BODYGRAM® PLUS

Body composition assessment software

Rev. 6 7/2019

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ACTIVATIONS MEMO

Complete and update on each new activation

Device serial number:	
Email:	
Password:	
Date:	PC name:
Date:	PC name:
Date:	PC name:
Date:	PC name:
Date:	PC name:
Date:	PC name:
Date:	PC name:

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DESCRIPTION

Bodygram PLUS is an application for assessing body composition by means of measurements made using Akern impedance analysers.

The main functions of this application are:

- ✓ Complete body composition estimates using three-compartment technique, new nutritional parameters, over 50 functions
- ✓ Estimations Function: the introduction of Fat Mass (FM) and Fat-Free Mass (FFM) estimation algorithms using the subject's actual tissue hydration level at the time of the test greatly reduces the estimation error.
- ✓ Interpretive Function: specific test interpretation algorithms which help the user to assess the subject's body composition.
- ✓ Weight Loss Assistant: setting BMI, daily calories and weight to be lost allows the application to determine the theoretical time in which the established weight will be reached. Regular physical activities that help to increase calorie expenditure can also be included in the weight loss plan.
- ✓ New Hydragram™ and Nutrigram™ tests as well as the established Biavector™ (BIVA) and Biagram™ techniques, for immediate assessment of the subject's hydration and nutritional status.
- ✓ Nutritional Estimations Function: use of FFMI (Fat Free Mass Index) and FMI (Fat Mass Index) percentiles for evaluating the subject's nutritional status over time; measurement of arm and leg force to monitor loss of muscle mass; assessment of muscle mass using the innovative SMI (Skeletal Muscle Mass Index) and ASMM (Appendicular Skeletal Muscle Mass Index) formulas.

USER LICENCE

Bodygram PLUS is licensed software.

A Bodygram PLUS licence allows you to activate 3 users.

Bodygram PLUS has a modular structure, allowing you to construct your ideal software platform, precisely tailored to your needs.

At the time of purchase, the complete software, comprising a full set of modules, is supplied free of charge for a trial period of 90 days.

New modules are published at regular intervals; a trial period of 90 days is granted for every new module published.

Bodygram PLUS interfaces with the Bodygram Cloud service, also supplied free of charge for 90 days.

Further details of the Bodygram PLUS modules and Bodygram Cloud service are provided in the relative manuals.

INTENDED USE

The Bodygram PLUS medical device has been developed to manage information derived exclusively from Akern impedance analysers.

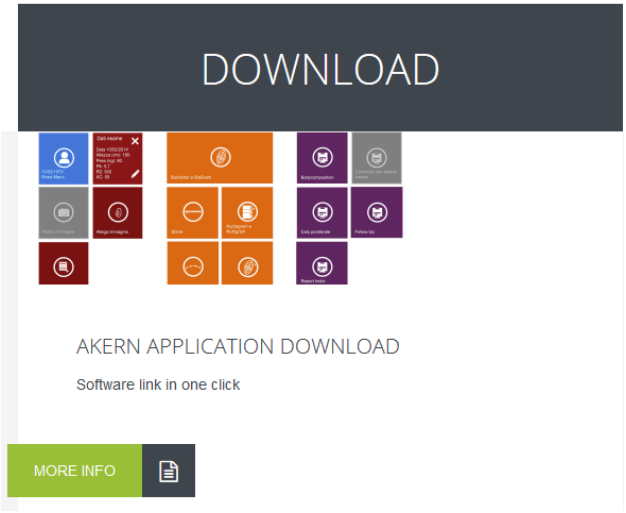
Using it with different makes of impedance analyser can result in a loss of safety and applicability.

The results generated by the software do not have absolute diagnostic value, but in combination with other parameters and a clinical assessment they can help to accurately identify body composition abnormalities.

Although anyone may use the software, results obtained from its application on persons with physiological disorders must only be interpreted by properly trained clinicians.

INSTALLATION

Go to the www.akern.com website.

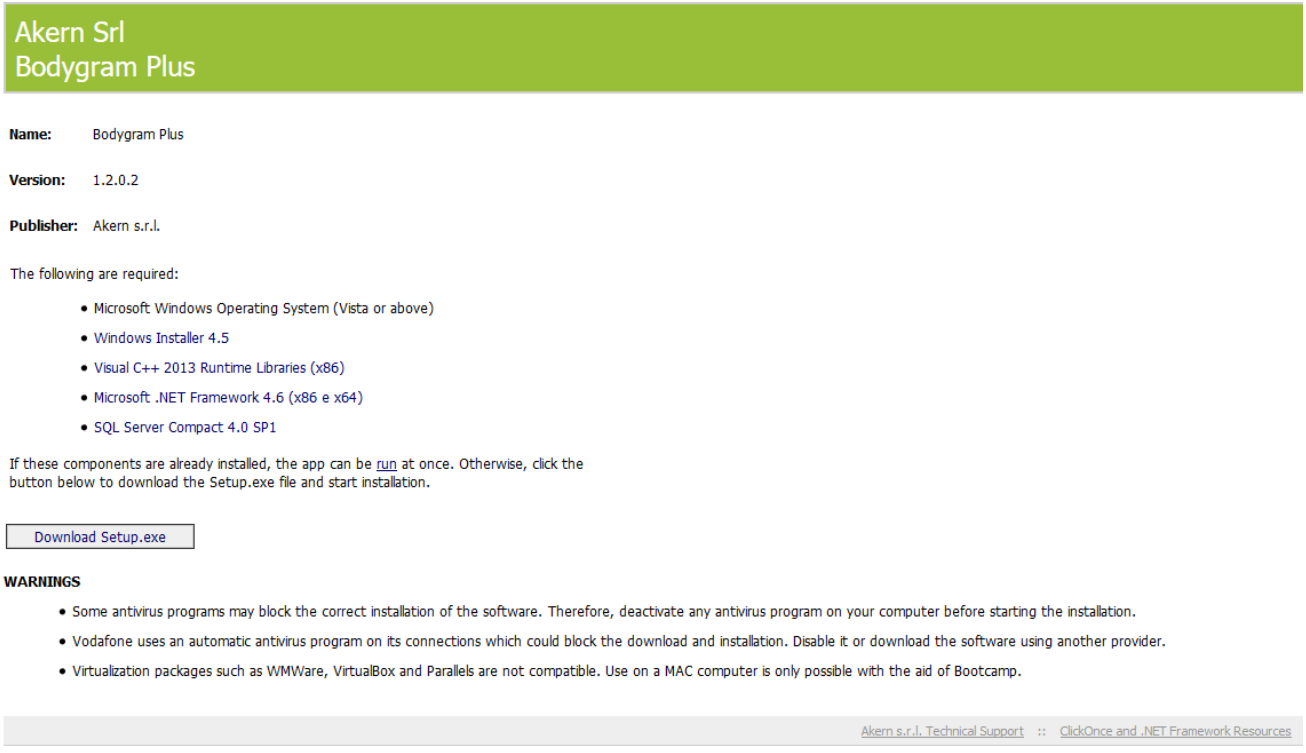


Find the Download area in the middle of the screen

Select

Select the Bodygram PLUS icon

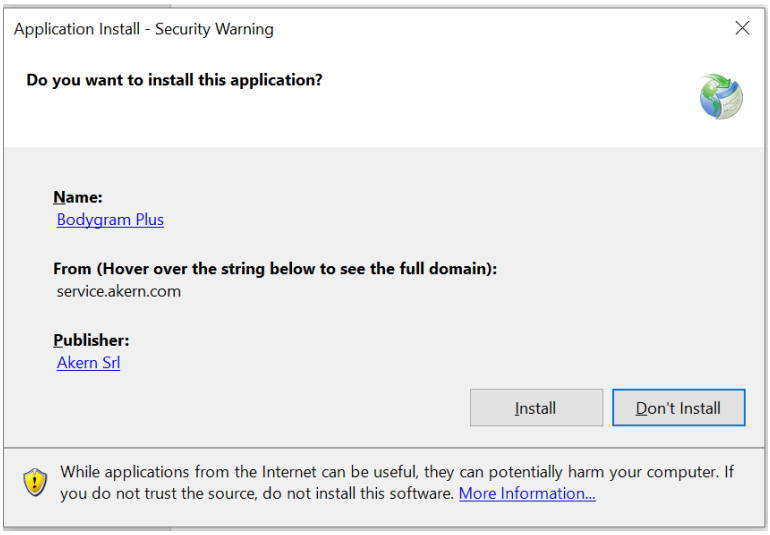
The installation window will open. Select Install



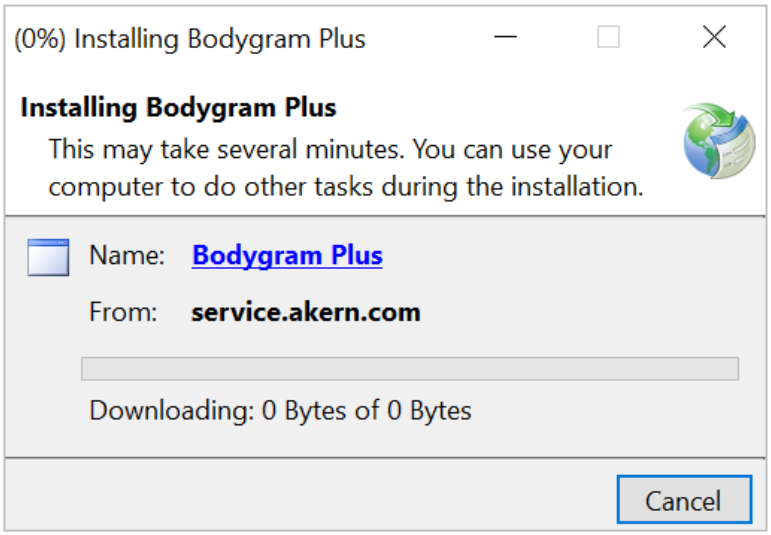
Some antivirus programs may block the correct installation of the software.

