Vet BIS1
Instructions For Use

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Contents

Notes on Safety

The warning signs and the symbols below are listed in order for you to use this product safely and correctly as well as to prevent risk and injury to you and others.

The meanings of the signs are as follows:

⚠ **Danger**	Indicates matters in which an imminent risk of death or serious injury may arise as a result of incorrect handling.
⚠ **Warning**	Indicates matters in which the possibility of death or serious injury may arise as a result of incorrect handling.
⚠ **Caution**	Indicates matters in which bodily harm or material damage or incorrect measurements may arise as a result of incorrect handling.
🚫	A prohibition - indicates what you should not do.
!	This indicates something that must be followed.

⚠ **Danger**

Only use the power adaptor (Amtex 9940) that is supplied with this device. The use of any other power adaptor may expose the patient to the risk of electrocution.

⚠ **Caution**

Do not use or operate the device in the presence of strong electromagnetic fields

This Device may interfere with other Devices in its vicinity

! Run a calibration check with the test cell prior to using on a patient

Contact ImpediMed or authorised distributor or local government regulators before disposing the device

🚫 There are no user adjustable parts in the device, do not disassemble unit

This device meets standard IEC60601-1-2.

Description of Features

Bioimpedance analysers offer rapid, non-invasive, inexpensive determination of body composition by measuring fat-free mass, fat mass, intra and extra cellular fluid. The instruments also enable long-term patient monitoring and provide reports to support clinical and research practices.

The VET BIS1 is a portable battery powered device. It takes 6 hours to charge the fully depleted battery, with 4 to 8 hours of operating time before recharging is needed.

Note Vet BIS1 is supplied with fully depleted battery. It should be charged for 6 to 8 hours before using the device.

The device has a tetra-polar set of leads, which are attached to needles by means of alligator clips.

The VET BIS1 operates in Bioimpedance Spectroscopy (BIS) mode.

Caution

Vet BIS1 is designed to be used on battery during the measurement process. This process combined with the advanced noise reduction engineering will ensure the high precision in each measurement by reducing the background noise. Running the device from the mains during the measurement process can cause noise in the measurements. The Vet BIS1 should be unplugged from the recharging unit before use to avoid this possible noise contamination of the measurement.

BIS Mode (Bioimpedance Spectroscopy)

BIS mode measures bioimpedance parameters over a frequency range of 4 - 1000 kHz with 256 data points defining the BIS mode as a true bioimpedance spectroscopy. On-screen graphs display the measured data in the form of a Cole-Cole plot, resistance vs frequency and reactance vs frequency. In addition the characteristic frequency for the subject is determined as well as total cell membrane capacitance. These estimates are then used in algorithms to give body water and fat free mass.

The VET BIS1 will store more than 1000 data records which can be analysed on the device or downloaded via an Ethernet connection to the supplied BioImp Vet BIS software running on a Windows PC.

Caution

Please read all these instructions completely before use.

User Information

Intended Use

The ImpediMed Vet BIS1 is a bioimpedance device, intended to be operated by users who have read this manual, for use on animal patients only for the purpose of Body Composition Analysis.

Components of the Vet BIS1 System

ImpediMed Vet BIS1 is supplied with following accessories

- Needles 25g x 25mm (1)
- Lead set (2)
- Four alligator clips (3)
- Test cell for calibration check (4)
- Power module for recharging the battery (5)
- Mains power Cable (Region specific) (6)
- Crossover network cable (7)
- Carry case*
- CD-ROM containing (8):

Disk 1:   Vet BIS1 - Instructions for Use

BioImp Vet Body Composition Analysis Software

BioImp Vet Body Composition Analysis Software Instructions For Use

Network Setup Guide

- Stylus pen(9)

- Microfibre cloth (10)
- Notepad*
- Warranty card*
- Ethernet network adaptor*

* Not shown in above photograph

Main Display and Control Functions

Front Panel

Vet BIS1 front panel has a On / Off button, measure button and touch screen. Always use the ImpediMed supplied rubber end of stylus pen to operate the touch screen.
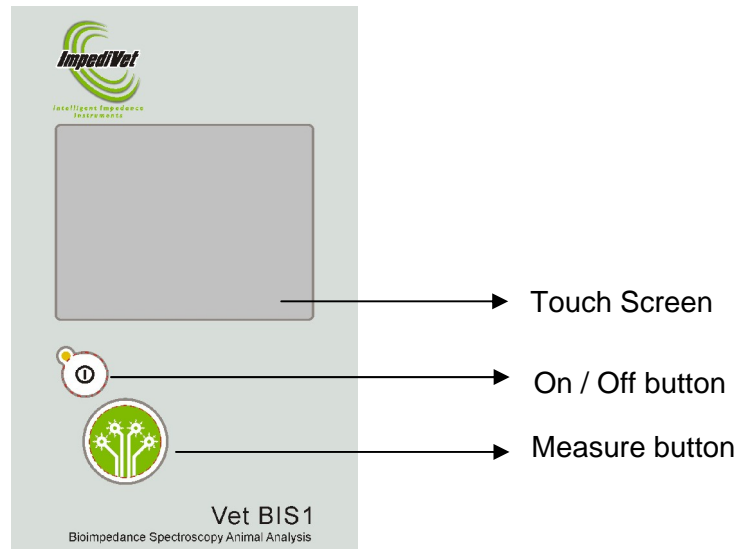
⚠ **Caution**

Do not use any sharp or metal objects to operate the touch screen. Use the stylus end (rubber tip) of the ImpediMed supplied pen. Avoid excessive force as this may damage the screen.

