

3 Channel ECG
Recorder
Model: 3000sl-b

Version: DRAFT

ENGLISH



Caution: FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE TO OR ON THE ORDER OF A PHYSICIAN.



Carefully read all instructions prior to use. Observe all warnings and precautions noted in these directions. Failure to do so may result in patient complications.



Read this manual before use. Keep it for future reference.

Thank you for purchasing the myPatch@sl-b ECG Recorder. Model: 3000-sl-b

The myPatch@sl-b ECG Recorder records ECG through the myPatch@sl ECG electrode (accessory to myPatch@sl-b ECG Recorder).

The myPatch@sl-b ECG Recorder acquires ECG signals and stores them internally and can transmit the signal via Wi-Fi and/or 4G cellular networks. The device interfaces to a myPatch@sl ECG electrode. The myPatch@sl-b ECG Recorder is rechargeable and reusable. The myPatch@sl-b ECG Recorder contains internal non-volatile storage that stores the ECG data and transmits the ECG data via Wi-Fi and/or 4G cellular networks.

The myPatch@sl-b ECG Recorder contains embedded software appropriate for recording ECG, storing ECG transmitting ECG recorded data and for charging the internal rechargeable battery. The recorded ECG data is transmitted to a secure server where the ECG data is automatically analyzed upon receipt and a report is generated.

Due to the continual wearing of the Ambulatory ECGr monitor, this is a medical device that is used both in professional healthcare facilities and also outside those facilities. This description meets the definition of a home use device.

During intended use, the myPatch@sl-b ECG Recorder is connected to the myPatch@sl ECG electrode and placed on the patient.

The myPatch@sl-b Ambulatory ECG Recorder has a 2- year warranty from date of purchase.



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Disclaimer

dms-service is responsible for the reliability, and performance of this equipment only if:

- The place where the device is installed or used meets the requirements for electrical installations IEC and other applicable regulations
- All repairs, revisions, or modifications, both in and out of the warranty period, are made by technical staff of dms-service llc.
- The equipment is used by qualified staff in accordance with the recommendations stated in this Instruction Manual

Information in this manual may change without notice. The manufacturer assumes no responsibilities for errors that may appear in this manual.

Trademark

myPatch® is a registered trademark of dms-service llc

Federal Communications Commission statement

Note: 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.

Changes or modifications made to the Affirm™ Anklet device not expressly approved by TraceX could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Innovation, Science and Economic Development statement

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following conditions:

- This device may not cause interference.
- This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil contient un ou des émetteurs/récepteurs exempts de licence conformes aux RSS exempts de licence d'Innovation, Sciences et Développement économique Canada. Le fonctionnement est soumis aux conditions suivantes :

- Cet appareil ne doit pas provoquer d'interférences.
- Cet appareil doit accepter toutes les interférences, y compris les interférences susceptibles de provoquer un fonctionnement indésirable de l'appareil.

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1. Package Contents

The package contains:

myPatch@sl-b ECG Recorder

Note: The operator manual for the myPatch@sl-b Ambulatory ECG recorder is available digitally and can be accessed at www.dms-service.com

Accessories Include:

myPatch@sl Electrodes

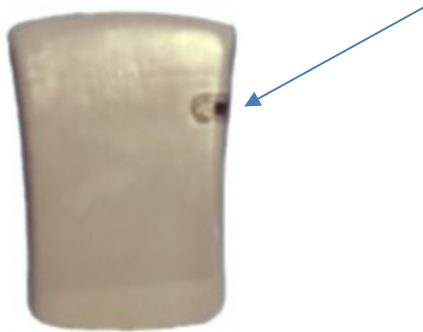
Wireless Battery Charger

Note: All accessories are packaged and sold separately.

