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Instructions for CMS-50D Plus Pulse Oximeter

Dear users, thank you very much for purchasing the Pulse Oximeter.

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is medical device, which can be used repeatedly.

WARNING:

- **Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special patients, there should be a more prudent inspecting in the placing process. The device cannot be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.**
- **Testee cannot use enamel or other makeup.**
- **Testee's fingernail cannot be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

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1 Safety

1.1 Instructions for safe operations

Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the device. In addition ,the overall check of monitor, including the safety check such as the leakage current ,should be performed only by qualified personnel once every 12 months.

- ü Necessary maintenance must be performed by qualified service engineers ONLY. There are no user serviceable parts and users are not permitted to maintain it by themselves.
- ü The oximeter cannot be used together with devices not specified in User's Manual. Only the accessory that appointed or recommendatory by manufacture can be used with this device.
- ü This product is calibrated before leaving factory.

1.2 Warning

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away High level electromagnetic radiation emitted from such devices may greatly affect the monitor performance.
- DO NOT use the oximeter while the testee measured by MRI and CT.
- Be careful with the use of the lanyard cord. Improper use of the lanyard cord will cause device damage not covered under the manufacturer's warranty. Swinging the device by the lanyard cord will void the warranty. Please do not use lanyard cord if allergic to lanyard cord.
  - The person who is allergic to rubber cannot use this device.
  - The disposal of scrap instrument and its accessories and packing's (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
  - Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
  - Please choose the accessories and probe which are approved or manufactured by the manufacturer, or else it may damage the device.
- Please don't measure this device with functional tester for the device's related information.
- When uploading, do keep the patient form touching the USB port. The computer used when uploading must be in accordance with EN60950.We recommended to use Lenovo Qitian M320,etc,in addition, when the data line connected to a computer, the medical electrical systems should be in accordance with IEC60601-1-1.

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1.3 Attention

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1)for instructions of cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- Please read the measured value when the waveform on screen is equably and steady-going, This measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- The hanging rope attached to the device is made from Non- allergy material, if particular group are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope , do not wear it around the neck on the purpose of avoiding harm to the patient.
- This device has the function of alarming, users can check on this function according to chapter 6.2 as a reference.
- The device has the function of limits alarming, when the measured data is beyond the highest or lowest limit, the device would start alarming automatically on the premise of the alarming function is on.
- The device has the function of alarming, this function can either be paused, or closed (default setting) for good. This function could be turned on through menu operation if you need. Please check the chapter 6.2 as a reference.
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

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2 Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patients to put one of his fingers into a probe for diagnosis, and a display screen will directly show the measured value of pulse oxygen saturation with the high veracity and repetition.

2.1 Features

A. Operation of the product is simple and convenient.
B. The product is small in volume, light in weight and convenient in carrying.
C. Low power consumption

2.2 Major applications and scope of application

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger. The product is suitable for being used in family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports, and it is not recommended to use the device during the process of having sport) and etc.

⚠**The problem of overrating would emerge when the patient is suffering from toxicities which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3 Environment requirements

Storage Environment
a) Temperature :-40℃~+60℃
b) Relative humidity :5%~95%
c) Atmospheric pressure :500hPa~1060hPa

Operating Environment
a) Temperature:10℃~40℃
b) Relative Humidity :30%~75%
c) Atmospheric pressure:700hPa~1060hPa

3 Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive

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Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

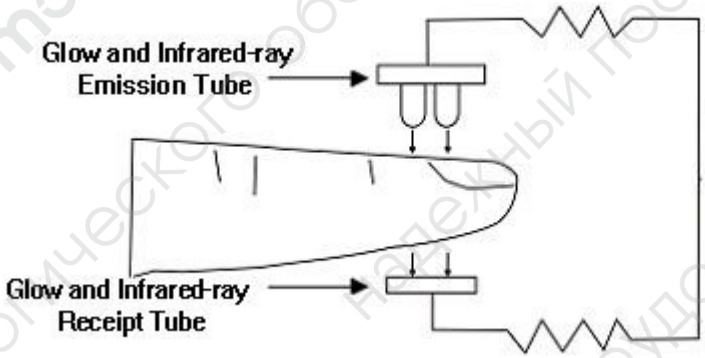


Figure 1.

