



BIRTH TECH

DISPOSITIVOS PARA A SAÚDE



PREEMIETEST

GA01 MODEL

User Manual

Equipment intended for use in a hospital environment by trained professionals.

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 BIRTH TECH DISPOSITIVOS PARA A SAÚDE	MANUAL UM 01	Review: 05 DATE: 18/06/2024
USER MANUAL		

REVIEW HISTORY

Version/Review	Brief history of the Change	Approval in:
00	Creation	28/08/2020
01	Review by medical professionals and with test results	10/09/2020
02	Review for correction of raised NCs	12/10/2020
03	Review for insertion of Pulmonary Maturity	29/12/2022
04	General review for the english version	31/01/2023
05	General review for the english version	18/06/2024

EQUIPMENT:

Technical Name: Neonatal skin maturity optical reader

TRADE NAME: PREEMIETEST **COMMERCIAL MODEL:** GA01 **SOFTWARE VERSION:** 1.2

Technical Manager: Paola Conceição da Silva – COREN/MG nº 313.685

ANVISA Registration nº: 82558239001



Birthtech Dispositivos para a Saúde Lda.
Rua Major Neutel de Abreu, 118, Complexo Empresarial da SONUMA, Espaço número 03
CEP 3260-427 – Figueiró dos Vinhos – Leiria – Portugal
Fone: (+351) 934937055 – Site: www.birthtech.pt
NIF: 515. 114.790

WARNING

For added security:

- Carefully read all instructions before installing or operating this product.
- This manual should be read by all product operators.



This manual was originally written in the portuguese.



Remember the PremieTest must be used in the first 24 hours of newborns life.

Calibration and Inspection

<u>Date:</u>	<u>Calibrated by:</u>

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1. GENERAL INFORMATION

BEFORE USING THIS PRODUCT, PLEASE READ THIS INSTRUCTION MANUAL CAREFULLY.

The PreemieTest provides a quick and accurate reading of gestational age as well as the need for intensive care, ventilatory support and identifies respiratory distress syndrome (RDS) of a newborn in the first 24 hours of life.

The PreemieTest is manufactured according to the requirements of the applicable standards: ABNT NBR IEC 60601-1, ABNT NBR IEC 60601-1-2 and IEC 60825-1. The RDC 16/2013 (Good Medical Product Manufacturing Practices) quality management system is applied throughout the device to ensure that all applicable customer and regulatory requirements are met.

Contents: 1 PreemieTest device, 1 Instructions for Use (which include calibration dates), and 4 AAA batteries.

DESCRIPTION

PreemieTest device is designed to contribute to a better diagnosis of preterm newborns by analyzing the photobiological properties of the newborns' skin.

This non-invasive, non-ionizing technology presents a probe that contains light emitters and receptors that is put in contact with the newborn's foot and, using Machine Learning algorithms, provides an estimated Gestational Age value in seconds, in addition to the probabilities of the need for intensive care, ventilatory support, and respiratory distress syndrome, related to lung maturity of the newborn.

The device provides automatic data acquisition with minimal operator influence and the value of gestational age, and the odds cited above are displayed directly on the device screen.

IMPORTANT:

The gestational age prediction model embedded in PreemieTest was designed with values equal to or greater than 18 weeks. Therefore, the equipment will not recognize gestational ages lower than this.

PreemieTest device is indicated for use by health professionals (obstetrician or neonatologist, obstetrician or neonatologist nurse and obstetrician (humanized delivery assistant) and can be used at home (by trained delivery assistants), neonatal SAMUs and maternity wards.

PreemieTest device should, whenever is possible, be used under the supervision of a physician and should be used as a screening device for the diagnosis of prematurity in conjunction with other clinical signs.

The PreemieTest operator must be trained for its use. Birthtech is not responsible for the incorrect and/or inappropriate use of the device or the operator's lack of knowledge.

At the end of the life of the equipment, it shall be returned to the establishments which market them or to the technical assistance network authorised by the respective industries, for transfer to manufacturers or importers, so that they can take, directly or through third parties, the procedures for reuse, recycling, treatment or environmentally appropriate final disposal. In Brazil, according to the resolution of Conama 257, primary (non-rechargeable) or secondary

(rechargeable) batteries may be disposed, together with household waste, in licensed landfills. Regardless of current legislation, Birthtech or its representatives may receive from customers unused batteries of this recycling equipment. The estimated service life expectancy of the equipment, provided that the appropriate usage guidelines are followed, is 5 years.

