LIMITED WARRANTY

The Fingertip Pulse Oximeter has a 2 year warranty to be free of manufacturing defects in materials and workmanship under normal applications for 2 years of the original owner. If this product becomes inoperable due to defect and requires repair, return the product with all component pieces and proof of purchase to the address listed below. This warranty does not cover any shipping/transport costs. This warranty does not apply if the product is subject to misuse, neglect, rough handling or damage.

Ship the unit prepaid and insured (at owner's option) to:

Thermor Ltd.
Attn: Repair Department
16975 Leslie Street
Newmarket, ON L3Y 9A1

www.biosmedical.com
Email: support@biosmedical.com

Limitations

This warranty covers all defects encountered in normal use of the equipment and does not apply in the following cases.

1) If the equipment has been serviced by other than a certified center.
2) Damage to the equipment due to mishandling, abuse, accident or not following operating instructions.
3) INSTRUMENTS: Warranty does not extend to display face, batteries, carrying case or lanyard.

For troubleshooting assistance please contact Consumer Support. Our representatives are trained to provide you assistance over the phone and may be able to resolve your problem without returning. For the best possible assistance please have your unit available when calling us.

Service Phone: 1 (866) 517-2970

www.biosmedical.com

OPERATOR'S MANUAL

OxyWatch™ **MD300C20**

Fingertip Pulse Oximeter

General Description

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO_2 level.
Diagram of Operation Principle
1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube

Precautions For Use

1. Before use, carefully read the manual.
2. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
4. Do not use the fingertip pulse oximeter in an MRI or CT environment.
5. Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the fingertip pulse oximeter in an explosive atmosphere.
7. The fingertip pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
8. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than 4 fours.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
12. Portable and mobile RF communications equipment can affect medical electrical equipment.
13. This equipment is not intended for use during patient transport outside the healthcare facility
14. This equipment should not be used adjacent to or stacked with other equipment.
15. Do not disassemble, repair or modify the equipment without authority.
16. These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.

Inaccurate measurements may be caused by

1. Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin;

Product Features

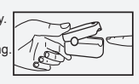
1. High brightness OLED display SpO_2, PR, Pulse bar and Plethysmograph.
2. Low power consumption; battery-low indicator
3. Automatically power off; 2 AAA alkaline batteries
4. When no signal or low signal is detected, the pulse oximeter will power off automatically in 8 seconds.

Intended Use

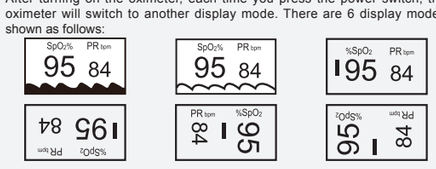
Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients in hospitals, hospital-type facilities. It is not for continuous monitoring.

Operation Instructions

1. Install two AAA batteries into battery compartment correctly.
2. Place clamp over finger nail as the right diagram.
3. Insert one finger into rubber hole of the oximeter fully.
4. Press the switch once on the front panel.
5. Finger and body should not tremble during measuring.
6. Read correspondent data from display screen.
7. Six display modes



After turning on the oximeter, each time you press the power switch, the oximeter will switch to another display mode. There are 6 display modes shown as follows:



When you press the power switch for more than one second, the brightness of the oximeter will be changed by degrees. There are 10 levels on brightness; the default is level four.

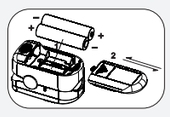
NOTE: Please use medical alcohol to clean the rubber inside the oximeter, and clean the test finger using alcohol before and after each test. (The rubber inside of the oximeter belongs medical rubber, which has no toxin and no harmful to the skin of human being).

Product Accessories

1. One lanyard
2. Two AAA batteries
3. One user's manual
4. One carrying case

Battery Installation

1. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally along the arrow .



Notes:
Please remove the batteries if the pulse oximeter will not be used for long periods of time.

Maintenance and Storage

1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
3. Remove the batteries if the oximeter is not operated for a long time.
4. It is best to store the product in -20□~+55□ and ≤93% humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter
Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.
Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.
The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.
The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:
● An error in the Possible Problems and solutions is displayed on screen.
● The oximeter cannot be powered on in any case and not the reasons of battery.
● There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
A functional tester is used to measure how accurately Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.
The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

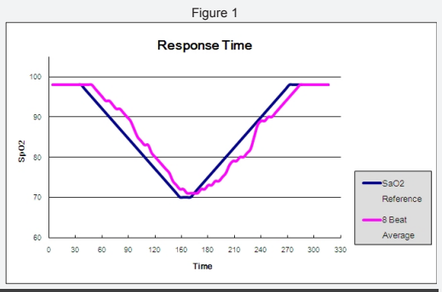
Specifications

1. Display Type:
OLED display
2. SpO_2
Display range: 0%~99%
Measurement range: 70%-99%
Accuracy: 70%~99%: ±3%; 0%~69% no definition
Resolution: 1%
3. Pulse Rate
Display range: 0bpm~250bpm
Measure range: 30bpm~250bpm
Accuracy:
30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%
Resolution: 1bpm
4. Probe LED Specifications