2. Description

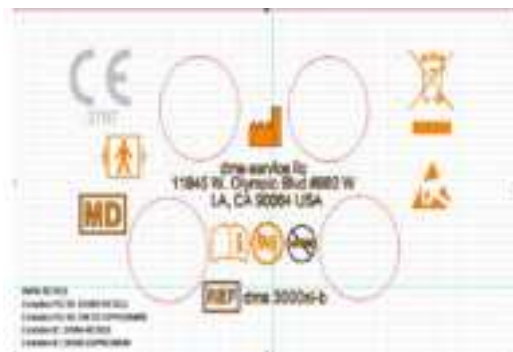
2.1. Top Side of myPatch®sl-b ECG Recorder

The light on the top/side of the recorder flashes different colors that indicate the state the recorder is in. Please see Page 7, myPatch®sl-b Light Sequence State Diagram, for a the different states with the associated color flashes and required button pushes



2.2. Bottom Side of myPatch®sl-b ECG Recorder

Snaps connect to the myPatch®sl electrode



Markings for myPatch®sl-b

2.3. Side of myPatch®sl-b ECG Recorder



UDI Description: The definition of the numbers after the () are as follows:

- (01) Company information and device information,
- (11) date of manufacture
- (21) serial number.

2.5. Top Side of myPatch®sl Electrode (bottom of myPatch®sl-b ECG Recorder)

Snap to connect myPatch®s-b Ambulatory ECG recorder to myPatch®sl 3 channel electrode.

3. Important Safety Information

Please read this section carefully before using the myPatch®sl-b Ambulatory ECG Recorder.

The 3 channel myPatch®sl-b ECG Recorder has been designed and developed for dms-service llc.

The myPatch®sl-b ECG Recorder is designed and manufactured in accordance with the Quality Management System of dms- service llc which is in consistency with the quality standard EN 13485 and Regulation (EU) 2017/745 (EU MDR) . The myPatch®sl-b Ambulatory ECG Recorder also complies with the EN 60601-1 Electrical Safety and Electromagnetic Compatibility EN 60601-1-2 standards, as specified in the Electromagnetic Compatibility Clause.

The myPatch®s-bl complies with the restriction of use of certain hazardous substances in electrical and electronic equipment 2002/95/EC (commonly referred to as the Restriction of Hazardous Substances Directive or RoHS) and the Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC.

The myPatch®sl-b Ambulatory ECG Recorder uses a rechargeable lithium ion battery and can record and transmit ECG up to 4 days (3 channels, 256 sample rate) using 4G cellular technology and 10 days using WiFi technology before needing to be recharged. The recorder is connected to a myPatch®sl ECG electrode which is worn on the torso of a patient's body. The length of recording time is based on the sample rate, channel selection and wireless transfer modality. The patient's ECG is recorded to the myPatch®sl-b ECG Recorder and then transferred via wireless technology to a predesignated server where the ECG data packet is decrypted and automatically analyzed upon receipt. The data can be stored and further analyzed by approved and validated Holter systems.

Due to the continual wearing of the myPatch®sl-b monitor, this is a medical device that is used both in professional healthcare facilities and outside those facilities. This description meets the definition of a home use device.

The intended use, expected service life and conditions for transport and storage were taken into consideration for selection and treatment of materials used in the construction of the myPatch®sl-b ECG Recorder.

The myPatch®sl-b Ambulatory ECG Recorder has been designed for maximum safety. All operating instructions should be read before using the myPatch®sl-b Ambulatory ECG Recorder. Failure to do so may result in injuries to the user and damage to the device and/or accessories.

The myPatch®sl-b ECG Recorder is intended to be used by trained medical clinical professionals to collect ECG data from patients in a clinical, point-of-care or outpatient setting. The medical clinical professionals must instruct the patient for correct use and it is important the patient can understand the instructions given by medical clinical professionals.

The myPatch®sl-b ECG Recorder can be worn in limited wet environments up to 1 hour. Do not submerge the device in liquid.

3.1. Intended use

The myPatch®sl-b ECG Recorder is a small digital Ambulatory ECG recorder intended for use by professionals to acquire ECG data from a patient in a clinical, point of care or at a patient setting. This device is intended to record up to 3 channels of ECG data continuously. The recorded ECG data can be sent wirelessly at preset intervals to a server which will automatically review the recorded data and generate a simple report of the recorded data. The entire ECG study session may be saved and reanalyzed in a validated and approved Holter analysis system. The device can be recharged in a home or clinical environment.

Due to the continual wearing of the monitor, this is a medical device that is used both in professional healthcare facilities and outside those facilities. This description meets the definition of a home use device.

