Bodygram PLUS Software

V. 1.0







Activations memo

Complete and update on each new activation

Device serial number:	
E-mail:	
Password	
1st activation date:	
2nd activation date:	
3rd activation date:	



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QUICK GUIDE

INSTALLATION



Go to the akern.com website.

Select the Bodygram+ icon in the DOWNLOAD AREA panel on the right-hand side of the screen.

Important: the application is not supplied on CD-ROM or other media.

For more details: **Installation**

ACTIVATIONaistered Use

		Registered User: Login		
	Register your license here!	Please fill the fields with your account information, if you don't have an account please create one by Sign Up function on the left.		
		Email		
		akern@akern.com		
		Password		
1.	Click on Register your license	akernsrl		
	here!	Device code	Serial number	
<i>2</i> .	Enter the login data.	ASE	123456789	
3.	Click <i>Login</i> .	I Agree to privacy terms	I.E. 211010001	
		\checkmark		
				Software status: Locked
		Forgot your password?		Login

Useful information:

- ✓ The first time Bodygram PLUS is run you must perform the Registration procedure.
- ✓ The software can be used in a demo version for 30 days.
- ✓ 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.
- ✓ A Bodygram PLUS license allows you to activate up to three different computers. You can, in any case, transfer a license from one computer to another if the computer is replaced.
- ✓ Fill in the <u>Activations Memo</u> and keep it up to date this will ensure you always have all data to hand, making activation simpler and faster.

For more details: License activation



CLASSIFICATION IN GROUPS



To create subject classification groups: select *Go to folder*.



Saves the group entered

The number of groups which can be created is unlimited.

Useful information:

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

 This function allows you to view all the tests for all subjects in the group on Biavector and

For more details: **Groups**

Biagram.

ENTERING A NEW SUBJECT



Select the group in which you wish to place the subject.

Select New Subject.

Enter the subject data.



Saves the data entered

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 about the PAL factor: PAL (Physical Activity Level) Factor



ENTERING A NEW ASSESSMENT



Select the subject for whom you wish to enter a new assessment.

Click on New Assessment.

Enter the required data.



Saves the assessment entered

Useful information:

- ✓ Measurements taken by the Akern sensor can be entered manually or acquired via USB.
- ✓ Weight Manager Module

It is possible to enter an image and notes which will be included on the report printout.

For more details: **Entering a New Assessment**

ASSESSMENT FUNCTIONS



Biagram® and Biavector®

Displays the selected test or all tests on Biavector and Biagram

Body Composition Estimates

Displays body composition estimates in kg/metre or % weight

Interpretive Module



Hydragram® and Nutrigram®

Displays positioning on the hydration and nutrition scale



Nutritional Scores and Indexes

Displays the values for the nutritional scores and indexes

Interpretive

Supplies a concise interpretation of the results obtained

Useful information:

✓ It is possible to select a basal test for comparison with other tests performed on the same subject.

For more details: Assessment Functions



REPORT



Body composition Report

Body composition estimates, Three-compartment model, Compartments distribution Polar Graph. Displays only the selected test



Compare with basal test

Body composition estimates, Three-compartment model, Compartments distribution Polar Graph. Displays the comparison between the selected test and the basal test



Follow-Up

Follows Weight, Fat-Free Mass (FFM) and Fat Mass (FM) trends over time

Weight Manager Module



Weight Loss Report

Creates the ideal weight loss curve over time and compares it to the actual weight loss readings obtained during the test sessions

Interpretive Module



Nutritional Scores and Indexes Report

Shows the values of the nutritional scores and indexes

Useful information:

Weight Manager Module

The weight loss program can be calculated taking into account the energy expenditure associated with one or more physical activities that the subject intends to perform. The influence of these activities are calculated with respect to the basal test.

For more details: PRINT REPORT

For more details on the weight loss program: Weight Loss Report

ADDITIONAL FEATURES

16.58 Wednesday, 19 March

Tests performed: 1906 Tests performed this month: 0 BIATRODES required to perform tests next month: 1 Supplies information on the tests performed.

Allows Biatrodes electrodes to be ordered online.



L'articolo del mese Settembre 2012 Tue, 25 Sep 2012 11:02:52 GMT

La distrofia di Duchenne è la più frequente e la meglio conosciuta tra le distrofie muscolari dell'infanzia la glutammina è il principale precursore della aluconeogenesi e stimola la secrezione di insulina. This window scrolls through the most recent articles of the month published on the site www.akern.com.

