Bodycomp MF Hexa Software

V. 1.0

INSTRUCTION MANUAL

Activations memo

Device serial number:	
Email:	
Password:	
1st activation date:	
2nd activation date:	
3rd activation date:	

QUICK GUIDE

INSTALLATION

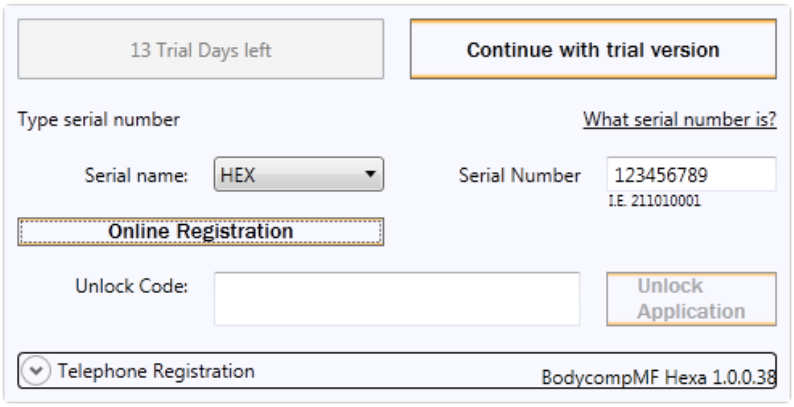
Point your browser at www.akern.com

Select the Bodycomp MF Hexa icon in the DOWNLOAD AREA panel on the right-hand side of the screen.

For more details: Installation

ACTIVATION

Select *Activate now!*



Enter the serial number and select *Online Registration*

Enter the login data.

Select *Unlock code request.*

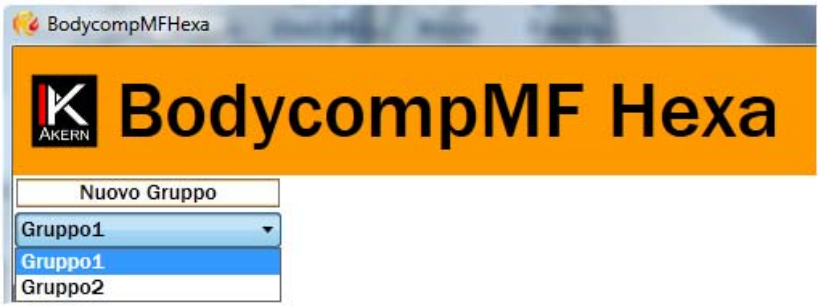
Enter the code shown in the *Unlock Code* box and click the *Unlock!* button.

Useful information:

- ✓ The first time Bodycomp MF Hexa is run you must perform the Registration procedure.
- ✓ You can use the software for 30 days without activating it, by selecting *Continue with trial version.*
- ✓ Make a note of the e-mail address and password entered during the initial registration process because you will need them for all future activations.
- ✓ The Bodycomp MF Hexa license allows 3 activations on different computers. You can anyway transfer a license from one computer to another if the computer is replaced.
- ✓ Compile the Activations memo and keep it up to date to ensure you have ready access to all the associated data and to make the activation process easier and faster.

For more details: License activation

CLASSIFICATION IN GROUPS



The software allows you to create subject classification groups.

Select *New Group*.

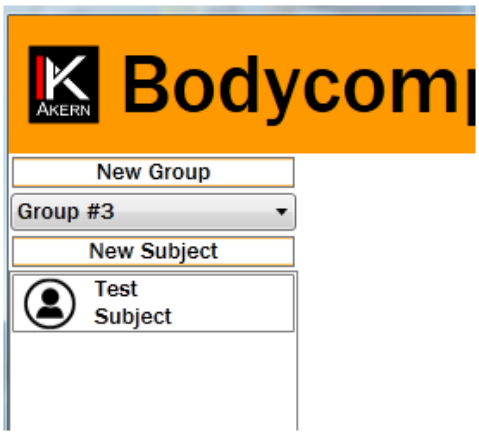
The number of groups created is unlimited.

Useful information:

- ✓ Groups appear in the drop-down menu in the order of creation and NOT in alphabetical order!

For more details: Creation of Groups

ENTERING A NEW SUBJECT



In the drop-down menu select the group in which the subject is to be entered.

Select *New Subject*.

Enter the subject's data and select *Save*.

Useful information:

- ✓ The PAL FACTOR coefficient is used to calculate daily energy expenditure based on the activities carried out by the subject. The PAL factor must be evaluated correctly in order to process the weight loss program.

For more details: Entering a New Subject

For more details of the PAL factor: PAL (Physical Activity Level) Factor

ENTERING A NEW TEST

Select the subject for whom a new test is to be entered.

Select *New Test.*

Enter the subject's height and weight in the test chart.

Perform the measurement on the subject with the Bodycomp MF Hexa analyser.

Select  to download the results via Bluetooth®.

	Date	Height	Weight	Z 5	Z 50	Z 100	Z 150	Z 200	Z 250
☑	06/11/2013	180	80	0	0	0	0	0	0

	Date	Height	Weight	Z 5	Z 50	Z 100	Z 150	Z 200	Z 250
☑	06/11/2013	180	80	430	400	367	337	307	279

Useful information:

- ✓ If your computer is not Bluetooth® enabled you can enter the results manually directly in the tests chart.
- ✓ The first time Bodycomp MF Hexa is switched on the following error message may appear:

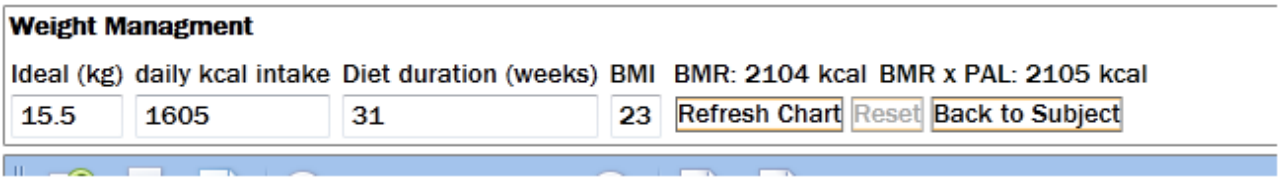
In this case follow the instructions in the Troubleshooting heading.

For more details: Entering a New Test

WEIGHT LOSS PROGRAM

Select the subject.

Select *Weight Loss Chart*



The default weight loss program proposed by Bodycomp MF Hexa is:

500 kcal less per day, 0.5 kg weight loss per week, BMI target 23.

Select the parameters bar to personalize the program.

Useful information:

- ✓ Click *Training* to select one or more sports activities that the subject intends to practise; the weight loss program is calculated taking account of the energy expenditure associated with the selected activities. The incidence of the activity is calculated by the first test performed on the subject.

For more details: Weight Loss Report

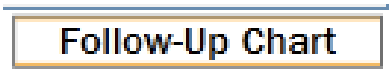
REPORT

Select the subject.

Select the test or tests to include in the report printout.

Body composition estimates, Three-compartment model, Compartments distribution Polar Graph.

Performs a comparison between 2 selected tests.
To enable the button you must first select 2 tests.



Follows the time trend of Weight, Fat-Free Mass (FFM) and Fat Mass (FM)

Useful information:

- ✓ If no tests are selected, the Bodycomp and Follow Up report will include all tests carried out on the subject.

For more details: Report Configuration and Printing

SETTINGS

Clicking  provides access to the following functions:

- ✓ Configure a logo and header in reports, select the language, choose an operating archive, choose the BMR calculation formula, set the target BMI to be proposed automatically in the Weight Loss program.
- ✓ Edit the reports text.
- ✓ Import databases from earlier versions of Bodycomp MF Hexa; save the current archive and import or restore the saved archive.

Useful information:

- ✓ The changes made will be applied to all tests in the database, including pre-existing tests.

