Ръководство за потребителя

Апарат за Фол диагностика, модел IKG

Manual

Voll test apparatus, model IKG

АПАРАТ ЗА ФОЛ ТЕСТ
МОДЕЛ: IKG-2
H.Ver: 1.43

ТЕХНИЧЕСКА
ДОКУМЕНТАЦИЯ

Съдържание

1. Правила за безопасност

Този апарат е безопасен за хората при докосване на електродите.

С цел безопасност за Вас, както и за апарата, молим да

бъдат спазвани следните правила за безопасност по време на измерването:
- Пазете уреда от влага, от висока температура и силно магнитно поле.
- Не пускайте в действие апарата в среда с експлозивен, или запалителен газ, водна пара, или в запрашена среда.
- За да се предотврати механична повреда на аналоговата магнитно индукционна бобина, не подлагайте прибора на вибрация, или шок.
- При всяка повреда на металния тествуващ електрод като счупване, деформация, или зацапване с чуждо вещество, не правете измервания, прекратете теста.
- Не тествувайте и не докосвайте никакви намотки под напрежение, превишаващо специфицираното за уреда напрежение.
- Когато приключите с измерванията, изключете прибора.
- Ако уредът няма да се използува дълго време, извадете батериите.

2. Общо описание

Драги купувачо, благодарим Ви за доверието. Апаратът, който закупувате ще Ви осигури точни и надеждни измервания, ако го използвате съгласно инструкциите в този наръчник.

Апаратът измерва специфичната проводимост на кожата в точките на класическите китайски меридиани и в меридианите на Фол.

Използвайки малката метална чинийка на корпуса на уреда или пък масичката, свързана с анода, операторът може да тества същите точки в присъствие на различни вещества: лекарства, билки, хомеопатични препарати, различни проби от храни, алергени, скъпоценни камъни, метали и др.

Може да се покаже ефектът от едно вещество или комбинираният ефект от няколко вещества върху имунната система и

различните органи, като например черен дроб, бъбреци, бели дробове и др.

Измерванията с Фол апарата могат да покажат кои органи и системи на човешкото тяло не са в ред и как да се балансира системата, за да се върне в нормално състояние.

Посредством този метод на измерване с апарата на Фол могат да се открият алергени и непоносимост към храни за пациента и операторът може да прецизира рецепта с най-добрите лекарства, или билки за този пациент.

Използувайки тестери (нозоди) за патогени, може да бъде определена етиологията на смущенията.

3. Захранващо напрежение

Инструментът се захранва с батерии, 3 X 1.5 V. MIGNON.LR6(AA). Те осигуряват приблизително

1000 часа непрекъсната работа.

4. Калибриране

Инструментът автоматично се калибрира всеки път при включване. Представените спецификации са гарантирани за една година.

5. Описание на уреда

5.1. Аналогова скала
5.2. Жълт бутон on/off
5.3. Кръгла метална чинийка на корпуса на уреда, свързана с анода. Използува се за малки проби.
5.4. Масичка за тестери, която се свързва с анода. Използува се за буркани, или бутилки с лекарства.
5.5. Цилиндричен анод. Той трябва да се държи с ръка от пациента.
5.6. Измервателен катод с черен кабел.
5.7. Място за USB връзка от дясната страна на корпуса.
5.8. Два червени кабела: един за цилиндричния

анод, другият за измервателната масичка.

6. Смяна на батериите

Всеки ден преди работа нивото на батериите трябва да се проверява по следния начин: Съединете анода и катода за 3-4 сек. Апаратът дава два сигнала. След втория сигнал нивото на батериите се отчита върху аналоговия дисплей (от 1 до 100). При ниво по-ниско от 10 е желателно батериите да се сменят.

- Отделете кабелите и електродите от уреда.
- Махнете предпазния капак и винтовете от дъното
- Заменете батериите с три нови от идентичния тип.

7. Почистване

За почистване използувайте само мека суха кърпа. Никога не почиствайте с влажна кърпа, разтворител, или вода.

