

Indications for Use:

The X4 System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, transmit, and display physiological signals from adult patients. The X4 System acquires, records, transmits, and displays electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), accelerometer, acoustical, photoplethysmographic signals. The X4 system only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision, and reliability.

Device description:

The Sleep Profiler (Model SP40) records data from the forehead device (a).



Contraindications: None

WARNING:

- DO NOT wear the Sleep Profiler (SP) while it is connected to an AC Power Supply.
- Possible strangulation from cables, or headbands; possible choking hazard if small parts are detached and swallowed.
- Do not use the X4 System as a substitute for clinical electrocardiography. The X4 is not intended to be used as a cardiac monitor or as life supporting equipment.
- Do not use the X4 System with high frequency surgical equipment or in a surgical suite or in proximity to a Magnetic Resonance Imaging System.



Cautions:

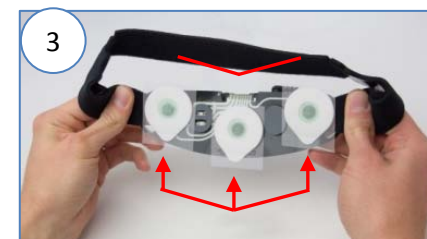
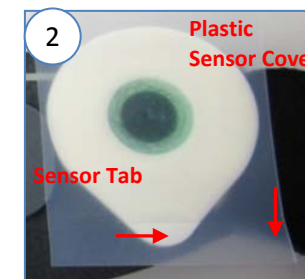
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Do not use the SP if it appears to be damaged in any way or if the LED does not properly illuminate during startup.
- Discontinue use of the SP and contact your provider in case of any significant pain.
- Do not use the SP if your head circumference less than 21 or greater than 25 in., your forehead vertical measurement (from top of eyebrows to hairline) is less than or equal to 2 in. or your horizontal measurement (from hairline to hairline) is less than or equal to 6 in.
- Possible allergic reaction or skin irritation from device components, e.g. silicone and adhesive sensors, and neoprene/Velcro headband. Wearing the SP may result in a mark on your forehead that usually disappears in a few hours; on extremely rare occasions the mark may remain for 2-5 days.
- The proper use of the SP requires patients to be dexterous in both hands, capable of reading and comprehending instructions, and able to see and hear the audio and visual indicators.
- Factors that may cause poor signal quality include the following; headband not adjusted properly (i.e. too loose or too tight), forehead not prepared according to instructions (e.g., makeup, lotion, or hair under the sensors), or loud snoring bed partner/significant ambient noise.
- The SP Device is not recommended for unassisted use by patients with the following conditions; deafness, blindness, severe arthritis which limits use of both hands, dementia, supplemental oxygen use at night, cardiac arrhythmia, atrial fibrillation, or tics or tremors of the head.
- The SP Device is not recommended for use by patients with the following conditions; skin sensitivity and/or open wounds on the body (i.e. head, face, finger, chest, or abdomen), allergic reactions to extended exposure to synthetic fabrics (e.g. polyester, rayon), or upper respiratory infection or congestion.
- Electrical Shock Hazard: Avoid touching the EEG sensor snaps with the USB cable is connected to the X4 System and a power source (i.e. PC workstation, USB hub, or USB wall charger).
- Electrical Shock Hazard: The X4 wall charger is approved for patient use. Do not allow the patient to recharge the X4 System without use of an approved wall charger.
- Limitations of Use with Accessories: Additional equipment connected to the patient must comply with the requirements of IEC 60601-1-1.
- Do not use the SP in any way that could cause an explosion (e.g. near an open flame, near any high heat device, or in the presence of flammable anesthetics or gasses). Do not replace the rechargeable battery with a non-rechargeable battery.
- IPX0: Device has not been tested for protected against solid objects and is not protected against liquids.
- To avoid damage not covered by warranty, keep the SP dry and clean, and out of reach of children and pets.
- SP is not defibrillator proof.

X4 Sleep Profiler Patient Instructions - Side 1

APPLYING THE DEVICE: **Begin 15 Minutes Prior to Sleep**

Forehead Device – Practice Applying the Device:

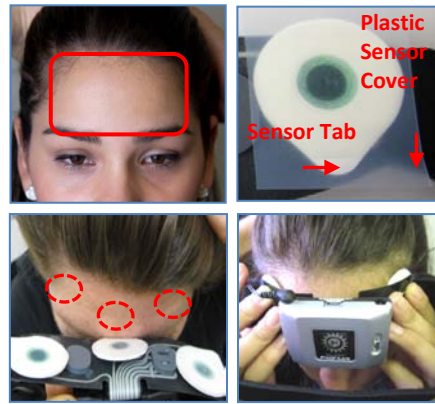
1. If you have long hair, pull your hair back in a way that is comfortable for you to sleep, so that your hair is away from your forehead.
2. Remove the forehead device from the carrying case. **Leave the plastic covers ON the sensors during practice application.**
3. Stand in front of a mirror. Hold the device as shown with the middle sensor low and the outer sensors high. Ensure the plastic tabs on the sensors are pointing down.
4. Center the middle sensor just above your eyebrows, and apply device to your forehead. The middle sensor tab should be aligned above your nose.
5. Pull the black headband over your head. Adjust the headband so it is straight across the side of your head. Make sure the headband is above your ears, and not resting on your ears. The headband and device should feel snug on your head. Carefully remove the device from your head and return it to the carrying case until you are ready to begin your sleep study.