Any antivirus programs on your computer should therefore be deactivated before starting the installation.

The Security Warning dialog will open. Select Install



The installation progress screen will open.



Confirm all the necessary authorisations.

Do not switch off your computer until the installation is complete.

Useful information:

Dialog screens can vary between operating system versions. In any case, it is always best to confirm all the authorisations requested by the system

UPDATES

Bodygram PLUS automatically looks for updates whenever the computer is booted up with Internet access.

The updates offered should always be installed.

ADMINISTRATOR/USER INSTALLATION PROCEDURE

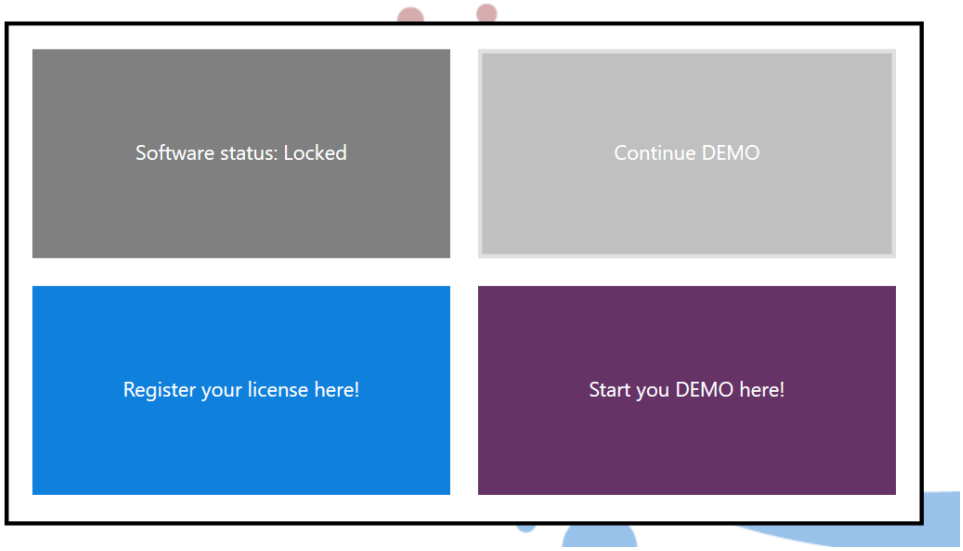
In certain situations, especially in public sector organisations and large companies, the software must be installed by a User client.

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

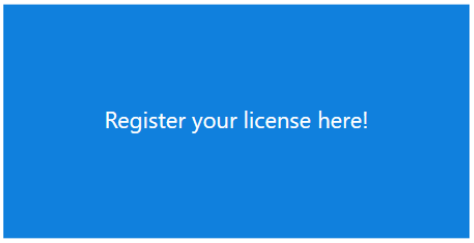
Requirements: .NET Framework 4.0 and SQL Compact edition. These can be obtained from the Microsoft website.

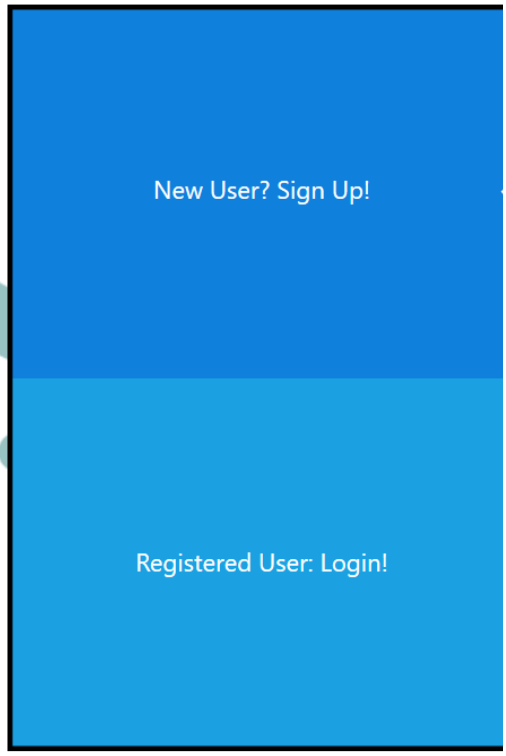
If the software is installed on a User computer it is best to install the software **first** as an Administrator client and then reinstall it as a User client.

ACTIVATION



Select Register your licence here!





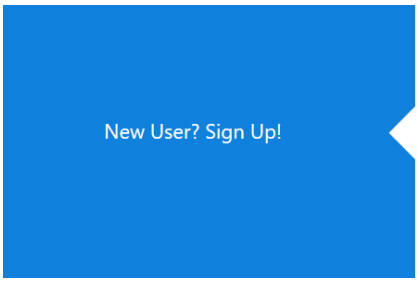
This opens the registration page.

Register as a new user or login if you already have an account, by selecting the option required in the blue panel on the left-hand side of the screen.

Useful information:

- ✓ A Bodygram PLUS licence allows you to activate up to 3 different computers.
  A licence can be transferred between computers if one is replaced. For more details: Software management
- ✓ Fill in the Activations Memo and keep it up to date – this will ensure you always have all data to hand, making activation simpler and faster.

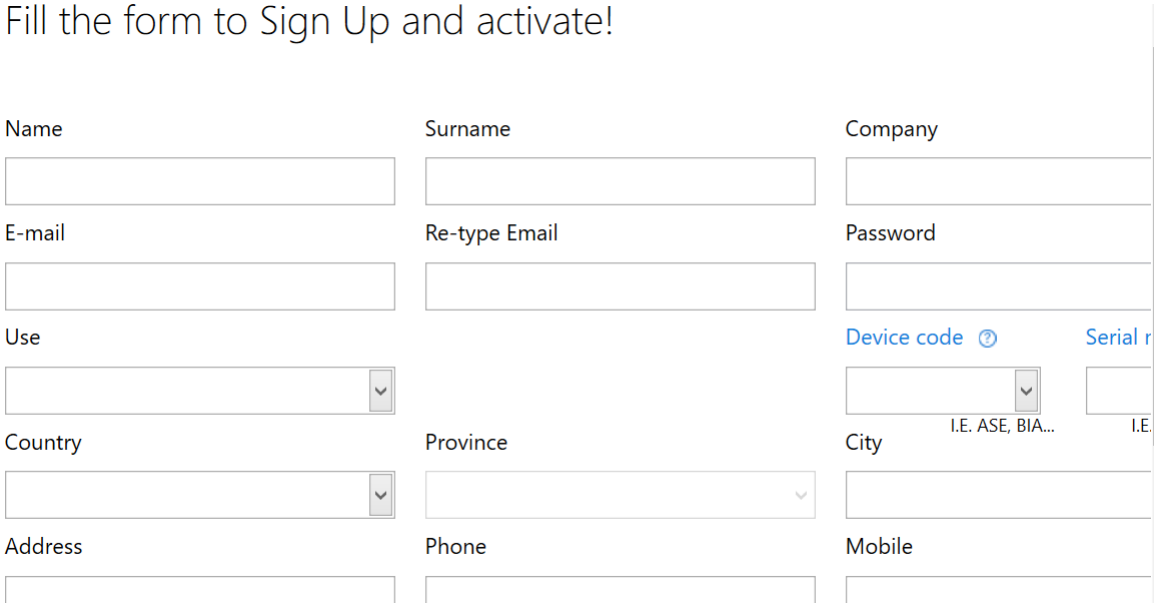
INITIAL ACTIVATION (REGISTRATION)



Select *New User? Sign Up!* in the blue panel on the left-hand side of the registration screen.

Only use this procedure if you do not already have Akern software.

If you already have Akern software, use the *Login* procedure

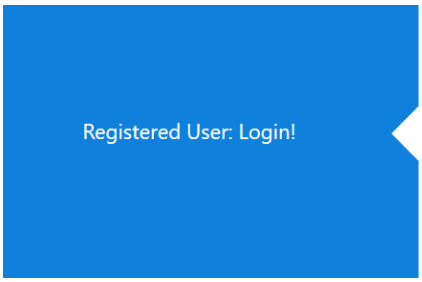


Fill in all the required fields.

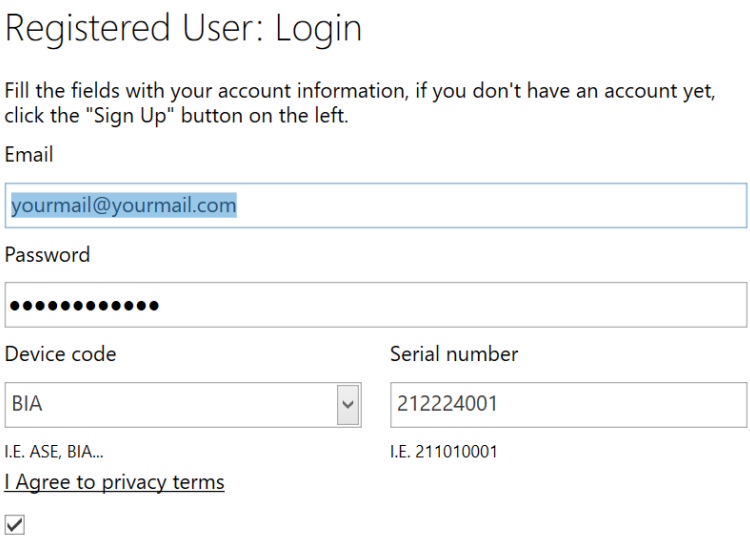
- ✓ *Email:* the address typed will be used for future activations and for accessing the Akern site
- ✓ *Password:* the password typed will be used for future activations, for protecting access to the software and for accessing the Akern site;
- ✓ *Device code:* select the alphabetic part of your Akern sensor's serial number from the drop-down menu
- ✓ *Serial number:* type the numerical part of your Akern sensor's serial number
- ✓ Tick the *I Agree to privacy terms* box
- ✓ Select *Sign Up!*

The email address and password entered at this stage will be required for subsequent activations and for accessing the Akern site. Therefore, take care to enter this data correctly and make a note of it

SUBSEQUENT ACTIVATIONS (LOGIN)



Select *Registered User: Login!* in the blue panel on the left-hand side of the registration screen.



