OXXIOM™
USER MANUAL

t true wearables™

29826 Avenida de Las Banderas, Suite 300
Rancho Santa Margarita CA 92688
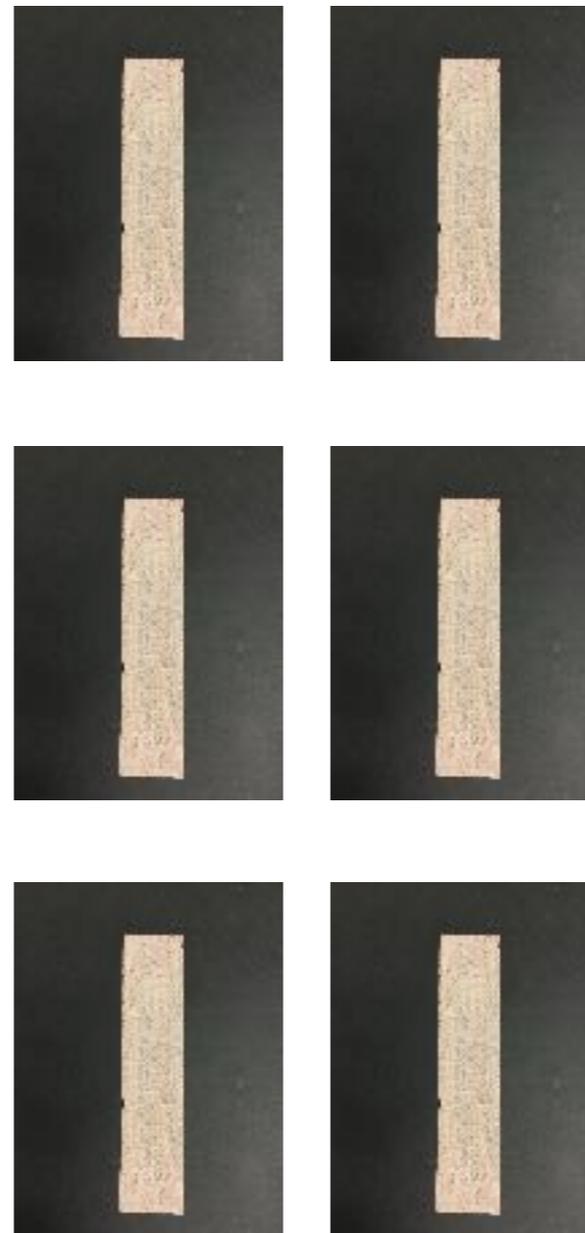
TABLE OF CONTENTS

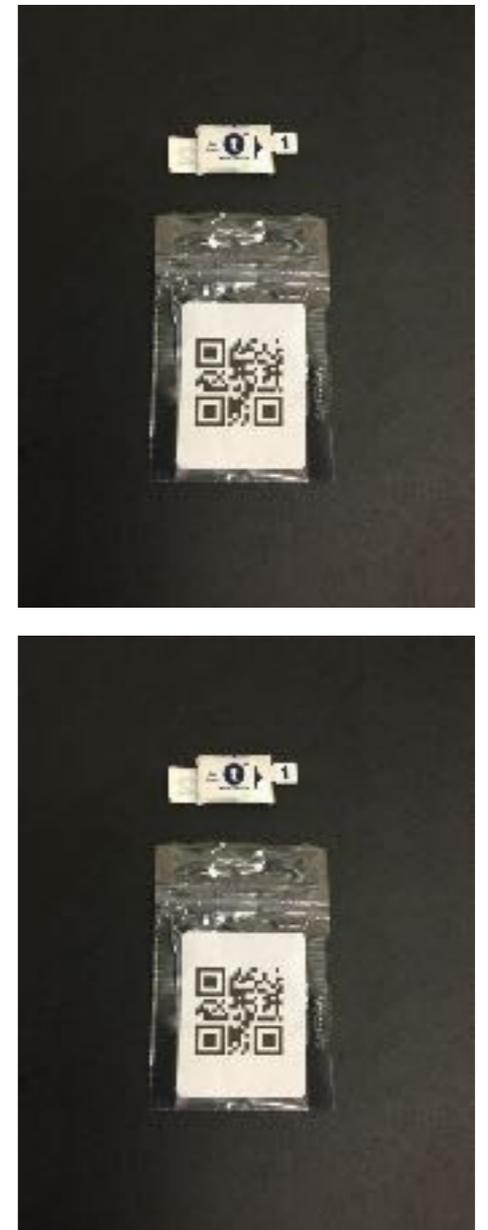# PACKAGE CONTENT

Each OXXIOM pack contains

① One User Manual

② Six 2 x 6 in self-adhering breathable gentle tapes

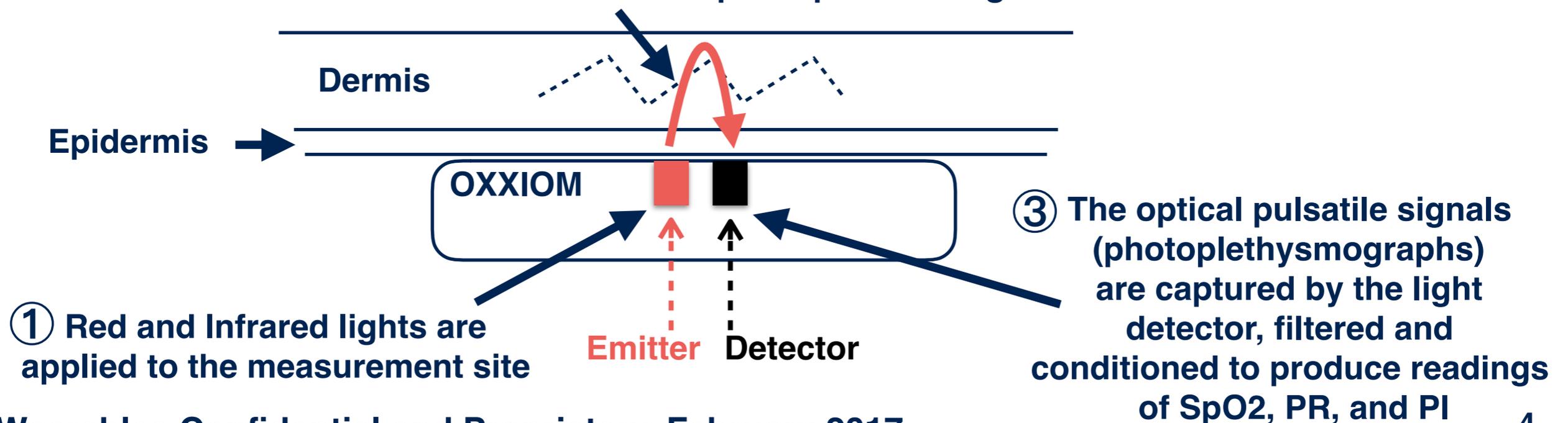**③ Two barcode packages with one OXXIOM unit each**

OXXIOM OPERATION

Oxxiom's innovative design has combined the latest electronics and biosensing technology for the measurement of the patient's functional arterial oxygen saturation (SpO2), perfusion index (PI), and pulse rate (PR).