4 Technical Specifications

4.1 Main performance

A. SpO_2 value display
B. Pulse rate value display, bar graph display
C. Pulse waveform display
D. Low-voltage indication: low-voltage indicator appears before working abnormally which is due to low-voltage
E. Automatically power off function: when the device is under the state of measuring interface . it will automatically power off within 5 seconds if the finger falls out of probe.
F. The display mode can be changed
G. A pulse rate sound indication
H. With alarm function
I. With SpO_2 value and pulse rate value of storage, the stored data can be uploaded to computers
J. Data can be transmitted to computers

4.2 Main Parameters

A. Measurement of SpO_2
Measuring range: 0%~100%
Accuracy:
When the SpO_2 measuring range is 70%~100%,the permission of absolute error is ±2%;
below 70% unspecified
B. Measurement of pulse rate
Measuring range:30bpm~250bpm
Accuracy: ±2 bpm or ±2% (select larger)
C. Resolution
SpO_2 : 1%, Pulse rate: 1bpm.
D. Measurement Performance in Weak Filling Condition

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SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select larger).

E. Resistance to surrounding light

The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

F. Power supply requirement: 2.6 V DC ~ 3.6V DC.

G. Optical Sensor

Red light (wavelength is 660nm, 6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range:

SpO_2 : 0%~100%

Pulse Rate: 0bpm~250bpm

5 Installation

5.1 View of the front panel



Figure 2. Front view

5.2 Battery installation

A. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.

B. Replace the cover.

⚠ **Please take care when you insert the batteries for the improper insertion may damage the device.**

⚠ **When you don't use the device for more than 2 hours，please take out the dry batteries.**

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Figure 3.

5.3 Accessories

A. a hanging rope
B. two dry batteries(AAA) (optional)
C. a user manual
D. a data line
E. a disk (PC software)

6 Operating Guide

6.1 Application method

A.

a) Insert the two batteries properly to the direction, and then replace the cover.
b) Open the clip as shown in Figure 4.
c) Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
d) Do not shake the finger and keep the patient in a stable state during the process.
e) The data can be read directly from the screen on the measuring interface.

⚠ **Fingernails and the luminescent tube should be on the same side.**

⚠ **If the alarm function is on, the device will provide medium-priority alarm signal when finger is out. Intermittent alarm will occur and the user interface presents "FINGER OUT". Medium priority indicating that prompt operator response is required.**



Figure 4. Put finger in position

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B. Change display direction

On the measuring interface, short press the button to change the display.

C. Pause alarm:

a) Alarm including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of finger's out of position.

b) On the measuring interface, if the alarm function is on, during the period of alarming, you can pause it by pressing the button shortly, but the function will be renewed in about 30 seconds.

c) If you want to turn off the alarm for good, you should enter the menu for operation.

D. Data transmission setting

Firstly, please install the affiliated software **i**nto the computer, and two icons would appear on the desktop after installation. The icon of "SpO_2 "is a program for receiving real-time data which is shown as Figure 5; the icon of "SpO_2 Review" is a program for receiving stored data which is shown as Figure 6.

a. Please connect the device to computer with the affiliated data line , then double click the "SpO_2 "icon to start the program.

b. When you unplug the data line from computer, there is a dialog box "Save data at view" appearing on the desktop, in which you can input some patient's basic information.



Figure 5. SpO_2 program



Figure 6. SpO2 Review program

⚠**If the users choose to turn on the synchronizing display function on computer, it would probably take several seconds for the data to appear on the computer screen.**

E. Menu operations

On the measuring interface , the display direction can be changed by pressing the power button with a short push (click). There are six modes of data display that can be viewed.

Press the power button with a prolonged push (1 second) to enter the Settings Menu Interface (see Figure 7).

The user can setup the following parameters in the Settings Menu –Turn on alarm, turn on pulse sound, alarm high-low limits, data storage (recording).