Intended Target Groups

The myPatch®sl is intended for use by adults and all pediatric sub-groups.

3.2. Clinical Benefit

The myPatch®sl-b ECG Recorder has ability to continuously record ECG signals, wirelessly send ECG data to a backend server and provide an immediate analysis without delays of the patient having to come to the physician's office or send it via the post increases significantly the diagnostic yield (the likelihood that a test or procedure will provide the information needed to establish a diagnosis) compared to the traditional 24-hour Holter monitor.

Once the study period is complete, all of the ECG data can be compiled and analyzed using software packages, for the purposes of assisting physicians and other clinicians, in the diagnosis of cardiac rhythm abnormalities or ruling out such findings.

The advancements with the peel & stick patch wearable monitoring technology have improved patient compliance, making extended monitoring periods more comfortable and tolerable for patient to such an extent that patients often report to their physicians that they forgot they were wearing the device.

3.3. Indications for Use

myPatch@sl-b is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, presyncope, syncope, fatigue, chest pain and/or anxiety. The data recorded by the myPatch@sl-b will be reviewed by a clinician to determine if the wearer has a heart rhythm problem.

Recording of ECG for the later detection and diagnosis of the following cardiac arrhythmias:

- supraventricular tachycardias;
- ventricular ectopic rhythms; sinus pause;
- atrial ectopic rhythms.

The myPatch@sl-b is indicated for use for recording ECG signals, sending the ECG data wirelessly at pre-determined intervals and analyzing the ECG data upon receipt at the server.

The myPatch@sl is intended for use by Adults and all Pediatric subgroups.

3.4. Limitations in Use – Contraindication

The acceptability of a recording with the myPatch@sl-b ECG Recorder is the responsibility of the medical professionals. The medical professionals should consider the symptoms presented by the patient before starting any recording with the myPatch@sl-b ECG Recorder.

Do not place the myPatch@sl-b ECG Recorder and Electrode on skin that is torn or has a rash.

3.5. Warnings and Precautions

In case of doubts, unexpected events, or complaints, contact your distributor OR you can contact dms-service llc. Contact information can be found on page 2 of this instruction manual.

Medical professionals should inform the patient about precautions to be found in this section and to be taken when wearing the myPatch@sl-b ECG Recorder.

Do not charge the device while it is connected to the patient!

The myPatch@sl-b ECG Recorder is not provided with physiological-type alarms, though the data is analyzed upon receipt at the server. The ordering physician will receive a report upon the automatic analysis of the data. It is advisable for the medical professionals to instruct the patient to react to any health symptoms that may arise, as he would do if he was not wearing the myPatch@sl-b ECG Recorder.

The myPatch@sl-b ECG Recorder does not maintain nor does it help to maintain the life of the patient. Patients must be warned that they must not open the myPatch@sl-b ECG Recorder or attempt to adjust it.

Do not use the myPatch@sl-b ECG Recorder in an X-ray, computed tomography (CT), or magnetic resonance imaging (MRI) environment, as this may affect the scanning results, can lead to malfunction of the myPatch@sl-b ECG Recorder, or may result in injuries to the patient (MRI can generate signals in the frequency spectrum and therefore can interfere with the interpretation of the ECG signal).

It is recommended that the user go through a security pat down to avoid the backscatter X-Ray and millimeter wave technologies when going through screening devices at airports, etc.

It is advised that the user placed the myPatch@sl-b recorder in Transmit Off Mode once they board an airplane and place the device in Transmit On Mode once the disembarked the airplane. ECG data will still be recorded during this time period and the recorded ECG will start to be sent once the device is in Transmit On Mode.

Use of a defibrillator while wearing the myPatch@sl-b recorder may cause a temporary loss of recorded ECG signal

Minor discomfort, skin irritation, reddening, itching, or rash may occur when wearing the myPatch@sl ECG Recorder. The adhesive used

on the electrodes may potentially cause an allergic reaction such as skin irritation, etc. This risk is unavoidable when using electrodes in general. The patient should stop use and contact their physician should irritation or other allergies occur. The medical professional should ask the patient if they have had any reactions to electrodes. If the patient has had a previous reaction to electrodes, do not place a myPatch@sl electrode on the patient. If the patient has an itchy or burning sensation when the electrode is placed on their torso, the medical professional should remove the electrode from the patient, following the suggested electrode removal procedures.