PREMIETEST ELIGIBILITY PROTOCOL

- Delivery occurred within the last 24 hours.
- Live and postpartum conscious newborn.
- **Absence of perinatal diseases affecting the structure of the skin: hydrops, anhydromemnum, evidence of intrauterine infection.**



SAFETY WARNINGS

- Choking hazard: the device cover and batteries can be fatal if swallowed. Do not allow children to manipulate or use this device.
- Do not place the batteries in the device near excessive heat or moisture. They could leak or explode.
- Remove the batteries from the device when not in operation for a long time, thus preventing leakage.
- It should not be carried to the mouth, this may lead to local injury.
- Do not attempt to disassemble or repair the device, warning no modification to this equipment is allowed.
- After each use, disinfect the device with 70% alcohol before and after each measurement to avoid contamination and cross-transmission of microorganisms.
- Do not press the probe against the newborn's heel with excessive force.
- It is recommended that the device be calibrated every 12 months.
- Do not immerse the device in water or other liquid.
- Do not direct the probe against the newborn's eyes and any human eyes.
- The device is not designed for use in an oxygen-rich environment.
- The device cannot be sterilized.
- Do not use the device near heat sources, such as radiant heat cradle, as excess heat may affect the performance of the device.



CAUTIONS

Device performance can be impaired if one or more of the following factors occur:

- Not measuring at the correct body place.
- **Use with wet newborn, with vernix or local lesions. This can cause inaccurate readings.**
- Operation that contradicts the storage and use rules suggested by the manufacturer.
- Repair or attempted repair by unauthorized service.
- Storage in disagreement with temperature and/or humidity suggested by the manufacturer.
- Mechanical shock (including fall).
- Do not boil the device to disinfect it.

- Do not immerse the device in any liquid (i.e., sterilization, etc.).
- Do not store the device with direct sunlight exposure or in areas of extreme heat.
- Do not use the equipment after the first 24 hours of the newborn's life
- Avoid proximity or contact of the device with strong electromagnetic interference, such as microwave ovens and mobile phones.
- Do not bend or drop the device. It is not shockproof, and the manufacturer and distributor are not responsible for malfunctions arising from misuse.
- We are not responsible for these cases, which constitute misuse.
- When replacing the batteries in the device, replace them all at the same time.
- Do not mix different batteries (alkaline and common; new and used). This impairs performance and durability.

SPECIFICATIONS

Feeding	4 LR03 (AAA) series batteries 1.5 V - 860–1,200 mAh
Battery life in continuous use with full charge	340 – 480 minutes
Voltage in the main circuit	+3.3VDC - regulated
Electrical rating according to IEC 60601-1	Class II
Electric shock protection according to IEC 60601-1	Type B
Before ABNT NBR IEC 60601-2-57:2015 Particular standard for light-ether equipment	Equipment belongs to the exempt risk group
Operation mode of the equipment	Continuous
Cabinet material	ABS
Cabinet dimensions	(L x W x H): 152x35x21,55mm
Probe dimensions	14 x 8mm cylindrical
Degree of penetration according to IEC 60529	IPX0
Light emitter	High-power infrared LED (If max=100mA) with peak intensity at 860nm
Relative Spectral Emission	Centroide at 850 nm +/- 30nm
LED light beam emission angle	+/-13 degrees
Radiant Intensity IF = 100 mA; tp = 20 ms	Typically 200mW/mr. Min= 63 mW/sr , Max=500mW/sr.
Typical Total Radiant Flow	70 mW

ESD Electrostatic discharge Max. LED Acc. to ANSI/ESDA/JEDEC JS-001 (HBM, Class 2)	$V_{ESDmax.} = 2 \text{ kV}$
Light Receiver	Centered on 860nm with passband from 20nm to 50% of normalized responsiveness
Net weight	72 g
Gross weight	145 g
Types of packaging	Cardboard box
Packaging dimensions	(L x W x H): 185x75x46mm

CONDITIONS OF OPERATION, TRANSPORT AND STORAGE

Environmental operating conditions

Room temperature	+10°C a +40°C
Relative humidity	30% a 75% (non-condensing)
Atmospheric pressure	700hPa a 1060hPa