The device is a cableless, completely wireless, continuous, fully disposable, single-use pulse oximeter with the combined function of a clinical grade pulse oximeter monitor and reflective sensor into a single disposable device. Oxxiom is a small, lightweight, easy to use, battery operated pulse oximeter that offers 24 hours of continuous monitoring.

Oxxiom wirelessly transfers the patient's data to a host device (such as an iPhone or an iPad). The host device functions as a primary display and is required for Oxxiom's operation. Measurements are continuously taken by Oxxiom and the data is simultaneously and wirelessly transferred to the host device for display, alarms, and storage.

Measurement Principle

② The red and infrared light rays penetrate the blood perfused dermis and interact with the heart's pulsatile signal in order to create red and infrared optical pulsatile signals

Dermis

Epidermis

OXXIOM
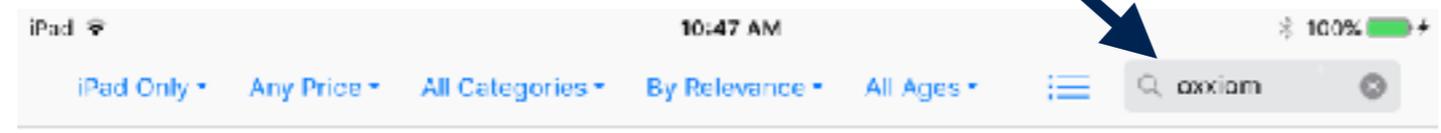
③ The optical pulsatile signals (photoplethysmographs) are captured by the light detector, filtered and conditioned to produce readings of SpO2, PR, and PI

① Red and Infrared lights are applied to the measurement site

Emitter   Detector

TECHNICAL SPECIFICATIONS

Features	Specifications
Safety	
Electrical, EMC, Pulse Oximetry, Biocompatibility	IEC 60601-1, IEC 60601-1-2, ISO 80601-2-61, ISO 0993-5, ISO 10993-10
Physical	
Dimensions, Weight	30 x 17 x 7.5 mm (12 x 0.7 x 0.3 in), 3.5 g (0.12 oz)
Optical Sensor	
Emitted light energy, Wavelength range	≤ 15 mW, 500-1,000 nm
Accuracy per ISO 80601-2-61	
SpO2 (70-100%)	+/- 3% on 68% of the population
PR (25-250 BPM)	+/- 3 BPM on 68% of the population
Measurements Range on Host Device	
SpO2	1-100%
PR	25-250 BPM
PI	0.03-20%
Alarms on Host Device	
SpO2, PR	Configurable high and low limits
Enviromental	
Operating temperature, Operating humidity, Operating altitude	5-40°C (41-104°F), 95% RH max. at 40°C (104°F), Up to 3,012m (9,882 ft)
Storage temperature, Storage humidity, Storage altitude	0-60°C (32-140°F), 95% RH max. at 60°C (140°F), Up to 5,574m (18,228 ft)
Wireless	
Protocol, Range	Bluetooth Low Energy (BLE), 10 m (33 f)
Battery	
Technology, Nominal voltage, Nominal capacity	Non-rechargeable lithium/manganese dioxide (LiMnO2), 3 V, 150 mAh
Life	24 h of continuous monitoring

WARNINGS

- Keep OXXIOM away from children and pets. OXXIOM is not a toy
- OXXIOM complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) OXXIOM may not cause harmful interference, and (2) OXXIOM must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to OXXIOM not expressly approved by True Wearables may cause harmful radio frequency interference and void your authority to operate OXXIOM
- OXXIOM is a wireless device. Other equipments may interfere with OXXIOM even if they comply with CISPR emission requirements
- OXXIOM uses a non-rechargeable LiMnO2 battery. Do not recharge, heat, expose to open flames, or disassemble OXXIOM
- OXXIOM must be used in conjunction with other methods of assessing clinical signs and symptoms (adjunctive device)
- Inspect OXXIOM measurement site at least every 8 hours to ensure correct sensor alignment and placement
- Patient sensitivity to OXXIOM biocompatible adhesive may vary due to skin condition
- Avoid excessive pressure to OXXIOM measurement site as this may cause damage to the skin beneath OXXIOM or inaccurate measurements
- No modifications to OXXIOM are allowed as they may affect OXXIOM performance
- Do not use a damaged OXXIOM. If OXXIOM is damaged, discontinue use immediately and replace OXXIOM unit
- OXXIOM general operation may be affected when in proximity to Electrosurgical Unit (ESU)
- Do not use OXXIOM in an Magnetic Resonance(MR) environment
- Do not use OXXIOM in an explosive atmosphere
- OXXIOM is not defibrillation proof (IEC 60601-1)
- OXXIOM has been tested and found to comply with IEC 60601-1-2 for electromagnetic compatibility of medical devices. This standard is designed to provide reasonable protection against harmful interferences in a typical medical installation. However, given the increased number of radio-frequency transmitting equipments and other interference sources in medical installations and other environments, high interference levels might occur and disrupt the operation of OXXIOM
- Follow governing ordinances and recycling instructions regarding disposal or recycling of OXXIOM and its components, including batteries
- OXXIOM contains WEEE materials. In compliance with the European directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose OXXIOM as unsorted waste. Please contact True Wearables regarding disposal or recycling of OXXIOM and its components.
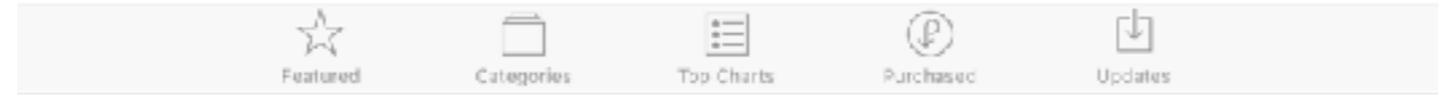
STEP 1: Download OXXIOM App