8. Технически характеристики

Напрежение: 2 µA (2 микро A)
Захранващо напрежение на батериите: 3 X 1,5V. MIGNON. LR6 (AA).
Точност: +/- 5% от измерването.
Предвижда се измерванията да се провеждат при стайна температура: 18ºC -28ºC при влажност RH<75%.
Температура на съхранение: -5ºC до +40ºC

Размери: 190(W) X 108(H) X 50(D)
Тегло: около 500 g.

9. Аксесоари към Фол апарата

Аксесоарите, съдържащи се в комплекта са следните:
9.1. Цилиндричен анод
9.2. Два червени кабела
9.3. Измервателен катод с черен кабел
9.4. Кръгла масичка за по-големи проби
9.5. Предпазваща кутия

9.6. Жълто пластмасово предпазно тяло
9.7. Книжка с документация
9.8. Три батерии

10. Условия за гаранция

Този уред има гаранция срещу всяка материална липса, или производствен дефект, съгласно общите условия за продажбата. През периода на гаранцията (една година) дефектните части могат да бъдат заменяни, като производителят решава дали да поправя, или да заменя продукта.

В случай на връщане на продукта за ремонт след продажбата в регионалния клон, или в централния офис, транспортните разходи се заплащат от купувача. Доставката обратно трябва да бъде предплатена.

Трябва да има поставена бележка при уреда, в която да се опише колкото е възможно по-ясно причините за връщане.

Апаратът трябва да бъде в оригиналната опаковка.

Всички повреди, причинени поради транспорт при лоша опаковка се заплащат от купувача.

Продавачът не е отговорен за щети, причинени от лица, или неща.

Гаранцията не важи при следните случаи:

-Аксесоарите и батериите не са включени в гаранцията.

- Ремонти, необходими поради неподходяща употреба на уреда, или поради комбиниране с неподходящо оборудване.

- Ремонти поради неподходящ транспорт.

- Ремонти поради сервиз от неакредитирано от компанията лице.

- Модификации на уреда без оторизация на нашия технически отдел.

- Адаптации към някакво приложение, непредвидено за уреда и извън упътването за работа.

Нашите продукти са патентовани. Логотипите са регистрирани. Ние си запазваме правото за модифициране на характеристиките и цените на изделието като част от технологичното развитие, което ги изисква.

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АПАРАТ ЗА ФОЛ ТЕСТ
Модел: IKG-2, H.Ver: 1.43
ГАРАНЦИЯ НА АПАРАТА
ЗА СРОК ЕДНА ГОДИНА
Дата на покупката:

Надежда Григорова:

БЕЛЕЖКИ

H. Ver: 1.43

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VOLL TEST MACHINE
Model: IKG-2

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VOLL TEST MACHINE
Model: IKG-2

H. Ver: 1.43

OPERATOR'S MANUAL

NOTES

MANUAL

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VOLL TEST MACHINE
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OPERATOR'S MANUAL

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Contents

1. Safety precautions and procedures

This apparatus is safe for people when the electrodes are touched.

For your own safety and that of the apparatus, take extreme care for the following conditions when measuring:

-During the measurements the connection of the patient to the high frequency surgical device could cause burns from the side of the electrodes and possible damage of the Voll machine;

-Measurements near (1-2 meters) shortwave and microwave therapeutic devices could cause instability of the original characteristics of the Voll machine;

-Application of the electrodes in the area of the chest could increase the risk of the heart fibrillation;

-Do not test and do not touch any wires under voltage, sources of the electricity and corpuses of the machines with voltage or current exceeding the specified overload protection;

-Keep the machine out of humid or wet environment, high temperature or high magnetic field.

-Keep away devices affecting electromagnetically the Voll machine and keep our machine away of the sensitive devices.

-Do not operate the machine under the environment with explosive or combustible gas, steam or filled with dust.

-To prevent mechanical damage of analog pointer coil do not submit the instrument to vibration or shock.

-If any unusual condition of testing end (metal part) and attachment of the instrument such as breakage, deformation, fracture, foreign substance, etc. do not conduct any measuring.

-The USB port should be connected only to the computer configuration conformable to the document EN 60950-1 for safety conditions;

- Once the measurements are completed, switch off the instrument;

- If the instrument is not be used for a long period, remove the batteries.