Start-up Screen

Turn the unit on by pressing the On/Off button on the front panel of the unit. After a couple of seconds, the unit will display the ImpediMed logo. The unit will then undertake several self-diagnostic tests before displaying the opening screen, as shown below:
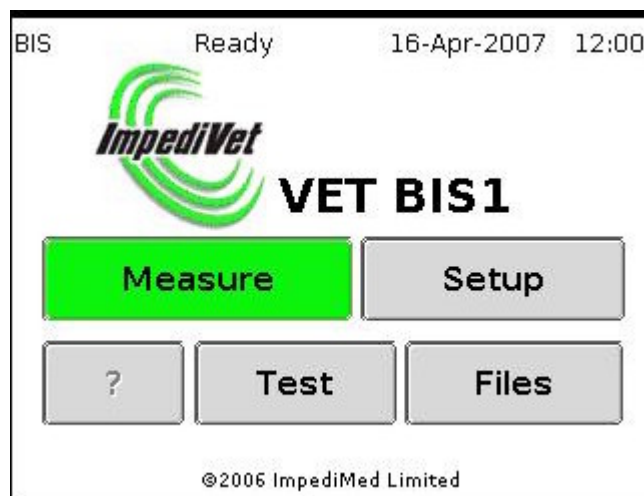
The Vet BIS1 will automatically switch OFF if there is no activity for five minutes.

Measure

Touching the "Measure" button brings up the loaded module's "Measurement Setup" screen, as described in the appropriate module section of this manual.

⚠ **Caution**
> Before use, check the battery status on the display. If the battery level is low, the red LED on the device flashes and device turns off, preventing from taking the measurements.

Setup

Touching the "Setup" button brings up the "System Setup" screen, as described in the "Setup" section.

Files

When the BIS module is loaded, touching the "Files" button will provide access to the list of saved measurement files on the device. From this list, measurement files can be viewed and/or deleted as described in the BIS Measurement Data Files section.

Help

Help is available on most screens by touching the "?" button.

Status Bar

The status bar is displayed at the top of the screen in all menu screens.

| BIS | Ready | 16-Apr-2007 | 12:07 |

Loaded Module Indicator

The text on the left side of the status bar shows the operating mode of the device as being: BIS (Bioimpedance Spectroscopy).

Status Indicator

Next to the loaded module indicator is a status indicator. In most cases, this will display "Ready", to indicate that the device is ready to receive commands. This status indicator will change while the device is busy or waiting.

Date and Time

Next to the status indicator is the current date and time. The date and time can be set in the device screen.

Keypad Screen
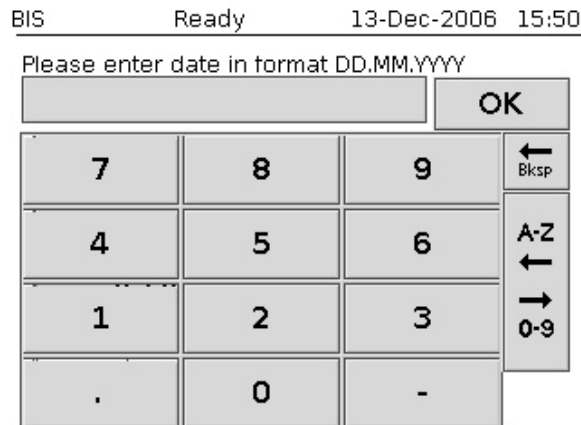
The keypad screen appears when text or numerical input is required. The Prompt will indicate what information is required. Touch the keys to type in the "Entered text" edit box. Touch the "OK" button to save the entered text.

Note   Touch "0-9" toggle button to access and use numerical inputs, and touch "A-Z" toggle button to access and use alphabets for text entry.

Setup

Touching the "Setup" button on the opening screen opens the "System Setup" screen as shown below:
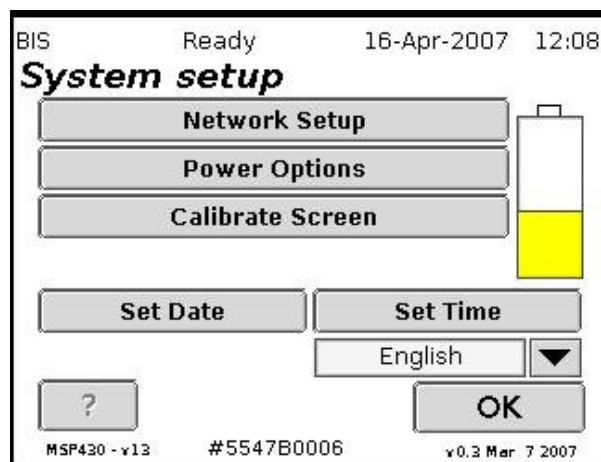
Setting date and time

The date and time should be factory set and displayed at the top of the LCD display. If, however, they are incorrect they can be selected by touching the "Set date" or "Set time" buttons. A keypad, as described above, will be displayed and the date or time can be edited, as instructed on the screen. Please note that a "full stop" must separate day, month and year, or hours, minutes and seconds.

Network Setup

The addresses used for intranet data communication can be set by touching the "Network setup" button, which opens the following screen:

**Note**   See Network Setup Guide supplied with the device for detailed information

The device can be setup to have it obtain an IP address from a DHCP server on the connected network or default to the IP for the supplied Ethernet to USB adapter. Touch the "OK" button to save the selections and return to the system setup screen.