Click to view the whole archive.

Clicking on an article allows you to access the Akern site and view it

Weight Manager Module



Opens the scheduler.

Right-clicking and selecting *New appointment* allows you to enter appointments by selecting the subject from a drop-down menu.

A shortcut to the next subject in the scheduler is displayed on the Bodygram PLUS home page.

The scheduler can be customised.

For more details: Additional features

FUNCTION AND SETTINGS BUTTONS



- ✓ User account management
- ✓ Functions reserved for Akern Technical Support Service



Return to previous screen



Return to home page



Search



Settings:

- ✓ Insert a logo and letterhead on reports
- ✓ Select language
- ✓ Define target BMI for the Weight Loss program
- ✓ Personalise reports text
- ✓ Choose working database
- ✓ Import archives from previous Akern software
- ✓ Save current archive and import or restore a saved archive

Useful information:

✓ Configuration settings will be applied to all tests in the database, including pre-existing tests.

For more details: Settings



Description

Bodygram PLUS is an application for the evaluation of body composition by means of measurements made using Akern impedance meters.

The main functions of this application are:

- ✓ Complete body composition estimates using three-compartment technique, new nutritional parameters, over 50 functions.
- ✓ Modular settings which allow you to precisely compose the ideal software platform which meets your requirements.
- ✓ Estimations Function: the introduction of Fat Mass (FM) and Fat-Free Mass (FFM) estimation algorithms that use the effective tissue hydration level present in the subject at the time of the test greatly reduces the estimation error.
- ✓ Interpretive Function: specific test interpretation algorithms able to help the user evaluate the body composition of the subject being examined.
- ✓ 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. It is also possible to enter regular physical activities in the weight loss plan, which contribute to increased calorie expenditure.
- ✓ New Hydragram[™] and Nutrigram[™] tests which join the well-known Biavector[™](BIVA) and Biagram[™] techniques for immediate assessment of the subject's hydration and nutritional state.
- 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.

Bodygram PLUS is licensed software. A Bodygram PLUS license allows you to activate three users.

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 lack absolute diagnostic value, although together with other parameters and a clinical assessment they can contribute to correctly defining altered body composition.

Although anyone may use the software, the interpretation of results obtained from the application relating to persons with physiological disorders must be entrusted to properly trained clinicians.



Installation

Installation is performed from the site <u>akern.com</u> (no CD-Rom or other installation media is supplied).



Select the Bodygram PLUS icon in the DOWNLOAD AREA panel on the right-hand side of the screen.

- ✓ A window will open containing 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 authorisation 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.

Updates

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

Administrator/User installation procedure

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

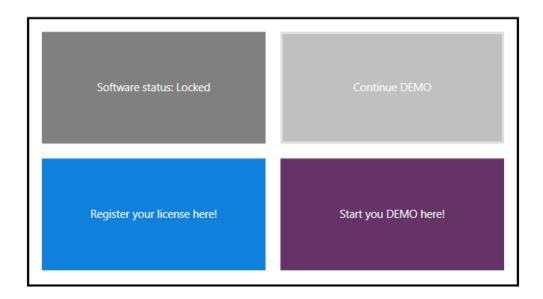
Clickonce, the application used to distribute the software, allows the installation procedure to be performed directly by a User client.

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



Activating Bodygram PLUS



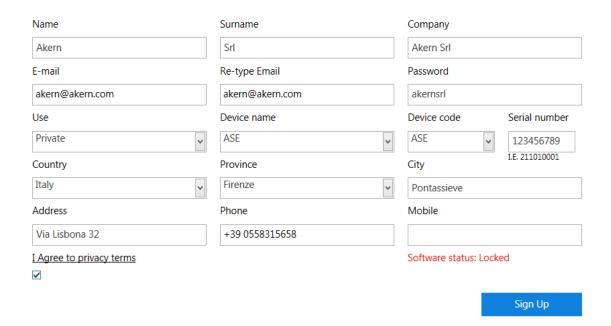
A Bodygram PLUS license allows you to activate the software on three different computers.

To activate Bodygram PLUS, click on Register your license here!

Initial activation (Registration)

Click on New User? Sign Up!

Fill the form to Sign Up and activate!



Fill in all the fields required and click on Sign Up!



The e-mail and password entered at this stage will be required for subsequent activations.

Therefore, take care to enter these data correctly and make a note of them.