The myPatch@sl-b ECG Recorder cannot be used for direct cardiac application.

Do not modify the myPatch@sl-b ECG Recorder. Modification of the myPatch@sl-b ECG Recorder can lead to electrocution, burns, and malfunction.

Use only the myPatch@sl-b ECG Recorder together with the myPatch@sl ECG electrodes supplied by dms-service llc. Use of other equipment may result in increased emissions or decreased immunity of the myPatch@sl-b ECG Recorder and can cause damage to the device or decrease the quality of the acquired signals. Use of unapproved electrodes might lead to skin irritations, allergy, electrical shock, and malfunction of the myPatch@sl-b ECG Recorder.

WARNING: It may be unsafe to use accessories (myPatch@sl ECG electrode) other than those that are provided by dms-service llc.

Keep the myPatch@sl-b ECG Recorder and the myPatch@sl ECG electrode out of reach of children and pets.

Danger of asphyxiation if the myPatch@sl-b ECG Recorder and/or accessories are swallowed. Do not submerge the myPatch@-b Ambulatory ECG Recorder in any liquid.

Avoid contact of liquids with the internal parts of the myPatch@sl-b ECG Recorder. This may cause electric discharge.

Store and use the myPatch@sl-b ECG Recorder within the temperature ranges, pressure, and humidity specified in Section 7.4. Avoid exposing any part of the myPatch@sl-b ECG Recorder to heat sources, heat radiators and fireplaces. Temperature changes cause condensation and moisture that can lead to malfunction of the myPatch@sl-b ECG Recorder. Before using the myPatch@sl-b ECG Recorder, allow the myPatch@sl-b ECG Recorder to acclimate to ambient temperature. For reference, if the temperature difference between the myPatch@sl-b ECG Recorder and the environment is above 10° C, a 20-minute wait time in an intermediate temperature is recommended. Do not connect myPatch@sl-b ECG Recorder and myPatch@sl ECG electrode until after the skin of the patient is prepped, as the myPatch@sl ECG Recorder powers on and starts the recording 30 seconds after the power button is pressed.

Do not use an electrode that has already been used as this may lead to a risk of infection. The myPatch@sl ECG electrode is a single use electrode.

Do not place the myPatch@sl-b ECG Recorder connected to myPatch@sl ECG electrode on damaged, or in any other way irritated, skin.

Do not use an electrode that does not adhere to the skin. Data may not be recorded or there may be a high incident of artifact. An electrode must make good contact with a clean skin surface to record quality ECG data.

Proper contact of the skin with the myPatch@sl ECG electrode, must be achieved to increase the quality of the acquired signals. Follow the placement procedure as described in Section 4.1. Avoid contact with the eyes or mucus membranes of gels, alcohol, acetone, or any substance used in the placement or removal of the myPatch@sl ECG electrode, as this can damage the eyes or mucus membranes of the patient.

Connect the myPatch@sl-b ECG Recorder to the myPatch@sl ECG electrode before placement on the patient, as this will ease the use of the myPatch@sl-b ECG Recorder.

Do not use an obviously broken myPatch@sl-b ECG Recorder, as this can cause electric discharge or decrease the quality of the acquired signals. See section 5.2 Preventive Maintenance.

WARNING: Do not connect any equipment with the myPatch@sl ECG Recorder that is not described in this manual!

Minimize the number of devices connected to a patient, as there is a risk of accumulation of leakage current. Do not reuse single-use accessories as there is a risk of infection to the patient

Carefully follow the instruction for the removal of the myPatch@sl ECG electrode, see Section 4.2, as careless removal of the myPatch@sl ECG electrode may cause damage to the skin.

Carefully follow the cleaning instructions of the myPatch@sl-b ECG Recorder, see Section 5.1, otherwise there is a risk of infection to the patient.