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	940±10nm	2.0mW

NOTE: The information about wavelength range can be especially useful to clinicians.
5. Power Requirements
Two AAA alkaline Batteries
Power consumption: Less than 25mA
Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours.
6. Environment Requirements
Operation Temperature: 5□~40□
Storage Temperature: -20□~+55□
Ambient Humidity: ≤80% no condensation in operation
≤93% no condensation in storage
Atmosphere pressure: 86kPa~106kPa
7. Equipment Response Time
As shown in the following figure.(Figure 1)
Response time of slower average is 12.4s.
8. Classification
According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART;
According to the degree of protection against ingress of water: IPX1
According to the mode of operation: CONTINUOUS OPERATION

Figure 1



Possible Problems and Solutions

Problems	Possible reason	Solution
SpO_2 or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1.Retry by inserting the finger 2. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.
SpO_2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Finger is trembling or patient's body is in movement status.	1. Retry by inserting the finger 2. Try not to move
The oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all. 2. Batteries might be installed incorrectly. 3. The oximeter might be damaged.	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. Power quantity of the batteries is started being inadequate	1. Normal 2. Replace the batteries
"Error3" or "Error4" is displayed on screen	1. Low power 2. Receiving tube being shielded or damaged together with broken connector. 3. Mechanical Misplace for receive-emission tube. 4. Amp circuit malfunctions.	1. Change batteries 2. Please contact local customer service center 3. Please contact local customer service center 4. Please contact local customer service center
Error 6	Err 6 means the screen is failure	Change the screen
"Error7" is displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunctions.	1. Please change battery 2. Please contact local customer service center 3. Please contact local customer service center

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part.	SpO2	No SpO_2 Alarm
	Attention, consult accompanying documents.		Power switch
IPX1	Protected against dripping water.	SN	Serial No.
%SpO_2	Oxygen saturation		Storage temperature and relative humidity
PR_{bpm}	Pulse Rate (bpm)		Manufacturer's information
	Low power indication		Date of Manufacture

Notes:
1. The illustrations used in this manual may differ slightly from the appearance of the actual product.
2. The specifications are subject to change without prior notice.

Declaration

Guidance and Manufacturer's declaration – electromagnetic emissions- For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic emission

The MD300C20 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of MD300C20 Pulse Oximeter should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic Environment – guidance
RF emissions CISPR 11	Group 1	The MD300C20 Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The pulse Oximeter (MD300C20) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's declaration – electromagnetic immunity-For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic immunity

The MD300C20 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C20 Pulse Oximeter should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's declaration – electromagnetic immunity- For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity

The MD300C20 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300C20 Pulse Oximeter should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter (MD300C20), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection structures, objects and people.

a Field strengths from fixed transmitters, such as base station for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter (MD300C20) should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Pulse Oximeter (MD300C20).
b Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and Pulse Oximeter (MD300C20)

The Pulse Oximeter (MD300C20) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter (MD300C20) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter (MD300C20) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Distributed by:
Thermor Ltd.
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Beijing Choice Electronic Technology Co., Ltd.
Room 4104, No. A12 Yuquan Road, Haidian District, Beijing P.R. Chine

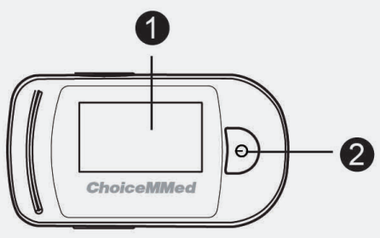
Revised date: October 31, 2019

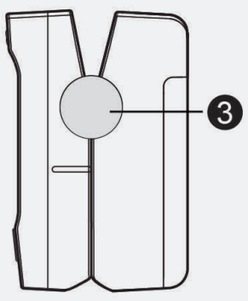
OxyWatch™

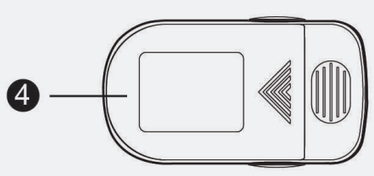
Quick Operation Guide

ChoiceMMed_OxyWatch_MD300C20

■ Before using the oximeter, please remove protective sticker covering the display.

