



# Imp DF50 Instructions For Use



#### ImpediMed Limited ABN 65 089 705 144

Unit 1 50 Parker Court Pinkenba Qld 4008 Australia

 Phone :
 +61 7 3860 3700

 Fax :
 +61 7 3260 1225

 Email:
 enquiries@impedimed.com

 Web site:
 http://www.impedimed.com

EC REP

MediMark Europe Sarl 11 rue Emile ZOLA, B.P. 2332, 38033 Grenoble Cedex 2 FRANCE

# **CE** 0120

For patent(s) and/or patent application(s) see: <u>www.impedimed.com.au/products/patents</u>

# Contents

Notes on Safety2		
Description of Features	3	
User Information	4	
Intended Use	4	
Contraindications	4	
Components of the Imp DF50 System	5	
Fitting the Batteries	6	
LCD Display and Control Buttons	7	
Modes of Operation	9	
Direct Mode	9	
Algorithm Mode	9	
Preparing for Measurements	10	
Patient selection	10	
Patient preparation	10	
Placing the electrodes on the patient	10	
Standard placement sites for the electrodes	11	
Plug lead into the Device	12	
Whole Body Impedance Measurements	14	
Imp DF50 Main Screen	14	
Device Setting	14	
Measurement Process	15	
Direct Mode Measurement	15	
Algorithm Mode Measurement	16	
Measurement results may be affected by:	18	
Data Transfer to Body Composition Analysis Software	19	
Calibration Check	20	
Care and Maintenance	. 22	
Care of the Imp DF50	22	
Care of the leads	22	
Care of the electrodes	22	
Battery Replacement and Disposal	23	
Repairs	23	
Technical Support	23	
Accessories	24	
Troubleshooting	. 25	
Imp DF50 Specifications	. 26	
Glossary	. 27	

# 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:

	Indicates matters in which the possibility of death or serious injury may arise as a result of incorrect handling.
	Indicates matters in which bodily harm or material damage or incorrect measurements may arise as a result of incorrect handling.
${igodot}$	What you should not do.
0	An action that must be followed.
<b>E</b>	Follow instructions for use



Do not use or operate the device in the presence of strong electromagnetic fields This Medical Device may interfere with other Medical Devices in its vicinity Read instructions completely before using the Imp DF50.

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

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



For EU Customers: All products at the end of their life may be returned to ImpediMed for recycling.



This device is rated CF as per IEC60601-1 This device meets the standard IEC60601-1-2

## **Description of Features**

The Imp DF50 is a single frequency electrical bioimpedance analyser. The device accurately measures current, voltage and phase angle, and calculates impedance, resistance and reactance. These measurements and calculations are used to estimate the body composition: fat-free mass (FFM) and fat mass (FM), and fluid distribution: total body water, intracellular water, and extracellular water.

The handheld device is battery powered. It has a tetra-polar set of leads, which are attached to self-adhesive skin electrodes by means of alligator clips.

The Imp DF50 has two operating modes: Direct and Algorithm.

**Direct Mode** measures and displays values for impedance (Z), phase (Ph), resistance (R) and reactance (Xc).

**Algorithm Mode** displays estimates of fat-free mass (FFM) and fat mass (FM), total body water (TBW), intracellular water (ICW), and extracellular water (ECW), plus their percentages. The device computes these values using one of three widely accepted peer reviewed published algorithms tailored to the patient type: general population, obese patients, or children.

ImpediMed provides Body Composition Analysis Software (Windows® compatible) to enable practitioners to store measurements and patient details in a database, display results graphically, and to generate reports.

Transfer of stored data is via an infrared port on the Imp DF50 or manually entering the data into a computer loaded with the Body Composition Analysis Software. It is then possible to generate patient databases for the analysis and report generation.



Please read all these instructions completely before use.

# **User Information**

## Intended Use

The ImpediMed Imp DF50 is a medical device with algorithm firmware, intended to be operated by users who have read this manual, for use on healthy patients for the purpose of Body Composition Analysis.