For more details: Tools

Description

Bodycomp MF Hexa software is an application for the evaluation of body mass composition in adults by means of measurements made using Bodycomp MF Hexa.
Bodycomp MF Hexa is licensed software.
The standard Bodycomp MF Hexa license is for 3 Users.
To purchase additional licenses contact Akern or an authorized dealer.

Intended use

The Bodycomp MF Hexa medical device was developed to manage information derived exclusively from Akern impedance analysers.
Using Bodycomp MF Hexa in conjunction with different makes of impedance analyser can result in a loss of safety and applicability.
The results generated by the software lack absolute diagnostic value, although together with other parameters and a clinical assessment they can contribute to the correct definition of altered body composition.
Although anyone can use the software, the interpretation of results obtained in relation to persons with physiological disorders must be entrusted to properly trained professional clinicians.

Installation

The software is installed from www.akern.com

Select the Bodycomp MF Hexa icon in the DOWNLOAD AREA panel on the right-hand side of the screen.

- ✓ A window will open with a series of program information. Select *Install*.
- ✓ A window will open prompting you to save the file Setup.exe. Save the file to the desktop.
- ✓ Double click Setup.exe.
- ✓ A window will open requesting authorization to run the file. Select *Run*.
- ✓ A window will open to start the installation process. Select *Install*.

The installation process takes several minutes. The computer must not be switched off during the installation procedure.

For security reasons the program can only be installed on the computer from which the link is activated.

The program cannot be copied to removable media and transferred to another computer.

To install the program on another computer the installation procedure must be repeated.

You can request an installation CD.

Automatic upgrade check function is disabled permanently when the program is installed from CD

Updates

Bodycomp MF Hexa automatically looks for updates whenever the computer with Internet access is booted up. Updates are not available if the software was installed from the CD.

Administrator/User installation procedure

In certain applications, especially public authorities and large companies, the software must be installed by a User client.

Clickonce, application utilised to distribute the software, allows the installation procedure to be performed directly by a User client.

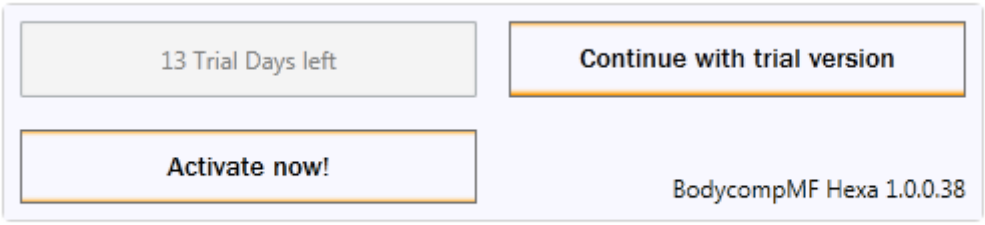
Requirements: .NET Framework 4.0 and SQL Compact edition. The required applications are supplied on the installation CD or can be downloaded directly from the Microsoft website.

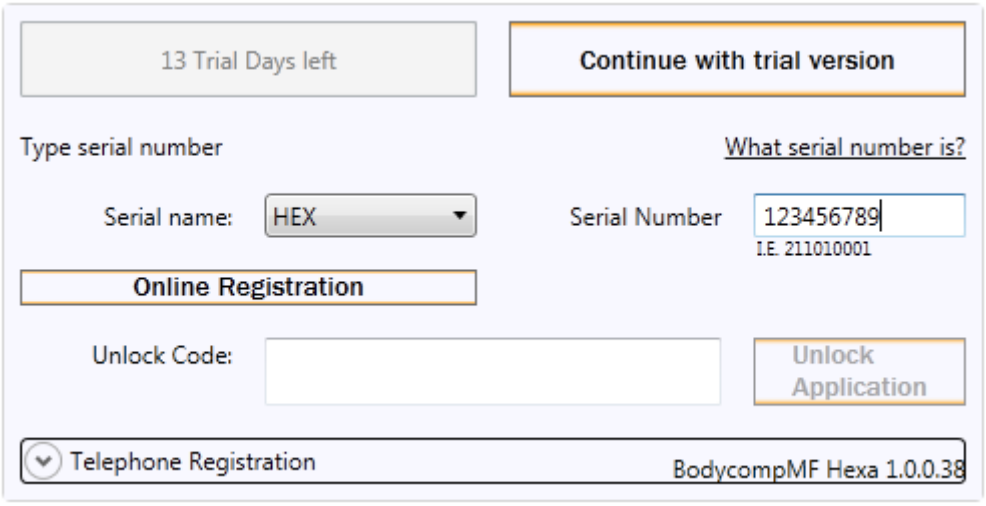
If the software is installed on a User workstation it is good practice to install the software **first** as an Administrator client and subsequently reinstall it as a User client.

License activation

Bodycomp MF Hexa requires an activation code (Unlock code).

From the time of installation the software has a 30-day trial period before the activation code must be entered. During this period the activation window is displayed whenever the program is launched; the user can activate the program at any time or continue to use it in trial mode by selecting *Continue with trial version*. The Trial version is identical to the unlocked version.





At the end of the 30-day trial period the application is disabled and remains disabled until the activation code is entered.

To activate Bodycomp MF Hexa insert the activation code in the Unlock Code box and select the Unlock! button. A message will appear to confirm that the application has been unlocked.

To obtain the activation code enter the device serial number, comprising a series of letters and numbers.

E.g. HEX 20xxxxxxx:

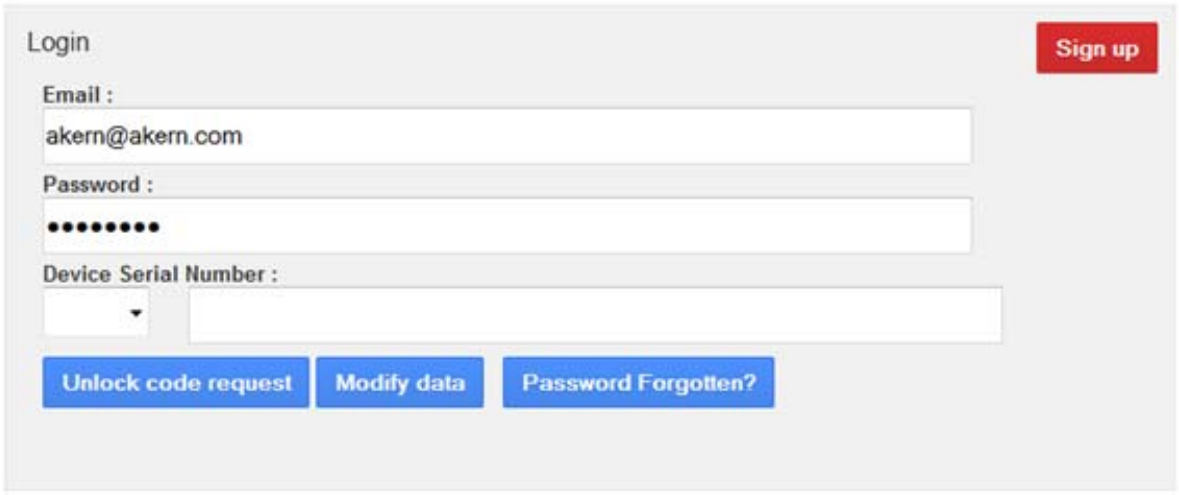
- ✓ type the letters (HEX) in the Serial name box after selecting it from the drop-down menu;
- ✓ type the numbers (20xxxxxxx) in the Serial Number box.
- ✓ Select Online Registration for automatic online activation, or select Telephone Registration to activate the software manually.

Online Registration

The automatic online procedure is faster and simpler than the telephone registration. We recommend using the automatic procedure whenever possible.