Note   Before connecting the device to a network please contact your network administrator

Power Options

Depending on the user requirements, battery power saving options "Idle Shutdown" and "Screen saver" can be set on this.
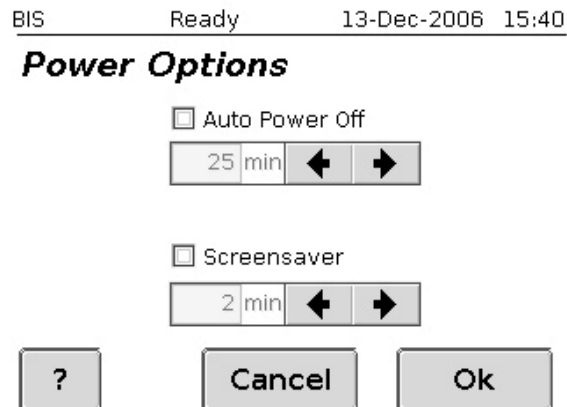
By enabling and setting the "Idle Shutdown" time, the device will automatically shut itself down if no actions are performed on the device in the set time limit. By enabling and setting the "Screen saver" time, the device displays a screen saver if no actions are performed on the device in the set time limit.

Calibrate touch screen

The touch screen can be recalibrated by touching the "Calibrate screen" button and following instructions. Once the calibration is complete, press the "OK" button on the calibration confirmation screen before the timer times out.
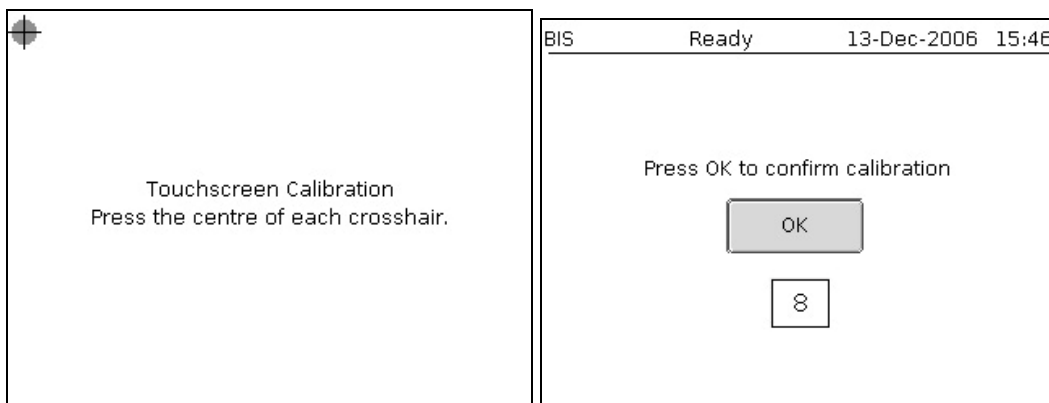
If a mistake is made while calibrating, continue to follow instructions and then allow the device to timeout before repeating the calibration.

Battery Status Indicator

The LED indicator on the Vet BIS1 indicates the status of the internally installed rechargeable Lithium-ion. The colour of the LED behaviour is defined as below:

LED Colour	LED behaviour	Description
None	Off	- Unit is turned off - No external power is present
Green	Off, flicking on at 1 second intervals.	- Unit is turned off - External power is present - Batteries are charging
Green	On	- Unit is operational - External power is present - Batteries are fully charged
Green	On, flicking off at 1 second intervals.	- Unit is operational - External Power is present - Batteries are charging.
Green	1 second on, 1 second off	- Unit is operational - No external power is present - Unit is running off batteries
Orange	On	- Unit is operational - Batteries are near flat
Red	Off, flicking on at 1 second intervals.	- Unit is operational - Batteries are flat - Unit will shut down after four seconds.
Red	Off, flicking on twice at 1 second intervals	- Battery Charger Fault
Red, Orange	Off, flicking on twice – once red, once orange – at 1 second intervals	- Battery Voltage Detection Fault

Note Vet BIS1 should be unplugged from the recharging unit before use to avoid possible noise contamination of the measurement

Note The colour of LED indicator on the power adaptor (Amtex 9940) indicates the level of current that the Vet BIS1 is drawing to recharge its built in battery. Red indicates higher current is being drawn because the internal battery is flat, yellow indicates moderate current is being used, and green indicates trickle current is being used to charge the battery.

Preparing For Measurements.

Animal preparation

Prior to analysis the animal should:

1. Be accurately measured, for height/length and weight.

2. Depending upon the species to be tested, it may be necessary to anesthetise the animal to ensure it is still for the time required to make the reading.

Placing the needles

1. Shave needle sites if necessary to gain good skin contact. Thoroughly clean the areas and allow to dry

2. Apply each needle to the skin, at one of the standard placement sites (an example is shown on page 17) so that the needle hub faces outward from the body

3. Position all four needles on the animal to be tested before connecting any alligator clips

Plug leads into the Device

The device includes four (blue, black, yellow, red) colour coded locking socket connectors designed to accept a single-lead patient cable on each connector.

Align the groove on the connector lead (female insert) to locking socket (male insert) head on the device

Groove on the connector lead

Locking socket head on the device
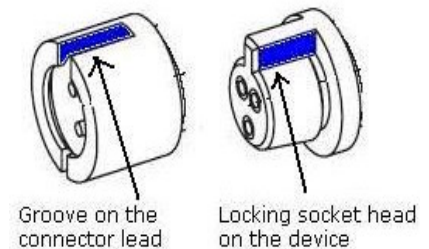
Press firmly to attach each colour coded lead plug to the similar colour locking socket on the Vet BIS1 one by one.

⚠ **Caution**

> Hold the locking socket plug on the connector lead firmly one at a time, and pull the lead off straight to avoid any damage to the leads

⚠ **Caution**

> Use only the cable leads supplied by ImpediMed Limited with the Vet BIS1. The use of non ImpediMed leads can cause damage to the device or give an incorrect reading.