Subsequent activations

- ✓ Click on Registered User: Login!
- ✓ Type the e-mail address and password entered during registration. If you have forgotten your password, click on *Forgot your password?* The password will be sent to your registered e-mail address
- ✓ Enter the serial number of the device, selecting the alphabetical part from the *Device code* drop-down menu
- ✓ Click on Login

Registered User: Login

Please fill the fields with your account information, if you don't have an account please create one by Sign Up function on the left.

Email

akern@akern.com

Password

akernsrl

Device code Serial number

ASE 123456789

I.E. 211010001

Software status: Locked

Forgot your password? Login

Offline Activation

If the computer does not have an internet connection, the offline activation procedure is activated automatically. Contact Akern by telephone, fax or e-mail and provide the following information:

- ✓ E-mail and password (all personal data required for registration if it is the first activation)
- ✓ Akern device serial number
- Computer ID and Volume ID (alphanumerical codes displayed if the computer is not connected to the network)

You will be sent e-mail 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 station to be activated
- ✓ Open the Bodygram PLUS software
- ✓ Click on *Unlock* and import the *license.xml* file

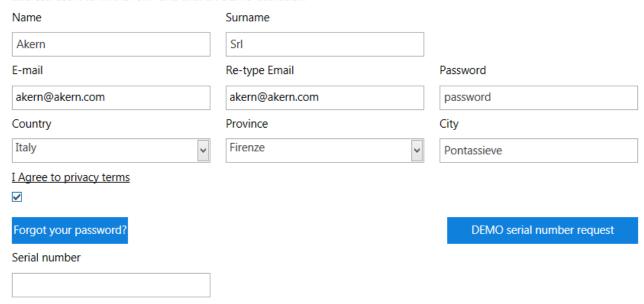


Demo Activation

Click on Start your demo here!

DEMO activation form 1/2

Please fill all the fields and click 'DEMO serial number request'. An e-mail with a DEMO serial number will be sent to your address: use it to fill the form and click on DEMO activation.



- ✓ Fill in all the fields and click on Demo serial number request
- ✓ The DEMO serial number will be sent to the indicated email address
- ✓ Enter the DEMO serial number in the Serial number field
- ✓ Click on Account registration.

For the next thirty days it will be possible to access the software by clicking on Continue Demo



If the DEMO license has expired and you then purchase the software, it will be necessary to perform **Registration** as a new user (not performing Login).

Deactivating a station

It is possible to deactivate a computer which is no longer used, making it possible to activate the software on another computer. To deactivate a station:



Click on the Bodygram PLUS logo on the top left of the screen



Click on Delete License and confirm.

The application will close automatically and remove the activation.



Home page

The Bodygram PLUS home page provides quick access to the main functions of the software, the settings and some additional functions.





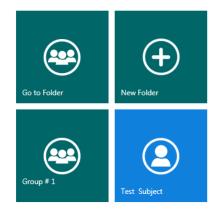




Home



Shortcuts



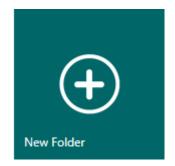


Quick access to:

- List of groups
- New folder creation
- Last group modified/entered
- Last subject modified/entered
- Next scheduled subject
- New assessment for next scheduled subject
- Scheduler



Groups



New folder creation

The *New folder* button allows you to create an unlimited number of subject classification groups.





The population and the BMR and MM calculation formulas can be selected from the drop-down menus.



Confirms the data entered and saves the group

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



Group functions



New subject

To enter a new subject in the group.

(See section Entering a new subject)



Back to: Test Subject

To go back to the last modified subject in the group.



Export group (.csv)

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

Interpretive Module



Group male/female BiaVector

Displays all Biavector and Biagram tests for the subjects in the group.

Moving the mouse over a test displays its details. The basal tests are marked with a star.

Editing/deleting a group



Allows you to modify the name and description of the group and to change the BMR calculation formula selection.



The modifications made will be applied to all tests in the group.



Confirms the modifications made



Allows you to delete the group.



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



Cancels the operation and goes back to the list of groups



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.



Subjects



Entering a New Subject

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

• New subject



Enter the subject data.



Confirms the data entered and saves the subject



PAL (Physical Activity Level) Factor

PAL defines the BMR multiplication value used to calculate the daily energy expenditure of a subject.

This factor is directly correlated with the physical activity level and lifestyle of the subject in question.