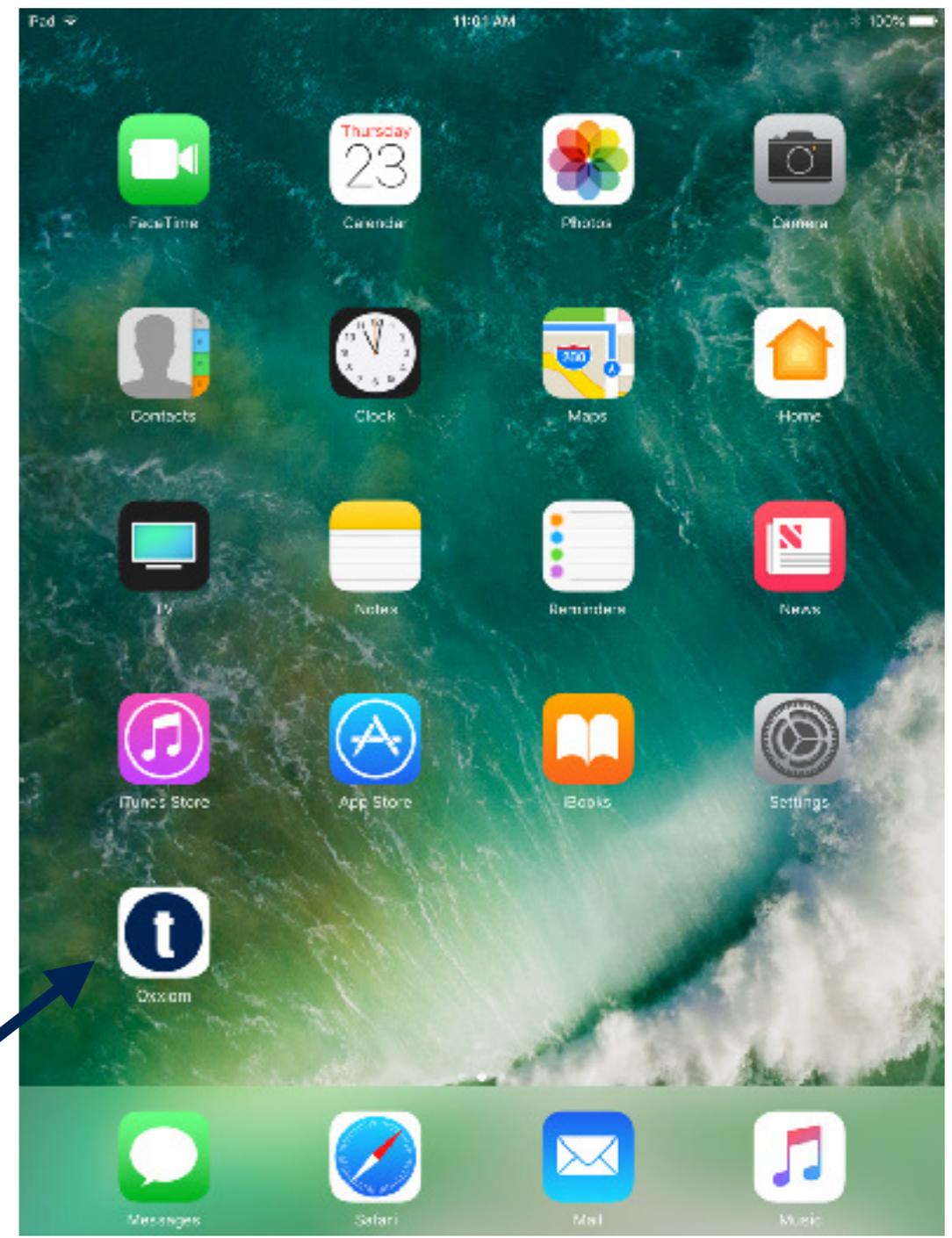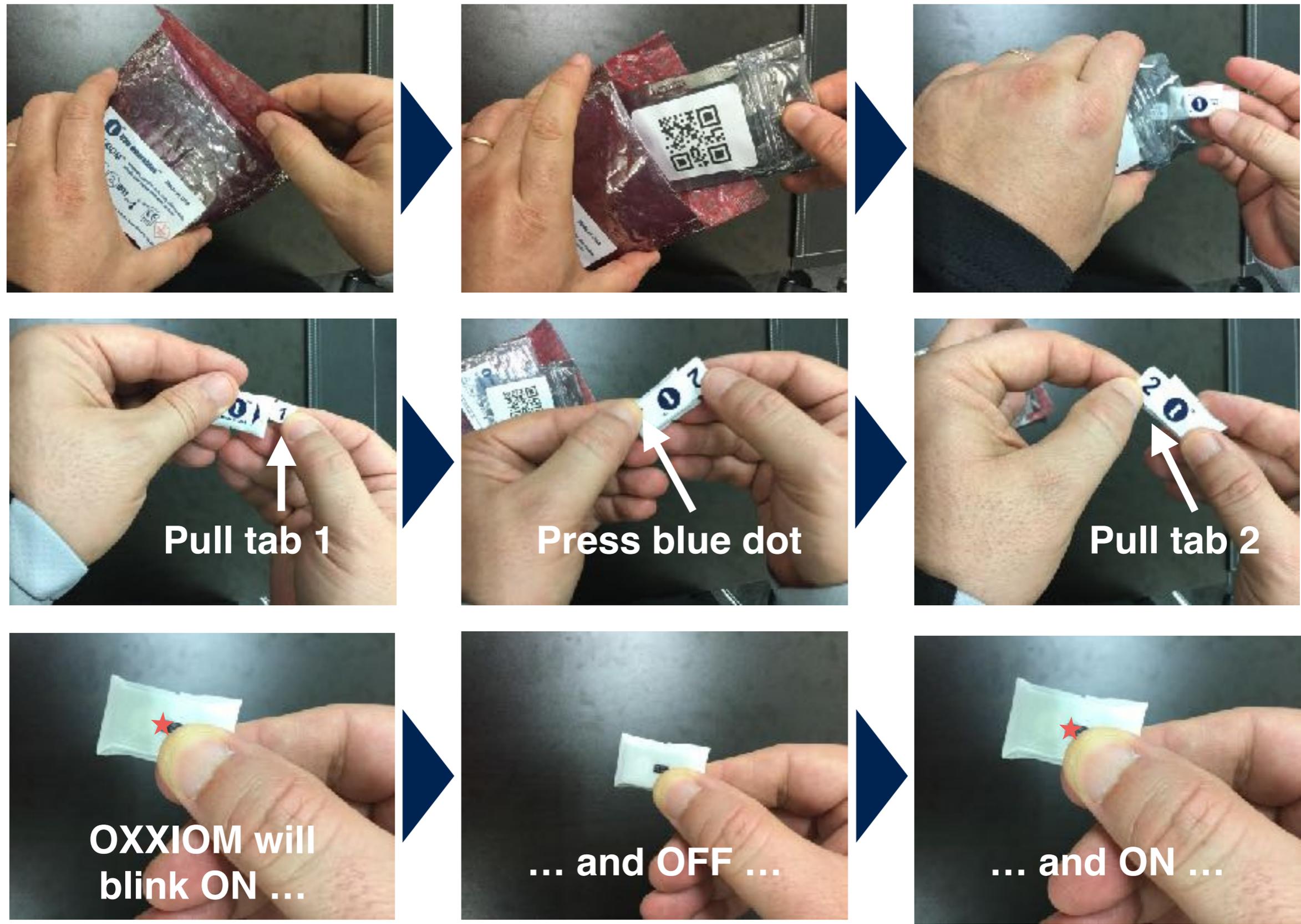**In your iPad or iPhone, select <u>App Store</u> and search for <u>Oxxiom</u>**