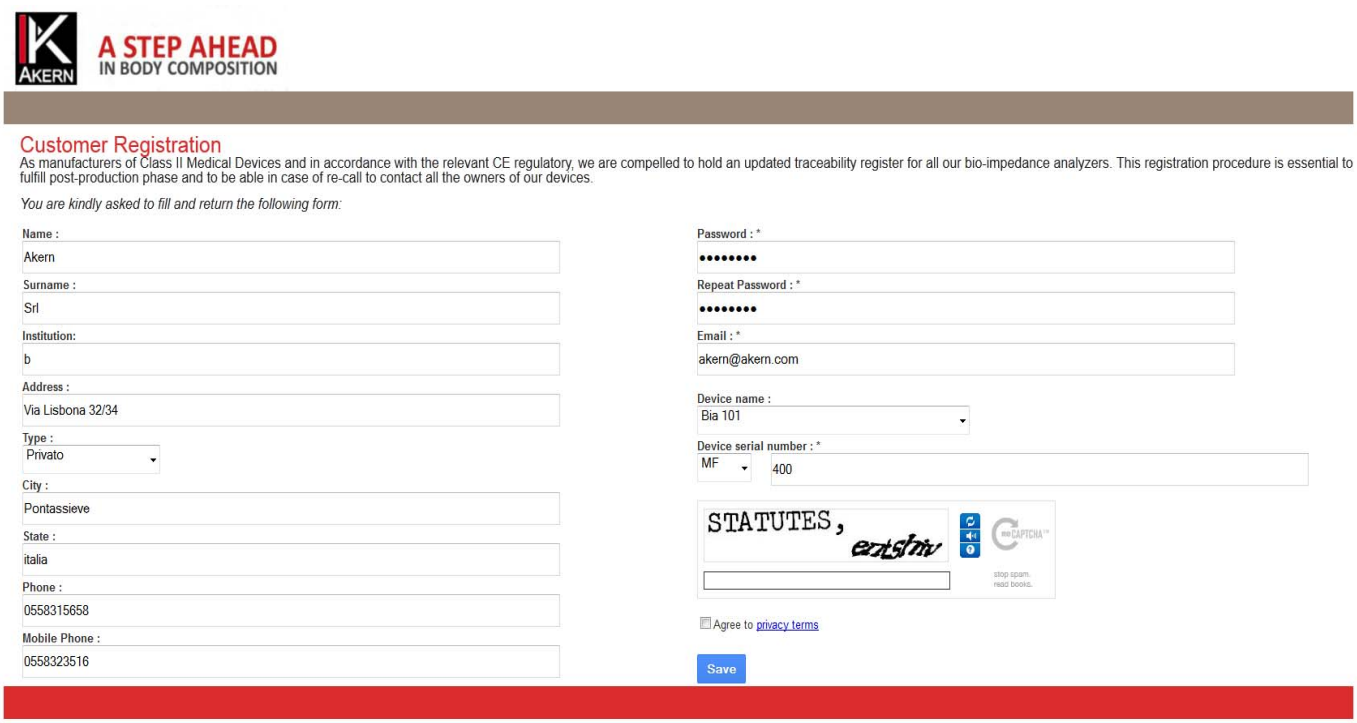
Select Online Registration.

The following screen will be displayed:

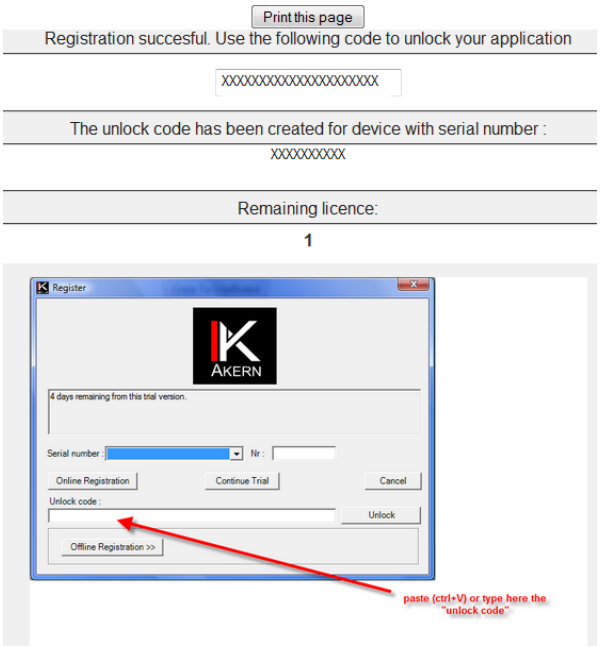


Registration (New user)	Login (Registered User)
Select the *Sign up* button	Type the E-mail address and Password entered at the time of registration.
The *Customer Registration Form* will appear. Compile all the required fields. The E-mail and Password entered by the user during this procedure will be used to access the site in the future. For this reason take care to ensure you enter these data correctly and make a note of them.	Select the '*Unlock code request*' button. The system provides a new unlock code, if available.
Enter the verification text.	
Select 'Agree to privacy terms' to consent to the use of your personal data.	
Select *Save*.	

Customer Registration form



At the end of the procedure a confirmation e-mail containing the account data is sent automatically to the e-mail address provided and the following page containing the activation code (Unlock Code) is displayed.



Copy and paste the Unlock Code in the specific area of the program window and select *Unlock!*

Telephone Registration

This procedure should be used only when you cannot register online.

Select Telephone Registration.

Contact Akern by telephone, fax or e-mail and provide the following information:

All the data requested in the Customer Registration form.

For registered customers: e-mail address and password entered at the time of registration.

Device serial number.

Computer ID and Volume ID (alphanumeric codes displayed when you select *Telephone Registration*).

The manual activation procedure takes about 15 minutes.