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

Activity level	BMR multiplication factor
Sedentary	1.1
Slightly active	1.4
Active	1.7
Vigorously Active	1.9
Athlete	2.3

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

Daily activities	Hours	Hourly energy expenditure	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	8	1.5	12	
(office, etc.)				
Household work	1	2.8	2.8	
Driving	1	2.0	2.0	
Walking	1	3.2	3.2	
Light leisure activities	2	1.4	2.8	
(TV)				
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



Subject archive functions



New Assessment

For entering a new test for the subject.

(See section Entering a new Assessment)



Display table of tests

Displays the results of all subject tests in database format.

The tests table can be exported as a .csv file (compatible with MS Excel).



Move to group

To move the subject to another group.

A search function is available to facilitate navigation between groups.

Weight Manager Module



Scheduler

To schedule subject appointments.



Add a note

Opens a free text field.

Notes entered are not shown in report printouts.

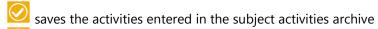
Activities



Bodygram PLUS allows you to manually and specifically insert daily activities performed by the subject so as to include any physical activities in their daily energy expenditure which contribute to reaching their diet target and maintaining Body Cell Mass and Fat Free Mass.



Click on New Activity to display the list of activities available. Enter the weekly hours for the activities performed by the subject



accesses the weight loss report calculated considering the activities entered

The list of activities is saved in the subject archive and identified with the entry date.

defines the basal list

deletes the list



Editing/deleting a subject





Allows you to modify the subject data and select the PAL.

The modifications made will be applied to all tests performed on the subject.



Confirms the modifications made



Deletes the subject.



Permanently deletes the subject and all tests performed



Cancels the operation and goes back to the subject



Warning: deleting a subject automatically deletes all the tests associated with that subject.

Once you have confirmed the deletion it will no longer be possible to recover the deleted data.

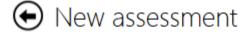


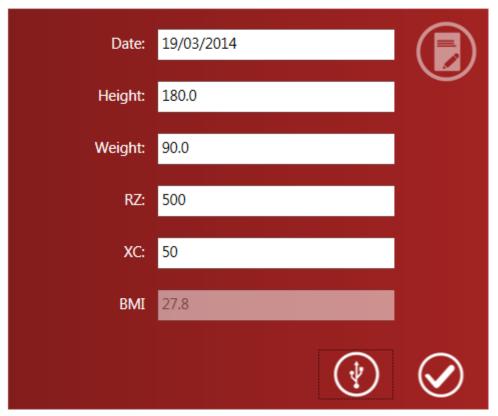
Assessments

Entering a New Assessment



Select the subject for whom you wish to enter a new test, then press the *New*Assessment button.





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

Enter the Rz and Xc data measured by the Akern sensor.



To acquire data via USB connection:

Connect the Akern sensor to the computer and click this button (see Akern sensor manual)



Confirms the data entered and saves the test in the subject archive



Assessment Functions

Defining the basal test



It is possible to select a basal test for comparison with other tests performed on the same subject.



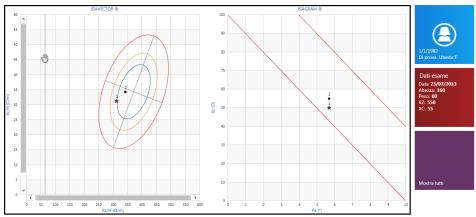
Selects the basal test

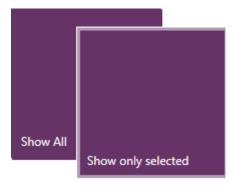
BiaGram and BiaVector

Select the test you wish to view and press this button to access the BiaVector and BiaGram screen.



⊕ Biavector e Biagram: Utente F Di prova





Show all: all assessments performed on the subject are displayed on the graph in chronological order.

Show only selected: only the selected test and the basal test are shown.

The basal test is highlighted by the star symbol.



Body composition estimates



Displays the body composition estimates.

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

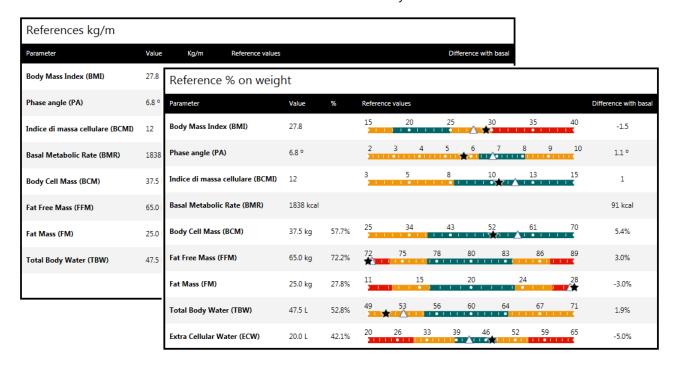


It is possible to view the absolute kg/metre or % weight references by clicking the corresponding button.