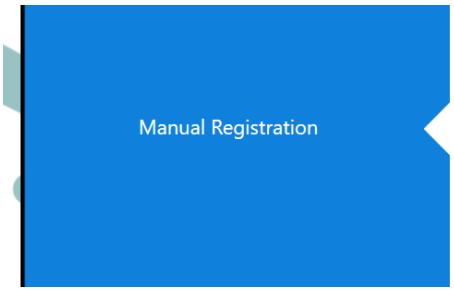
Fill in all the required fields.

- ✓ *Email:* type the address used when registering
- ✓ *Password:* type the password created when registering
- ✓ *Device code:* select the alphabetic part of your Akern sensor's serial number from the drop-down menu
- ✓ *Serial number:* type the numerical part of your Akern sensor's serial number
- ✓ Tick the *I Agree to privacy terms* box
- ✓ Select *Login*

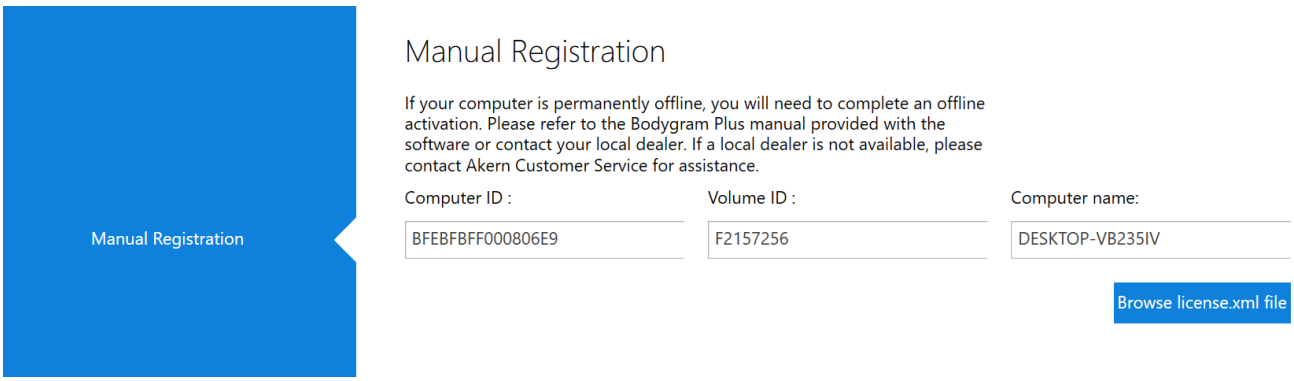
If you have forgotten your password, select *Forgot your password?*

The password will be sent to your registered email address.

MANUAL REGISTRATION



The manual registration screen will open when the computer has no Internet access.



Contact the Technical Support Service, stating the following:

- ✓ email address and password entered during registration (or all data needed for registration) as described in the previous points
- ✓ Akern sensor serial number
- ✓ Computer ID, Volume ID and Computer name shown on the manual registration screen

You will be sent an email containing a file named *license.xml*

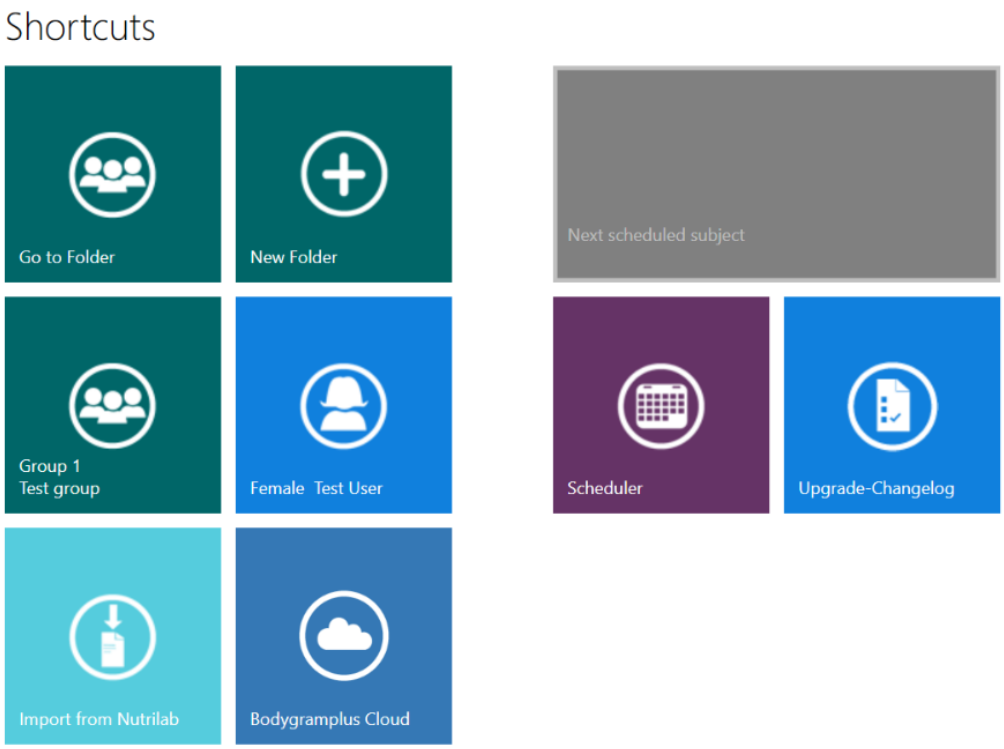
- ✓ Download this file to any Internet-enabled computer and save it to a removable device (USB pen drive or CD).
- ✓ Transfer the file to the Bodygram PLUS PC to be activated
- ✓ Select *Browse licence xml file*
- ✓ Load the *license.xml* file

⚠ Manual registration is not possible if your computer has Internet access.

You cannot perform manual registration without your account details (email and password) and your Akern sensor's serial number.

HOME PAGE

SHORTCUTS



Shortcuts on the Home Page give quick access to the software's main functions:

- ✓ List of subject classification groups
- ✓ Creation of a new subject classification group
- ✓ Last group modified
- ✓ Last subject modified
- ✓ Import from Nutrilab/EFG+ (only active for Nutrilab and EFG+ sensor owners)
- ✓ New assessment for the next subject scheduled (only active if the scheduler contains appointments)
- ✓ Scheduler (only active for Weight Manager Module owners)

SEARCH

Select this button to find a subject on file.

Type one or more letters to display all subjects whose names contain the search string entered.

ADDITIONAL FEATURES

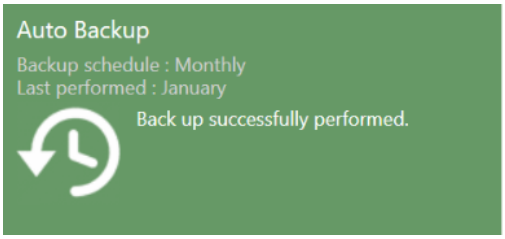
Gives changelog information after an upgrade.

The icon is only shown after an upgrade.

This window scrolls through the most recent articles of the month published on the www.akern.com website.

Select to view the whole library.

Select an article to view it on the Akern site.

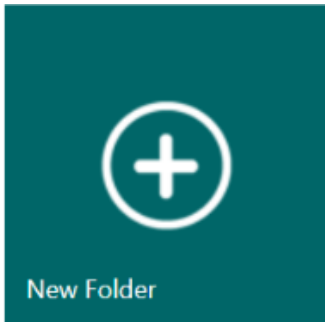


Provides information about the auto backup and can be used to perform a manual backup.

Manual backup is only carried out if changes have occurred since the previous backup.

CLASSIFICATION IN GROUPS

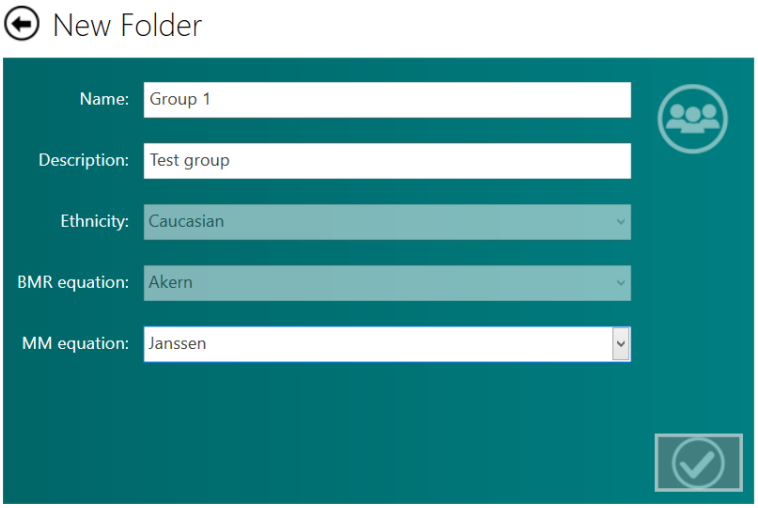
CREATING A GROUP



To create subject classification groups:

select New Folder

The number of groups which can be created is unlimited.