! Apply lead wires according to the colour code shown above. Use an alligator clip to connect each lead to respective needles.

⚠ **Warning**

> Do not plug VET BIS1 leads to any mains power outlet/point.

The Vet BIS1 can be used for body composition analysis on a range of animals. Below is a description of a typical measurement setup for the species rat. For other species it will be necessary for the user to decide on and validate the appropriate needle placements.

The device is supplied with a packet of 25 gauge needles which can be used for most small animals. For best results it is recommended the needle be bent at 90^0 about 5mm from the end to create a "hook" which can be inserted under the skin of the animal to be measured. This ensures the needle does not pull out once the leads are attached.

Ensure that the metallic part of the clip is in direct contact the needle, and that the needles are not touching.

Yellow (Sense lead)

The **yellow** lead end is attached to the needle at the lower head section.
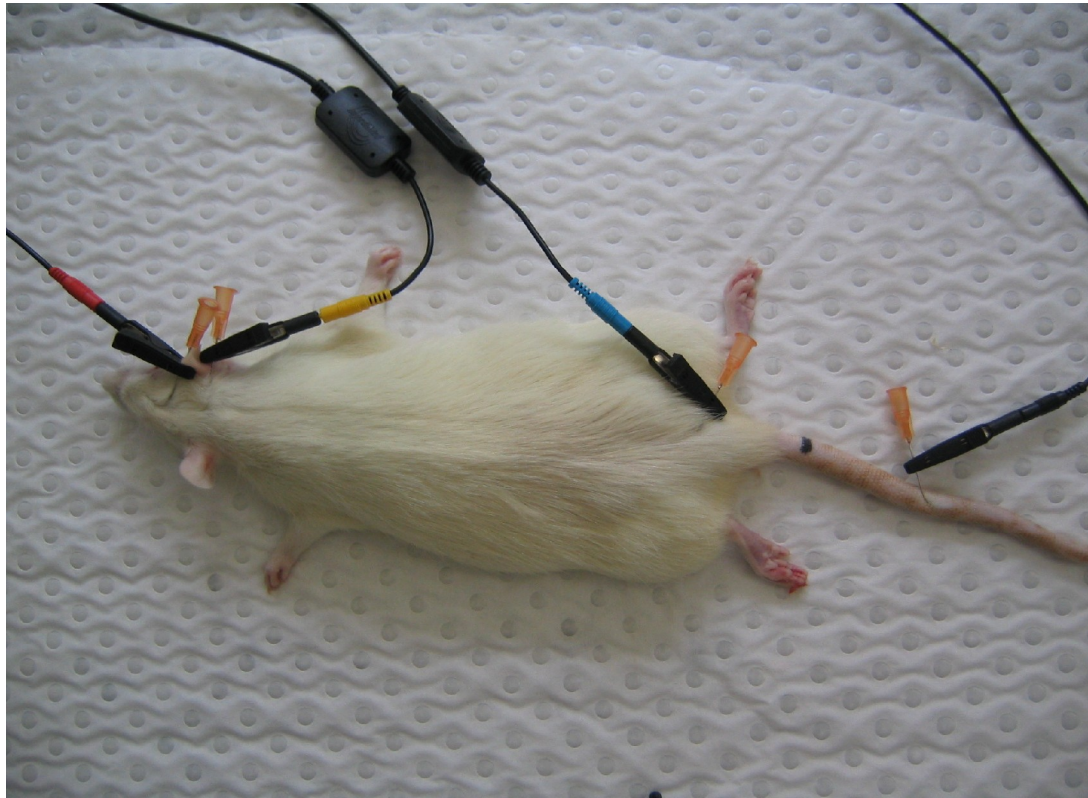
Red (Current source lead)

The **red** lead end is attached to the needle at the upper head section.

Blue (Sense lead)Blue

The **blue** lead end is attached to the needle at the base of the tail section.

Black (Current sink lead)

The **black** lead end is attached to the needle in the tail of the rat about half way along.

Typical final set-up ready for measurement (rat species shown)

Taking a Measurement in BIS Mode (Bioimpedance Spectroscopy).

Measurement setup

Touching the "Measure" on the opening screen opens the "Measurement Setup" screen as shown below:

File Name

Touching the "File Name" edit box brings up the keypad as described in the Start up Screen section.

A filename may be specified for saving the measurement data for later analysis. When measurement data is saved, an incrementing number is attached to the specified filename. If no filename is specified, measurement data will not be saved.

Animal Details

Touching the Animal Details "Edit…" button gives access to the BIS Animal Details screen, where the species dependant parameters required for the TBW calculations may be entered. .

Touching the arrow button next to the "Gender" selection box toggles the selection of gender. The current settings for Length, Weight and Age are displayed and can be changed by touching the "Edit" button. The next screen allows for entries/changes to "Length, Weight and Age to be made. The values can also be entered using the keypad (see Start up Screen section) that is selected by touching the appropriate edit box itself.

Note   Maximum length is either 250cm or 250m, maximum weight is either 250g or 250kg, and maximum age is either 110 weeks or 110 years.

The species can be edited by selecting either "New" to add a new species, "Edit" to change the parameters of an existing species, or Delete to remove a species.

Touch the "OK" button to return to the previous screen.

Additional information relating to the calculation of body composition parameters can be set up by touching the "BCA" button, which opens the following screen:

As with the previous screen, the values of each parameter can be selected by touching the arrow buttons adjacent to the parameter edit box or by using the keypad that is selected by touching the appropriate edit box itself. Touch the "OK" or "Cancel" button to return to the "Animal Details" screen.