## Contraindications



Do not connect the Imp DF50 device to:

- Patients with active implanted medical devices, e.g. cardiac pacemakers, defibrillators or patients connected to electronic life support devices
- Patients undergoing external defibrillation



Pregnant patients
 While the use of bioimpedance technology in pregnant patients has been shown to have had no adverse effects<sup>123</sup>, the Imp DF50 has yet to be clinically validated for use with that population group.

<sup>&</sup>lt;sup>1</sup> Ritsuko Y *et al.* Bioelectrical impedance analysis in the clinical management of preclamptic women with edema. *J Perinat.Med* 31 (2003) 275 - 280

<sup>&</sup>lt;sup>2</sup> Valensise H *et al* Multifrequency bioelectrical impedance analysis in women with a normal and hypertensive pregnancy. *Am J Clin Nutr* 72 (2000) 780 - 783

<sup>&</sup>lt;sup>3</sup> Larciprete et al., Body composition during normal pregnancy: reference ranges. Acta Diabetol 40 (2003) S225 – S232

## **Components of the Imp DF50 System**



The following are supplied with the Imp DF50 device:

- Set of standard electrodes (1)
- Lead set (2)
- Test cell for calibration check (3)
- Four alligator clips (4)
- Carry case \*
- Quick Reference and electrode placement chart \*
- CD-ROM \* containing
- Imp DF50 Instructions For Use
- Body Composition Analysis Software Instructions For Use
- Body Composition Analysis Software
- Stylus pen\*
- Microfibre cloth \*
- Alcohol swabs\*
- Notepad\*
- Warranty card\*

\* Not shown in above photograph

## Fitting the Batteries

- 1. Use a small flat screwdriver to remove the nylon screw from the battery cover retaining clip
- 2. Remove the battery cover by gently pulling the retaining clip in the direction of the arrow
- 3. Pull the battery cover away from the case
- 4. Insert two AA-size 1.5 volt alkaline batteries, making sure that the polarity is correct
- 5. Replace the battery cover
- 6. Replace the nylon screw and tighten using a screwdriver
- 7. Do not over tighten the screw
- 8. The Imp DF50 is ready for use



## **LCD Display and Control Buttons**

When switched ON, the Imp DF50 initially displays the serial number and firmware number, then:

ImpediMed Imp-DF50 www.impedimed.com



On the right hand side of the screen is a battery meter.

Five bars indicate fully charged batteries.

One bar or less, replace the batteries.



Before use, check that the battery status on the display indicates two or more bars

The device automatically switches OFF if the batteries are below 2.0 volts.

When switched ON subsequently, the Imp DF50 will display a message "Batteries Too Low, Please Replace Batteries".

The Imp DF50 has a dot matrix graphical LCD panel for display of alphanumeric information.

There are five control buttons to operate the device.



#### Table 1 - Control buttons and functions

Buttons	Functions
Θ	Turns the device ON and OFF
4	<ol> <li>Moves the cursor to select options</li> <li>Increments the value of a parameter digit</li> </ol>
-	<ol> <li>Selects a parameter digit</li> <li>Returns the user to either the previous screen or main screen</li> </ol>
EDIT	Edits a selection
MEASURE	<ol> <li>Takes user to next screen</li> <li>Initiates a measurement</li> </ol>

## **Modes of Operation**

The Imp DF50 device is designed to operate in two modes: Direct or Algorithm.

## Direct Mode

The device accurately measures current, voltage and phase angle, then displays values for: impedance (Z), phase (Ph), resistance (R), and reactance ( $X_c$ ).

## Algorithm Mode

The device accurately measures current, voltage and phase angle, and displays values for: impedance (Z), phase (Ph), resistance (R), and reactance ( $X_c$ ). Using the selected algorithm this data is transformed to yield estimates of fat-free mass (FFM), fat mass (FM), total body water (TBW), intracellular water (ICW), and extracellular water (ECW) (plus their percentages) for the patient being measured.