Name	Type a name for the group (folder)
Description	A short description of the group can be entered
Ethnicity	Select the reference population from the drop-down menu (only Caucasian available)
BMR equation	Select the BMR calculation equation from the drop-down menu (only copyrighted Akern proprietary equation available)
MM equation	Select the Muscle Mass calculation equation from the drop-down menu

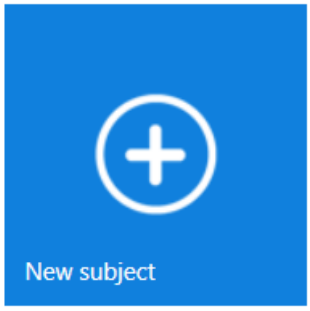
The selected calculation equations are applied to all the assessments in the group and can be changed at any time. For more information on the calculation equations, see the Information on the equations used section

Saves the data entered and accesses the group functions

GROUP SCREEN FUNCTIONS

The *Group* screen lists all the subjects in the group in alphabetical order.

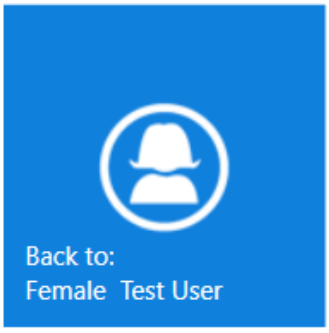
Several functions are also available:



New subject

For entering a new subject in the group.

(See Entering a new subject section)



Back to

For returning to the last modified subject in the group.

Creates a .csv file (compatible with MS Excel) containing the results for all the assessments of the subjects in the group.

EDITING/DELETING A GROUP

For editing the group's name and description and the equation settings.

The changes made will be applied to all assessments in the group

Confirms the changes made

Permanently deletes the group and all the assessments and subjects it contains

Confirms deletion

Cancels the operation and goes back to the list of groups

Deleting a group automatically deletes all the assessments and subjects it contains. Before deleting a group the software automatically creates a backup copy in the database.

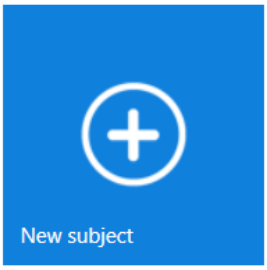
Useful information:

- ✓ A subject can be moved from one group to another at any time.

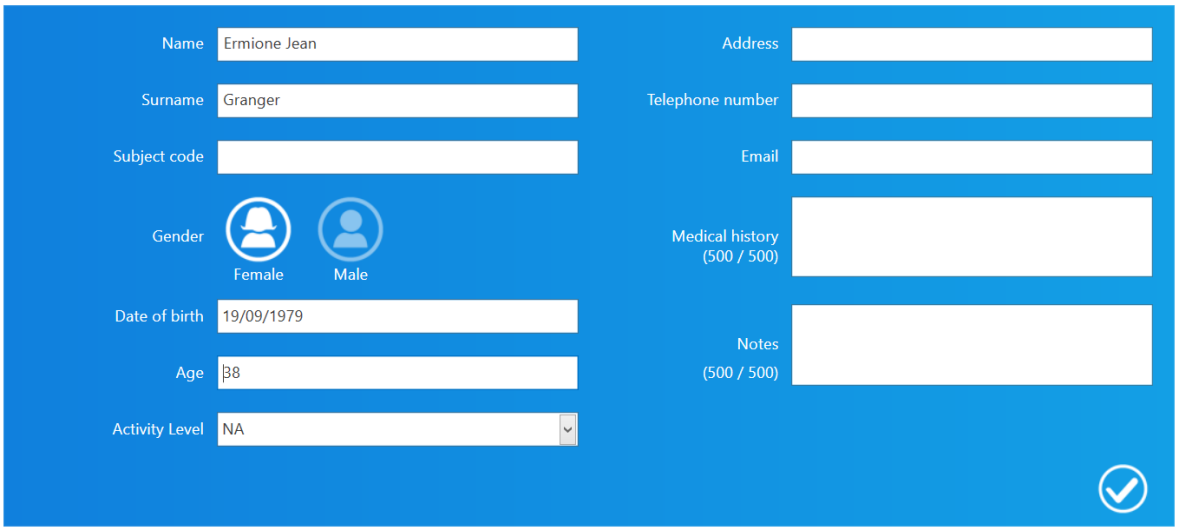
  For more details: Subject screen functions

THE SUBJECT DATABASE

ENTERING A NEW SUBJECT



Select the group in which you wish to enter the subject, then press the *New Subject* button.



Enter the subject's data.

Name, Surname, Gender and Date of Birth (or Age) are compulsory.

The PAL FACTOR coefficient is used to calculate daily energy expenditure based on the subject's physical activity level.

The PAL factor must be evaluated correctly in order to develop the weight loss program.

More information is provided in the next section.

Confirms the data entered and saves the subject.

PAL (PHYSICAL ACTIVITY LEVEL) FACTOR

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

The following chart shows the values utilised by the Bodygram PLUS software.

Lifestyle	PAL
Extremely inactive	1.1
Sedentary	1.3
Slightly active	1.4
Active	1.5
Vigorously active	1.7
Athlete	2.3

Correct selection of the PAL factor is only possible through accurate estimation of the subject's typical daily activity. Example:

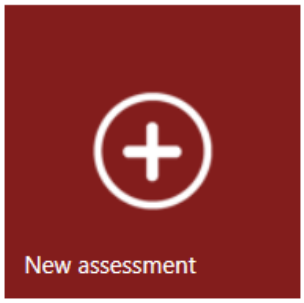
Daily activities Slightly active level	Hours	Hourly energy expenditure	Value	
Sleep	8	1	8	
Personal care	1	2.3	2.3	
Eating	1	1.5	1.5	
Cooking	1	2.1	2.1	
Seated (office, etc.)	8	1.5	12	
Housework	1	2.8	2.8	
Driving	1	2.0	2.0	
Walking	1	3.2	3.2	
Light leisure activities (TV)	2	1.4	2.8	
Total	24		36.7	36.7/24=1,53

Source: Human energy requirements Report of a Joint FAO/WHO/UNU Expert Consultation *ISBN 92-5-105212-3*

SUBJECT SCREEN FUNCTIONS

The *Subject* screen includes all assessments performed on the subject.

Several functions are also available:



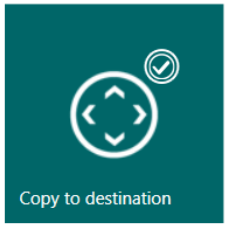
New Assessment

For entering a new assessment for the subject.

(See Entering a new Assessment section)

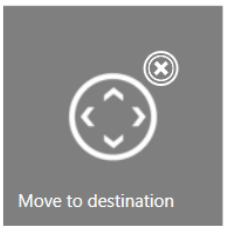
For moving the subject to another group.

A search function is available to facilitate navigation between groups.



Copy to destination

Copies the subject and all their assessments into the destination group, while also maintaining them in the origin group.



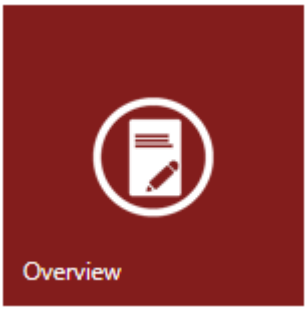
Move to destination

Moves the subject and all their assessments into the destination group, deleting them from the origin group.

Displays the results of all the subject's assessments in database format.

The assessments chart can be exported as a .csv file (compatible with MS Excel).

This function is also available in the Assessment screen.

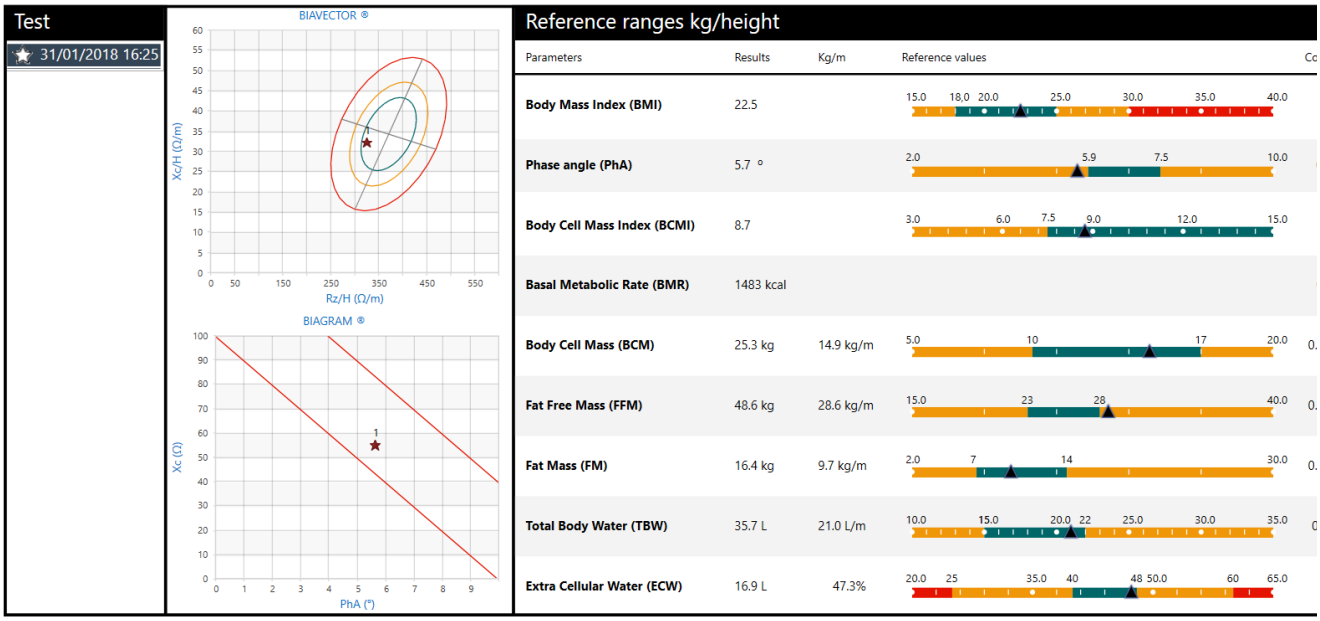


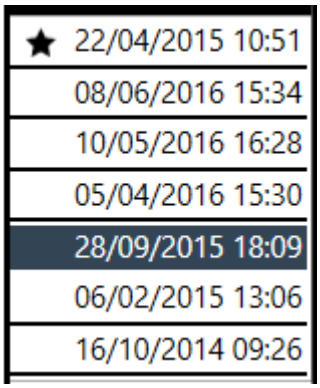
Displays BiaVector and BiaGram together with the body composition estimates.