Measurements setting (and interval & number of measurements)

Touching the arrow button next to the "Measurements" selection box allows the selection of single or continuous measurements, or several measurements made spaced at a selected interval of time. In continuous mode, another measurement is commenced immediately after the previous measurement has been completed. In interval mode, another sequential measurement is made after the interval of time selected (in seconds).

For Interval measurement setting, the interval between measurements can be selected by touching the arrow buttons next to the "Interval" edit box or by using the keypad (see Start up Screen section) that is selected by touching the "Interval" edit box.

For Interval and Continuous measurement settings, the number of measurements can be selected by touching the arrow buttons next to the "Number" edit box or by using the keypad (see Start up screen section) that is selected by touching the "Number" edit box.

! The "Number" and "Interval" edit box are greyed out and inaccessible when they are not applicable to the current "Measurements" setting.

Making a Measurement

Touch the "Measure" button on the Measurement Setup screen or press the large green button on the device front panel to enter the Begin Measurement screen (see BIS Patient Settings section immediately below).

Begin Measurement

Touching the "Measure" button on the opening screen, or pressing the large green button on the front panel of the device, opens the "Begin measurement" screen as shown below. The screen shows a summary of the measurement setup for confirmation.
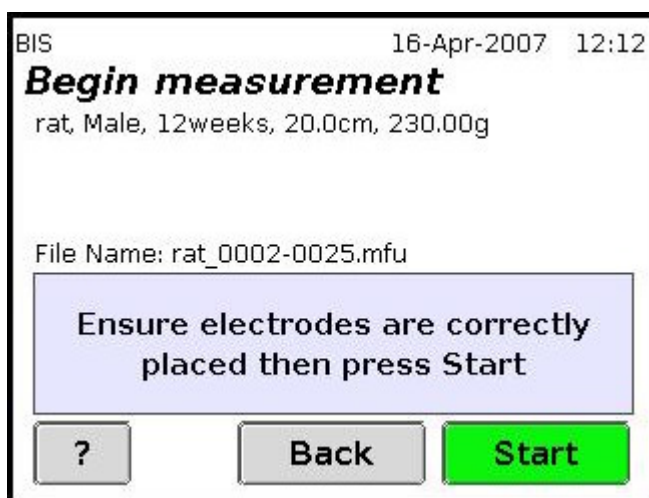
⚠ Caution

If the combination of the file name specified in the "Measurement setup" screen and the current increment number already exists in the device file memory, a warning message will appear in the "Begin measurement" screen: "One or more files already exist. Press start to overwrite". Touching the "Start" button overwrites the existing files with new measurement data and touching the "Back" button displays the "Measurement setup" page for editing the file name.

Note If the grey box in "Begin measurement" screen displays a message "Not Calibrated", please contact ImpediMed or an authorised agent for device calibration

Making a measurement

A measurement is made by touching the "Start" button on the "Begin measurement" screen, or by pressing the large green button on the front panel of the device when in the "Begin Measurement" screen. The device will take a measurement, and then bring up the Measurement Results screens as described in Measurement Results section immediately below.

Measurement Results

The first results screen displays the measurement analysis results
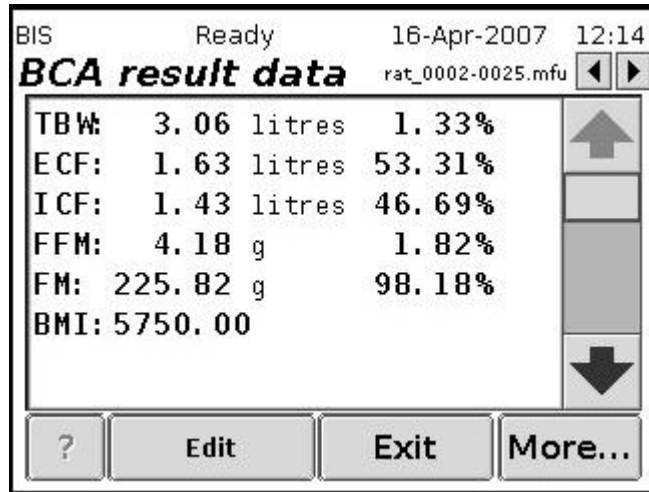
Touch the up and down arrow buttons or the scroll bar to show the full results. The animal settings may be modified, and the results recalculated, by touching the "Setup" button, which brings up the "Animal Details" screens, as described in "BIS animal settings" above.

! The file navigation arrows are greyed out and inaccessible. These are only accessible when viewing files from the file list

Touching the "More…" button will display a Cole-Cole plot (Reactance vs. Resistance).
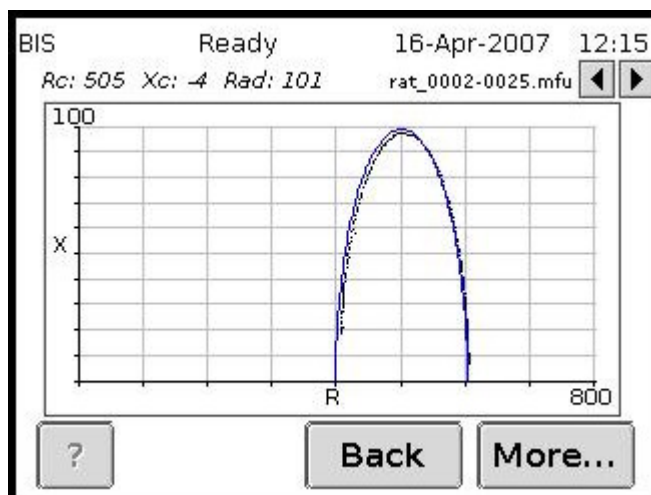
! The Cole-Cole plot gives a visual representation of the measurement and is used to indicate a valid measurement has been taken. The absence of scattered data points and well fit Cole-Cole plot signifies noise free data and that a valid measurement has been performed.