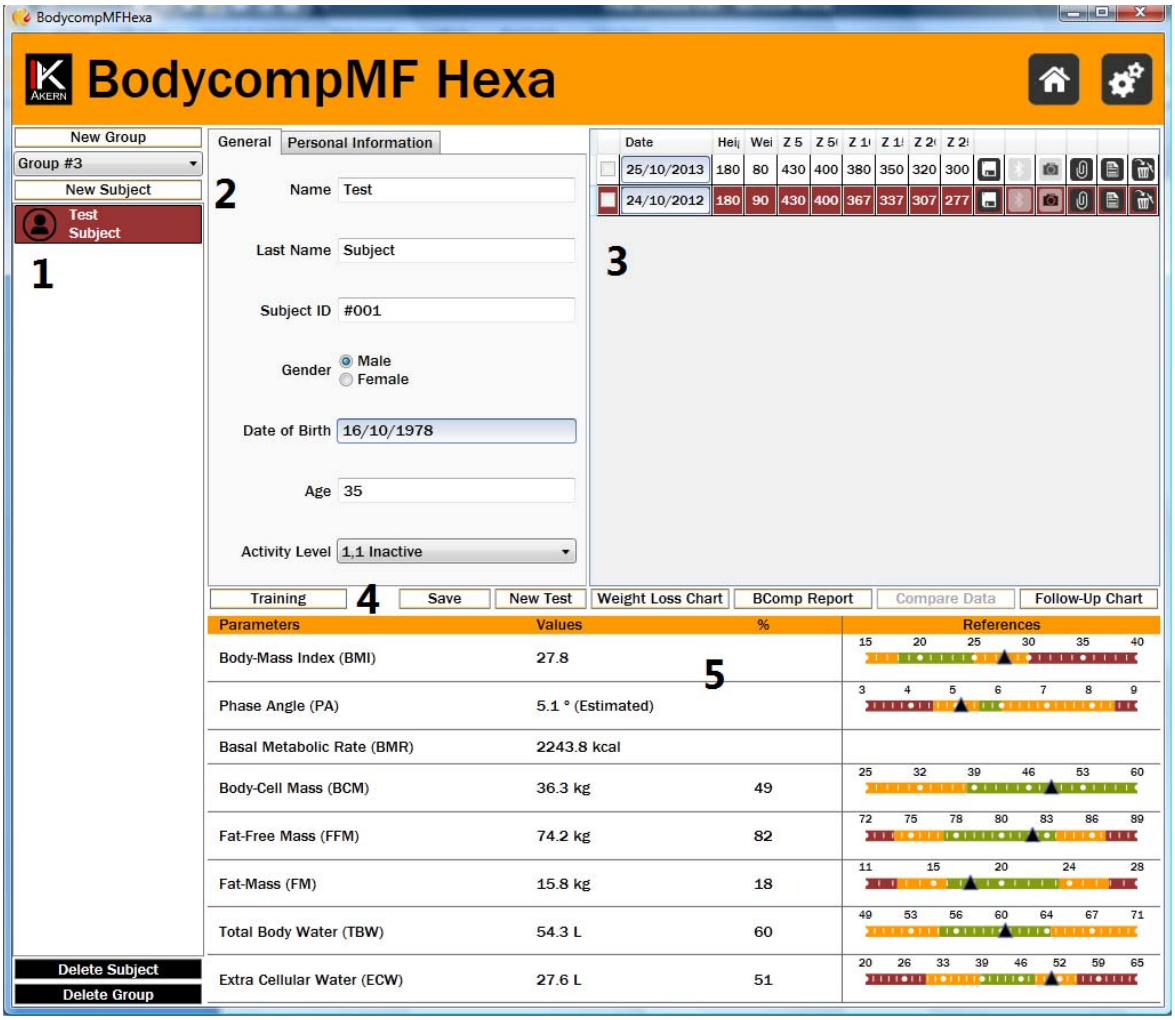
Cancelling a license

You can deactivate a license to make it available for activation on another PC.

For this function you need to contact Akern Customer Service on +39 0558315658 and follow the instructions given by the operator.

During the call you will need to access the PC on which the User is to be deactivated; you will also need the serial number of the Akern device and your Akern website registration credentials.

Main page



The Bodycomp MF Hexa program is designed to minimize the number of data entry windows. As far as possible, the main page will remain constantly displayed

Data entry, the display of tests and the print options are therefore always clearly visible to make it easier to navigate around the various functions.

1-Groups and subjects display column (Archive)

2-Subjects data and input area

3-Tests performed and input chart

4-Report Controls and Subject Controls

5-Test results area

The minimum resolution to display the main page is 1024x768.

Using the program

Creation of Groups

The *New Group* button allows you to create an infinite number of subject classification groups.

By clicking on the drop-down menu in the Archive column under the *New Group* button you can see the groups created and select the group in which you wish to work.

The groups are displayed in the order of creation.

Deleting a group: from the drop-down menu select the group you wish to delete. Select the *Delete Group* button at the bottom left of the screen.

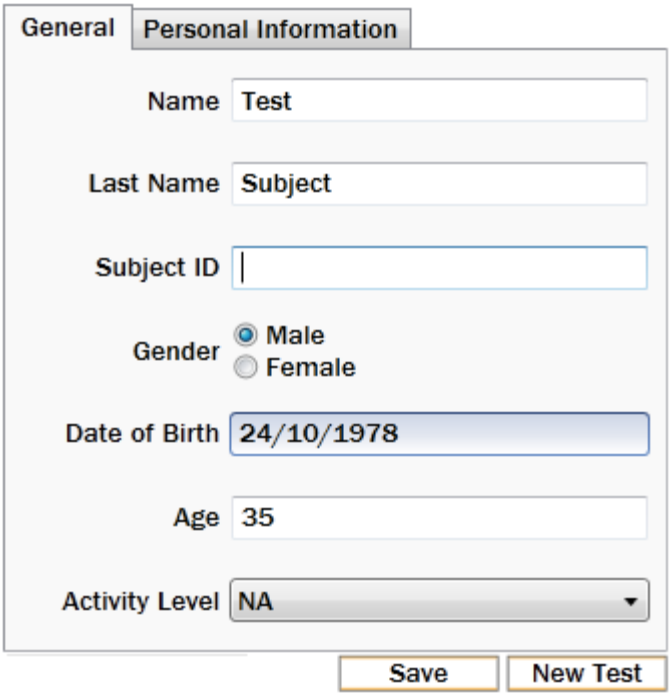
Warning: deleting a group automatically deletes all the tests and subjects it contains. Before deleting a group the software automatically creates a backup copy in the archive.

Entering a New Subject

To enter a new subject:

In the drop-down menu select the group in which the subject is to be entered

Press the *New Subject* button



Enter the information requested in the *General* page.

Select the *Save Subject* button to save the subject to the database and prepare for insertion of a new test.

Select *Personal information* to enter additional subject details.

Deleting a Subject: select the subject you intend to delete. Select the *Delete Subject* button at the bottom left of the screen.

Warning: deleting a subject automatically deletes all the tests associated with the subject. Once you have confirmed the deletion the operation is irreversible.

PAL (Physical Activity Level) Factor

PAL defines the BMR multiplication value used to calculated the daily energy expenditure of a subject. This factor is directly correlated with the physical activity level and lifestyle of the subject.

The following table shows the values utilised by the Bodycomp MF Hexa software.

Activity level	BMR multiplication factor
Inactive	1.1
Sedentary	1.4
Moderately Active	1.7
Vigorously Active	1.9
Extremely Active	2.3

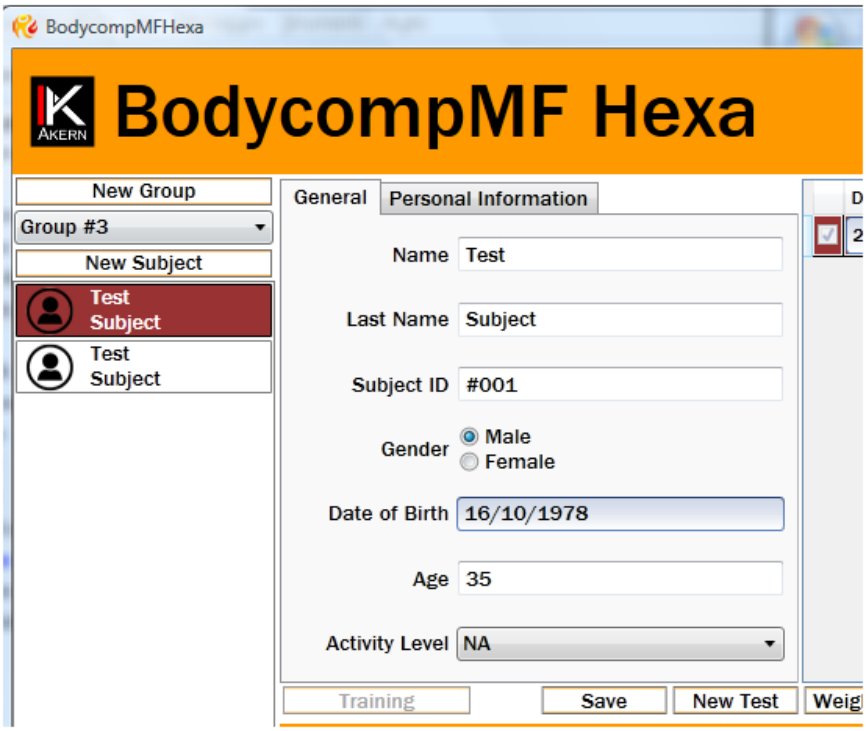
Correct selection of the PAL factor is possible only by accurately estimating the daily activity schedule of the subject. Example:

Daily activities	**Hours**	**Hourly energy cost**	**Value**	
Light activity level				
Sleep	**8**	**1**	**8**	
Personal care	**1**	**2.3**	**2.3**	
Eating	**1**	**1.5**	**1.5**	
Cooking	**1**	**2.1**	**2.1**	
Sitting (office, etc.)	**8**	**1.5**	**12**	
Household work	**1**	**2.8**	**2.8**	
Driving	**1**	**2.0**	**2.0**	
Walking	**1**	**3.2**	**3.2**	
Light leisure activities (TV)	**2**	**1.4**	**2.8**	
Total	**24**		**36.7**	**36.7/24=1.53**

Sources: FAO Corporate Document Repository –Human Energy Requirements-
ftp://ftp.fao.org/docrep/fao/007/y5686e/y5686e00.pdf

Entering a New Test

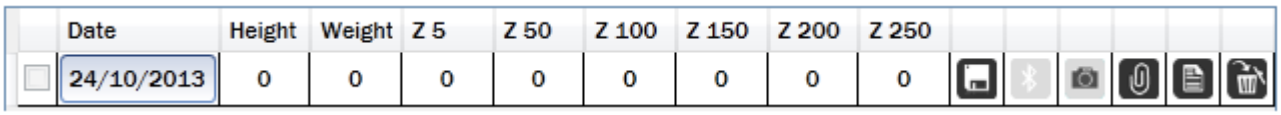
New tests are entered directly in the Tests chart.



