Calibration



Slope = β_Count $_{step}$ J/kg/count

Intercept = α_Count $_{step}$ J/min/Kg

Appendix 5: Calculation of Energy Expenditure



Appendix 6: Validation Posters

The following posters are available from CamNtech, and may be found on the software CD:

Søren Brage[1], Niels Brage [2], Paul Franks [1], Ulf Ekelund [1], Nicholas J Wareham [1] Karsten **Froburg[2]** Cross Validation of Intensity Prediction equations for treadmill walking and running. The combined heart rate and motion sensor , Actiheart Institute of Public Health, University of Cambridge, UK, and 2 Institute of Sport Science & Clinical Biomechanics, University of Southern Denmark, Odense, DK**.**

Kirsten Corder[1], Ulf Ekelund [1], Søren Brage[1,] Nicholas J Wareham [1] Cross Validation of Intensity Prediction equations for treadmill walking and running. The combined heart rate and motion sensor, Actiheart Medical Research Council Epidemiology Unit Cambridge UK

Appendix 7: Glossary of Data Export Terms

This is a list of terms used in the Actiheart software and the data exports from it, to clarify the meaning of those items.

Activity

An empirical measure of the amount of movement within an epoch, in 'counts' per unit of time.

AEE

Activity Energy Expenditure, the portion of energy expended which is above resting and related to some additional activity.

BMI

Body Mass Index, the weight of a person (in kilograms) divided by the square of their height (in metres). This is used as a standardised measure of weight which is compensated for the individuals height.

BPM

The heart rate during a period of time in Beats Per Minute.

Branch

The branch of the model used to weight between activity and heart rate for calculating energy expenditure. For more details see Appendix 2.

Cal factor

The calibration factor recorded for an Actiheart accelerometer. Each Actiheart is calibrated during manufacture and the scale level recorded to scale each recording from it correctly.

DIT

Diet Induced Thermogenesis is a portion of energy expenditure which is used as part of the process of digesting food or making use of the energy produced. It is in principle related to the food consumed but is often estimated as it is difficult to measure and unlikely to change suddenly for an individual.

ECG

Refers to the ElectroCardioGraph, a representation of the electrical signal detected on the chest electrodes. Actiheart exports with this column header refer to the magnitude of the electrical signal. This is an approximate measure of the size of the peak in microVolts, but is not directly calibrated.

Epoch

Short and Long term recordings are divided into "epochs", fixed periods of 15 to 60 seconds which are summarised by a heart rate and activity level.

HF

The component of the heart rate variability in the High Frequency band. See VLF for the definitive reference.

HRMax

Maximum heart rate of a user. This may be measured and input directly for the user, or estimated from their age at the time of a test.

IBI

The Inter-Beat-Interval, usually written in milliseconds, is the time between one heart beat and the following one. The sequence of these gives the exact timing of every heart beat rather than just the heart rate

LF

The component of the heart rate variability in the Low Frequency band. See VLF for the definitive reference.

LF/HF

The ratio between LF and HF heart rate variability. This is a normalised measure, sometimes described as indicating the balance between sympathetic and parasympathetic nervous system activity in the body.

Lost Secs

This is the total amount of time during an epoch that the Actiheart could not adequately count as beat interval and was instead effectively 'lost' for the purposes of measuring heart rate.

Max 1

The longest single IBI recorded during an epoch, in milliseconds.

Max 2

The second longest single IBI recorded during an epoch.

MET

Metabolic Equivalent of Task, a normalised measure of intensity, expressed as a multiple of resting metabolic rate. So a value of 1 is the minimum level at resting and higher values signify greater intensity calibrated for the individual's size.

Min 1

The shortest single IBI recorded during an epoch, in milliseconds.

Min 2

The second shortest single IBI recorded during an epoch.

PAL

Physical Activity Level is the total energy expenditure over a longer period (such as a day or more) divided by the resting metabolic rate. It is equivalent to the average MET value, but is of much lower typical values than MET during exercise due to the longer time averaging.

Quality

A measure of the reliability of IBIs recorded during a calculation epoch. This is not a standard measure, but allows an objective quantitative decision to be made about which data might be included in a study.

RMR

Resting Metabolic Rate. The energy which a person will use without performing any activity at all.

RMSSD

The root mean square of the successive differences of the IBIs.

Sleep HR

Sleeping heart rate, which can be measured from a recording using the tool in Long Term or Advanced Energy Expenditure. It is used to adjust real heart rate into a level above sleep to indicate likely intensity. It should be determined from a recording taken during sleep if accurate energy expenditure results are required.

SD

Standard deviation of a set of data. On heart rate variability statistics, this refers to the standard deviation of the set of IBIs.

Still HR

The average heart rate taken during all epochs where there was no movement.

TEE

The Total Energy Expenditure is the total of all components of energy expenditure. In the Actiheart system it is equal to AEE + RMR + DIT.

Time

The time at the start of a recording epoch. For example, an epoch labelled 9:30:00 is a 30 second recording will be that running from 9:30:00 to just before 9:30:30.

Trimmed

A trimmed recording is one where the start or end has been marked out, usually because the Actiheart was not worn for these period and it is more convenient to show results excluding it.

VLF

The component of heart rate variability contained in a Very Low Frequency band. This is defined within 'Heart Rate Variability, Standards of Measurement, Physiological Interpretation, and Clinical Use.' Task Force of the European

Society of Cardiology and the North American Society of Pacing and Electrophysiology.

VO2 Max

The maximum oxygen consumption rate of an individual. This is a measure of power output that is estimated by the Actiheart system from a step test, but not a core aim of that test. It is not used for the calculation of energy expenditure in daily living.

Document Revision History

Issue From	Issue To	Date	Description	Initiator
4.0.109	4.0.116	25/02/16	Added EDF import details	HS
4.0.116	4.0.116b	21/03/16	Added Glossary of Export Data terms Appendix 7	TE
4.0.116b	4.0.116c	03/08/16	Update description of data cleaning process	TE
4.0.116c	4.0.116d	02/11/16	Added rev history table	HS
4.0.116d	4.0.129	12/01/17	EU change of device classification from Class 2a to 'non-medical'	HS
4.0.129	5.0.6	18/12/18	Updated screenshots and various detailed points for Actiheart 5	TE
5.0.6	5.0.6a	22/02/19	Updated to add EM information to section 6, minor layout corrections	HS
5.0.6a	5.0.28	01/12/19	Addition of Live Display notes for Step Test and Waveform setup, and flat battery guidance.	TE
5.0.28	5.0.29	31/12/19	Updated CamNtech address, corrected document ref	HS
5.0.29	5.1.11	24/02/20	Updated predicted recording lengths and description after testing of two-week recordings.	TE
5.1.11	5.1.14	04/06/20	Sleep Analysis chapter	TE
5.1.14	5.1.18	08/10/20	Updates to IBI Analysis	TE
5.1.18	5.1.24	02/11/21	Removed mentions of Actiheart 4 and Cardio, to simplify documentation and because the products are no longer in active support period.	TE
5.1.24	5.1.31	30/6/22	Include instructions to access sleep analysis from initial setup.	TE