Triangle symbol: current test

Star symbol: basal test





$Hydragram^{\mathsf{TM}} \ and \ Nutrigram^{\mathsf{TM}}$

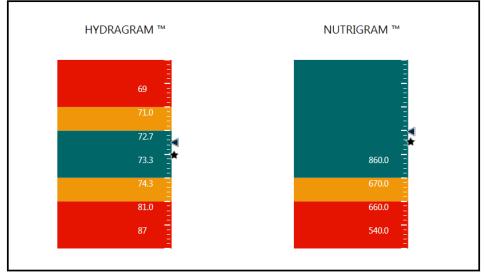


Displays positioning on the hydration and nutrition scale.

For more information on the hydration and nutrition scale: <u>Information on body</u> <u>composition algorithms and equations</u>

Triangle symbol: current test Star symbol: basal test

• Scores: Subject Test



Test date 29/01/2014
Hydration: 73.1 % (FFM/TBW)
Nutrition: 1043.8 (mg 24h/htm)
Nutrition scale 29/12/2013
Hydration: 73.5 % (FFM/TBW)
Nutrition: 962.3 (mg 24h/htm)



Nutritional Scores and Indexes



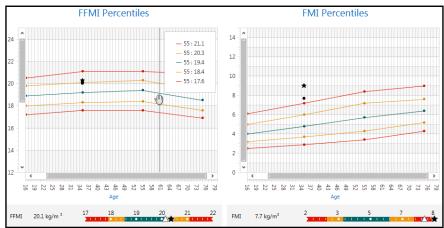
Displays the nutritional scores and indexes values.

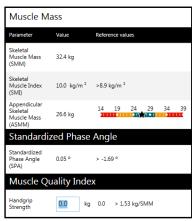
For each parameter, the estimated value, the reference graph and the difference compared to the basal test are shown.

The results of the dynamometric test of handgrip strength can be entered on this screen.

Triangle symbol: current test Star symbol: basal test

• Nutritional Scores and Indexes: Subject Test





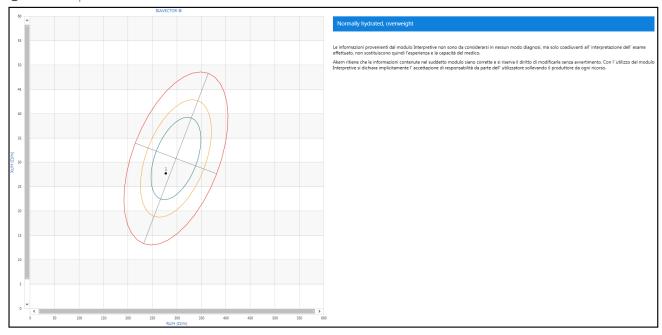


Interpretive



Displays the test on the BiaVector graph and provides a brief interpretation of the result.

• Risultati Interpretive





Print Report

Printing Commands



Print

Allows you to selects the printer and print options before the print job



Instant print

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



Page setup

Sets the page layout and margins







Zoom (display only)



Export Report in PDF format



Export Report in XPS format

Body Composition Report

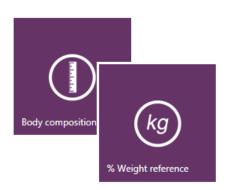


Shows the results of the body composition analysis

Three-compartment model

Compartments distribution Polar Graph

Glossary



Displays the body composition values as % weight references



Compare with basal test Report



Shows a comparison between the estimates of the current test and the basal test.



Displays the body composition values as % weight references

Follow-up Report

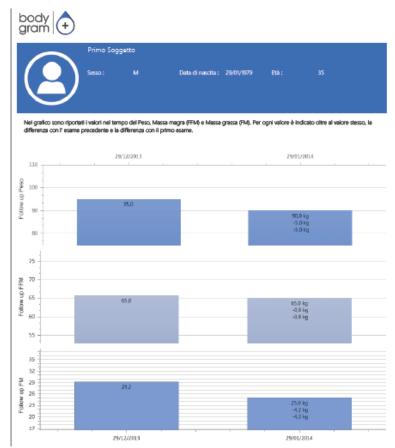


Shows trends for these values over time:

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.

The graph includes all tests performed on the subject.