Please note in the Settings Menu:

CLICK = short press of power button and **PRESS** = prolonged push of power button (1sec)

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Figure 7. Main Menu Interface

a) Alarm setting

On the main menu interface, click the power button to select “Alarm”, Press the power button (1sec) to enter the alarm setting interface as shown in Figure 8:

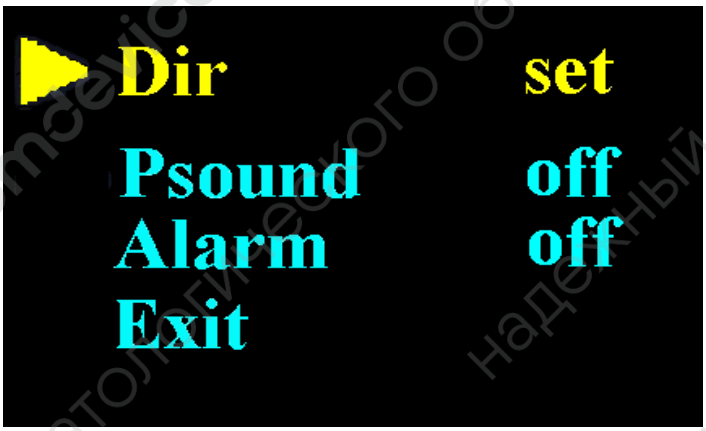


Figure 8.

a. Adjusting the high and low limits of alarms

On the alarm setting interface, Click the power button to select “Dir”, then Press the button (1sec) to enter the alarm direction setting interface as shown in Figure 9:



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Figure 9.

On the alarm direction setting interface, Click the power button to select "SpO_2 Alm"or "PRAlm",then Press the button (1 sec) to enter the SpO_2 or PR direction setting interface as shown in Figure 10:



Figure 10.

Click the power button to select "Dir", then Press the button to choose Up or Down (this will be the direction the value of the high-low limits of SpO_2 and pulse rate will be adjusted).

To raise the SpO_2 and pulse rate limit, choose "Dir" as 'Up', then Click the power button to select high limit (High) or low limit (Low),Press the power button and hold to adjust the selected limit to the desired higher value and release the power button once the higher limit has been reached.

To lower the SpO_2 and pulse rate limit, choose "Dir" as 'Down', then Click the power button to select high limit (High) or low limit (Low). Press the power button and hold to adjust the selected limit to the desired lower value and release the power button once the lower limit has been reached.

⚠**If the alarm function is on, the device will provide medium-priority alarm signal when the data of SpO_2 or pulse rate is beyond the limit. Intermittent alarm will occur and the measuring value will be flashing.**

Medium priority indicating that prompt operator response is required.

b. Pulse sound indication setting

On the alarm setting interface as shown in Figure 8,Click the power button to select "Psound", then Press the power button to choose to have the Pulse Sound (heart beat) alarm "on" or "off".

c. The alarm state setting

On the alarm setting interface as shown in Figure 8,Click the power button to select "Alarm", then Press the power button to choose alarm on or off, press " on" to turn on the alarms and " off" to turn off the alarms.

d. Exit the Alarm settings , the alarm direction setting , the SpO_2 or PR direction setting

Click the power button to select "Exit", then Press the power button to exit the Menu and return to the previous Menu .

b) Data storage setting

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This instrument has the ability to store 24 hours' worth of data. It can store the measured pulse rate and SpO_2 value accurately, transfer the data to the computer, display the data and print reports (with the included SpO_2 Software - Green Heart)

a. On the main menu interface as shown in Figure 7, Click the button to select "Record", then press the button to choose whether store the data or not, choose "on" to permit storing, choose "off " to forbid storing.

b. If the data storage function is being turned on, when return to the measuring interface, a flashing yellow dot would appear on screen, which means the device is in a state of storing.

c. In the state of storing, the device is on measuring interface, the sign "Recording" would appear on the screen in 30 seconds, and then the screen will be automatically shut down, only a flashing yellow dot appear on screen. If short press the button at this moment, the sign "Recording" would appear on the screen, and then the screen will be automatically shut down again; if long press the button, the device would return to the measuring interface.