The device computes these values from the impedance of the body tissues together with patient parameters entered by the user: age (years), height (cm/inches), weight (kg/lbs), and gender. Three published and widely accepted algorithms are used in these calculations. The algorithms are based on research conducted in the following populations: general patients<sup>4</sup>, obese patients<sup>5</sup>, and children.<sup>6</sup>

- **General patients:** This algorithm is suitable for the general patient who does not fit the obese or child parameters.
- **Children:** This algorithm is suitable for children<sup>6</sup>.
- **Obese patients:** When the body mass index (BMI) of the patient is greater than  $30 \text{ kg/m}^2$  the patient is generally deemed to be obese.

 $BMI = \frac{\text{weight (kg)}}{\text{Height x Height (m<sup>2</sup>)}}$ 

#### Table 2 - BMI Categories

(From National Institute of Health/ World Health Organisation guidelines)

BMI	Category
Less than 18.5	Underweight
18.5 to 24.9	Normal weight
25 to 29.9	Overweight
30 or greater	Obese

## **Note:** The Imp DF50 can be programmed by ImpediMed with a customised algorithm that is specific to the practitioner or researcher's requirements.

<sup>&</sup>lt;sup>4</sup> Lukaski HC, Johnson PE, Bolonchuk WW. Theory and validation of tetrapolar bioelectrical impedance method to assess human body composition. In: Ellis K J, Jasumura S et al., editors. *In vivo body composition studies*. London: Institute of physical science in medicine; 1987. pp. 410 –41 4.

<sup>&</sup>lt;sup>5</sup> Segal K, van Loan M, Fitzgeral PI, Hodgdon J, van Italie T. Lean body mass estimation by bioelectrical impedance methods; a four-sit cross validation study. *American Journal of Clinical Nutrition*, 47:1988 pp 7-14

<sup>&</sup>lt;sup>6</sup> Cordain L, Whicker R, Johnson J. Body composition determination in children using bioelectrical impedance. Growth Development & Aging, 52:1988 pp 37-40

## **Preparing for Measurements**

#### Patient selection

Certain situations are known to affect body water concentration:

- Just prior, during, just after menstruation
- Use of diuretics
- Renal or heart failure
- Excessive exercise 2 hours prior to bioimpedance analysis (BIA)
- Consumption of excessive alcohol within 12 hours prior to BIA

For patients whose hydration status is affected by these conditions, use of the algorithm(s) to estimate total body water, intracellular fluid, extracellular fluid, fat-free mass, or fat mass may lead to results that do not reflect the individual's normal state<sup>7</sup>

## Patient preparation

Prior to analysis the patient should:

- 1. Remove all jewellery (rings on fingers may be left on)
- 2. Remove stockings / pantyhose or socks
- 3. Have an empty bladder
- 4. Be accurately measured, for height (to the nearest 0.5cm) and weight (to the nearest 0.1kg), if the Imp DF50 is to be used in Algorithm Mode
- 5. Lie on their back in a fully supine position on the examination table
- 6. Extend their arms by their side, hands resting next to their body, palms down, with their legs slightly apart
- **Note:** It is preferable if the measurements are undertaken under similar conditions, e.g. time of day, activity levels, and food and fluid intake and the analysis is completed within 10 minutes of the patient assuming the supine position.

#### Placing the electrodes on the patient

- 1. Application sites with heavy or curly hair that cannot be parted may need to be shaved.
- 2. Prepare skin sites by either briskly rubbing with gauze or alcohol wipes, to remove any excess oil that may cause measurement inconsistencies, being careful not to break or damage the skin; allowing the skin to dry by evaporation following the use of alcohol. ImpediMed recommends the use of 70% Isopropyl Alcohol.
- 3. Tear open sealed foil pouch, slowly and carefully remove electrodes from backing sheet
- 4. Apply each electrode adhesive side to the skin, at one of the standard placement sites (as shown below) so that the tab faces outward from the body
- 5. To ensure good electrode contact, start from the outer edge and run your finger around the electrode several times, working toward the centre

<sup>&</sup>lt;sup>7</sup> Bioelectrical Impedance Analysis in Body Composition Measurement, National Institutes of Health Technology Assessment Conference Statement, December 12-14, 1994, p 13