Displays the selected assessment and the baseline test.

Triangle symbol: selected assessment

Star symbol: baseline test.





For selecting assessment for display.

The baseline test appears on the top line of the chart and is marked by the star, followed by all the other assessments in decreasing order of date.

The selected assessment appears in white characters on a grey background.

Toggles between display of the reference ranges in absolute kg/metre values or in %/weight.

Returns to the *Subject* screen

EDITING/DELETING A SUBJECT

For modifying the subject's data and PAL setting.

The changes made will be applied to all assessments performed on the subject

Confirms the changes made

Permanently deletes the subject and all assessments performed

Confirms deletion

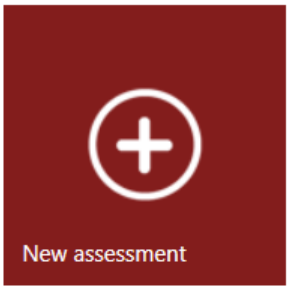
Cancels the operation and goes back to the Subject screen

Warning: deleting a subject automatically deletes all assessments.

Once deletion has been confirmed it will no longer be possible to recover the deleted data.

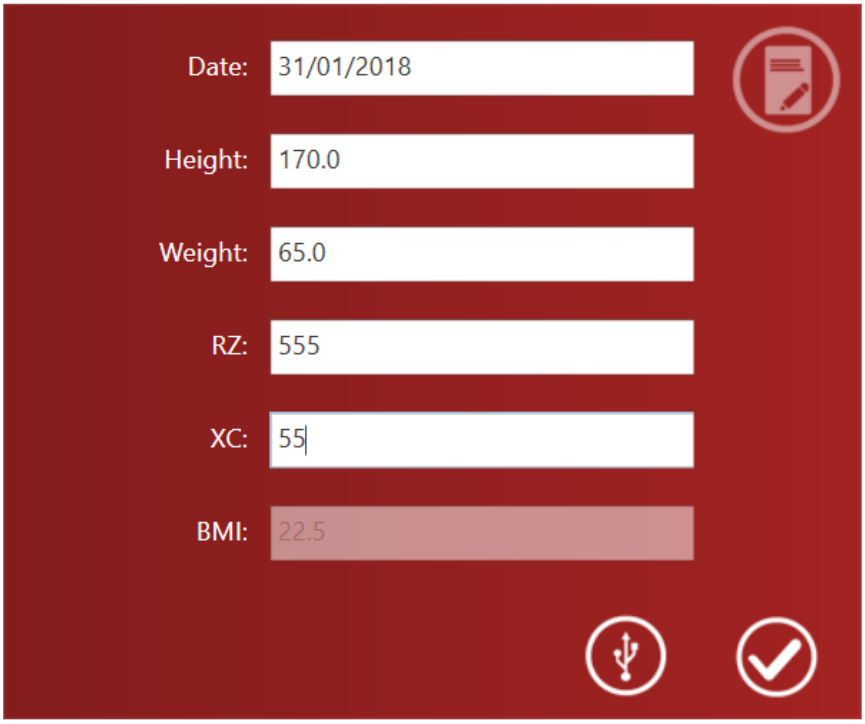
ASSESSMENTS (TESTS)

ENTERING A NEW ASSESSMENT



To enter a new assessment:

- ✓ select the group containing the subject for assessment
- ✓ select the subject
- ✓ select New Assessment in the Subject screen



Enter the subject's height and weight. If previous assessments have been performed on the subject, the data from the previous assessment will be displayed in the height and weight fields.

Enter the Rz and Xc data measured by the Akern sensor manually or by USB connection

To acquire data via USB connection:

Connect the Akern sensor to the computer by USB cable and select the icon (See Akern sensor manual)

Confirms the data entered and saves the assessment in the subject database

BASELINE TEST SETTING

A baseline test can be selected for comparison with other assessments performed on the same subject.

From the Subject screen, select an assessment and then click the star to set it as the "baseline test"

The assessment selected as the baseline test appears in a lighter colour and is marked *Baseline Test*

EDITING/DELETING AN ASSESSMENT

To edit or delete an assessment:

- ✓ select the group
- ✓ select the subject
- ✓ select the assessment and access the assessment screen

To edit the data entered

Confirms the changes made

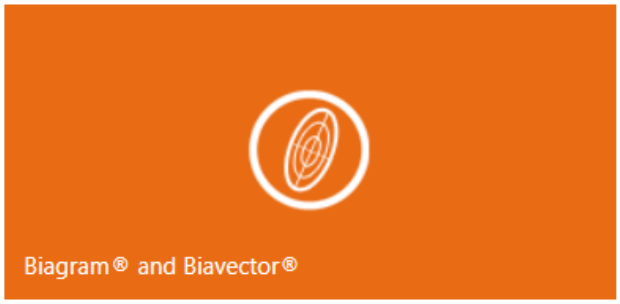
Permanently deletes the assessment

Confirms deletion

Cancels the operation and goes back to the list of groups

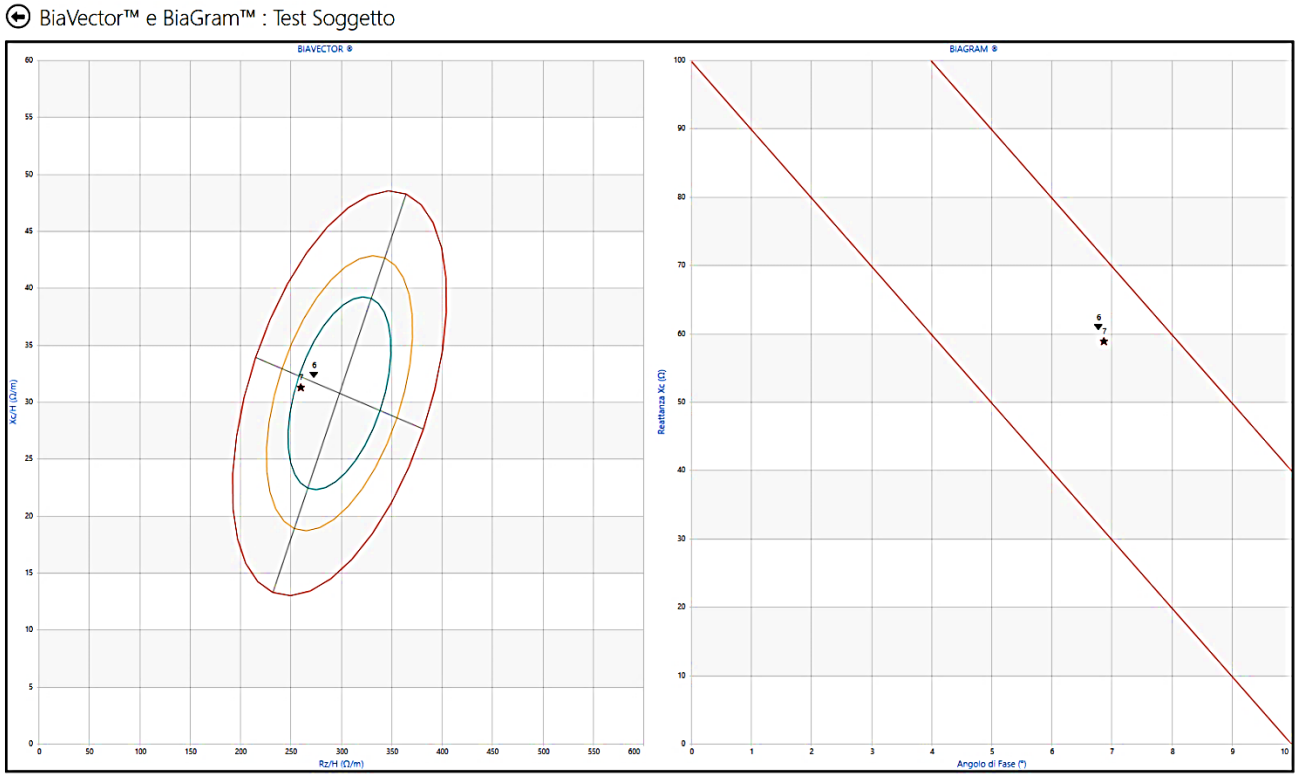
ASSESSMENT FUNCTIONS

BIAVECTOR™ AND BIAGRAM™



Accesses the BiaVector and BiaGram screen.

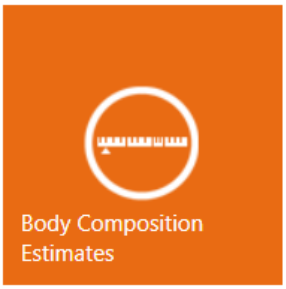
Displays the selected assessment (triangle symbol) and baseline test (star symbol) on BiaVector and BiaGram



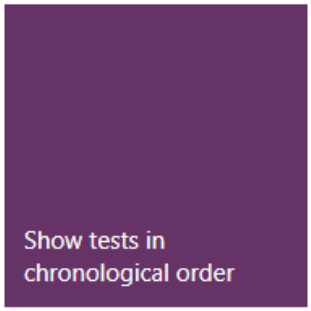
Move the mouse onto each test to view it in detail.