Pediatric Population Recommendations:

Electrode: The myPatch@sl electrode is available in 4 sizes, mpE3sl, mpE3sl-p, mpE3sl-T and mpE3sl-n. It is recommended that the model number mpE3sl-n is used for neonates and the mpE3sl-p on children 1-5 years of age. This recommendation is based on the size

of the patient and the medical provider should make the final decision on which size is most appropriate for the patient. Please instruct the patient to refrain from pulling, tugging or peeling the electrode.

Notice: In the event that any serious incident has occurred in relation to the device, it should be reported immediately to *dms-service llc* and the competent authority of the Member State in which the user and/or patient is established.

4. Operating Instructions

The following instruction describes the use of the myPatch®sl-b ECG Recorder and must be followed point by point.

Should you need any assistance in setting up the myPatch®sl-b Recorder, please contact your sales representative or dms-service llc at the contact information on Page 2 of this manual.

4.1. Start Recording

Remove the myPatch®sl-b Recorder from the packaging. Check battery status before use and recharge if necessary. See Section 4.3. Take the electrode out of the pouch. Place foil pouch in trash container.

Remove or unbutton patient's shirt so the chest is exposed.
If the patient has hair where the electrode will be placed, shave the skin to remove the hair. Clean the electrode site with soap and water. Pat the entire area dry. Do not apply the electrode on wet or moist skin!

Snap the myPatch®sl-b ECG Recorder onto the 4 snaps of the myPatch®sl ECG electrode. The recorder can snap on only one way. Press the recorder and electrode together firmly making sure all the snaps are connected

Press the power button on the myPatch®sl ECG Recorder for two seconds. The light on the myPatch®sl-b ECG Recorder will flash green to indicate that the myPatch®sl-b ECG Recorder has turned on. If not, consult Section _ for trouble shooting

To check in with the server, press the button 1 time in 2 seconds. A blue light will flash. If you need to connect the device using WiFi mode, press the power button 3 times in 2 seconds. The recorder will flash blue and white during broadcast and setup.

Hold the myPatch®sl-b ECG Recorder with one hand. Get a hold on the back liner of the myPatch®sl ECG electrode with the other hand and peel it away from the myPatch®sl ECG electrode, taking care not to touch the adhesive area.

Advise the patient to roll their shoulders back. Hold the myPatch®sl ECG electrode with the recorder in a straight up and down position. The gel pad at the bottom of the electrode should be placed on the sternum between V1 and V2. Take care **not to touch the adhesive area**. Gently roll the electrode up the sternum, patting it down firmly on the skin. Once the electrode is firmly placed on the torso, the patient may relax their shoulders.

After placement, **press around the edges** of the myPatch®sl ECG electrode to improve the adherence. Advise the patient to not put lotion or oil within 1 inch of the edge of the electrode.

Electrode Placement Description:

RA, a modified placement of the standard Right Arm placement
LA, a modified placement of the standard Left Arm placement
V2, a modified placement of the standard V2 placement
V1, a modified placement of the standard V1 placement

Channel Descriptions

Channel 1: LA-RA=LEAD I modified

Channel 2: LA-V1=V1 modified

Channel 3 RA- V2=V2 modified

The myPatch@sl electrode placement versus the standard placement for a 12 lead ECG will result in the leads being similar in nature and appearance but lower in amplitude.

The recording will start after the device has completed its check-in with the server. To verify the state of the recorder, press and hold the power button down for 1 second. A green light will flash twice if the device is recording. A red light will flash twice if the device has an error and a yellow light will flash twice if the recorder detects an electrode is popped off the body (lead off).

To mark and send an event during the recording tap the logo of the device twice to mark an event. A green light will flash. The recorder will automatically send the event data to the server. A blue light will flash on the device while the event data is being sent to the server.

If the patient needs to place the device in No Transmit Mode, press the power button once and the status light will blink twice. After the second blink, press the power button again and the device will enter No Transmit mode. The lights will flash purple, orange, blue and then white. The WiFi, cellular and blue tooth radios will shut down. A purple light will flash on the device. While in No Transmit Mode the purple light will flash 3 times every 30 seconds. The ECG will still be recorded during this time. To reactivate Transmit mode, press the power button once and the status light will blink twice. After the second blink, press the power button again and the device transmit mode will be activated. The device will flash white, blue, orange and purple. The WiFi, cellular and Bluetooth radios will turn back on. A green light will flash.