- 6. Do not squeeze too hard during electrode placement as this will displace gel on the electrode and may cause separation of the gel from the electrode tab during removal
- 7. Place all four electrodes on the patient before connecting any alligator clips
- 8. Reseal pouch after opening, to prevent electrode gel on unused electrodes from dehydrating



Caution

Only use ImpediMed Electrodes Avoid placing an electrode on irritated skin or wound sites If skin irritation occurs seek professional advice Allow skin to dry thoroughly before placing electrodes on skin Do not connect alligator clips to patient's skin Do not mix single use and reusable or different brands of electrodes Do not cut the electrode, use whole electrode only Do not use extra electrode gel with solid gel electrodes Do not leave the electrodes attached to the skin for longer than 1 hour

#### Standard placement sites for the electrodes

Note: Measurements can be done on either the right hand side or the left hand side, but do not mix sides.

**RIGHT HAND** 

On the right hand between the two protruding bones

Ensure that the two electrodes on the hand are 5cm apart

#### **RIGHT FOOT**

On the right foot, on the ankle at the level of and between the medial and lateral malleoli (the large protruding bones on the side of the ankle)

Ensure that the two electrodes are 5cm apart



## Plug lead into the Device

Attach the lead plug to the socket of the Imp DF50 by aligning the dots on the lead plug and the device socket so that the pins on the plug match the holes in the socket. When aligned correctly, press the plug in firmly and completely.



Attach an alligator clip to each of the probe ends of the four leads.



Apply lead wires according to the colour code below. Use an alligator clip to connect each lead to the tab portion of an electrode.

Ensure that the metallic part of the clip is in direct contact with the conductor side (underside) of the electrode tab and that the clips are aligned to the centres of the electrode tabs.

#### Yellow (Sense lead)

The **yellow** lead end is attached to the electrode on the right hand, on the wrist next to the ulnar head (wrist joint)

#### Red (Current source lead)

The **red** lead end is attached to the electrode on the dorsal surface of the right hand



1200



#### Blue (Sense lead)

The **blue** lead end is attached to the electrode on the dorsal surface of the right foot, on the ankle at the level of medial and lateral malleoli (large protruding bones on the side of the ankle)

#### Black (Current sink lead)

The **black** lead end is attached to the electrode on the dorsal surface of the right foot

Ensure that the patient's limbs are not crossed (so the electrical path is not short-circuited) and that their legs are completely separated

For patients who cannot effectively separate their inner thighs, it may be necessary to place insulating material (e.g. dry clothes) between them.

Note Hanging up the leads vertically for storage mitigates tangling



Typical final set-up ready for measurement

## Whole Body Impedance Measurements

Press the 0 button to power up the Imp DF50. Pressing again will switch device OFF.

#### The Imp DF50 will automatically switch OFF if there is no activity for five minutes.

#### Imp DF50 Main Screen

From this screen you have 2 options:

- 1. Press the EDIT button and go to the **Device Setting** screen to change the device settings:
  - Units
  - IR
  - Buzzer
  - Timer
  - Language
- 2. Press the MEASURE button to initiate a measurement process.

## **Device Setting**

The EDIT button is used to edit the setting.

The UP ARROW button will enable you to select the setting to be edited.

The RIGHT ARROW button will take you back to the main screen at any stage during the setting process.



EDIT









#### Table 3 - Device Settings

Description	Settings/Actions
Units	Enable imperial or metric units of measure
IR	Select ON to enable electronic download of data from the Imp DF50 to Body Composition Analysis software on your computer or OFF to disable
Buzzer	Enables buzzer to be set to beep at end of analysis
	Press Edit to turn OFF or ON
	Once ON press Measure to change pitch of beep
Timer	Enable a 15 second delay from initiating measurement to actual measure being taken
Language	Press EDIT button to select the language (English, French, German, Italian and Spanish). Press any other button to initiate the selected language

## **Measurement Process**

#### **Direct Mode Measurement**



The Screen displays the two mode options, Direct and Algorithm

2. Press **V** to place the cursor on the **Direct** measurement option

3. Press voir to select Direct Mode

The Screen displays the message "Attach electrodes to patient, Connect colour-coded leads to electrodes"