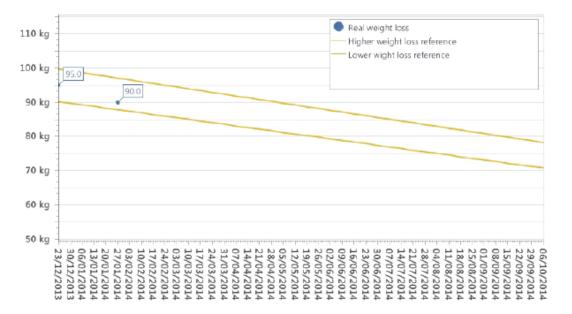
Weight Manager Module

Weight Loss Report

Creates the ideal weight loss curve over time and compares it to the actual weight loss readings obtained during the test sessions. The graph includes all tests performed on the subject, starting with the basal test.



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.



The ideal weight loss curve is calculated automatically assuming a weight loss of 0.5 kg/week towards a target weight corresponding to the target BMI set.



Weight Manager Module

Formula used: 500 kcal reduction per day, 0.5 kg weight loss per week.

Weight losses of above 1 kg a week are not recommended.

Weight loss paramet Weight to lose(kg)	ters	
20.5		
Daily calories:		
1422		
Diet duration (week)		
41		
BMI		
23		
BMR: 1747 kcal BMR X PAL: 1922 kc	al	
	Refresh	Reset

The ideal weight loss parameters can be customised: 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 parameters entered 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 \leq 0.0).

Refresh: recalculates all the parameters in accordance with changes made and refreshes the graph. *Reset*: returns to the software's default parameters.



Adds one or more physical activities which the subject intends to perform and accesses the report which also keeps track of the calorie expenditure provided by performing such activities.

A further curve appears on the report which identifies the estimated weight loss taking into consideration the calorie expenditure provided by the selected activities. The influence of these activities on the weight loss are calculated with respect to the basal test.



Nutritional Scores and Indexes Report

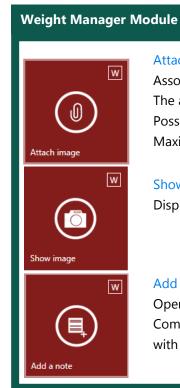
Nutritional Scores and Indexes Report

Shows the values of the nutritional scores and indexes





Assessment screen: other functions



Attach image

Associates an image file with the test.

The attached image appears on the reports.

Possible formats: *.jpg, *.png

Maximum recommended size: 1Mb

Show image

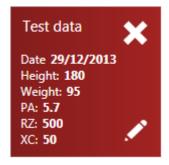
Displays the image associated with the test

Add a note

Opens a free text field in which it is possible to enter a comment.

Comments entered are displayed on Weight Loss, Body Composition and Compare with Basal Test report printouts.

Editing/deleting an assessment





Edits the test data.



Confirms the modifications made



Deletes the test.



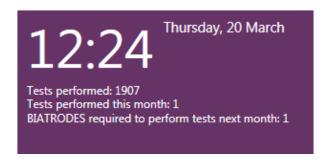
Confirms deletion



Cancels the operation and goes back to the assessment screen



Additional features



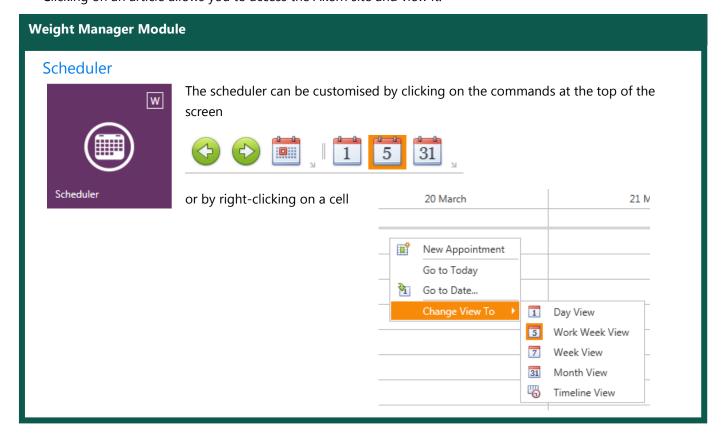
Supplies information on the tests performed.

Click to go to the online form for ordering Akern Biatrodes electrodes.