Environmental conditions of transport and storage operation

Room temperature	-12°C a +50°C
Relative humidity	0% a 90% (non-condensing)
Atmospheric pressure	700hPa a 1060hPa

DEVICE RATING

The PreemieTest prematurity meter - GA01 - meets the requirements of the following classifications:

- Protection against electric shock: internally powered.
- Type of part applied: B
- Common IPX0 equipment (Degree of protection against harmful water penetration: does not apply).
- Not suitable for use in the presence of flammable anesthetic mixture, with air, oxygen or nitrous oxide.
- Operation mode of the equipment: still while in use.

EMC GUIDANCE AND MANUFACTURER STATEMENT

Device: GA01		
Manufacturer's guidance and statement - electromagnetic emissions		
The PreemieTest prematurity meter is intended for use in the electromagnetic environment specified below. The PreemieTest client or user must ensure that it is used in an environment like this.		
Emissions test	Compliance Level	Electromagnetic-orientation environment
RF CISPR 11 emissions	Group 1	PreemieTest uses RF energy only for its internal function. Therefore, their RF emissions are very low and probably do not cause interferences to nearby electronic equipments.
RF CISPR 11 emissions	Class B	PreemieTest is suitable for use in all establishments. PreemieTest is powered internally by 4 LR03 (AAA) batteries in series.
Harmonic emissions IEC 61000-3-2	Does not apply	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Does not apply	

Manufacturer's guidance and statement - electromagnetic immunity
The PreemieTest is intended for use in the electromagnetic environment specified below. The PreemieTest client or user must ensure that it is used in an environment like this.

Immunity test	Test level IEC60601-1-2	Compliance level	Electromagnetic-orientation environment
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact There were no points for unloading	Suitable for all environments.
Electric/break transient IEC 61000-4-2	± 2 kV for power lines ± 1 kV for input/output lines	Does not apply	Not applicable as an internally powered device
Surge IEC61000-4-5	± 1 kV differential mode ± 2 kV common mode	Does not apply	Not applicable as an internally powered device
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	30 A/m	30 A/m	Magnetic power frequency fields should be at characteristic levels of a typical location in a typical commercial or hospital environment
Irradiated RF IEC61000-4-6	3V/m; 80MHz a 2,7GHz	3V/m	Suitable for all environments as long as the following warnings are respected.

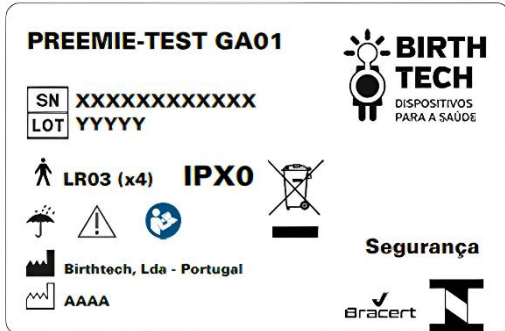
WARNINGS:

- Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used less than 30 cm from any part of the PreemieTest, including cables specified by the MANUFACTURER. Otherwise, performance degradation of this equipment may occur.
- Use of the adjacent PreemieTest or other equipment should be avoided as this may result in improper operation. If this use is necessary, you may want PreemieTest to be observed to verify that it is operating

normally.

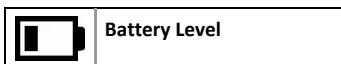
- The PremieTest has been tested successfully? with the current Safety Standards IEC 61000-4-2 for immunity against electrostatic discharge (ESD). In some circumstances, the device may shut down when subjected to ESD: however, the device is not damaged and will operate normally as soon as it is turned back on.

IDENTIFICATION TAGS



SYMBOLOLOGY

	Follow the instructions for use.
	Applied part of type B.
	WARNING - Refer to the Manual.
IPX0	Degree of penetration according to IEC 60529.
	Year of Manufacture.
	Manufacturer.
	Do not dispose of in household waste.
	Serial Number.
	Batch Code.