Select <u>Oxxiom</u> to download App

Oxxiom

<u>Oxxiom</u> App will be now available in your iPad or iPhone

STEP 2: Unpack and Turn On OXXIOM

Pull tab 1

Press blue dot

Pull tab 2

OXXIOM will blink ON …

… and OFF …

… and ON …

STEP 3: Attach OXXIOM to Patient

Align OXXIOM to finger tip and press it against tip for adhesion

Make sure blue arrow points outwards

Wrap self-adhering breathable tape …

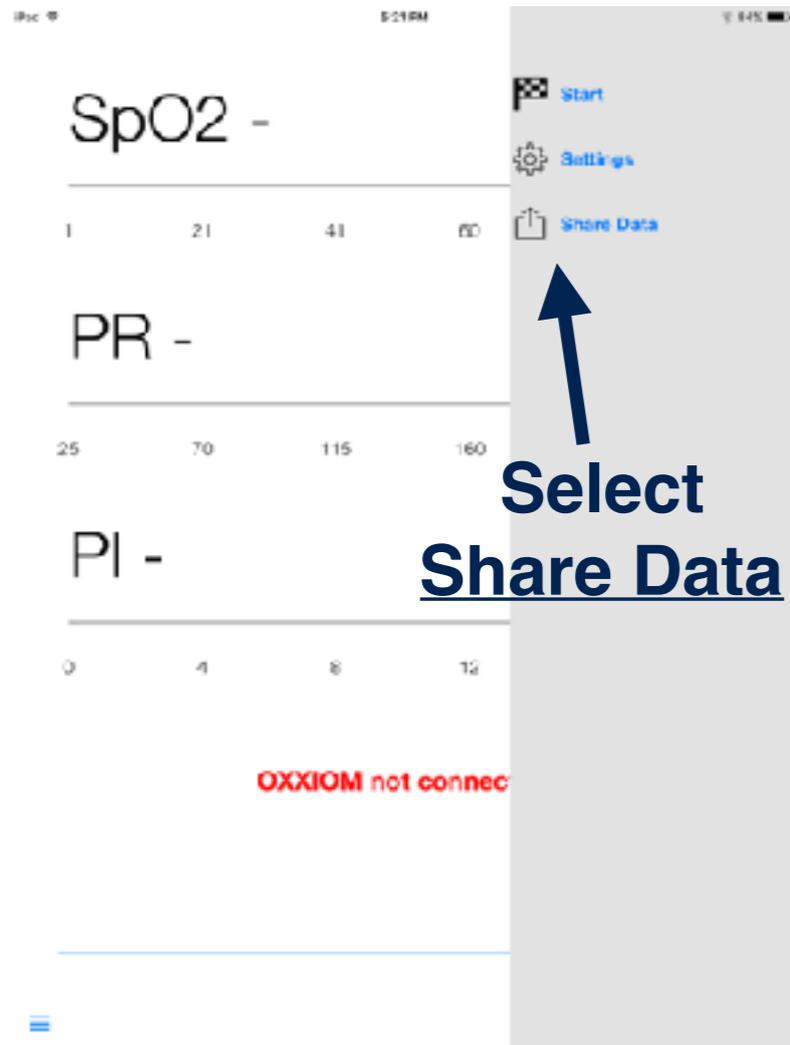**… around digit to properly keep …**

… OXXIOM in place

Do Not wrap tape too tight or too loose

Make sure it is comfortable for the patient

STEP 4: Pair OXXIOM With App

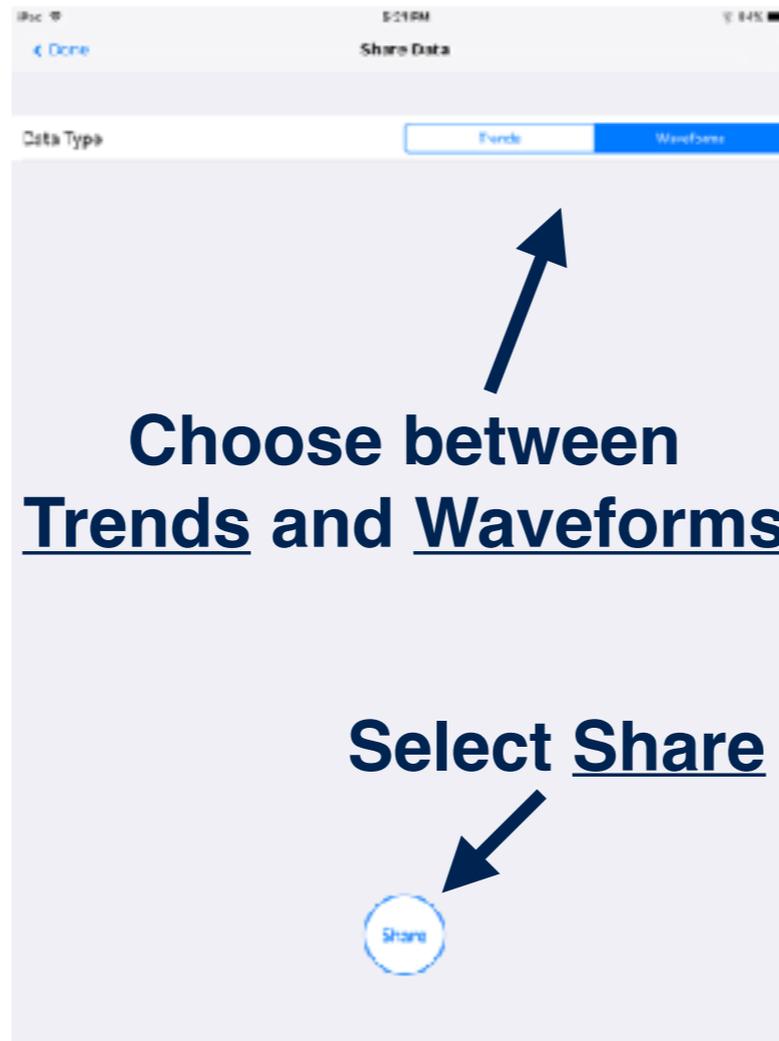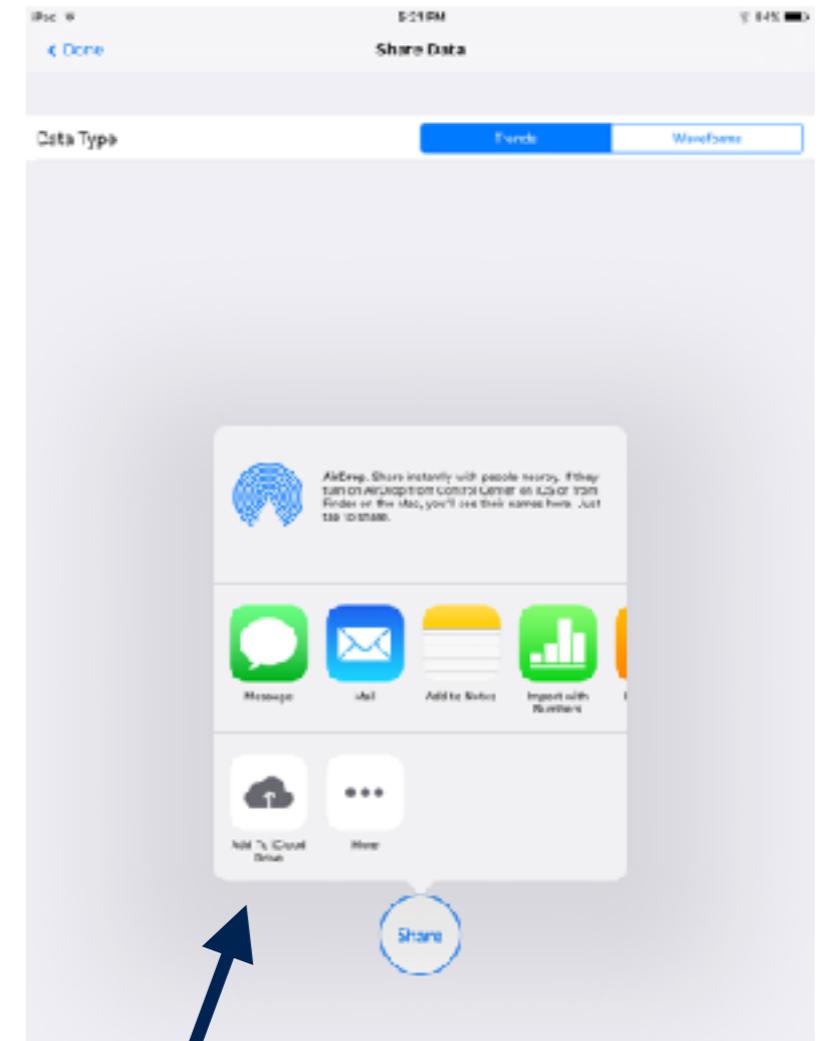**OXXIOM App**