4. To proceed with this option, check the electrodes and leads are correctly attached to the



The "Measuring" message and moving measuring bar is displayed

If the electrodes have been incorrectly placed or the leads were not connected correctly, the screen will display the message, "Out of Range Check Leads and Electrodes"

If the electrodes are correctly placed and the leads are connected correctly, the screen will display values for:

Impedance (Z=) Phase (Ph=) Resistance (R=) Reactance (Xc=)

- 5. To repeat the measurement, press and the device will repeat the measurement process
- 6. Press

to return to the Main Menu

#### **Algorithm Mode Measurement**

1. Press

The screen displays the two mode options, Direct and Algorithm

- 2. Press **v** to place the cursor on the **Algorithm** measurement option
- 3. Press V to select Algorithm Mode

The screen displays a choice of algorithms:

- General
- Obese
- Child

4. Press 📂

to place the cursor on the desired algorithm option

5. Press

The Screen displays the patient parameters:

- Height
- Weight
- Age
- Sex
- 6. Enter the patient's height, weight and age

For example:

- Press voice to select parameter e.g. Weight
- Press
- Select a digit using
- Press to increment the digit

- If vou make a mistake, Press to re-enter the data •
- Maximum height is 250cm, maximum weight is 250kg, and maximum age is 110 Note: vears.
- 7. To select the patient's gender, press between F and M

to select Sex and press



8. When values have been entered for all four parameters, press

The Screen displays the message "Attach electrodes to patient, Connect colour-coded leads to electrodes"

9. Before proceeding, check the electrodes and leads are correctly attached to the patient and press

The "Measuring" message is displayed

- If the electrodes have been incorrectly placed or the leads were not connected • correctly, the Screen will display the message, ""Out of Range Check Leads and Electrodes"
- If the electrodes are correctly placed and an algorithm was selected, the Screen will • display values for:

FFM: %FFM

FM: %FM TBW: % TBW

ICW: %ICW

ECW: %ECW

10. To repeat the measurement, press and the device will repeat the measurement process

11. Press to view raw data Impedance (Z=) Phase (Ph=) Resistance (R=) Reactance (Xc=)

12. Press

to return to the Main Menu

#### Measurement results may be affected by:

- Placing a mobile phone in close proximity to the device during operation
- Metal implants, clips or other types of artificial limbs or implants in the patient
- Patients touching a metal surface during the measurement process
- Using the device when the patient is connected to other medical devices (due to the effect of electrical interference)
- Selecting the incorrect body type algorithm
- Incorrect height and/or weight values entered into the device
- Incorrect electrode placement
- Using electrodes which are past their use by date
- Re-using disposable electrodes
- Using a part of the full electrode tab
- Using extra electrode gel with solid gel electrodes

# Data Transfer to Body Composition Analysis Software

Data recorded by the Imp DF50 may be transferred to ImpediMed Body Composition Analysis Software for storage in the database, analysis and report generation. This is accomplished by infrared transfer or manually entering the data.

For infrared download of data the following is required:

- An infrared adapter kit (available from ImpediMed) supplied with an IR adaptor and USB to single serial port converter for use with desktop PC and portable laptops
- Body Composition Analysis software installed, and the patient's file to be created and open
- The Imp DF50 set to infrared download enabled (see Table 3)
- The infrared transmitter port on the Imp DF50 (oval insert at the top of the device) is pointed at the infrared adapter port (connected to the computer).

Note: Integrated infrared port in laptops can not be used for automated data transfer

Please refer to detailed instructions in the *Body Composition Analysis Software Manual,* on the CD-ROM



Ensure that the correct patient file is open in the software prior to uploading the data from the device

## **Calibration Check**

There are no user-adjustable parts in the Imp DF50. However, to enable regular validation of the consistency of readings a test cell has been provided.

Calibration is checked with the Imp DF50 set to Direct Mode and connected to the test cell.

If the device does not display readings within the specified limits (see Table 4), recalibration may be required.