L'articolo del mese Gennaio 2014 Tue, 07 Jan 2014 11:46:35 GMT Uno stato di iperidratazione ha persistito durante la degenza in terapia intensiva. I pazienti sottoposti a CRRT hanno mostrato uno stato di iperidratazione significativamente superiore dal 2 ° giorno di ricovero.I pazienti deceduti hanno mostrato un modello di

This window scrolls through the most recent articles of the month published on the site www.akern.com. Click to view the whole archive.

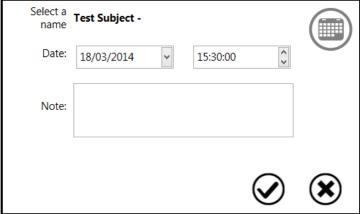
Clicking on an article allows you to access the Akern site and view it.





Weight Manager Module





Accessing the scheduler from the home page

- ✓ Double click on the box corresponding to the date and time of the appointment
- ✓ Select the subject from the drop-down menu

Accessing the scheduler from the subject screen

- ✓ The subject's name is shown automatically
- ✓ Select the date and time of the appointment from the drop-down menu

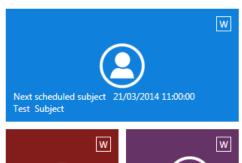
Any notes entered will be visible on the scheduler screen.

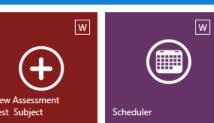


Confirms the appointment entered



Cancels the operation and goes back to the previous screen





The next scheduled subject is shown on the home page.

Click on *Next scheduled subject* to access the subject screen directly.

Click on *New assessment (Test Subject)* to directly access the screen for entering a new assessment for the next subject in the scheduler.



Function buttons



Opens a screen containing information on the computer and software, technical support contacts and some functions



Delete License

Disables the computer currently in use.

For further information: **Deactivating a computer**



Modifies account data



Password recovery



Use the other functions ONLY following instructions from technical support.



Return to previous screen



Return to home page



Search:

Displays all subjects whose names contain the search string entered



Opens the settings window

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Settings

Configuration

Logo

Allows you to customise reports by inserting an image.

Possible formats: *.jpg and *.png



Selects the image to use as a logo

Letterhead

Allows you to customise reports with a letterhead.

Maximum length: 3 rows of 36 characters.

Language

Allows you to choose the user interface language from a drop-down list.

BMI Target

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



Saves the settings entered and returns to the home page

Edit Printout Text

Allows you to modify the text which appears on the report printouts.

Changes made will be active on all reports.

You can restore the original text at any time by clicking the *Reset* button.



Reset: restores original text



Saves the settings entered and returns to the home page

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Database Tools

Change Database

Changes the default database to another database.



Browse: selects the database



Reset: returns to the default database



Saves the settings and returns to the home page

Importing/Exporting the database

Import

Allows you to import the database from Bodygram 1.31, Bodygram Pro or other installations of Bodygram PLUS.



Browse: selects the database to import

Export

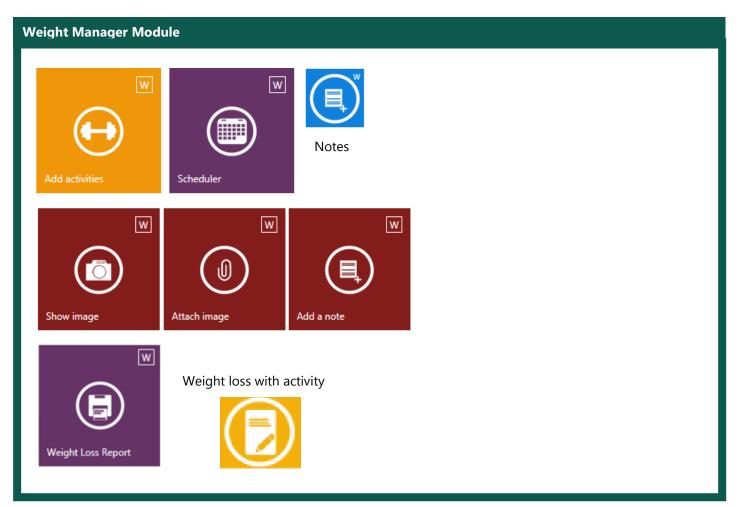
Allows you to export the database to a .csv file (compatible with MS Excel).