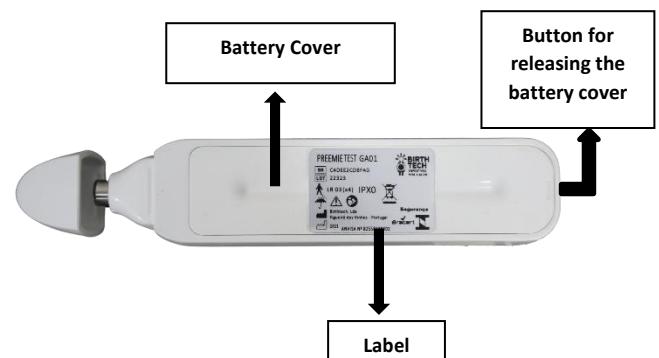
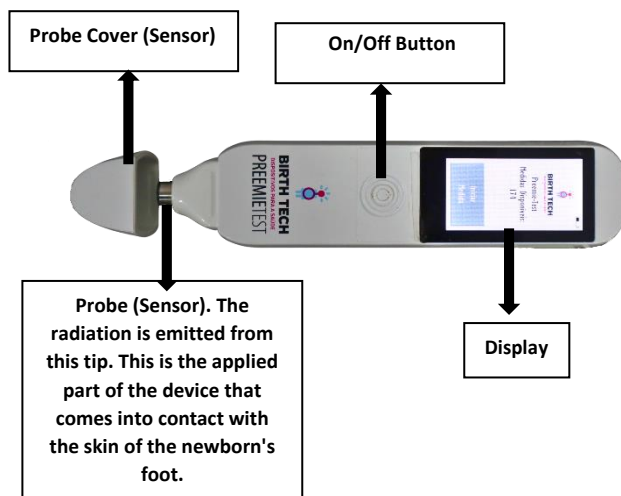


	Change the batteries
	Device Emitting Light

Packing Product Display

	Store or transport carefully (should not be impacted).
	Store or carry with the side of the arrow up.
	Store or transport with sunlight protection.
	Store or transport with moisture protection (do not expose rain splashes of water or wet floor).
	Store or transport the product respecting the maximum and minimum ambient temperature limit.
	Maximum amount of stacking
	Store or transport the product respecting the maximum and minimum humidity limit.

2. PREMIETEST ILLUSTRATIONS



3. INSTRUCTIONS FOR USING PREMIETEST

STAGES OF PRE-EXAM

- 1) Check the health conditions of the newborn, which should be clinically stable enough to perform the test.
- 2) Remove the probe cover (sensor protection).
- 3) Check the equipment for dirt. If there is:
 - A) Clean it using a shimcome lightly moistened with liquid soap and water available in the institution without soaking it so as not to damage the equipment.
 - B) Then remove the soap using compress or other fabric lightly dampened in water and dry with clean, dry compress.
- 4) Use 70% alcohol compress throughout the equipment sensor FIRST, and then in the most touched parts, before and after the use of the device.
- 5) Sanitize your hands according to NOTE ANVISA, summarized in 4.
- 6) Wear gloves if indicated.

EXAM STAGES

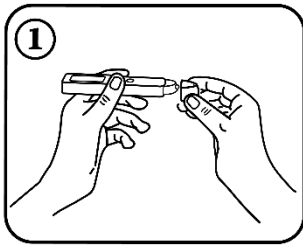
- Examine the newborn at the place where it is being assisted: incubator, warm crib or mother's lap.
- Expose the newborn's foot gently while always keeping it horizontal. Do not take up the lower limb to perform the exam.
- The examination should be performed on the skin of the posterior part of the sole of the foot. Imagine two diagonal lines passing in the heel region of the child and choose the central region where these lines meet.
- At this point the sensor should touch the skin perpendicularly 90 degrees with the surface of the skin. See the figures below:



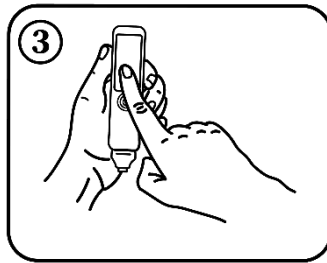
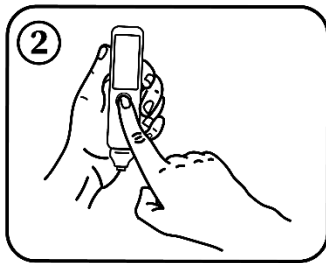
Target here



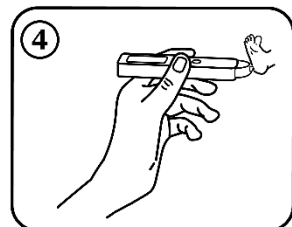
- Remove the cover at the end of the PreemieTest, it serves to protect the probe.