Select the subject in respect of whom you wish to enter a new test in the archive column.

Select the *New Test* button.

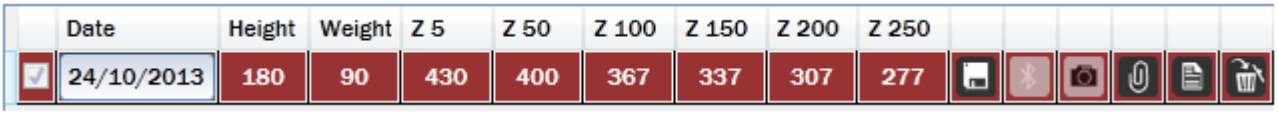
An empty tests chart will appear in the Tests area of the main page.



Enter the height and weight of the subject in the chart.

Perform the measurement on the subject with the Bodycomp MF Hexa analyser.

Select  to download the results via Bluetooth®.



If the PC is not Bluetooth® enabled enter the data manually.

The entered data are saved automatically.

Tools in the Test

Save: save the entered data.

Data are saved automatically when all the fields have been compiled.

Bluetooth®: automatically upload the data read by the Bodycomp MF Hexa instrument.

Transparent icon: the PC is not Bluetooth® enabled.

Display: display an image linked to the test.

Transparent icon: no image available for the test.

Attach image: Link an image to the test.

The image file must be in .jpg format. The software adapts the size of the image to the window and saves a copy in the software folder.

Enter notes

The entered note appears in the report printout.

Delete

Delete a test.

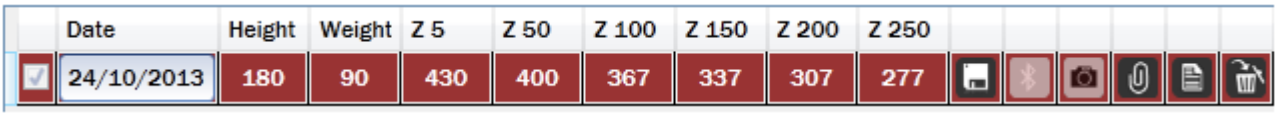
Display in the results area

To display a test in the results area click in any point of the test line.

The line is highlighted red.

Select

To select a test click the left-hand box (before the date).



	Date	Height	Weight	Z 5	Z 50	Z 100	Z 150	Z 200	Z 250						
☑	24/10/2013	180	90	430	400	367	337	307	277						

The selected tests have a tick (√) in the selection box.

To deselect a test: click the selection box. The tick will disappear.

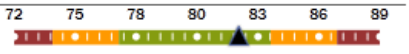
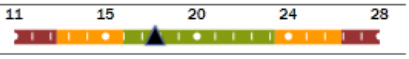
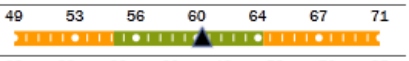
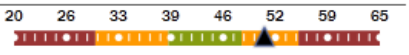
You can select more than one test to include in reports.

Edit

To edit an entered value: double click the cell to be edited

Test results

The body composition estimate values are shown in the test results area

Parameters	Values	%	References
Body-Mass Index (BMI)	27.8		
Phase Angle (PA)	5.0 ° (Estimated)		
Basal Metabolic Rate (BMR)	2243.8 kcal		
Body-Cell Mass (BCM)	35.8 kg	48	
Fat-Free Mass (FFM)	74.2 kg	82	
Fat-Mass (FM)	15.8 kg	18	
Total Body Water (TBW)	54.3 L	60	
Extra Cellular Water (ECW)	27.6 L	51	

Wherever possible each parameter is displayed with the estimated value, the percentage value, and the graphic representation of the reference model.

Reference values

FM and FFM: Fat-Free Mass and Fat Mass reference values by dual-energy X-ray absorptiometry (DEXA) in a 20-80 year-old Italian population. Coin et al. Clin Nutr. 2008 Feb;27(1):87-94.

BMI: WHO http://apps.who.int/bmi/index.jsp?introPage=intro_3.html

BMR Estimates and Calculation

Estimates are calculated with Akern's copyrighted proprietary formulas, the divulgation of which is strictly prohibited.

In view of the importance of the BMR calculation the user is given the facility to choose the formula to use. The formula can be selected from Akern's proprietary versions or the classic Harris-Benedict formula based on Fat-Free Mass (FFM):

Male under 40: FFM*27.717+188.21

Male over 40: FFM*25.333+188.21

Female under 40: FFM*24.039+427.64

Female over 40: FFM*21.956+434.38

To choose the BMR calculation formula click  .

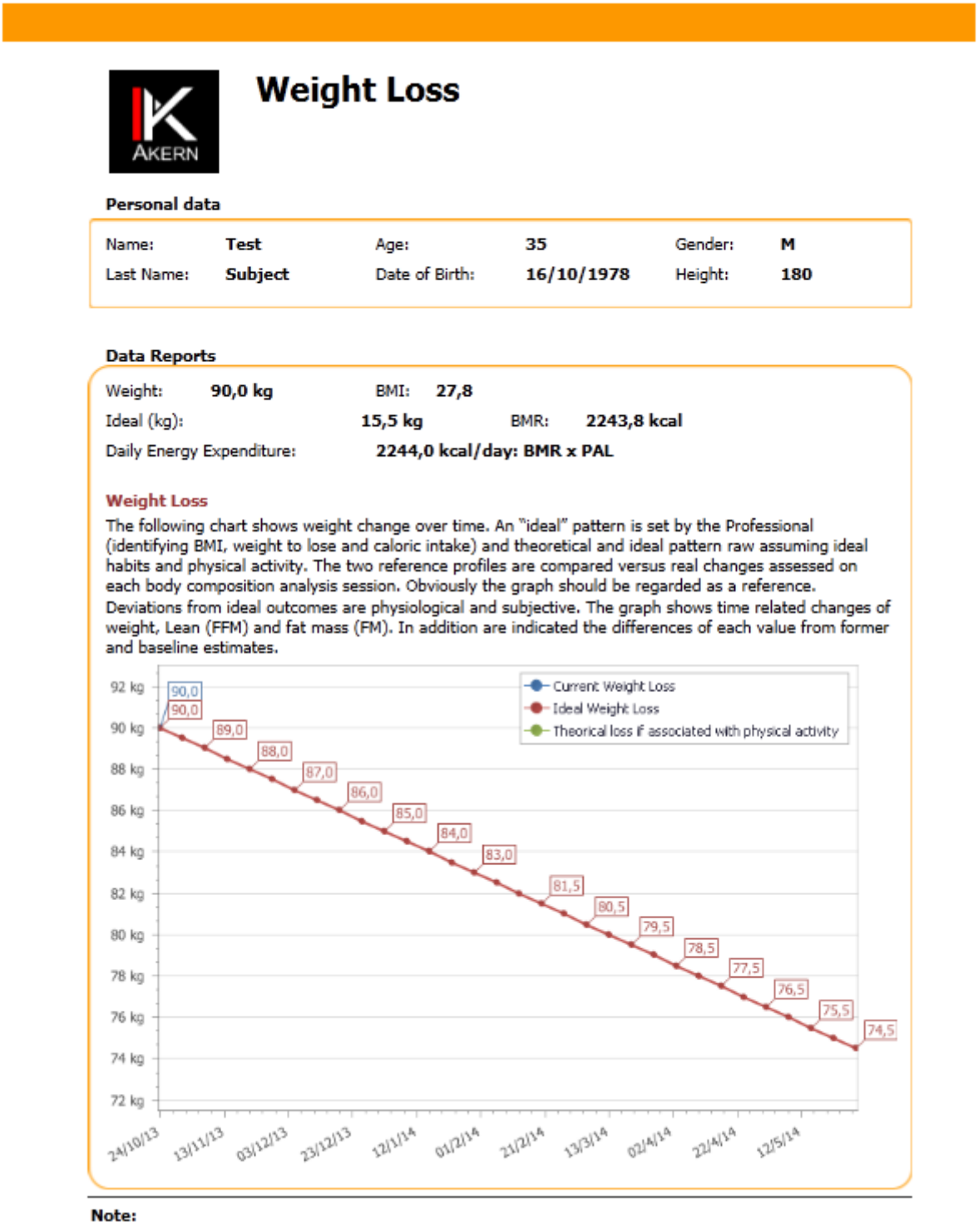
The selected BMR calculation formula is applied to all the tests in the archive and can be changed at any time.