! The file navigation arrows are greyed out and inaccessible. These are only accessible when viewing files from the file list

Touching the "More…" button will display resistance and reactance plots as below:

! Resistance vs. frequency plot and reactance vs. frequency plots are visual representation of the measured bioimpedance data

! The file navigation arrows are greyed out and inaccessible. These are only accessible when viewing files from the file list

BIS Measurement Data Files
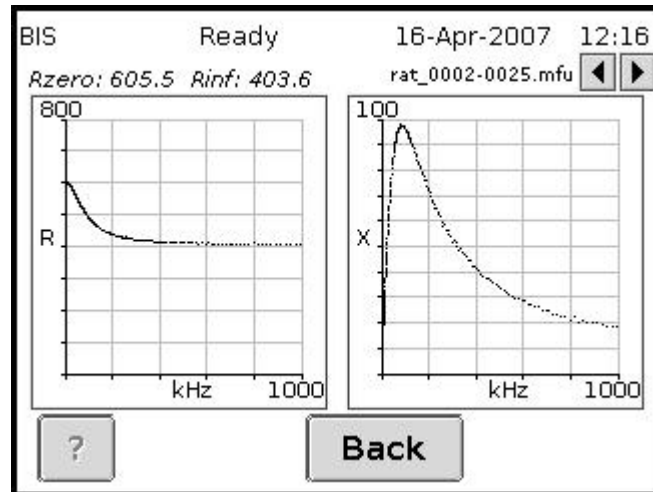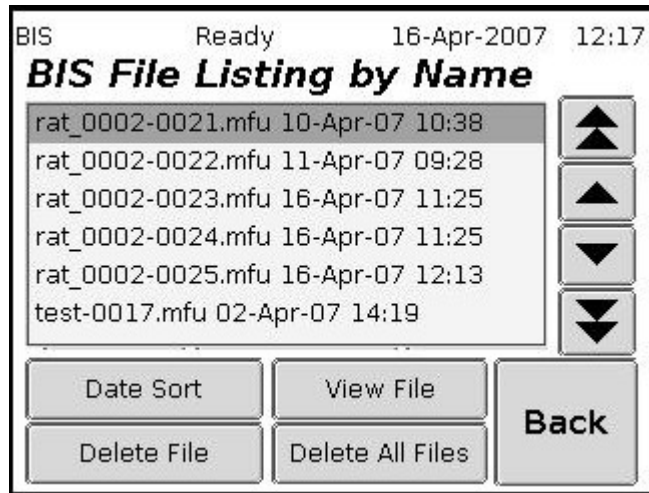
Stored files of previous BIS measurements can be deleted or viewed by touching the "Files" button on the opening screen when the BIS module is loaded. Touching the "Files" button opens the "File listing" screen, similar to that shown below:

Touching the "OK" button returns to the opening screen.

Navigating the file list

The arrow buttons navigate the file list. The single arrows moves the selection bar at a time, the double arrows move one page at a time. Keeping an arrow button touched will move through the list quickly. The selected file is shown with a darker background. A file can also be selected by touching the appropriate file detail line.

Sort stored files

The stored files can be sorted either by name or by date and time, by touching the lower left hand button titled either "Name sort" or "Date sort".

Viewing files

The selected file can be viewed by touching the "View File" button. This brings up the BCA result data screen. Touching the "More…" button will display a Cole-Cole plot (Reactance vs. Resistance). In addition, the file BCA result data screen and Cole-Cole plot screen allows the use of the file navigation tool, allowing the user to move through the file list from the result data screen and plot screen.

Deleting files

Select the desired file using the arrow buttons or by touching the device detail line (the selected file will be shown in reverse video). The selected file can be deleted by touching the "Delete File" button, at which time a confirmation message will be displayed, as below:

Confirm or cancel the action by touching the appropriate button.

 Caution

Use with caution. Deleted files cannot be retrieved

Deleting all files

The whole file list can be deleted by touching the "Delete All Files" button, at which time a confirmation message will be displayed, as below:

Confirm or cancel the action by touching the appropriate button.

⚠️ **Caution**

Use with caution. Deleted files cannot be retrieved.

File Storage

In BIS or Selected Frequencies mode, when the file storage memory on the device is full, the device stops taking measurements and displays the "File system full remove files to make space" screen.

In order to continue taking measurements, transfer the files on to a PC loaded with BioImp Vet Body Composition Analysis software or delete the files which are not required.

If the user tries to make measurements when the file system is full, it will show the error message in the grey box of "Begin measurement" screen that "No file space left! Remove old files", and the start button on the "Begin measurement" screen become grey preventing the user to make any measurements.

Data Transfer to Analysis Software

Ethernet

Follow the instructions in the BioImp Vet Analysis Software Instructions For Use to connect to the device and retrieve the stored BIS measurement data.

! If battery runs flat during data/file upload from the Vet BIS1 via an ethernet, the data/file will be saved on the device.

Note Uploaded files are automatically deleted from the Vet BIS1. Sophisticated file transfer ensures that each file is transferred, confirmed as received, before deletion.

Calibration Check Instructions

There are no user-adjustable parts in the VET BIS1. Calibration may, however, be checked for quality assurance purposes with the test cell provided. Remove clips and connect the leads to the test cell according to the colour-coding. After making a measurement, the following values should be displayed:

Ro: 604 ohms (± 7ohms)

Rinf: 403 ohms (± 5 ohms)

**!** If the readings are not within the specified limits, contact ImpediMed for recalibration of the unit

! For consistently accurate readings we recommend calibration checks be performed at the start of each day of use using the test cell.