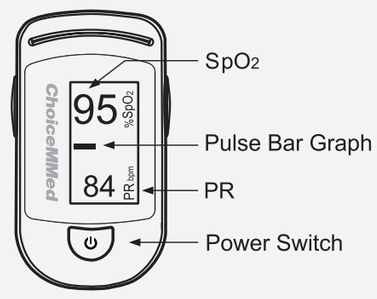






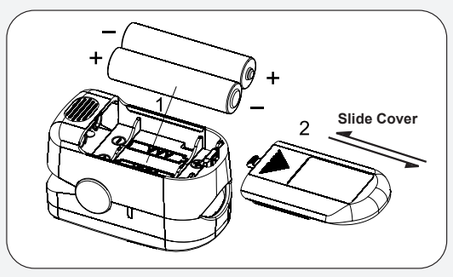
1 Displaying Screen
2 Power Key
3 Shaft Cover
4 Battery Box Cover

■ Brief Description of Front Panel



The pulse bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.

■ Battery Installation



Please put in the batteries according to the polarity marked inside the battery compartment.

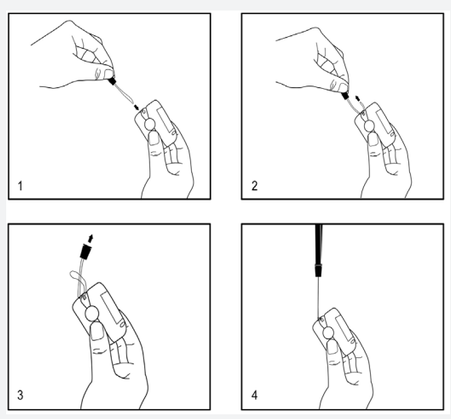
■ Using the Lanyard

1. Thread thinner end of the lanyard through the loop.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.

Warnings!

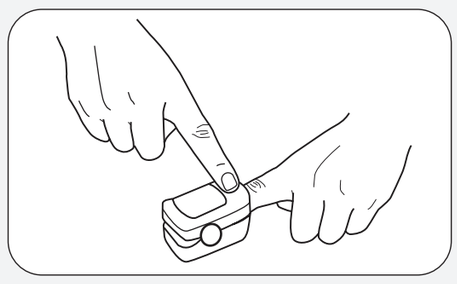
• Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.

• Do not hang the lanyard from the device's electrical wire.

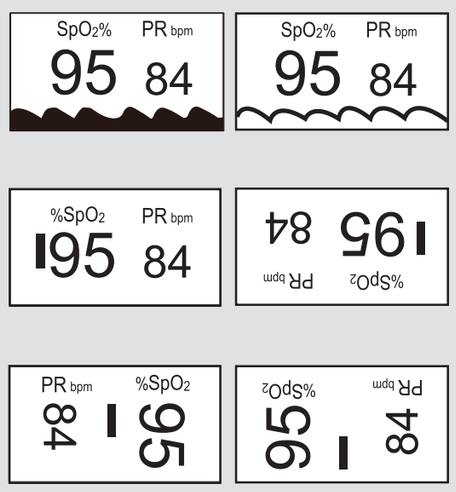


■ Operation Instruction

Place one of your fingers into the pulse oximeter to the end and press the switch button one time on front panel to turn it on.



There are 6 display modes. After turning on the pulse oximeter, each time you press the power switch, the pulse oximeter will switch to another display mode.



When you press the power switch for more than one second, the brightness of the pulse oximeter will be changed by degrees. There are 10 levels on brightness. The default level is level 4.

Keep your hands still for the reading.

The pluse oximeter will power off automatically in 8 seconds if there's no finger inside.

■ Warnings and Notes

Warnings:

1. Keep the pulse oximeter away from young children. Small parts such as the battery door and the batteries etc. May be hazardous if swallowed.
2. The lanyard may cause strangulation in conditions that may cause it to twist around the neck.

Notes:

1. Read the manual carefully before use.
2. The illustration used in this manual may differ slightly from the appearance of the actual product.
3. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

■ Frequently Asked Questions

What is a Pulse Oximeter?

A pulse oximeter is a non-invasive device that indirectly monitors the blood oxygen saturation (SpO_2) and pulse rate (heart rate). It displays both blood oxygen saturation (SpO_2) & pulse rate (heart rate). Pulse oximeters provide an easy way of assessing your blood oxygen level and pulse rate.

What is SpO_2?

SpO_2 is also known as oxygen saturation. Oxygen saturation is a measure of how much oxygen the blood is carrying as a percentage of the maximum it could carry.

What is the normal range of SpO_2?

The normal range for SpO_2 is typically considered from 95%~99%. The SpO_2 measurement may be lower for people who live at high altitudes. Ask your health professional this question as it pertains to you.

What is the normal range for pulse rate?

The normal resting range for Pulse rate is typically considered from 60 ~100 beats per minute. Ask your health professional this question as it pertains to you .

What kind of conditions may cause an inaccurate reading?

Cold hands, poor circulation, very weak pulse, fingernail polish and acrylic nails may cause inaccurate results.

The SpO_2 is not changing – it's stuck?

SpO_2 does not change like pulse rate. It is slow to change.

The Pulse Rate is changing rapidly.

Your heart rate changes with emotions, excitement and exercise.

I do not see the battery light indicator.

The battery light indicator only appears when the battery is low.