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



- 1. Remove the alligator clips from the leads and insert the probe ends into the test cell provided, matching the colour coding
- 2. Insert the lead plug into the socket on the Imp DF50
- 3. Ensure leads are not tightly coiled or resting on any metal objects or chair arms as this may confound the readings
- 4. Press the <sup>(1)</sup> button to power up the Imp DF50
- 5. Press

The Screen displays the two mode options, Direct and Algorithm

- 6. Press **V** to place the cursor on the **Direct** measurement option
- 7. Press voit to select Direct Mode

The Screen displays the message "Attach electrodes to patient, Connect colour-coded leads to electrodes"

- MEASURE
- 8. Check all leads are matched to the socket colour on the test cell and press The "Measuring" message is displayed Then Screen will display values for:
  Z: Ph:
  - R:
  - Xc:

The following values will be displayed if the Imp DF50 is correctly calibrated.

Parameter	Approximate Value	Limits*
Z	1000 ohms	995 to 1005 ohms, i.e. ± 0.5%
Ph	0°	- 0.5 to + 0.5°
R	1000 ohms	995 to 1005 ohms, i.e. ± 0.5%
Xc	0 ohms	0 ± 9 ohms

#### Table 4- BIA measurements in Direct Mode for Imp DF50 calibration check

\* The industry standard is within 1% as outlined in the UK guideline on Electrical Impedance Analysers.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> A Guide to Measuring Resistance & Impedance Below 1 MHz. National Physical Laboratory, The Institute of Measurement and Control, 87 Gower Street, London WC1E 6AA, 1999

## **Care and Maintenance**

## Care of the Imp DF50

Clean the Imp DF50 with a damp cloth if required.

When not in use always store the Imp DF50 system in the carry case.

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

If the Imp DF50 is not to be used for a long period, remove the batteries before storage.

## Care of the leads

Clean the leads with a damp cloth if required.

The leads should be disconnected from the device, loosely coiled and placed in the carry case when not in use.

Hanging up the leads vertically for storage mitigates tangling

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 electrodes

The electrodes are for single use for a maximum duration of 1 hour.

Please dispose after use according to local regulations.

Reseal the electrode pouch after use.

Unused electrodes should remain in the supplied pouch and in a cool dry place to prevent electrode gel from dehydrating.

Use by expiry date



) Single use only

Refer to the expiration date that is printed on each package.

Do not use an electrode IF the conductive adhesive is dry and no longer pliable or sticky. This may result in inaccurate measurements.

## **Battery Replacement and Disposal**



Disconnect patient lead connections before removing the battery cover or replacing the alkaline batteries

Remove depleted batteries from the Imp DF50 immediately and dispose of in accordance with your local government regulations.

Never dispose of batteries in a fire, as they could explode.

Ensure that the alkaline batteries are correctly positioned. Incorrect battery polarity or orientation may damage the Imp DF50.

Replace with AA alkaline batteries only.

Never mix batteries of different types or mix new and depleted batteries.

## Repairs

S There are no user serviceable parts in the device, do not disassemble unit.

Please contact ImpediMed or an authorised service agent for technical advice if the device does not function according to specifications.

## **Technical Support**

Phone: +1 877 247 0111

Fax: + 1 858 558 8540

Email: <a href="mailto:technicalsupportusa@impedimed.com">technicalsupportusa@impedimed.com</a>



For consistently accurate readings we recommend periodic checks using the test cell.

If the readings from the test cell are not within the specified limits, (refer to Table 4) contact ImpediMed or an authorised agent for recalibration and or repair.

## Accessories

The following accessories and consumables are available from ImpediMed.

Description	ImpediMed Part Number
Electrodes (pack of 100)	292-STE
Infrared computer adaptor Kit	292-IRAD
Test cell	292-SFTC
Lead set	292-SFULD
Alligator Clips	292-ALLCP
CD-ROM (containing Body Composition Analysis Software and user manuals for the Software and the Imp DF50)	292-DF50CD

Please contact <u>info@impedimed.com</u> for further information.