2. General description

Dear customer, we thank you for your patronage. The machine you have just purchased will grant you accurate and reliable measurements provided that it is used according to the present manual's instructions.

The device IKG-02 performs the requirements of the
Standard EN60601-2-10 of EU.

The Voll machine is supplied with batteries- internal sours of electricity. Class –IP20 (not protected against humidity).
The machine is capable to the continuous regimen of work during the day.
The apparatus can measure the specific conductivity of the skin in the points of the classical Chinese meridians and Voll meridians.
Using the table connected with the cathode the operator can test the same points in the presence of different substances: medicine, herbs, homeopathic remedies, different samples of food or allergens, gemstones, metals etc.
It can show the effect of one substance and the combined effect of several substances on the immune system and the different organs such as liver, kidneys, lungs etc.

The measurements with the Voll machine can show which organs and systems of the human body are out of order and how to balance the system back to the normal condition.
By means the Voll machine could be found allergens and intolerance to foods for specific patient and the doctor could adjust the prescription with the best medicine or herbs for this patient.
Using testers for the pathogens it could be found the etiology of the disturbances.

3. Supply voltage

The instrument is battery supplied, 3 X 1.5V. MIGNON.LR6 (AA). It is about 1000 hours of continuous work.

4. Calibration

The Instrument is automatically calibrated every time at switching on. The performances of the specifications are guaranteed for one year.
It is suggested to be done tests by the service officer every two years.

5. Instrument description

5.1. Analog type display
5.2 Yellow button on/off
5.3. Table for testers which has to be connected with the cathode.
5.4. Cylindrical cathode. It should be hold in the hand of the patient.
5.5. Measurement anode with black cable.
5.6. USB connection at the right side of the corpus.
5.7. Two red cables: one for the cylindrical cathode, the other for the table.
5.8. For the normal measurements the device should be in horizontal position

6. Instruction for work

6.1. The preparation of the device

- The two red cables are connected in the places marked as cathode. One of them is connected with the cylindrical electrode and the other- with the metal table for samples.
-The black cable is connected with the measurement nib and the other side- with the device in the place marked as anode.
-Put on the yellow button. If the batteries are there it should the needle to go to the “100”of the scale and than to go back to “0”.This is the automatic calibration of the Voll machine.

-For checking the level of the batteries you should connect the anode and the cathode for 5 seconds. The machine gives two signals. After the second signal the level of the batteries is shown on the analog display (from 1 to 100). At the level under 10 it is advisable to change the batteries.
This way the machine is ready for work.

6.2. The working conditions

-It is desirable to work under room temperature.
-The room should be far from X-rays and electromagnetic fields.
-Working near by high frequency, short wave and microwave devices could cause instability of the original characteristics and a damage of the Voll machine.
-The device is placed on wooden table. It is not right to be put on a metal table and to use metal chairs in the room.
-The electrodes in contact to the skin of the patient should be cleaned with 90% ethanol or some disinfectant which does not make corrosion of the metal of the electrodes.
-The operator should work with white overload and white cotton gloves.
-The patient should take off any metal jewel, cell phones and electronic devises.
-A patient with pacemaker cold not be tested.
-The hands of the patient are measured on a clean white cloth or a changeable white paper and the feet are barefooted, step on a little chair (high 40-50 cm) covered with white changeable paper.

6.3 How to work

The patient holds the round electrode with one of his hand and the other hand is measured in the meridian points. The process is painless and the electrical current is so minimal, at the level of micro amperes that it could not be damaging to anybody. The meridians should be tested at two sides: right and left. Very often appears a big difference between the results from the right and left sides and this needs a special attention and interpretation.

The result above 60 is a sign for an over activation of the point and a result under 40 is a sign for lack of energy in this meridian point.
The interpretation of the measurements is as follow:
50- it is the best result for any point, it is a normal condition.
40-60- is accepted as practically a normal condition.
60-65- shows an excitement of the point.
65-75- means an irritation in the point.
75-85- shows an inflammation.
85-100- shows a high inflammation.
40-35 means the beginning of degeneration.
35-25- means a progressive degeneration
< 25- shows some destructive changes.