Start App

Select
side drawer icon

Select Start

Select Scan

Scan barcode from package

Enter ID, Gender, and DOB …

… and then, select Done

First, waveforms are displayed…

… and then, measurements

10
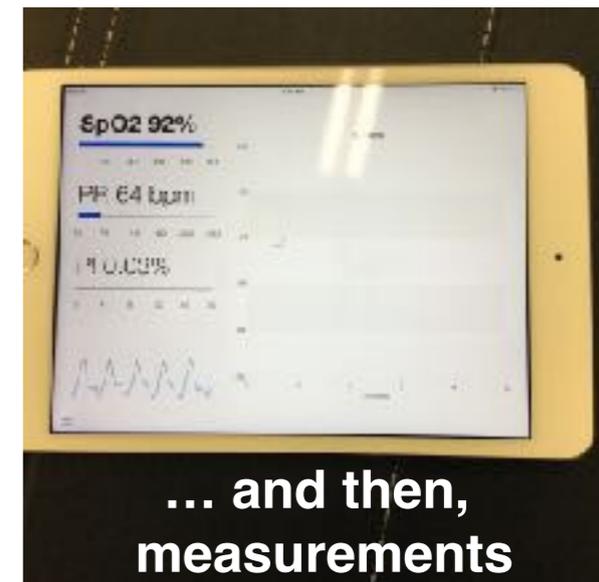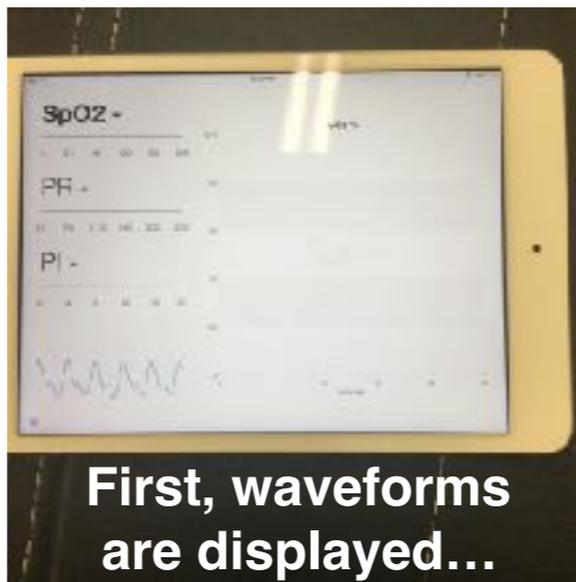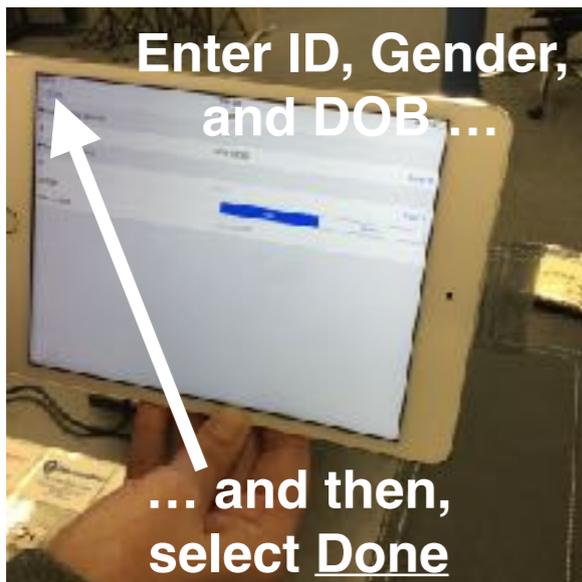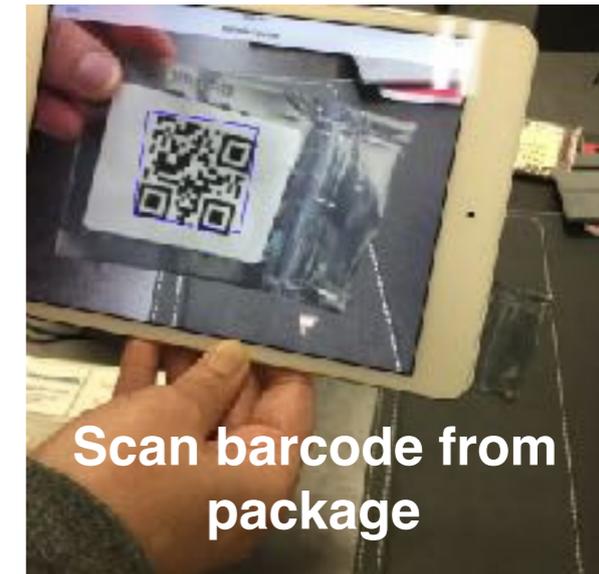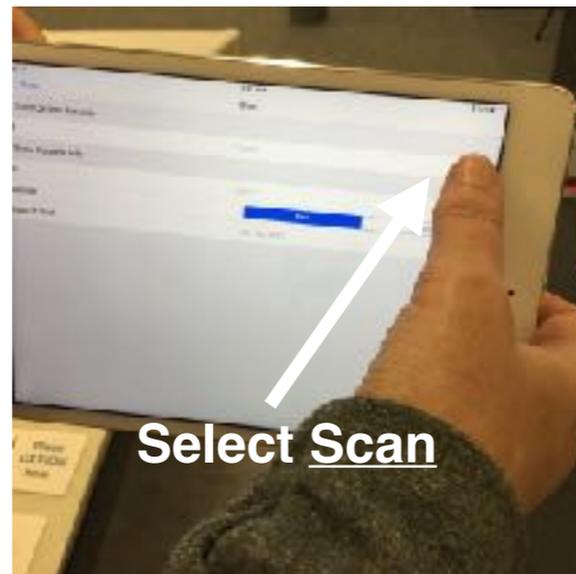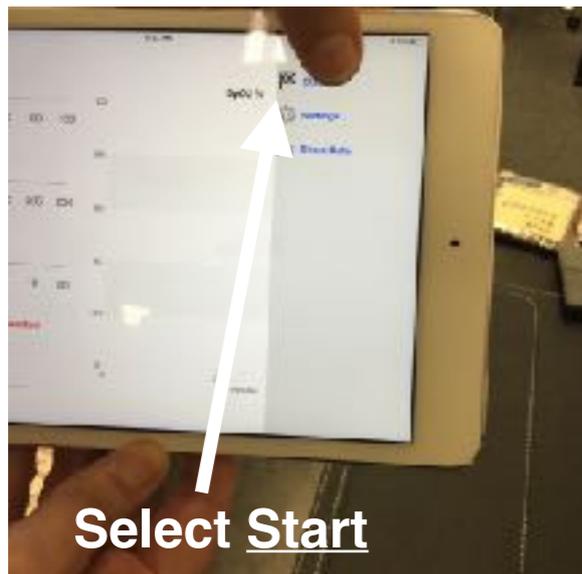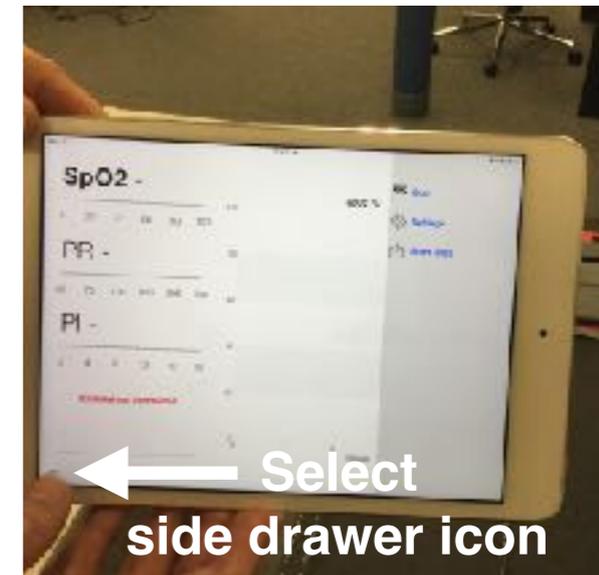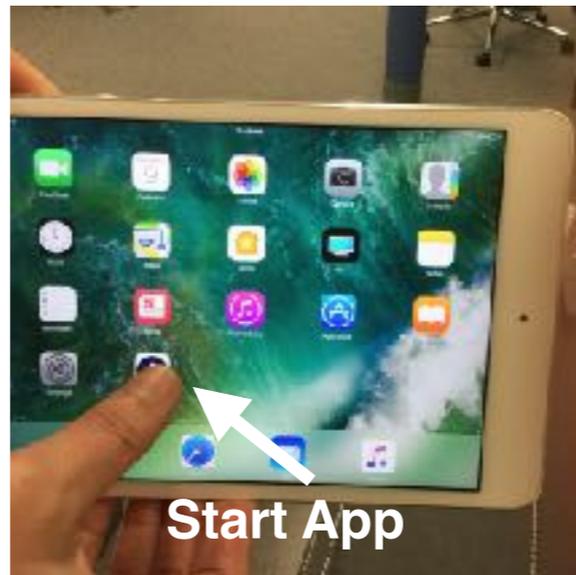
SHARING DATA