Returns to the Subject screen

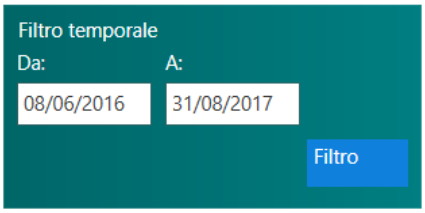
Displays the details of the current assessment



Accesses to the *Estimates* function (see next section)



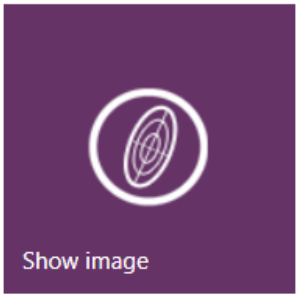
Includes all the assessments performed on the subject in the display



A time filter can be applied.

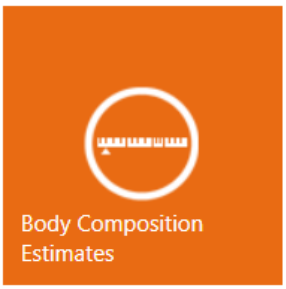
Returns to display of the current assessment.

Displays general information on the Biavector data reading.



Returns to display of the current assessment.

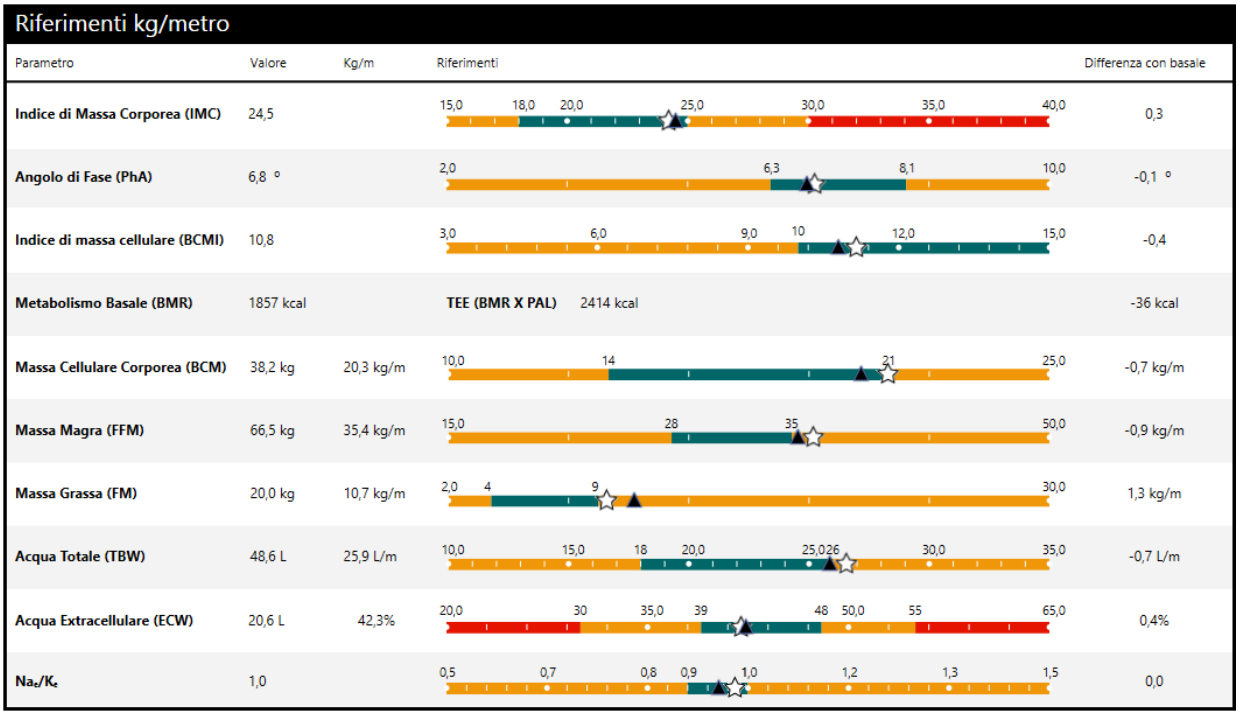
ESTIMATES



Displays the body composition estimates.

The estimated value, the reference graph, the percentage value (where possible) and the difference compared to the baseline test are shown for each parameter.

The reference ranges can be displayed as absolute kg/metre values or in %/weight.



Triangle symbol: current assessment

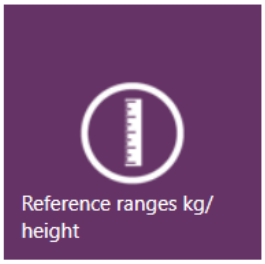
Star symbol: baseline test.

The button provided can be used to toggle between display of the reference ranges in absolute kg/metre values or in %/weight.

Returns to the Subject screen

Displays the details of the current assessment

Accesses the *BiaVector* and *BiaGram* function (see next section)



Toggles between display of the reference ranges in absolute kg/metre values or in %/weight.

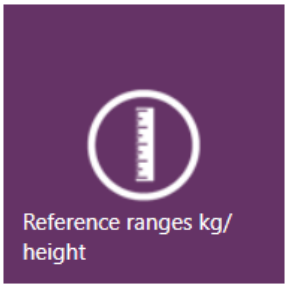
Accesses the glossary

PRINTOUTS

ANALYTIC BODY COMPOSITION REPORT

Shows the results of the body composition analysis: Biavector and Biagram, Body composition estimates, Three-compartment model and Compartment distribution Polar Graph.

Displays only the selected assessment

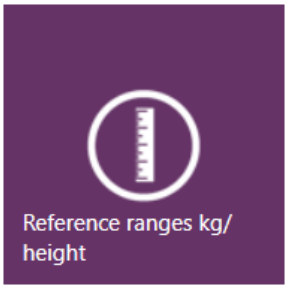


For selecting the display mode required: reference ranges as absolute kg/metre values or in %/weight.

BODY COMPOSITION SUMMARY REPORT

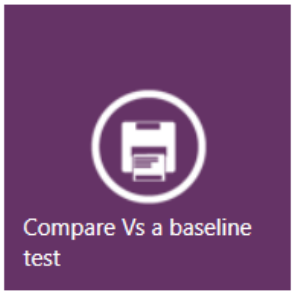
Shows the results of the body composition analysis: Biavector and Biagram, Body composition estimates, Three-compartment model.

Displays only the selected assessment



For selecting the display mode required: reference ranges as absolute kg/metre values or in %/weight.

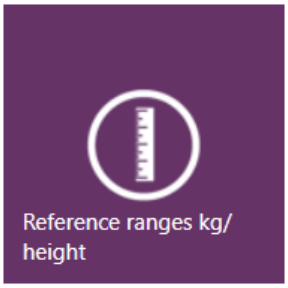
BASELINE TEST COMPARISON



Displays the comparison between the selected assessment and the baseline test: Biavector and Biagram, Body composition estimates, Three-compartment model and Compartment distribution Polar Graph.

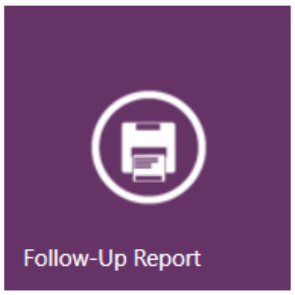
Selected assessment: triangle symbol

Baseline test: star symbol



For selecting the display mode required: reference ranges as absolute kg/metre values or in %/weight.

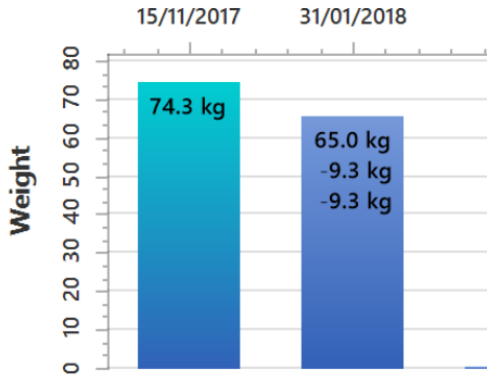
FOLLOW UP



Shows trends for these values over time:

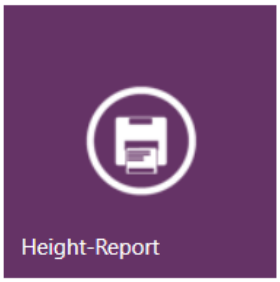
- Weight
- Fat-Free Mass (FFM)
- Fat Mass (FM)

The graph includes up to 10 assessments starting with the baseline test.



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

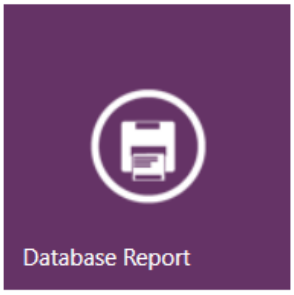
HEIGHT REPORT



Displays the comparison between the weight in kg per metre of height and the absolute difference compared to the average BCM, FFM, FM and ECM values

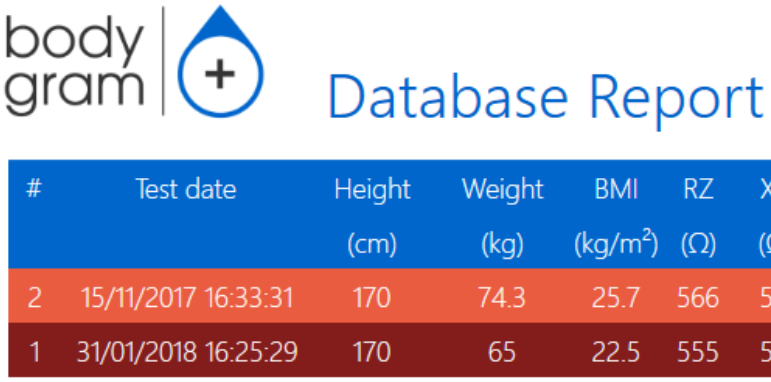
Displays only the selected assessment.