The use of the Cortizons leads to strong suppression of the signal even several days after the stop of the medication.

The skin should not be pressed much and it should not be injured. The meridian points are not on the surface of the skin, they are in the mesoderm and as conductive points they send the signals from point to point. The pressure during the measurement should be moderate and equal in any point.

It is desirable the measurements to be repeated and after that to be recorded.
Any medications, herbs, homeopathic remedies, supplements, minerals etc. are tested being placed on the metal table. As the table is connected electrically with the cylindrical electrode in the hand of the patient, the effect of contact of the tested material with the meridian point is observed and this way is shown the effect of the medicine on the results of the test.

7. Battery replacement

Every day before work the level of the batteries should be controlled as it was described in 6.1:
Connect anode and cathode together for 5 sec. The machine gives two signals. After the second signal the level of the battery will be shown on the analog display (from 0 to 100). At a level under 10 it is desirable to replace the batteries.
Fr the replacement of the batteries please follow the procedure:
- Disconnect the cables and the electrodes from the device.
- Remove the protective case and the screws from bottom cover.
- Replace the batteries with 3 new ones only with the identical type.
The used up batteries and the retired equipment should be placed according to the national regulations for the environmental protection.

8. Cleaning

For cleaning the instrument use a soft dry cloth. Never use a wet cloth, solvents or water.

The electrodes in contact to the skin of the patient should be cleaned with 90% ethanol or some disinfectant which does not make corrosion of the metal of the electrodes.

9. Technical characteristics

.Battery supply voltage: 4,5 V (3 X 1,5V). type MIGNON. LR6 (AA).
Current of the measurements < 10 µA (patients current)
Impedance from 0 Ω to 2M Ω for which the parameters of the output signals are valid.
Accuracy: +/-5% of reading.
Consumed power <135 mW (0,135 W)
It is recommended to do the measurements at room temperature: from 10ºC to 40ºC at humidity RH<75%.
Transport and storage temperature: from -10ºC to +50ºC at humidity HR<85%.
The device has degree of protection from environmental effects IP20 (EU).
Size in mm: 190(W) X 108(H) X 50(D)
Weight: about 500 g.
The device is electrically safe. The applied parts of the device are type BF as a degree of protection against electrical injuries.

10. Accessories to the Voll machine

The accessories contained inside the packaging are the following:
10.1. Cylindrical anode
10.2 Two red cables
10.3 Measuring anode with a black cable
10.4 Protective case
10.5 Yellow plastic protective body
10.6 Operator's manual
10.7 Three batteries placed inside

10.8 Round table for samples
10.9 A black bag

11. **Warranty conditions**

This device is guaranteed against any material fault or manufacturer's defect in accordance with the general conditions of sale. During the warranty period (one year) faulty parts may be replaced, with the manufacturer reserving the right to decide either to repair or to replace the product.
The device does not contain parts which could be repaired by the technical officers of the user and all types of repairing works should be done by the representative of the manufacturer.
Cables and electrodes if necessary should be replaced only with the type R120CK02 and RE02.
In the event of returning the equipment to the after-sales service or to a regional branch, the outward transport is payable by the customer. The delivery must be agreed in advance with consignee.
For delivery indicate by means a note enclosed with the equipment, as clear as possible, the reasons for returning..
The device should be only in the original packing.
Any damaging caused by shipment using NOT original packaging will be charged in any case to the consignor.
The manufacturer will not be responsible for any damage caused by incompetent third persons.

The warranty doesn't apply to the following cases:
- Accessories and batteries aren't included in warranty.
- Repairs following unsuitable use of the equipment or by combining with incompatible equipment.

- Repairs resulting from a not correct transport.
- Repairs resulting from servicing carried out by a person not approved by the company
- Modifications to the equipment without explicit authorization from our technical departments.
- Adaptation to a particular application not provided for by the definition of the equipment or by the instruction manual.