**Select
Share Data**
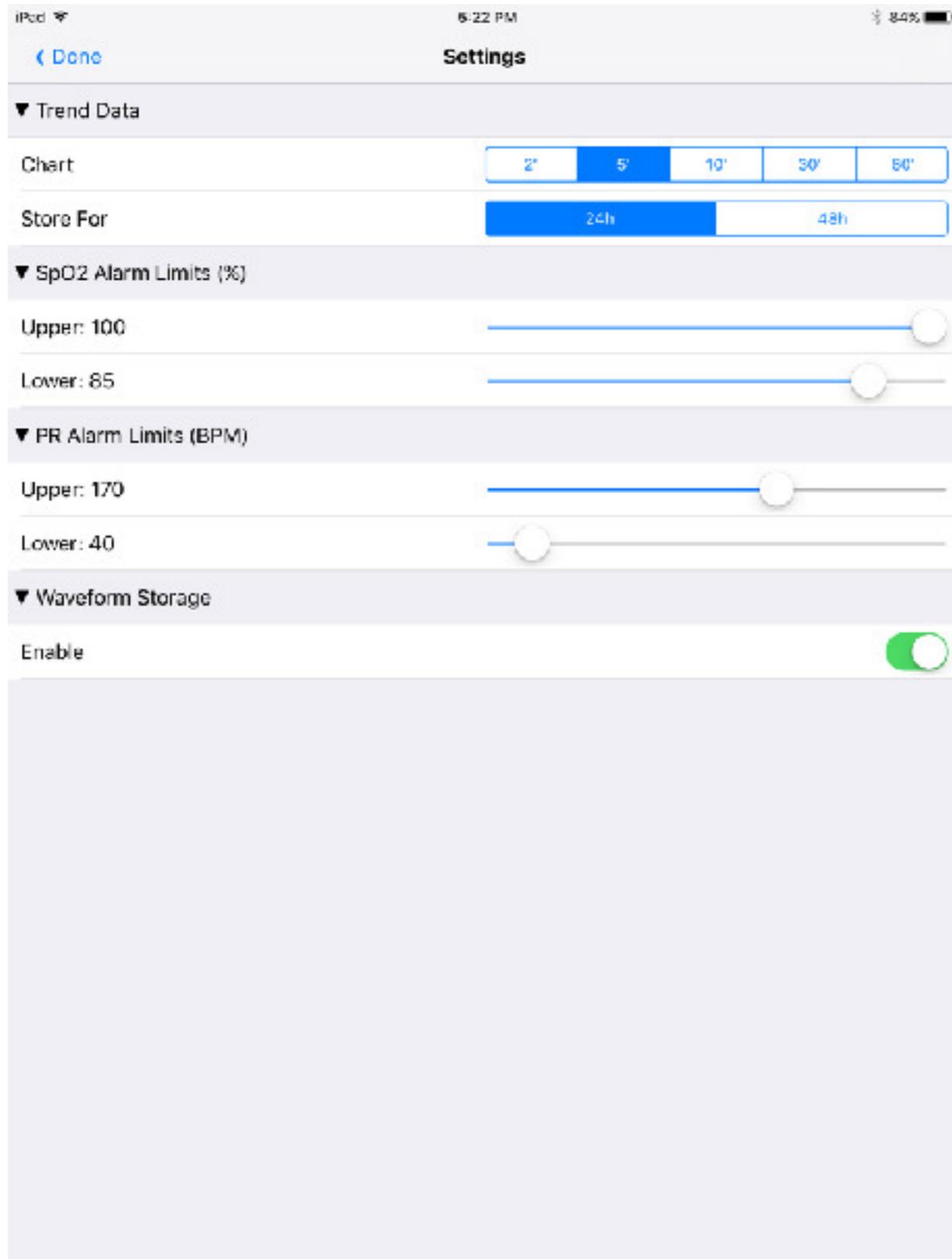
Select side drawer icon

**Choose between
Trends and Waveforms**

Select Share

**Choose sharing method