See Page 2 for Recording Your Study

Applying the Device for your Study:

1. Wash your forehead with soap and water. Scrub the entire forehead with an alcohol swab for 15 seconds. Air-dry.
2. Grasp the sensor tab and peel the plastic covers from the sensor. Remove the covers from all 3 sensors.
3. Center the middle sensor just above your eyebrows and press the middle sensor against your forehead. Press the left and right sensors to your skin.
4. Pull the black headband over your head.
5. Press firmly on the outer edges of all 3 sensors to ensure complete contact with your forehead.

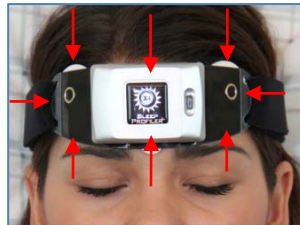


See additional instructions if you've been requested to apply the chest (ECG) or chin (EMG) sensors.



Recording Your Study:

1. Firmly press the ON/OFF button down for 1-second and release.
2. Lie on your back and wait for voice messages to notify you if any sensors need to be adjusted.
3. If the tests fail then press firmly against the outer edges of the sensors (area indicated by the blue circles). A voice message will indicate when the second sensor test begins.
4. When the sensor tests pass, you will be instructed to go to sleep.



In the Morning:

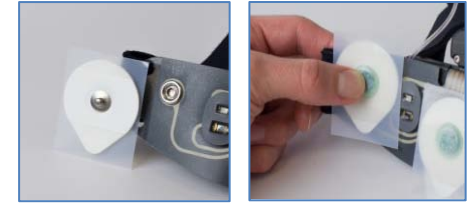
1. Press the ON/OFF button for 1-second and release to turn off the device.
2. Lift the headband forward, over your head.
3. Grasp the sensor tabs and slowly lift away the forehead device from the forehead, one sensor at a time. Unsnap and discard the 3 used sensors from the device.
4. Place the device and these instructions in the carrying case.

See "Preparing for Night Two" or follow the "Returning the Device" section.

PREPARING FOR NIGHT TWO – OPTIONAL

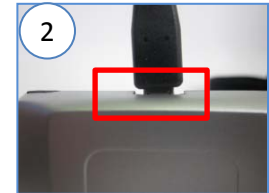
Replace used sensors:

1. Ensure used sensors have been removed from the device and discarded. Snap 3 new sensors into snaps.



Recharge the Device:

1. Plug the USB cable into the forehead device. **Note: cable will not sit flush with enclosure edge, do not force.** Plug the wall charger into a wall outlet.
2. Voice message will confirm "The device is charging." The device will automatically turn off when charging is completed. Once charging is complete (~4 hours), disconnect the forehead device from the outlet and charging cable.
3. You are now ready to Apply the Device for your second night.

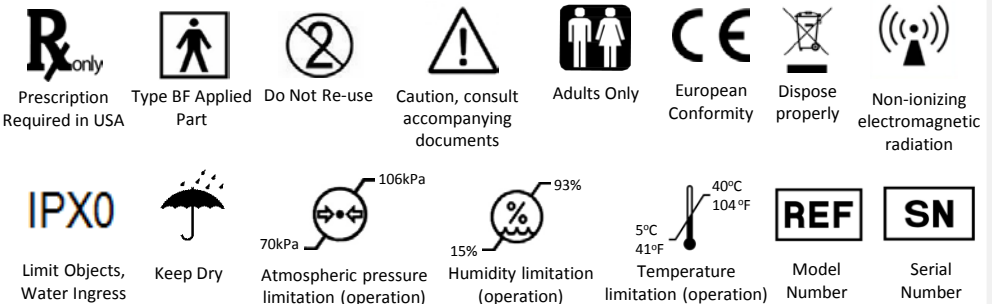


Warning: Do NOT wear device when connected to a wall charger!

RETURNING THE DEVICE

1. Insert components into Carrying Case and ensure all paperwork and cables are tucked in prior to closing the case.
 - a) Wall Charger
 - b) Forehead Device

Explanation of Symbols:



Manufactured by:
Advanced Brain Monitoring, Inc.
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EC REP European Representative:
MPS Medical Produce Service GmbH
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