12. List of the fully applied Standards and Regulation Documents for designing and producing the Medical device Voll Test, model IKG-02:

-EN 60601-2-10:2000+A1:2001(BDS EN 60601-2-10+A1:2004) “Electro medical devices. Part 2-10: Specific safety requirements for the nerve-muscular stimulators”
-EN 60601-1:1990+A1:93+A2:95+A13:96 (BDS EN 60601-1+A1+A2+A13:2003) “Electro medical devices. Part 1: Principal safety requirements”
-EN 60601-1:1990+A1:93+A2:95+A13:96 (BDS EN 60601-1+A1+A2+A13:2003) “Electro medical devices. Part 1: Principal safety requirements”
- EN 60601-1-2:2007 (BDS EN 60601-1-2:2007) “Electro medical devices. Part 1-2: General safety requirements and important

characteristics. Complementing standard: "Electromagnetic compatibility. Requirements and testing"
- EN 55011:2009+A1:2010 (BDS EN 55011:2009+A1:2010) "Industrial, scientific and medical devices. Characteristics of the radio frequency disturbing influences. Borderline limits and methods of measurements".
- EN 61000-4-2:2009 (BDS EN 61000-4-2:2009) "Electromagnetic compatibility. (EMC). Part4-2: Methods for testing and measurements. Testing for resistance to electrostatic discharges".
- EN 61000-4-3:2006+A1:2008 (BDS EN 61000-4-3:2006+A1:2008) "Electromagnetic compatibility (EMC). Part 4-3: "Methods for testing and measurements. Testing the resistance to emanated radio frequency field"
- EN 61000-4-8:2010 (BDS EN 61000-4-8:2010). Part 4: "Methods for testing and measurements. Testing the resistance to magnetic field, produced from the frequencies of the supplying voltages."
- EN 61000-4-20:2010 (BDS EN 61000-4-20:2010) Part 4-20: Methods for testing and measurements. Radiation and testing for resistance in transverse electromagnetic wave conductors (TEM).

EU Declaration for conformity

Undersigned on behalf of:

BIOBALANCE LTD
19 Dobrotitch Str.1330 Sofia,
Republic Bulgaria
Tel. +359 878 573 240.

I declare at my own responsibility that:

The product: **Electromedical device Voll test**
Trade mark**: BIO-BALANCE®**

Model**: IKG-02**
Manufacturer: **"BIOBALANCE LTD", Sofia, Republic Bulgaria**

Has been designed, constructed, packed, labelled applying the principals of safety and according to the contemporary technologies in conformity with the principal requirements of:
"The directive 93/42/EU", put in action with "Instruction on principal requirements and the procedures for estimation of the conformity with the principal requirements for the medical devices in art. 2, par. 1, cl. 3 of the Low for the medical devices,"
following in full the Bulgarian Standards, introducing harmonized European Standards:

EN 60901-2-10:2000+A1:2001
(BDS EN 60601-2-10+A12004)
EN 60601-1:1990+A1:93+A2:95+A3:96
(BDS EN 60601-1+A1+A2+A13:2003)
EN 60601-1-2:2007
(BDS EN 60601-1-2:2007)

Being in the right way connected, maintained, used in an appropriate way, shown in the instructions and safety precautions, the device is safe for the patients, medical specialists and third persons.
The CЄ marking on the medical device means that it was estimated the conformity of the device with all the applied principal requirements, determined in the shown above Directive (Instruction) and it was performed the procedure "EU declaration of conformity" according to the appendix No 6 of the Directive and it means that
BIOBALANCE LTD supports and keeps the technical documentation and the EU declaration for conformity available to the authorities for control of the market (officials in art. 68 par.2 of the Low for the Medical Devices).
The year of placing the mark CЄ 11

I declare that I know my responsibility according to par.313 of the NK.
Sofia Name, Family:
15.11 2011 Nadejda Grigorova, Director.

WARRANTY

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VOLL TEST DEVICE
Model: IKG-02, H.Ver:1.43
Serial number:
……..
The Voll test device is guaranteed for one year from this date.

Date of the purchase:
……
Director: N. Grigorova

- EN 60601-1-2:2007 (BDS EN 60601-1-2:2007) “Electro medical devices. Part 1-2: General safety requirements and important characteristics. Complementing standard: ”Electromagnetic compatibility. Requirements and testing”
- EN 55011