(Mail, Cloud, Message, AirDrop, etc.)**
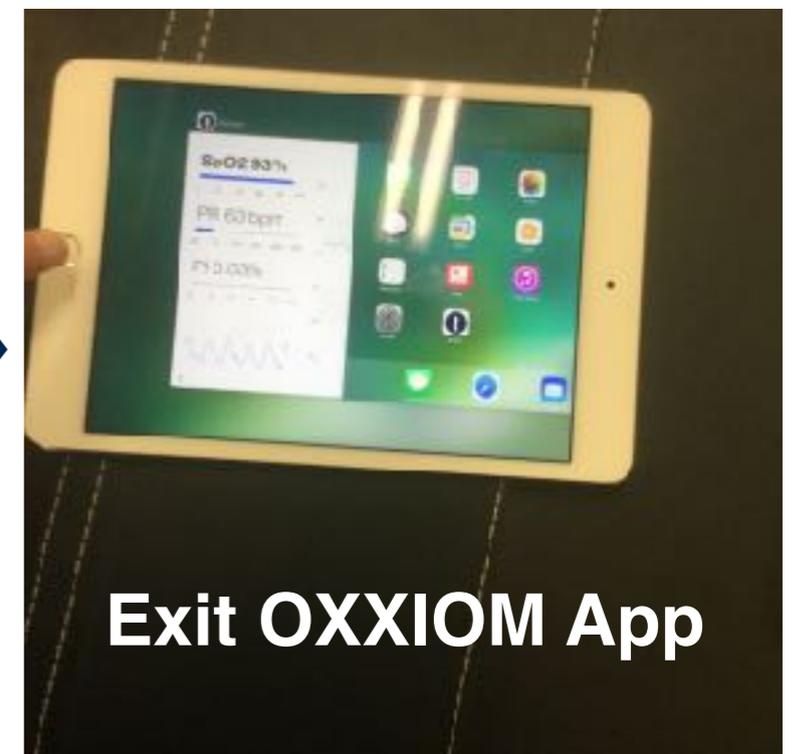
SETTINGS
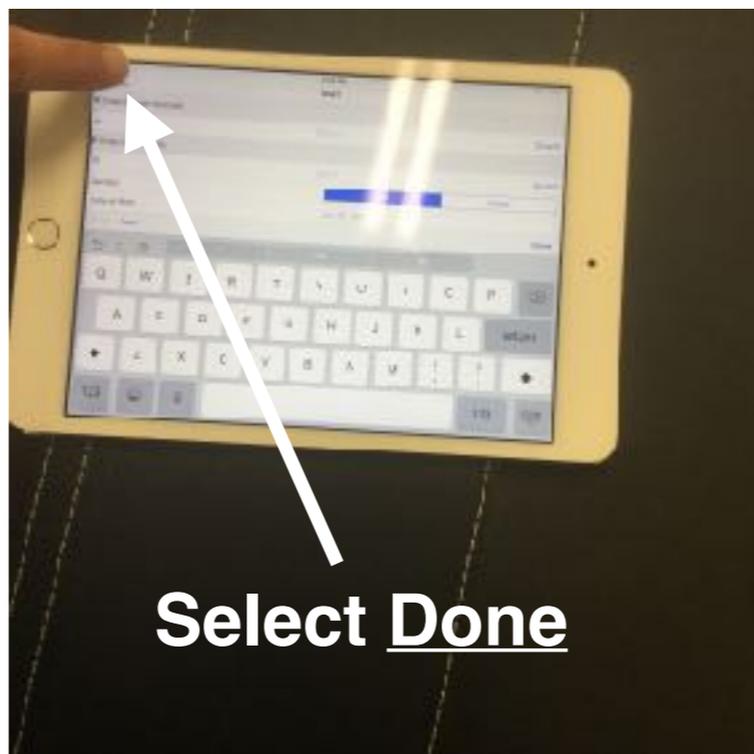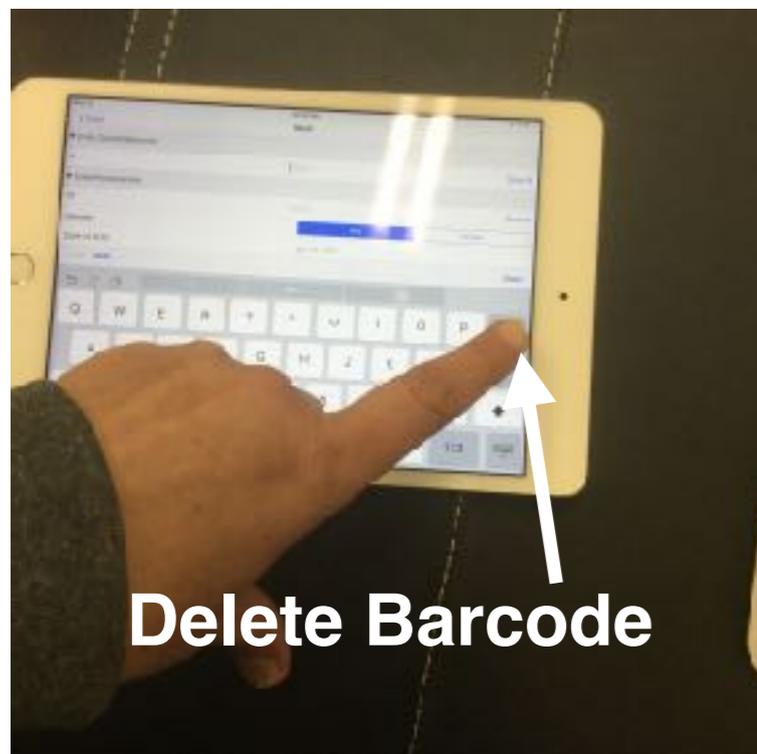