Weight Loss

Select *Weight Loss* to open a graph that shows the ideal weight loss curve over time and compares it to the actual weight loss readings obtained during the test sessions.

On the main page select the tests you wish to include in the graph and then select the *Weight Loss* button.

No test selected: the graph includes all the tests present in the chart.



Weight Loss

Personal data

Name:	**Test**	Age:	**35**	Gender:	**M**
Last Name:	**Subject**	Date of Birth:	**16/10/1978**	Height:	**180**

Data Reports

Weight: **90,0 kg** BMI: **27,8**

Ideal (kg): **15,5 kg** BMR: **2243,8 kcal**

Daily Energy Expenditure: **2244,0 kcal/day: BMR x PAL**

Weight Loss

The following chart shows weight change over time. An "ideal" pattern is set by the Professional (identifying BMI, weight to lose and caloric intake) and theoretical and ideal pattern raw assuming ideal habits and physical activity. The two reference profiles are compared versus real changes assessed on each body composition analysis session. Obviously the graph should be regarded as a reference. Deviations from ideal outcomes are physiological and subjective. The graph shows time related changes of weight, Lean (FFM) and fat mass (FM). In addition are indicated the differences of each value from former and baseline estimates.

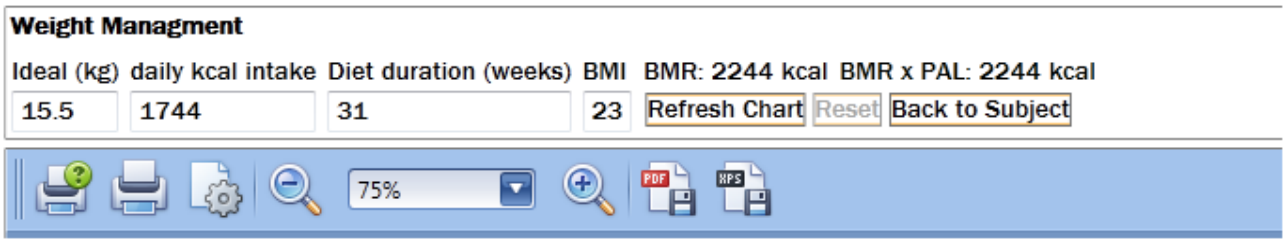
Note:

The ideal weight loss curve is plotted assuming a weight loss of 0.5 kg/week towards a target weight corresponding to a given BMI.

Formula used: 500 kcal less per day, 0.5 kg per week.

Faster weight loss is not recommended.

You can personalize the parameters by means of the *Weight Management* line:



When the Daily calorie intake or BMI is adjusted the duration of the diet is calculated accordingly; when the diet duration is adjusted, the daily calorie intake is calculated accordingly.

The entered parameters are saved automatically.

An error message warns the user if the entered parameters are incorrect (Daily calorie intake too low; Weight loss > 1 kg/week or ≤ 0.0).

Refresh Chart: recalculates all the parameters in accordance with changes made and refreshes the graph.

Back to subject: to quit the report and return to the main page

Reset: to return to the parameters set automatically by the software

To set the pre-defined BMI: click  .

Activities - Workouts

Bodycomp MF Hexa can calculate the effect of workouts on the weight loss program.

Select *Add Activity*.

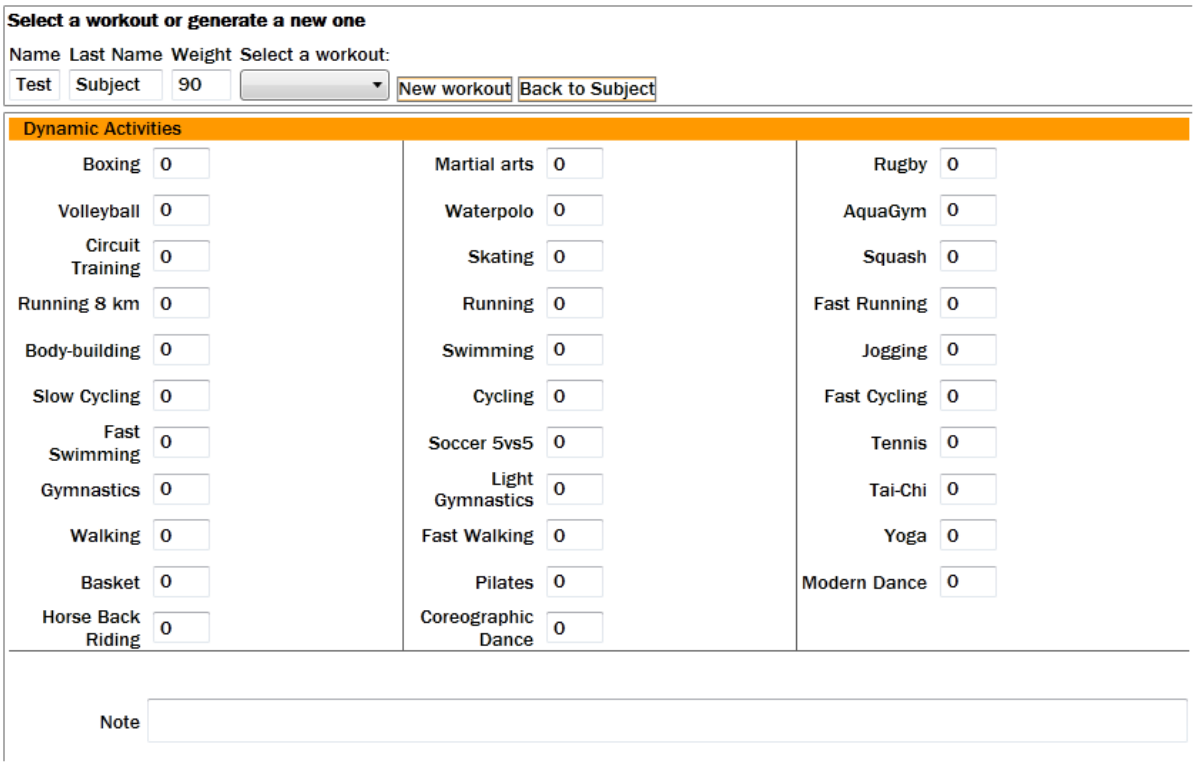
The software proposes a list of workouts.

Enter the hours per week that the subject intends to devote to the chosen workout.

Select *Weight Loss*.

A weight loss program with activity will be displayed, showing, in addition to the ideal and actual weight loss, a curve that identifies the estimated weight loss taking account of the calorie expenditure associated with the entered activities.

The incidence of the activity is calculated by the first test performed on the subject.



Save: saves the list, identifying it with the date and time.

Cancel: to abandon a list that has not yet been saved.

Weight Loss Report: to access to Weight Loss with activity Report printing.

Delete: to delete a saved list.

To display, edit or delete a list: select the required list from the pull-down menu. The selected list is displayed so that any changes or deletions can be carried out.

Report Configuration and Printing

Printing Methods

Each Report has common printing properties:

Print

Select the printer and print options before the print job.