- To turn on the device, use the on/off button located in the center back of the device. When you turn it on, the device will vibrate, and the screen will light up. The display will show the name Birthtech with our logo and below it PreemieTest. In the upper right corner, there will be an icon showing the battery charge, and space to enter the date and time. Enter the data and press "OK" to continue. Validate if the entered data is correct or go back if you need to make corrections. After validating the data, the number of available measurements on the device will appear, and a box will say **"Start Measurement"**. Tap this box to activate the device. If the battery charge is low, change the PreemieTest batteries before taking the measurement.



- Start measurements: When the  **"Waiting for 1st measurement" screen command**, tap the skin in the standardized location. Gently touch the PreemieTest sensor and press the device head (probe) into the region to be examined, the trigger is automatic, and you will feel the device vibrate. During the measurement, which lasts a few seconds, the touch screen will display the signal that indicates a measure in progress. When the measurement reaches the end the light bulb signal will disappear, and you will feel the device vibrate.



- Perform 3 measurements consecutively, however, be careful to fully remove the sensor from contact with the newborn's skin between each measurement. Follow the instructions for messages that will appear on the PreemieTest display.
- Remake the measurement if there is any fact that has damaged it, such as an abrupt movement that has caused the probe to move away from the newborn's heel causing the external light to enter. An error message will appear and you must redo the measurement.
- When the **"Waiting 2nd measure" screen command**, remove the skin sensor completely and then return to the same place by pushing against the region to be examined again. Proceed as the first time, keeping an eye on the start and end signal of the measurement (the signal of the lamp on) and at the end the vibration of the device.
- When the **"Waiting 3rd measure" screen command**, remove the skin sensor completely and then return to the same place. Press again against the newborn's heel and proceed as at other times, keeping an eye on the start and end signal of the measurement (the lamp signs on) and the vibration at the end of the measurement.

- To the **"Insert weight (g)" screen command**, enter the weight of the newborn in grams and squeeze ok. Then **"Validate"** if it is the desired weight or **"Back"** if you want to correct the value you entered.
- When validating the weight will appear **on screen the question about "Antenatal use of corticosteroids"**, with 3 options, **"Yes", "No" or "No information"**, choose one of them and then **"Validate"**, if it is the desired information or **"Return"** if you want to correct this information.
- On the Display will now appear **the options of "Results to view"**, we have the **options "Gestational Age" or "Lung Maturity"** and if you want you **can press "Exit"** by returning the home screen.
- Choose **"Gestational Age"** to visualize the gestational age of the newborn in months and days with a background of a color that indicates the degree of maturity of the newborn. Green means that the newborn is term, yellow that is a premature moderate too late and red means that the newborn is very premature. Below the gestational age value, we will have two options: **"Back"** if you want to have information about **"Pulmonary Maturity"** or **"Exit"**.
- Choose **"Lung Maturity"** for the following information: **"SV" (Ventilatory Support), "DrS" (Respiratory Distress Syndrome), or "NICU" (Neonatal Intensive Care Unit)**. If you choose one of them, you will get as a result the probability of the **newborn needing Ventilatory Support** or an **Intensive Care Unit, or the probability of the newborn having Respiratory Distress Syndrome**.
- For each screen after choosing the results to view we will always have **two options "Back" or "Exit"**, choosing back to the previous screen to continue and view other results, or exit. If you select **"Exit"**, you will be taken to the **"Baby ID"** screen. Here, you have the option to enter an ID if you already have one. If you don't have one, you can simply click **"OK"** and an automatic ID will be created for you. After entering the baby's ID, you will see the option to **"Validate" or go "Back"**. Choose **"Validate"** if the ID is correct or select **"Back"** if the ID was entered incorrectly and needs to be corrected.
- The screen will display the available number of measurements along with the options **"Turn off" and "Start Measurement"**. When you're done, select **"Turn off"** (always turn off the device after using it). If you want to redo or take a new measurement, choose **"Start Measurement"** and you will be taken back to the **"Waiting for 1st Measurement"** screen to repeat the entire process.
- Store PremieTest and follow the storage conditions described in this manual.