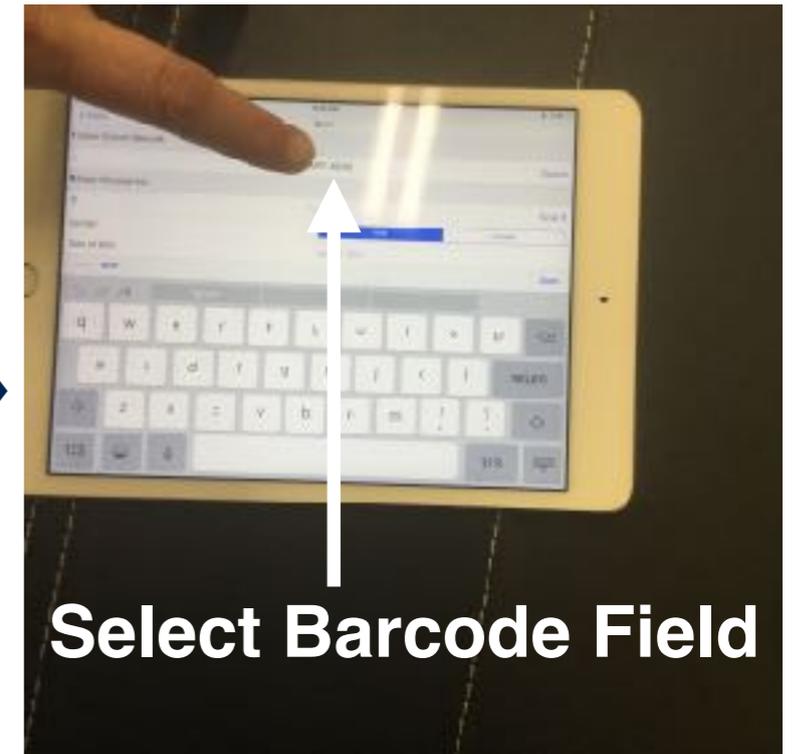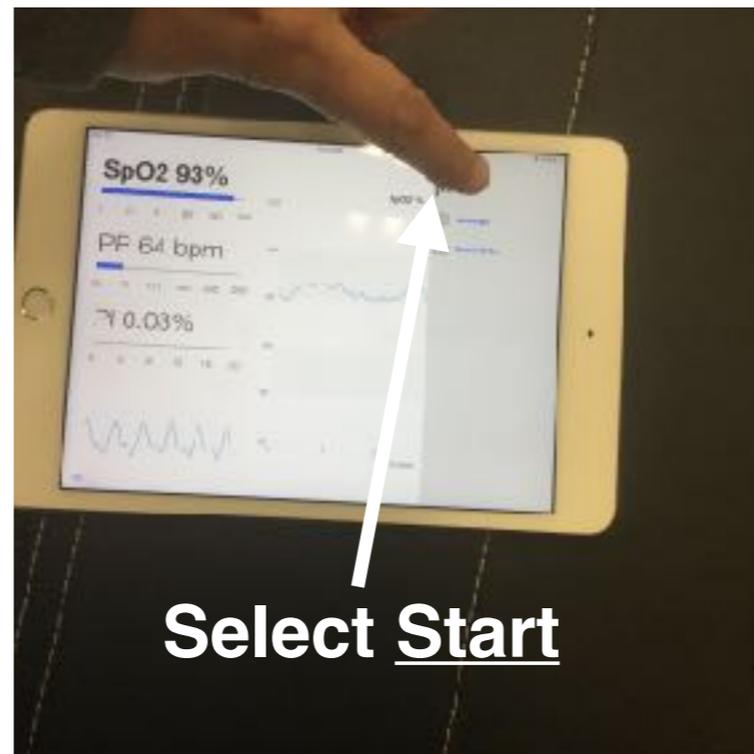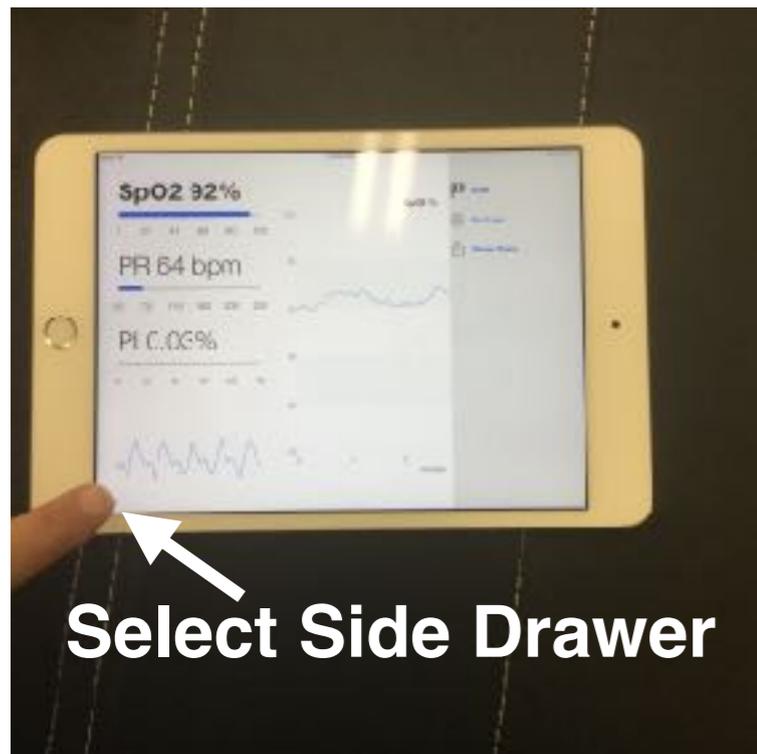Set memory trend data chart (landscape mode)

Set storage time for trend data (Measurements)

Set upper and lower SpO2 alarm limits

Set upper and lower PR alarm limits

Set waveform storage ON or OFF

UN-PAIRING OXXIOM

Select Side Drawer

Select Start

Select Barcode Field

Delete Barcode

Select Done

Exit OXXIOM App

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CONTACT INFORMATION

At True Wearables, we value our customers and take great pride in our products and technology. We welcome your inquiries and comments. Please direct all inquiries and/or comments regarding OXXIOM by email to:

<p align="center">contact@truewearables.com</p>

or by mail to:

<p align="center">True Wearables, Inc
29826 Avenida de Las Banderas, Suite 300
Rancho Santa Margarita CA 92688</p>

with message subject:

<p align="center">Customer Service, OXXIOM</p>

and message *with inquire and/or comments*
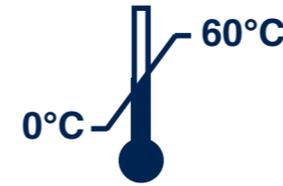
OXXIOM LABEL INFORMATION

OXXIOM should not be used on a sterile field and should not be sterilized

Latex — **Not made with natural rubber latex**

Consult User Manual for instructions on how to use OXXIOM

Storage temperature range: 0°C to 60°C (60°C, 0°C)

IPX1 — **Resistant to liquid ingress**

Do not re-use

Type B Applied Part (Comply with specified requirements for protection against electric shock)

CE 0123 — **Mark of Conformity to European Medical Device Directive 93/42/EEC**

FCC DECLARATION

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna

- Increase the separation between the equipment and receiver

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

- Consult the dealer or an experienced radio/TV technician for help