Instant print

Send the document directly to the default printer without making any changes.

Page setup

Set the page layout and margins.

Zoom (display only)

Export Report in PDF format.

Export Report in XPS format.

Body Composition Report

The Body Composition Report shows the results of the impedance analysis test.

Body composition estimates

Three-compartment model

Compartments distribution Polar Graph.

From the main page select the test you wish to show on the report and then select the *BComp Report* button.

If more than one test is selected one Report will be printed for each selected test.

No test selected: a Report will be printed for all tests in the chart.

Test Report

Personal data

Name:	**Test**	Gender:	**M**
Last Name:	**Subject**	Date of Birth:	**16/10/1978**

Test data

Test:	**24/10/2013**				
Age	**35**	Height:	**180,0 cm**	Weight:	**90,0 kg**
5 kHz :	**430 Ω**	50 kHz :	**400 Ω**	100 kHz :	**367 Ω**
150 kHz :	**337 Ω**	200 kHz :	**307 Ω**	250 kHz :	**277 Ω**

Bodycomp Estimates

			Reference Values
BMI:	**27,8 kg/m²**		
PA:	**5,0 °**	(Estimated)	
BMR:	**2243,8 kcal**		
BCM:	**35,8 kg**	**(48 % | FFM)**	
FFM:	**74,2 kg**	**(82 % | Weight)**	
FM:	**15,8 kg**	**(18 % | Weight)**	
TBW:	**54,3 L**	**(60 % | Weight)**	
ECW:	**27,6 L**	**(51 % | TBW)**	

Note:

Comparison Report

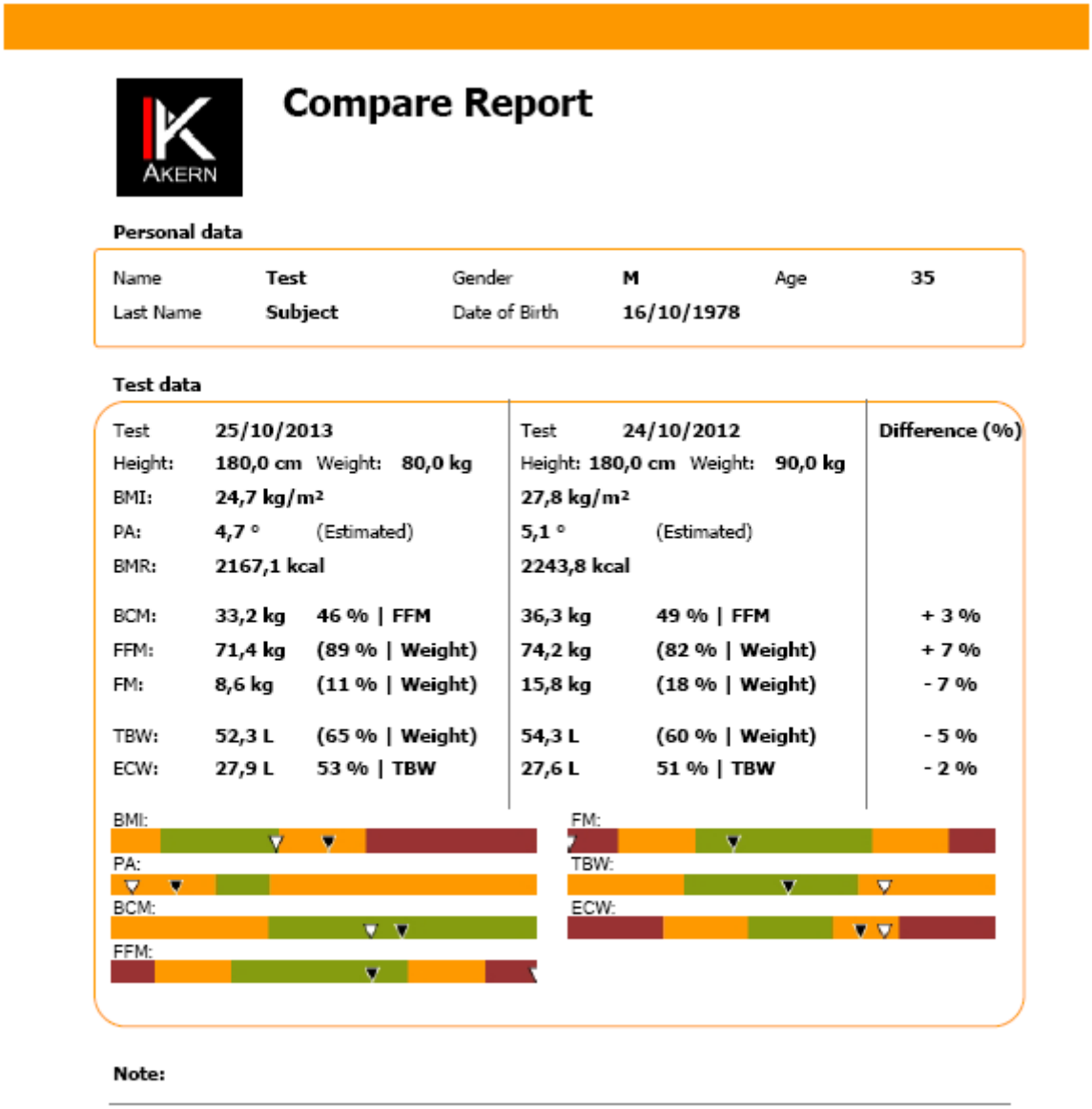
The Comparison Report shows a comparison between two tests selected from the tests chart.

- Body composition estimates comparison
- Three-compartment model comparison
- Polar Graph Comparison

Select 2 tests in the main page and click the *Compare* button.

No test selected: the button is not enabled; to enable the button you need to select 2 tests to compare.

If more than 2 tests are selected the report compares the 2 most recent tests.



Compare Report

Personal data

Name	**Test**	Gender	**M**	Age	**35**
Last Name	**Subject**	Date of Birth	**16/10/1978**		

Test data

	Test **25/10/2013**	Test **24/10/2012**	**Difference (%)**
Height:	**180,0 cm** Weight: **80,0 kg**	Height: **180,0 cm** Weight: **90,0 kg**	
BMI:	**24,7 kg/m²**	**27,8 kg/m²**	
PA:	**4,7 °** (Estimated)	**5,1 °** (Estimated)	
BMR:	**2167,1 kcal**	**2243,8 kcal**	
BCM:	**33,2 kg** **46 % | FFM**	**36,3 kg** **49 % | FFM**	**+ 3 %**
FFM:	**71,4 kg** **(89 % | Weight)**	**74,2 kg** **(82 % | Weight)**	**+ 7 %**
FM:	**8,6 kg** **(11 % | Weight)**	**15,8 kg** **(18 % | Weight)**	**- 7 %**
TBW:	**52,3 L** **(65 % | Weight)**	**54,3 L** **(60 % | Weight)**	**- 5 %**
ECW:	**27,9 L** **53 % | TBW**	**27,6 L** **51 % | TBW**	**- 2 %**

BMI: PA: BCM: FFM: FM: TBW: ECW:

Note:

Follow-up

The Follow-up report follows the time trend of:

Weight

Fat-Free Mass (FFM)

Fat Mass (FM)

Each bar shows the value of the column, the difference with respect to the previous test and the difference with respect to the first test.

Select the tests you wish to display and click the *Follow-up* button in the main page.

No test selected: the graph includes all the tests present in the chart.

Settings

The  button opens the program settings window.