CARE

- Never use the incubator as an auxiliary table or place anything on it. The noise generated is harmful to the health of the newborn.
- Always use the cover to keep the PremieTest sensor from being from a fall. If the fall occurs, report it to the manufacturer/distributor, even if the device appears to work normally.

4. CLEANING AND PACKAGING

- Check the equipment for dirt (*).
- Place the device on an auxiliary table.
- Sanitize hands according to Technical Note 01/2018 - ANVISA (**).
- To sit with gloves if necessary.
- Use the alcohol sing 70% of the entire sensor of the device and in the most touched parts.
- Perform the PremieTest.
- Use another alcohol compress 70% of the device's sensor and in the most touched parts.
- Remove the gloves.
- Clean the device whenever it is used.

(*) If there is visible dirt, clean the equipment by observing cleaning and disinfection by observing the hospital protocol.

(**) 1) BRASIL. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. General guidelines for hand hygiene.

Available in: <http://portal.anvisa.gov.br/documents/33852/271858/Nota+técnica+nº+01-2018+GVIMS-GGTES-ANVISA/ef1b8e18-a36f-41ae-84c9-53860bc2513f>Acesso 10/10/18

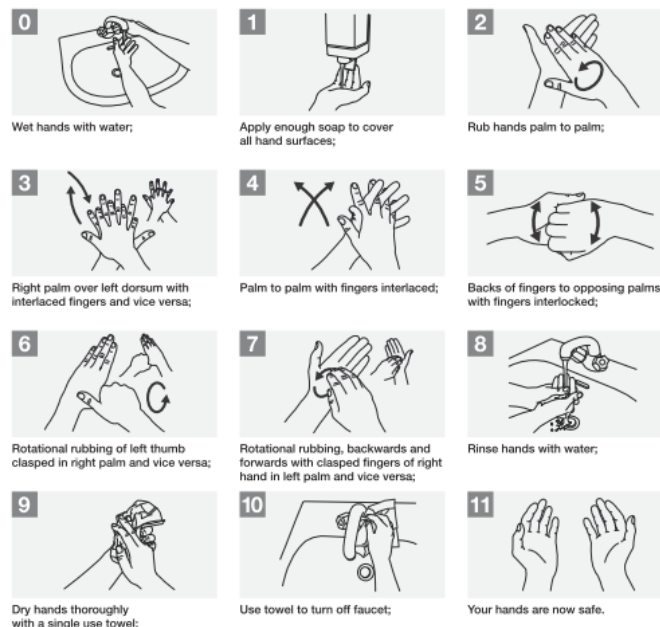
2) BRASIL. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Segurança do paciente em serviços de saúde: limpeza e desinfecção de superfícies/Agência Nacional de Vigilância Sanitária. – Brasília: Anvisa, 2012

<https://www20.anvisa.gov.br/segurancadopaciente/index.php/publicacoes/item/seguranca-do-paciente-em-servicos-de-saude-limpeza-e-desinfeccao-de-superficies>. Acesso: 10/10/18

How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

 Duration of the entire procedure: 40-60 seconds



5. BATTERY REPLACEMENT

- Replace the battery when this symbol appears  in the upper right corner of the display.
- Press the button that releases the cover that covers the batteries as shown in Figure 3.
- Carefully remove the plastic cover with the battery compartment (Figure 4).
- Remove the 4 old batteries and replace all batteries with 4 new AAA-type batteries. Make sure the batteries are installed with the correct polarity (Figure 5).
- Slide the battery compartment back into place and secure the cover.
- Dispose of old batteries in accordance with current local legislation.

Figure 3



Press here to
release the cover

Figure 4



Figure 5



6. DISPOSAL



Dispose of used batteries in an appropriate location in accordance with current local law, and keep the batteries out of the reach of children.

7. MAINTENANCE

GENERAL INFORMATION:

- It is forbidden to open any part of the equipment, other than authorized technical assistance, resulting in loss of warranty. If maintenance is required, contact your nearest authorized technical assistance (see addresses on [the www.birthtech.com.br](http://www.birthtech.com.br));
- Preventive maintenance should be carried out only at the factory or authorized technical assistance;
- Circuit diagrams, parts list and components are provided only for authorized technical assistance.