4.2. End of Recording

After the recording period or when the recording is terminated the device will flash red and yellow twice and then turn off. The electrode and recorder need to be removed from the patient. For patient comfort, it is recommended to place a warm cloth on top of the electrode. This will help loosen the electrode adhesive from the skin. Move skin down and peel electrode up for gentleness of removal. Grab the bottom end of the myPatch@sl ECG electrode and gently pull it upwards and outwards in the direction away from the myPatch@sl-b ECG Recorder. This will reduce the adhesive property of the myPatch@sl ECG electrode and hereby reduce the stress of the skin, as the myPatch@sl ECG electrode is removed from the skin.

Adhesive residue can be removed using soapy water.

If the recorder was removed from the patient prior to the study ending, press and hold the power button for 3 seconds. A red light will flash and the device will stop recording and sending ECG data and turn off.

Hold the myPatch@sl-b ECG Recorder with one hand and unsnap the device from the electrode.

The myPatch@sl ECG electrode is for single-use and is disposable and should be handled as normal waste and discarded in accordance to hospital or physician guidelines.

4.3. Charge

To charge the myPatch@sl-b ECG Recorder place the recorder top side down on the Wireless Charger. Our recommendation is the Spigen PF2004 ArcField Wireless Charger. You will be able to see the light from the top of the recorder on the side of the device. A yellow light will flash while the unit is charging and will go solid once the device is fully charged. In addition, check the properties of the wireless charger you are using. Many have a light feature on the charging device that will go solid once the battery is charged. The myPatch@sl-b ECG Recorder will take approximately 2 hours to charge a completely drained battery. Make sure the device is charged completely prior to use.

NOTE: Once myPatch@sl-b is fully charged, the charging will stop and it will go to trickle mode. This means myPatch@sl is no longer being charged. If you have left the myPatch@sl charging over 24 hours, please remove myPatch@sl-b from charge and place the myPatch@sl-b back onto the charging source. The myPatch@sl-b may need to charge for another 10 minutes or so. Make sure you see a solid yellow light prior to hooking up the patient.

5. Cleaning, Maintenance, and Disposal

The myPatch@sl-b ECG Recorder requires, like any electronic equipment, maintenance to:

- Ensure the safety of the patient, the medical professional, and its environment
- Ensure the reliability and accuracy of the functions for which the myPatch@sl-b Recorder was developed

5.1. Cleaning

The myPatch@sl-b ECG Recorder shall be cleaned properly.

For general cleaning, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry. Use a clean, lint-free cloth. Don't use solvents. Don't use abrasive cleaners or materials.

- DO NOT use abrasive or highly alkaline cleaners
- Never scrape with squeegees, razor blades or other sharp instruments.
- Benzene, gasoline, acetone, or carbon tetrachloride should never be used.
- DO NOT clean products in hot sun or at elevated temperatures.

The recorder may be damaged by some common household solvents including Lysol, Pinesol and Isopropanol alcohol. In fact, you should avoid any of the stronger chemical-based cleaning solutions to be safe.

Compatible Cleaners: The following cleaning agents have been found to be compatible. The manufacturer's recommendations and instructions should be followed. Joy, Freon T.F., Palmolive liquid, Top Job, VM&P grade Naphtha and Windex Ammonia Free

Wash with a mild soap or detergent (e.g., Joy dishwashing liquid) and lukewarm water using a clean sponge or a soft cloth. Rinse well with clean water. Dry thoroughly with a chamois or moist cellulose sponge to prevent water spots. Do not scrub or use brushes on these products: their coating is UV-resistant, not mar-resistant.

To disinfect the recorder, we even recommend the unit be sprayed with a 50% Isopropyl Alcohol/50% water mix. Immediately rinse with clear, lukewarm water.

Do not leave cleaners sitting on polycarbonate for periods of time; wash off immediately.

5.2. Preventive Maintenance

Preventive maintenance consists of all actions needed to keep the equipment in good working order.

Check periodically that the myPatch@sl-b ECG Recorder and its accessories are in perfect condition, not broken, with no external damage, and that the performance is okay.