# Troubleshooting

Problem	Possible cause	Solution
No display when Imp DF50 is switched ON.	<ul> <li>Batteries are incorrectly installed.</li> </ul>	<ul> <li>Remove and replace alkaline batteries correctly.</li> </ul>
	Battery power is low.	Replace alkaline batteries.
In Direct Mode, no reading for Z, Ph.	<ul> <li>Electrodes improperly placed.</li> </ul>	Ensure electrodes are correctly placed.
	<ul> <li>Lead set not connected correctly to electrodes or device.</li> </ul>	Ensure leads are correctly connected.
In Direct Mode, values for Z, Ph, R, Xc are very different from previous readings for the patient.	• Device or leads may be damaged. Values are expected to vary as the parameters measured vary with the continuous changes in body composition.	<ul> <li>Perform calibration check. Contact ImpediMed if readings are outside normal limits.</li> </ul>
In Algorithm Mode, no reading for FFM, FM, TBW, etc.	<ul> <li>Electrodes improperly placed.</li> </ul>	<ul> <li>Ensure electrodes are correctly placed.</li> </ul>
	<ul> <li>Lead set not connected correctly to electrodes or device.</li> </ul>	Ensure leads are correctly connected.
	<ul> <li>No algorithm selected.</li> </ul>	Select an algorithm.
In Algorithm Mode, values for FFM, FM, TBW, etc, are very different from	<ul> <li>Device or leads may be damaged.</li> </ul>	<ul> <li>Perform calibration check. Contact ImpediMed if readings are outside normal limits.</li> </ul>
patient.	<ul> <li>Inappropriate algorithm selected for patient.</li> </ul>	Change to another algorithm.

# **Imp DF50 Specifications**

Drive AC current	200μA ± 10μA peak-to-peak at a frequency of 50 kHz ± 100 Hz.
Sense Voltage	1.68 V Max
Impedance range	40 to 1500 Ω
Impedance resolution	0.1 Ω
Impedance accuracy	<u>+</u> 0.5%
Phase range	-5° to +50°
Phase resolution	0.1°
Dimensions	L=140 mm, W=100 mm, D=55 mm
Weight	230 g approx. (including batteries)
Display	Graphic LCD 128 x 64 pixels resolution
Data displayed	Raw Data: Resistance (R), reactance (X <sub>C</sub> ), impedance (Z), phase (Ph), Calculated data: Fat-free mass (FFM), % Fat-free mass, Fat mass (FM), % Fat mass, Total body water (TBW), % Total body water
	Intracellular water (ICW), % Intracellular water Extracellular water (ECW), % Extracellular water
Environmental transport, and storage conditions	Intracellular water (ICW), % Intracellular water Extracellular water (ECW), % Extracellular water -10° to +50°C temperature 5% to 95% relative humidity
Environmental transport, and storage conditions Environmental operating conditions	Intracellular water (ICW), % Intracellular water Extracellular water (ECW), % Extracellular water -10° to +50°C temperature 5% to 95% relative humidity +10°C to +40°C 5% to 95% relative humidity
Environmental transport, and storage conditions Environmental operating conditions Power requirements	Intracellular water (ICW), % Intracellular water Extracellular water (ECW), % Extracellular water -10° to +50°C temperature 5% to 95% relative humidity +10°C to +40°C 5% to 95% relative humidity Two AA-size 1.5 V alkaline batteries. Current consumption typically less than 40 mA
Environmental transport, and storage conditions Environmental operating conditions Power requirements Electrode leads	Intracellular water (ICW), % Intracellular water Extracellular water (ECW), % Extracellular water -10° to +50°C temperature 5% to 95% relative humidity +10°C to +40°C 5% to 95% relative humidity Two AA-size 1.5 V alkaline batteries. Current consumption typically less than 40 mA Shielded cable of 1.2m lengths with tetra polar electrodes. (Patient circuit is d.c. isolated.)

# Glossary

BIA	bioimpedance analysis
ECW	extracellular water
FFM	fat-free mass
FM	fat mass
ICW	intracellular water
Ph	phase
R	resistance
TBW	total body water
Хс	reactance
Z	impedance

## Notes

## Notes