d. If turning on the data storage function, the former data storage will be automatically removed.

e. When the storage space is full, it displays "Memory is full" on the screen, and then shut down in a few seconds. But it will still display "Memory is full" by the next time you turn on the device on the purpose of warning the user, and a few seconds later enter the measuring interface.

c) Uploading the data to the PC after recording

a. Please connect the device with computer by the data line which is equipped with the device, then double click "SpO_2 Review" icon which is shown as Figure 5 to open"SpO_2 Review" program, click the 'New Session' Icon in the software, enter the patient data and then click 'ok'. The Software will then display "device connected, waiting for data".

b. On the main menu interface, the users to upload the stored date to computer when the symbol "Record" shows "off ".

d) Exit the main menu

On the main menu interface, Click the button to select "Exit", then press the button to exit the main menu.

F. Power off

If the measuring finger out of the device on the measuring interface, The device will power off automatically when it gets no signal within 5 seconds. The device can't being power off when it is in a state of storing.

6.2 Attention for operation

A. Please check the device before using, and confirm that it can work normally.

B. The finger should be in a proper position (see the attached illustration of Figure 4 for reference), or else it may result in inaccurate measure.

C. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject' s arteriole in a position there between.

D. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.

E. Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate

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measure of SpO_2 and pulse rate.

F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.

G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

H. Testee cannot use enamel or other makeup.

I. Please clean and disinfect the device after operating according to the User Manual(7.1).

6.3 Clinical restrictions

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.

C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.

D. As the SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

7 Maintain, Transportation and Storage

7.1 Cleaning and Disinfecting

Using medical alcohol to disinfect the device, nature dry or clean it with clean soft cloth.

7.2 Maintain

A. Please clean and disinfect the device before using according to the User Manual(7.1).

B. Please change the battery when the screen shows .

C. Take out the battery if leave the equipment unused for long time.

D. The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3 Transportation and storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device cannot be transported mixed with toxic, harmful, corrosive material .

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C~60°C; Humidity: ≤95%.

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8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate cannot be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm.
The device cannot be turned on	1. The battery is drained away or almost drained away. 2. The battery is installed incorrectly. 3. The device's malfunction.	1.Please change batteries. 2.Please Install the battery again. 3. Please contact the local service center.
The display is off suddenly	1. This device is set to be automatically power off within 5 seconds when it cannot detect any signal 2. The battery is drained away or almost drained away.	1. Normal 2. Please change batteries.

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9 Key of Symbols

Signal	Description
	Warning – See User Manual
%SpO_2	The pulse oxygen saturation(%)
PRbpm	Pulse rate (bpm)
	Low-voltage
	Open the alarm sound indication
	Open the pulse sound indication
	menu button/power button/function button
	Type BF
SN	Serial number
	1. the finger clip falls off (no finger inserted)] 2. Probe error 3. Signal inadequacy indicator
	battery positive electrode
	battery cathode
	USB
IPX1	Ingress of liquids rank
	WEEE (2002/96/EC)

10 Function Specification

Information	Display Mode
The Pulse Oxygen Saturation(SpO_2)	2-digit digital OLED display
Pulse Rate(PR)	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	0%~100%, (the resolution is 1%).
Accuracy	70%~100%: ±2% ,Below 70% unspecified.
Average value	Calculate the Average value in every 4 measure value. The deviation between average value and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30bpm~250bpm, (the resolution is 1bpm)
Accuracy	±2bpm or±2% (select larger)
Average pulse rate	Moving calculate the Average pulse rate every 4 cardio-beat's cycle. The deviation between average value and true value does not exceed 1%
Safety Type	Interior Battery,BF Type
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2	
Battery working life	
Two1.5V (AAA size)600mAh alkaline batteries can work continually for 24 hours	
Dimensions and Weight	
Dimensions	58.5(L) × 31(W) × 32 (H) mm
Weight	About 52g (with the batteries)