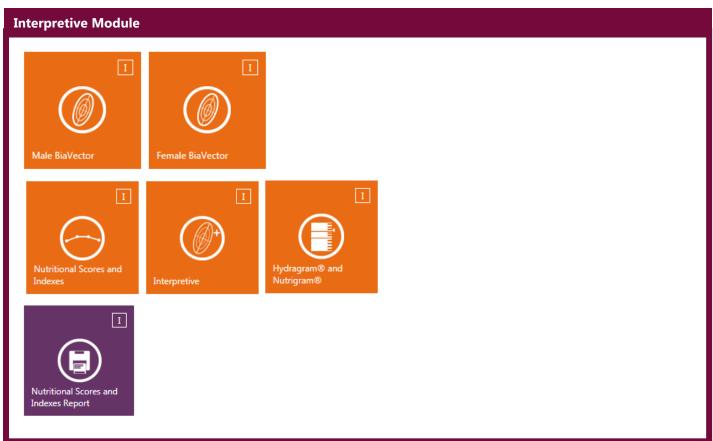


Allows you to choose the destination of the export file; the software then automatically starts exporting the archive



Specific functions of the individual modules







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 per *EN 62304:2006*.

Technical Characteristics

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 mode: ClickOnce User client

Requirements: Microsoft .NET framework 4, SQL engine

License: Via 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, 8.1 PRO

Minimum screen resolution 1366x800 (recommended 1920x1080 HD)

Dual Core 1GHz Processor

2 GB RAM (4 GB recommended)

1.5 GB free disk space



Not compatible with Windows 8 RT



Declaration of Conformity

Medical device: Bodygram PLUS (software)

Manufacturer: Akern S.r.l.

Via Lisbona 32/34

50065 Pontassieve (Firenze - Italy)

Authorized representative: Antonio Talluri

Sole Director

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.

The manufacturer declares that the Bodygram PRO medical device is also a Class A device in conformity with the definitions of **IEC 62304:2006** concerning the software life cycle. It also conforms to the SEMP requirements of **IEC 60601-1-4:2000**.

Conformity marking

ANTONIO TALLURI



Information on body composition algorithms and equations

Glossary of Abbreviations

Rz: Electrical **resistance** of the tissues

XC: Capacitive **resistance** of the cell membranes

PA: **Phase angle**; this is the relationship between the two electrical measurements of resistance and reactance. It represents an indicator of general physical condition. Normal values range between 4 and 9 degrees.

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

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

ICW: **Intra Cellular Water**; water content inside the cells. Healthy cells maintain their integrity and keep their fluid 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**; this represents 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**; this is composed of 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 the difference from other parameters and is reliable only in the event that the subject measured has a normal level of hydration.

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 energy expenditure throughout the day.

MM: **Muscle Mass**; this is the component of the 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.).

These proprietary equations have, in some populations, demonstrated significantly improved predictive results (e.g. 1, 2) than the equations published in the most important journals in the sector.

In publishing the 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, BCM, FM, TBW, ECW, MM parameters using AKERN/RJL SYSTEMS-manufactured instrumentation are suggested below:

ADULTS

Males:

Females:

TBW = $1.2 + 0.45 * (HTM ^ 2) / RZ + 0.18 * WTM$ FFM = $-10.68 + 0.65 * (HTM ^ 2) / RZ + 0.26 * WTM + 0.02 * RZ$

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

Jordan R. Moon et al.: Journal of the International Society of Sports Nutrition 2007, 4:16

Donadio et al.: Single- and multi-frequency bioelectrical impedance analyses to analyse body composition in maintenance haemodialysis patients: comparison with dual-energy x-ray absorptiometry Physiol. Meas. 29

(2008) S517–S524

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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. <u>Clin Nutr.</u> 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 formulas, the divulgation of which is strictly prohibited.

In view of the importance of the BMR calculation, it is possible to choose the formula used. 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



General rules for interpreting the R-Xc nomogram graph

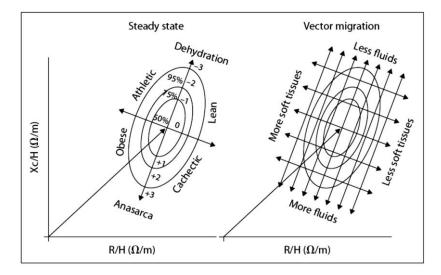


Image used with the kind permission of Prof. A. Piccoli, contrib nephrolog 2005; 49:150-161

The body composition variations visible on the RXc graph are associated with variations in tissue hydration (variations in impedance). Clinical evaluations performed up to the present day allows us to formulate a very simple rule for reading the RXc graph.

- 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 major axis of the tolerance ellipses.
- b) Faced with the same variation in hydration, the short vectors migrate 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 tissular 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 principal directions.
- 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, unstable cable connection circuit).