Care and Maintenance

Self test lead function

The VET BIS1 is equipped with a function enabling the user to perform a quick test on the lead set prior to use. This allows the user to perform a degree of self diagnosis on the device to check the device is performing within specification. From the Main Screen press the "Test" button to bring up the screen below, then remove clips and connect the leads to the test cell according to the colour-coding. Select the BIS module on the device. Press the "Start" button to make a test reading.
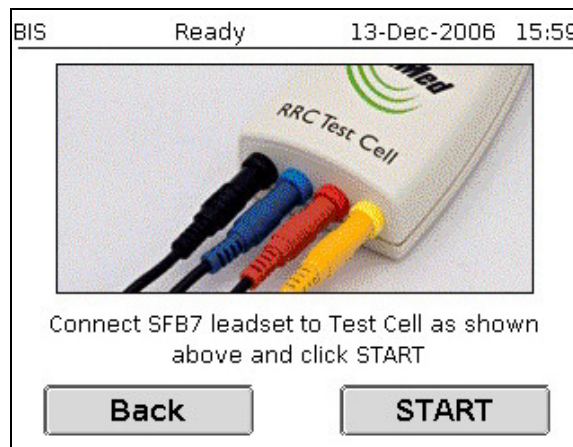
The VET BIS1 will make a reading while presenting a "Calculating" screen, after which the result of the test will be shown. A "Passed" screen signifies the leads are in a serviceable condition.
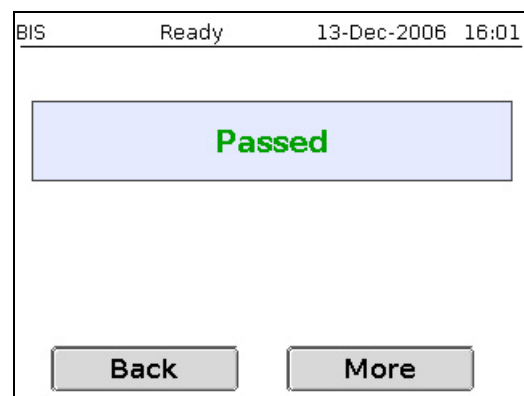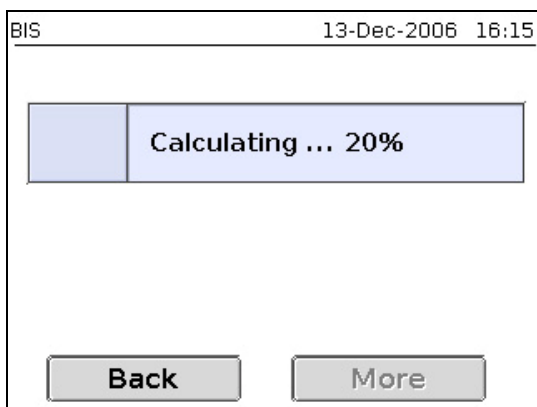
The Cole plot, reactance and resistance plots are also available by pressing the "More" button.
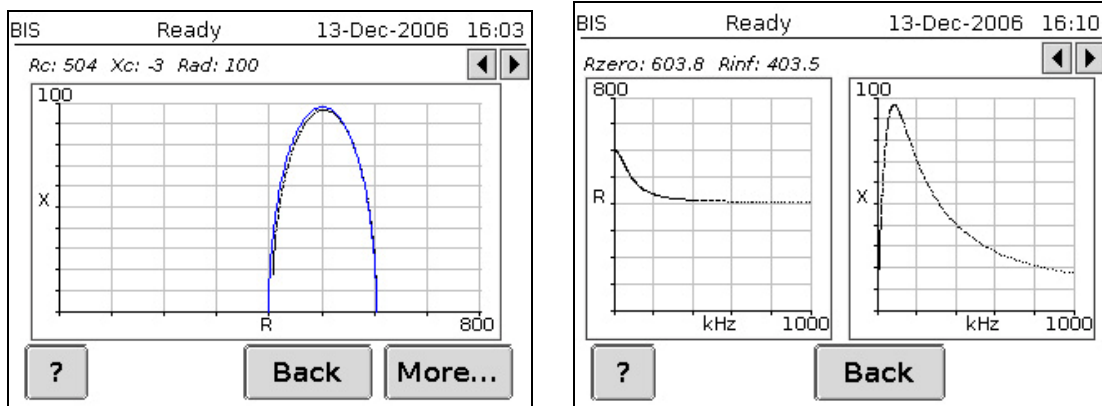
If the lead set fails the test, a "Failed" screen with a corresponding error code will be shown. In this case, contact ImpediMed, your distributor or an authorised service centre, quoting the error code, to arrange for service or repair of the leads and/or device.
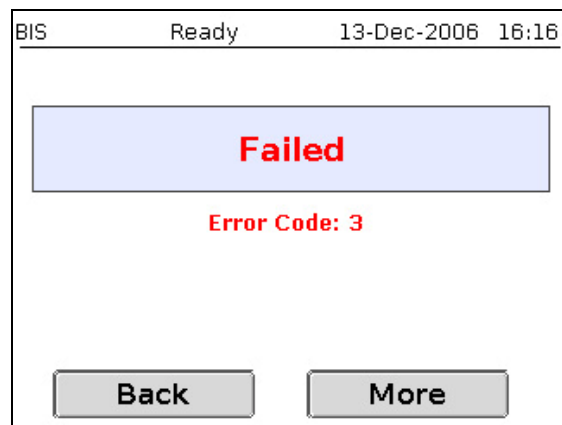
Care of the product

When not in use always keep the VET BIS1 in the carry case.