Options:

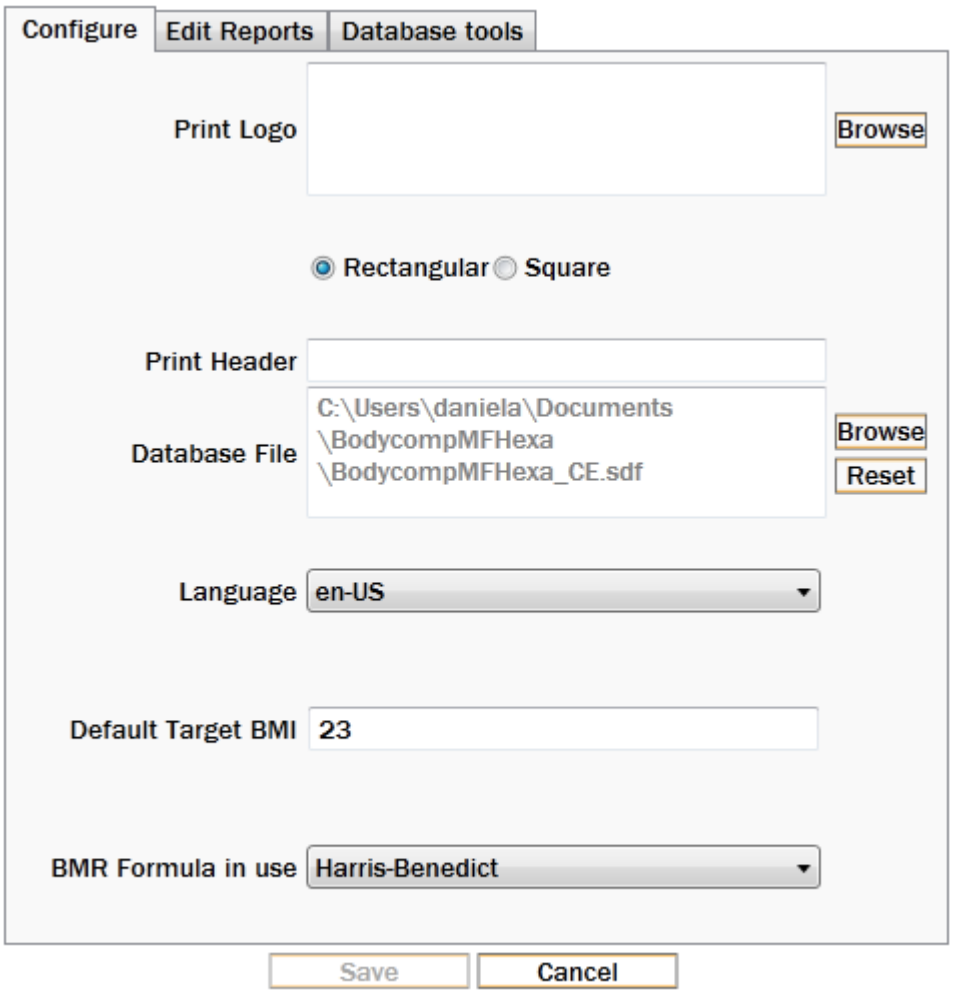
Personalize the configuration

Edit printout texts

Import data from earlier software versions

Save: save and activate the changes made.

Cancel: return to the main page without saving your changes



Personalize the configuration

Change print logo

Click browse and select the required file.

Compatible formats: *.jpg / *.gnp

The program automatically adapts the size of the image to the chosen format (square/rectangular).

The selected image appears in all reports.

Edit print heading

Type the text to enter in the heading.

The entered text (max. 3 lines) appears in all reports.

Database

The default database of Bodycomp MF Hexa is /Documents/Bodycomp/Bodycomp.mdb.

This function allows you to:

- share the database among several users: copy the file to a shared server-based folder.

This operation should be reserved for expert users; an error in this stage could block execution of the program.

Make sure the destination folder and the file **are not** set to read-only mode.

- work with multiple separate archives, choosing the database on which to work time by time.

Language selection

Click the arrow to show the available languages and select the required one.

BMI Target

Enter the BMI target, which will be proposed automatically in the weight loss calculation.

BMR formula

Click the arrow to select the BMR calculation formula (re. BMR Formula)

The formula is applied automatically to all the tests in the archive.

Edit Printout texts

Select *Edit printout texts* to display and edit the report texts.

Save: changes made will be active on all reports.

Reset: reset the original texts at any time.

Cancel: quit the page without saving your changes.

Database Tools

Export Database

Click *Export*.

An SDF file will be created, identified by the export date (yyyymmdd).

Import Database

Adds data from other database to the database in use.

Click *Browse:* the file selection window opens.

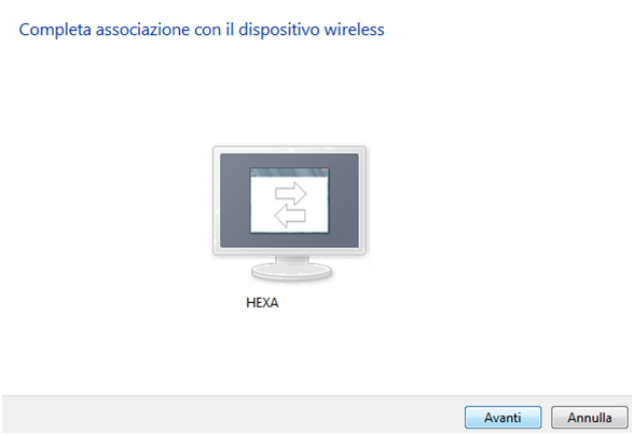
Select the file and click *Import*.

Troubleshooting

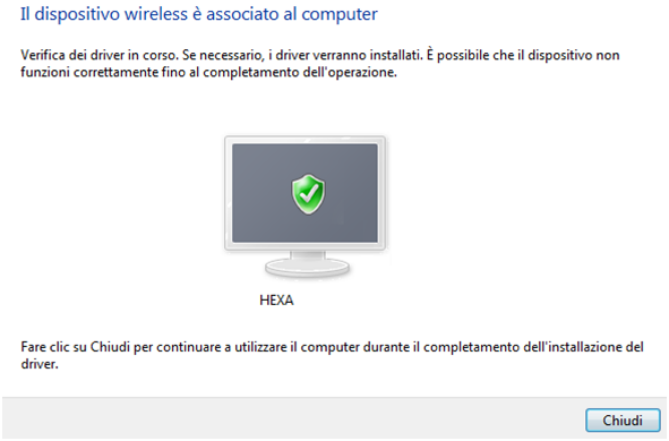
Bluetooth connection problems

If the following error message appears first time Bodycomp MF Hexa is launched:

Click the message



Select *Next*



Select *Close*

Technical Characteristics

Medical Device Classification

Bodycomp MF Hexa is identified as a CLASS I medical device in compliance with directive 93/42/EEC; it is also a Class A medical device in compliance with ***EN 62304:2006.***

Technical characteristics

Program type: C# Windows Presentation Foundation.

Database type: Microsoft SQL, direct password-protected access, encrypted subject names.

DB access: local or with network path, via utility included in the software.

Database and config file installation folder: username/documenti/BodycompMF.

Installation method: User client.

Requirements: Microsoft .NET framework 4, SQL engine.

License: By means of activation key available online and offline.

Respect for subject data protection: subject names encrypted in direct DB access.

Minimum system requirements

Microsoft Windows VISTA, Windows 7, Windows 8 Desktop

Minimum screen resolution 1024x768

1GHz processor

1GB RAM

1.5 GB free disc space

Declaration of Conformity

Medical device: Bodycomp MF Hexa (Software)

Manufacturer: Akern S.r.l.
Via Lisbona 32/34
50065 Pontassieve (Firenze), Italy
Person in charge: Antonio Talluri
Sole Director

The manufacturer declares conformity with directive 93/42/EEC and subsequent amendments as a Class I medical device; conformity is obtained by means of a self-certification procedure as defined by the Directive. The manufacturer undertakes to retain the necessary documentation and has entered the medical device in the company quality system.

The manufacturer declares that the Bodygram PRO medical device is also a Class A device in conformity with the definitions of standard *IEC 62304:2006* ***concerning the software life cycle. And is in compliance with the prescriptions set down in standard*** *CEI EN 60601-1-4:2000* ***concerning "programmable electrical medical systems".***

Conformity marking

CE

ANTONIO TALLURI