PREVENTIVE MAINTENANCE:

Birthtech recommends factory maintenance and calibration or authorized SERVICE of LEDs to ensure the correct functioning of the PreemieTest every 1 year.

CORRECTIVE MAINTENANCE:

FAULT DETECTION AND CORRECTION Before calling authorized service, verify that the problem presented does not fit one of the items listed below:

Defect:	Correction:
The PreemieTest doesn't turn on!	Check that the batteries are in the correct position. Replace the batteries with new ones. Check that the batteries fit perfectly inside the appliance, some batteries are slightly smaller in size.
The display shows the visual indication: "Error re-measure"	Redo the measurement by repositioning the PreemieTest on the newborn's heel. Follow the Exam Steps Again.

SENDING THE EQUIPMENT FOR TECHNICAL ASSISTANCE

If your equipment is not working according to the characteristics of this manual and you have already checked the ITEM FAULT DETECTION AND CORRECTION and has not been successful, please contact Birthtech technical assistance or authorized assistance for sending the equipment.

Along with the equipment, a letter should be sent reporting the problems presented by the equipment, the contact details and address for return of the equipment or sending a new replacement equipment.

When contacting technical assistance by phone it is important to have the following data at hand:

- Equipment model;
- Equipment serial number;
- Description of the problem that the equipment presents.

ATTENTION:

- The replacement of components, parts or maintenance of the equipment by a technician not authorized by Birthtech implies the loss of the warranty.
- Send the following items for maintenance:
 - PreemieTest, only the equipment, without the batteries.
 - Problem report.
 - Copy of the Invoice, for the cases of equipment under warranty.
 - User manual for completing the calibration date.

PRECAUTIONS IN CASE OF CHANGE IN THE OPERATION OF THE PRODUCT

If the equipment malfunctions, check to see if the problem is related to any of the items listed in item 3.3. If the problem cannot be resolved, request authorized technical assistance. In this case, unplug the equipment, remove the power supply cord from the outlet and request the authorized service assistance. Consult the nearest authorized assistance through the <http://www.birthtech.com.br> website or through customer service at the factory by phone: (+351) 236 550 057.

8. WARRANTY TERM

The warranty covers defects in workmanship or materials, respecting the considerations set forth in this manual for a period of 12 months, from the date of purchase proven by the Invoice (purchase) of the equipment. This warranty service will be provided only by Birthtech, or by companies accredited by Birthtech. During the warranty period, Birthtech becomes responsible for the cost of the transportation, defined by Birthtech, of equipment that requires maintenance for manufacturing defects. However, if it is proven in the Birthtech Technical Assistance assessment that the equipment is not damaged or that the damage is not a manufacturing defect, maintenance will be charged and the amount of transportation of receiving and shipping the equipment will be increased.

THE WARRANTY IS AUTOMATICALLY INVALID IF:

1. The equipment is used outside the technical specifications mentioned in this manual;
2. The product undergo modification or conversion electrical, mechanical, aesthetic, which change its original characteristics;
3. The appliance shows internal or external signs of knocks or mistreatment;
4. The appliance suffers damage caused by accident, misuse, operation in environments or conditions outside its specifications and recommendations indicated in the manual, transport or any other agent of nature (atmospheric discharge, rain, etc.);
5. The appliance is opened for repair, handled or has the original circuit altered by an unauthorized technician;
6. There is damage from improper storage or signs of tampering;
7. The serial number of the appliance is removed or changed.

EXAMPLES OF DAMAGE NOT COVERED BY THE WARRANTY:

1. Damage to equipment due to transport and handling accidents. Example: scratches, dents, broken printed circuit boards, cracked cabinet, etc.
2. Damage caused by nature's disasters. Examples: atmospheric discharges;

9. WARRANTY

Birthtech warrants to the user of the PreemieTest equipment specified herein, the services of technical assistance, exchange of components or parts, as well as the labor required for repairs of any defects, proven to be proven to be in the factory, during 12 MONTHS, from the date of purchase by the first buyer and within the terms

In case of questions, information and / or complaints, please contact the Customer Service (SAC), by e-mail sac@brithtech.com.br, Monday to Friday from 8am to 6pm.