Clean the VET BIS1 with a dry, clean cloth only.

Avoid exposure to water, impact and excessive heat (direct exposure to sunlight).

⚠️ **Caution**

> Vet BIS1 should not be subjected to ingress of liquid or liquid spillage, impact and excessive heat (direct exposure to sunlight). This can cause damage to the device or harm to the patient or give an incorrect reading. Vet BIS1 should be used in a dry environment. Contact ImpediMed or an authorised agent for repair.

Care of the leads

Clean the leads with a damp cloth if required.

Wherever possible leads should remain connected to the device.

Unnecessary removal of the leads from the device may reduce lead life.

Ensure that the lid of the case does not close on the leads.

Do not wind the leads tightly, crinkle, or twist the leads, as this may cause the fine wires inside to break.

If the leads appear to be damaged, contact ImpediMed or a licensed distributor for replacements.

! Leads are consumables. So, handle them carefully.

Care of the Touch Screen

Always use the stylus pen provided to operate the touch screen.

Note The stylus included in the Vet BIS1 kit is a dual purpose stylus pen. Use the rubber end of the stylus pen to operate Vet BIS1 touch screen

If necessary clean the touch screen with a soft damp cloth, and do not use any liquids directly.

Do not use any sharp or metal objects to operate the touch screen. Use the stylus end (rubber tip) of the ImpediMed supplied pen. Avoid excessive force as this may damage the screen.

⚥ Fragile

Battery Replacement and Disposal

The batteries in the VET BIS1 are rechargeable Lithium Ion batteries and cannot be replaced by the user. Please contact ImpediMed for instructions on the replacement of these batteries by qualified technical personnel.

Repairs

There are no-user repairable electronic parts within the VET BIS1. Please contact ImpediMed or an authorised agent should service or repair of the Vet BIS1 be required.

Technical Support

Phone: + 61 7 3423 1777

Fax: + 61 7 3423 1496

Email: technicalsupport@impedimed.com

Accessories

The following accessories and consumables are available from ImpediMed.

Description	Part Number
Test cell	IU03SFB7
Lead set	IU04SFB7
Alligator Clips	IU0GALCP
CD-ROM containing BioImp Vet Analysis Software, BioImp Instructions For Use and the VET BIS1 Instructions For Use	IU05VET1

Troubleshooting

Problem	Possible cause	Solution
No display when VET BIS1 is switched ON.	• Battery power is low.	• Attach external power pack and try again.
	• No external power.	• If external power pack is attached, check that power pack is plugged in and switched on (light on power pack will be on).
The message "Out of Range Check Leads and Electrodes" is displayed on the screen. or The reading is obviously incorrect.	• The device is not correctly set up.	• Ensure the leads have been correctly fitted according to the colour coding (see section "Plug lead in to the device"). • Ensure the leads are inserted properly into the lead sockets. • Ensure the leads are not damaged or tangled. • Ensure the leads are properly inserted into the alligator clips. • Ensure the alligator clips are securely attached to the needles. • Ensure the needles are attached correctly to the animal. • Perform the calibration check (see section "Calibration Check Instructions") to determine if the device is faulty. • If performing the calibration check, ensure the colour coding is correct and the leads are pushed snugly into the test cell.

The device stops responding to touch screen commands.	• Internal software fault.	• Power the device off. Power the device on. • Report the fault to ImpediMed.
Power light is blinking. Or Power light is red. Or Power light is orange.	• Normal behaviour	• Refer to section "Battery Status Indicator".

Product Specifications

Drive AC current	1000μA RMS at a variable frequency of 4 kHz to1000 kHz.
Frequency Scan	Range: 4 to 1000 kHz (256 frequencies)
	Scan speed: <700ms
Battery Charging	13.8V DC, 2.3A
Impedance	10 to 1100Ω
	Resolution: 0.1Ω
	Accuracy: ±1.0% 50Ω to 1100Ω
	±5.0% <50Ω
Phase	Range: -90° to +90°, only positive phases displayed
	Resolution: 0.1°
	Accuracy: ±0.5° 50 to 1100Ω
	±0.5° <50Ω, <315kHz
	±5.0° <50Ω, 315 to 1000kHz
Dimensions	L=190mm, W=130mm, D=110mm
Weight	1 kg
Display	320x240 pixel ¼-VGA LCD display
Data displayed	Total body water (TBW), % Total body water
	Intracellular fluid (ICF), % Intracellular fluid
	Extracellular fluid (ECF), % Extracellular fluid
	Fat-free mass (FFM), % Fat-free mass,
	Fat mass (FM), % Fat mass,
	BMI
	Raw data : X centre, R centre, Radius, SEE, R_0, R_8, Re, Ri, Z char, f char, Membrane capacitance
	Graphs : Cole-Cole plot, Frequency-Resistance plot, Frequency-Reactance plot
Environmental transport, and storage conditions	+10° to +40°C temperature 5% to 95% relative humidity
Environmental operating conditions	+10°C to +40°C 5% to 95% relative humidity
Electrode leads	1.5m lengths with tetra polar electrodes. (Patient circuit is d.c. isolated.)
Device (IEC 60601-1) electrical classification	Type BF

Glossary

BIA	bioimpedance analysis
ECF	extracellular fluid
FFM	fat-free mass
FM	fat mass
ICF	intracellular fluid
P	phase
R	resistance
TBW	total body water
Xc	reactance
Z	Impedance
SFBI	Selected frequency bioimpedance
BIS	Multi frequency bioimpedance analysis

Notes