DATABASE REPORT



Displays all assessments on Biavector and Biagram and in a chart.

The baseline test is identified by a star on Biavector and Biagram.



#	Test date	Height (cm)	Weight (kg)	BMI (kg/m²)	RZ (Ω)	XC (Ω)	PhA (°)
2	15/11/2017 16:33:31	170	74.3	25.7	566	54	5.5
1	31/01/2018 16:25:29	170	65	22.5	555	55	5.7

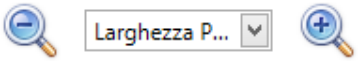
The baseline test appears in orange on the top line of the chart, followed by all the other assessments in decreasing order of date.

The current assessment appears in brown.

GENERAL PRINTING COMMANDS

For selecting the printer and print options before the print job

Sends the document directly to the default printer without making any changes



Zoom (display only)

Creates an email attachment in the format selected from the drop-down menu

Export Report in PDF format

Export Report in XPS format

SETTINGS

CONFIGURATIONS

Used to customise parameters and printouts.

Configuration settings are automatically saved and will be applied to all assessments in the database.

- ✓ Logo: for selecting an image to be included in all reports

  Possible formats: *.jpg, *.png

  For accessing the computer's resources to select the logo file

  For restoring the default software configuration
- ✓ Type of logo: for selecting a format for application to the logo
- ✓ Print Footer: for entering a text which will appear at the bottom of all report pages
- ✓ Language: for selecting the interface language
- ✓ Target BMI: for setting the target BMI for the Weight Loss program
- ✓ Device type: for setting the screen display mode for the type of device used
- ✓ Nae/Ke enabling: for enabling / disabling display of the Nae/Ke parameter

- ✓ Hide glossary: to omit printout of the glossary in the Analytical Body Composition and Baseline Test Comparison report printout.
- ✓ Login with password: for enabling / disabling the requirement for a password whenever the software is started. The password used to register the software must be entered.

EDIT PRINTOUT TEXT

For customising the text which appears on the report printouts.

Configuration settings are automatically saved and will be applied to all assessments in the database.

For restoring the software's default texts

DATABASE TOOLS

For selecting a database to be used and setting the automatic backup frequency and location

The settings made are automatically saved.

- ✓ Database: for selecting the database to be used.

  This function allows several users to share a single database.

  For accessing the computer's resources to select the database to be used.
- ✓ Backup frequency: for setting the automatic backup frequency
- ✓ Automatic backup: for enabling/disabling automatic backup
- ✓ Backup folder: for selecting the folder in which the automatic backup will be saved

  For accessing the computer's resources to select the automatic backup destination folder

IMPORT/EXPORT

(TRANSFERRING DATABASES BETWEEN PCS)

This function allows databases to be imported from other PCs or a previous Bodygram program version (Bodygram 1.31 – Bodygram Pro) and exported for subsequent import.

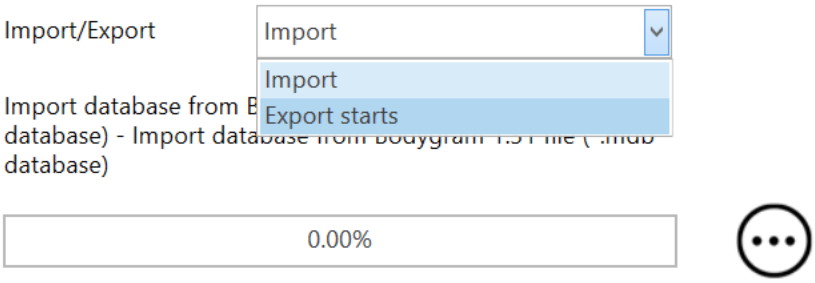
To transfer a database to another Bodygram PLUS PC:

- ✓ Export the database from the origin PC
- ✓ Transfer the exported file to the destination PC
- ✓ Import the database on the new PC

EXPORTING THE DATA FROM THE ORIGIN PC

1 Open the Bodygram PLUS software

2 Select *Import/Export* from the Settings menu



3 Select *Export* from the drop-down menu

4 Select the export button next to *Export database in .CSV format*

5 Select the destination and file name and press *Save*

The export process starts at once, displaying the percentage progress on the bar.

Do not close the Bodygram PLUS software or shut down your computer until the operation is complete

Transfer the file created to the new PC using a USB drive or as an email attachment

IMPORTING THE DATA TO THE NEW PC

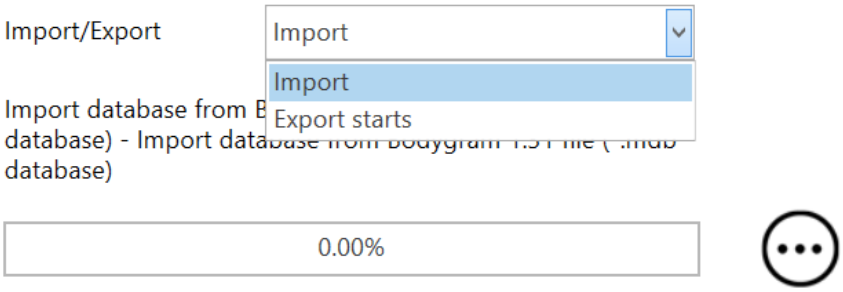
6 Open the Bodygram PLUS software

7 Select *Import/Export* from the Settings menu

8 Select *Import* from the drop-down menu

9 Select Browse next to *Import database from .MDB file […]*

Import database from .CSV text file



1 Select the file created earlier and press *Open*

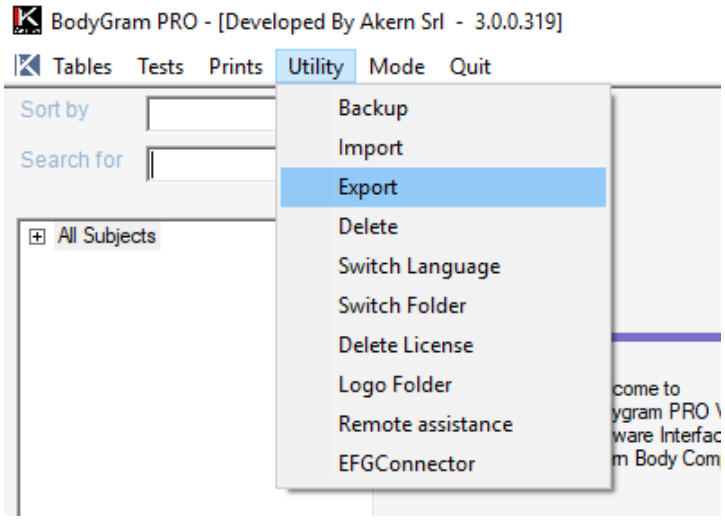
The import process starts at once, displaying the percentage progress on the bar.

Do not close the Bodygram PLUS software or shut down your computer until the operation is complete

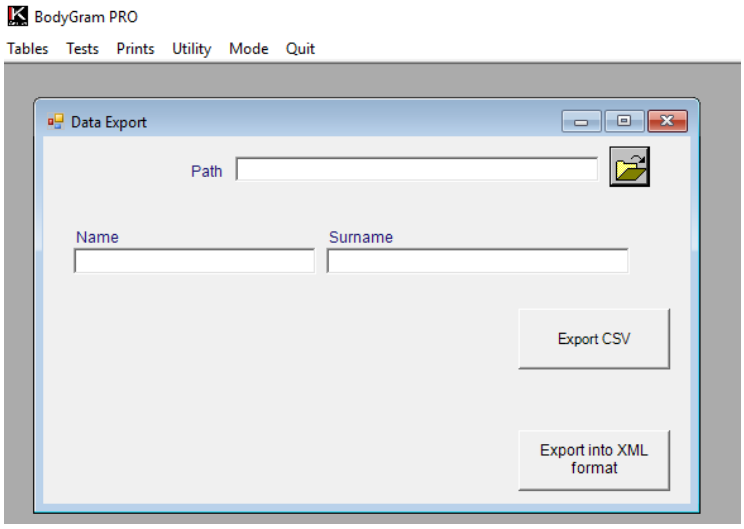
The same procedure can be used to import databases from earlier software versions:

- from Bodygram 1.31: .mdb file format
- from Bodygram Pro: .csv file format

TRANSFERRING DATA FROM BODYGRAM PRO TO BODYGRAM PLUS SOFTWARE



- Open the Bodygram Pro software
- Select *Export* from the *Utility* menu



- Select and choose the file's destination.
- Assign a name to the file and select *Open;*
- the path of the file saved appears in the *Path* box
- Select *Export CSV*

Open the Bodygram PLUS software and perform the import, selecting the .csv file created earlier.

If necessary, before import transfer the .csv file using a USB drive or as an email attachment.

TRANSFERRING DATA FROM BODYGRAM 1.31 TO BODYGRAM PLUS SOFTWARE

Copy the bodygram.mdb file containing the Bodygram 1.31 database

The default file path is:

C/Program Files/Bodygram 1.xx

Open the Bodygram PLUS software and perform the import, selecting the .mdb file copied earlier.

If necessary, before import transfer the .mdb file using a USB drive or as an email attachment.

PAL

For setting the PAL value

The settings made are automatically saved and will be applied to all assessments in the database.

For more information about the PAL (Physical Activity Level) factor, refer to the PAL Factor section

For restoring the software's default values

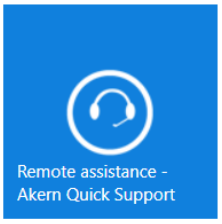
BIBLIOGRAPHY AND PUBLICATIONS

Provides bibliographic references

To copy the publication and make it available for inclusion on the web browser search bar

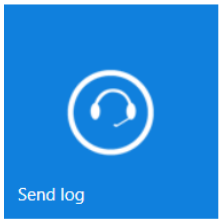
SOFTWARE AND LICENCE MANAGEMENT

Select the Bodygram PLUS logo in the top left-hand corner to access a set of software and licence management functions



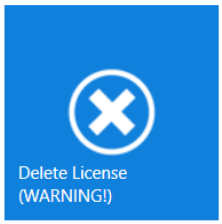
Remote assistance – Akern Quick Support

Function reserved for Akern Technical Support Service



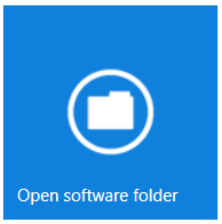
Send log

Function reserved for Akern Technical Support Service



Delete Licence

For recovering the licence if the PC is replaced

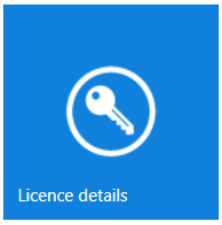


Open software folder

Accessing the software folder is useful for various operations, such as backup restore, only for expert users or the Akern Technical Support Service

Licence details

Provides information about the PCs and modules associated to the licence, including any module expiry dates.



Can also be used to:

- ✓ Request commercial information for licence upgrades, by sending an automatic email to the Akern Sales Department
- ✓ Edit the account data
- ✓ Recover a forgotten password

Changelog

Gives changelog information after every upgrade.

Displays the log of all the software updates with the relative details.

TECHNICAL STANDARDS AND CLASSIFICATION

MEDICAL DEVICE CLASSIFICATION

Bodygram PLUS is classified as a CLASS I medical device (Directive 93/42/EEC); it is also a Class A medical device in compliance with ***IEC 62304:2006.***

TECHNICAL DATA

Program type: WPF C#

Database type: Microsoft SQL

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

Database and config file installation folder: username/documents/Bodygram PLUS

Installation method: ClickOnce User client

Requirements: Microsoft .NET framework 4, SQL engine

Licence: Via activation key available online and offline

Subject data protection: subject names encrypted in direct DB access

MINIMUM SYSTEM REQUIREMENTS

Microsoft Windows VISTA, Windows 7, Windows 8, 8.1 PRO, Windows 10

Minimum screen resolution 1366x800 (recommended 1920x1080 HD)

Dual Core 1GHz Processor

2 GB RAM (4 GB recommended)

1.5 GB free disk space

WARNING: the Bodygram plus is not compatible with Windows 8 RT and Windows XP

DECLARATION OF CONFORMITY

Medical device: **Bodygram PLUS (software)**

Registered office: Akern S.r.l.
Via U. Forti 6
56121 Montacchiello (PI) Italy

Operational Headquarter: Via Lisbona 32/34
50065 Pontassieve (Firenze - Italy)

Authorized representative: Yann Inghilesi Gialloni - CEO

The manufacturer declares conformity with directive **93/42/EEC**, as amended, 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.

Conformity marking

CE

YANN INGHILESI

GLOSSARY OF ABBREVIATIONS

Rz: Electrical **resistance** of tissues

XC: Capacitive **resistance** of cell membranes

PA: **Phase angle**; the relationship between the two electrical measurements of resistance and reactance. It is an indicator of general physical condition. Normal values range between 5 and 7 degrees.

TBW: **Total Body Water**; this is divided into 2 parameters: Intracellular Water, ICW; and Extracellular Water, ECW.

ECW: **Extra Cellular Water**; ECW represents the volume of fluid outside the cells.

ICW: **Intra Cellular Water**; water content inside the cells. Healthy cells are intact and retain their fluids inside.

FFM: **Fat Free Mass**; this is composed of muscle, bone, minerals and other non-fatty tissue. It contains approximately 73% water, 20% protein and 7% minerals. It is subdivided into Body Cell Mass and Extracellular Mass.

BCM: **Body Cell Mass**; the total volume of living cells. It represents the body's metabolically active tissue. Value which determines physical condition. Normal values range from around 35% - 40% of body weight.

FM: **Fat Mass**; all lipids extractable from the adipose tissue and other body tissue. External adipose tissue is often identified as subcutaneous fat, while internal adipose tissue is often identified as visceral fat. The fat mass parameter can vary as it is calculated by subtracting fat free mass from weight.

BMR: **Basal Metabolic Rate**; this is the energy consumed by an organism at rest, including all energy necessary for vital metabolic functions (breathing, blood circulation, digestion, nervous system activity etc.). It represents around 45-75% of total daily energy expenditure.

MM: **Muscle Mass**; the component of musculoskeletal tissue essentially composed of red and white fibres. It differs from body cell mass as it is a real anatomical component. Muscle mass in a young, healthy subject will be around 50% of FFM.

INFORMATION ON THE EQUATIONS USED

The body composition results which can be obtained with the program represent estimates derived from linear regression analysis.

These estimates are obtained using proprietary AKERN algorithms which have been subjected to comparison in combination with other algorithms in the public domain and results obtained using reference methods (DEXA, biohumoral parameters, isotope dilution etc.).

In some populations, the predictive results provided by these proprietary equations have been significantly better (e.g. 1, 2) than those obtained with the equations published in the top medical journals.

When publishing results, it is sufficient to declare that "The estimates obtained derive from proprietary manufacturer algorithms" and cite the instrument model used alongside the software version (Bodygram PLUS Vers. Xxx).

Other estimation equations published (Am J Clin Nutr 2003; 77:331-40; Am J Clin Nutr 1996 [suppl]; 489S-97S) for FFM, FM, TBW parameters using AKERN/RJL SYSTEMS-manufactured instrumentation are suggested below:

ADULTS

Males:

TBW = 1.2 + 0.45 * (HTM ^ 2) / RZ + 0.18 * WTM

FFM = -10.68 + 0.65 * (HTM ^ 2) / RZ + 0.26 * WTM + 0.02 * RZ

Females

TBW = 3.75 + 0.45 * (HTM ^ 2) / RZ + 0.11 * WTM 'females

FFM = -9.53 + 0.69 * (HTM ^ 2) / RZ + 0.17 * WTM + 0.02 * RZ

FAT (M & F) = WTM – FFM

N.B.: TBW= Total Body Water in litres; FFM= Fat Free Mass in kilograms; HTM= Height in centimetres; WTM= Weight in kilograms; BCM= Body Cell Mass in kilograms; ECW= Extra Cellular Water in litres.

Rz = Resistance; Xc= Reactance in Ohms, measured using BIA Akern/Rjl system

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

The software's "Bibliographical References" section contains information on the scientific articles used in designing the application.

BMR ESTIMATES AND CALCULATION

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

In view of the importance of the BMR calculation, it is possible to choose the equation used. The choice of equation is between Akern's proprietary formulae or the classic Harris-Benedict equation 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

GENERAL RULES FOR INTERPRETING THE R-XC NOMOGRAM GRAPH

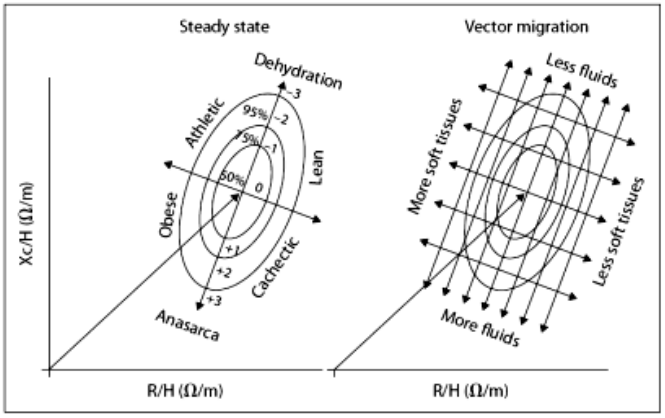


Image used with the kind permission of Prof. A. Piccoli, contrib nephrolog 2005; 49:150-161

The body composition variations visible on the RXc graph are associated with variations in tissue hydration (variations in impedance). Follow the rules listed below:

a) Variations in hydration without alterations to the tissue structure (typically acute) are associated with a shortening (hyperhydration/oedema) or a lengthening (dehydration) of the impedance vector along the main axis of the tolerance ellipses.

b) For the same variation in hydration, the short vectors migrate only a little, while the long vectors migrate a lot. The RXc graph is therefore more sensitive in the dehydration region than in the oedema region. This property is due to the non-linear (hyperbolic) relationship between body fluid and impedance. A vector is considered short if it fluctuates below the lower pole of the 50% tolerance ellipse (lower limit of normal median). It is considered long if it fluctuates above the upper pole of the 50% tolerance ellipse (upper limit of normal median).

c) Variations in the "nutritional state" of the tissues (hydrophilic interstitial structural proteins and cells), without alterations in tissue hydration, are associated with a migration of the vector in the direction of the ellipse's minor axis, with progressive increase in the phase angle (obesity for the short vectors, muscle mass for the long vectors), or with progressive reduction of the phase angle (cachexia for the short vectors, anorexia for the long vectors).

d) Combined variations in hydration and tissue structure are associated with migrations of the vector along the combination of the two main axes.

e) Orthogonal variations (only R or only Xc) with the analyser calibrated (fixed R and Xc tester), are measurement errors (short circuit from contact between limbs and torso, worn or insufficiently adhesive electrodes, skin covered with creams, damaged cable).

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