The myPatch@s-bl recorder should be fully charged and discharged at least every two months to help maintain battery health.

If you detect any problems that you cannot solve, please get in contact with your distributor or dms-service at the contact information on page 2 of this manual.

During transportation, storage, and between use, it is recommended to store the myPatch@sl-b ECG in the provided packaging to keep all items protected from shock and vibration and to keep the device free of debris.

The manufacturer is not responsible for malfunction or damage to the myPatch@sl-b ECG Recorder resulting from poor maintenance performed by personnel not employed by the manufacturer or certified in writing by the manufacturer.

5.3. Corrective Maintenance

Corrective maintenance is the process of correcting errors and keeping the myPatch@sl-bl ECG Recorder in good condition for use after an episode of failure due to malfunction or misuse.

If you detect a fault in the myPatch@sl-b ECG Recorder that prevents normal operation, please contact your distributor

(if applicable), and specify the type of problem OR contact dms-service llc. See page 2 of this Instruction Manual for dms- service llc contact details.

5.4. Service

The myPatch@sl-b ECG Recorder has no user-serviceable parts. The myPatch@sl-b ECG Recorder requires no calibration. The myPatch@s-bl is a sealed device and not serviceable.

5.5. Disposal of Electrical and Electronic Devices



Never dispose of the myPatch@sl-b ECG Recorder or the myPatch@sl ECG electrode in the household trash. It must be disposed of properly and may need to be recycled in accordance with the statutory requirements in your country. Please contact your local authorities to determine the proper method of disposal of potentially bio- hazardous parts and accessories. Information on proper disposal is available from your local distributor.

5.6. IP Classification

Ingress Protection (IP) is an international classification system indicating the degree of protection against particulate matter and water. This classification system uses the letters “IP” followed by 2 digits.

The first digit is for protection against particulate matter. The second digit is for protections against water.

TBD

6. Troubleshooting

- 6.1. The myPatch@sl-b ECG Recorder Does not Start
 - 6.1.1. Make sure that the myPatch@sl-b ECG Recorder is not placed in direct sunlight, as this make reading the light diodes difficult
 - 6.1.2. Make sure that the myPatch@sl-b ECG Recorder is correctly connected to the myPatch@sl ECG Electrode, see Section4.1
 - 6.1.3. Make sure that the myPatch@sl-b ECG Recorder is fully charged and ready, see Section 4.3
- 6.2. The Yellow LED Charge Light is not Turned on at the myPatch@sl-b ECG Recorder when Connected to the charger.
 - 6.2.1. Make sure that the myPatch@sl-b ECG Recorder is not placed in direct sunlight, as this make reading the light LEDs difficult
 - 6.2.2. Make sure that the top side of the myPatch@sl-b ECG Recorder is placed on the top of the charger. The snaps should face up.
- 6.3. The LED light on the myPatch@sl-b ECG Recorder Lights up Red
 - 6.3.1. If the LED onf the myPatch@sl-b ECG Recorder lights red, myPatch@sl -b ECG Recorder has a malfunction that prevents normal operation. Please contact your distributor and specify the type of problem. See page 2 of this Instruction Manual for contact details

7. Specifications

7.1. Type and Model

Type:	myPatch@3000sl-b
Model:	Internally Powered, Type BF applied parts, no functional earth terminal
Device classification (EN60601-1): Class:	Internally Powered, Type BF applied parts, no functional earth terminal
Data acquisition:Placement:	1, 2 or 3 channels ECG Upper Sternum
Resolution:	12 bit
CMRR (common mode rejection ratio):	
Connections:	4 Snaps myPatch@sl Connector for connection to myPatch@sl electrode
Storage medium:	8GB internal storage
Expected Service life:	Minimum 500 lifecycles
Frequency Response:	128 samples per second 0.05 -20 Hz 256 samples per second 0.05 - 40Hz 512 samples per second 0.05 - 55Hz 1024 samples per second 0.05 - 175 Hz
Recording Time:	128 Hz:
	256 Hz: 3 channels WiFi 10 days 4G 4 days
	512 Hz:
	1024

7.2. Battery










Manufacturer:Type:	Power Stream
Model:	Rechargeable lithium-ion polymer battery GM503040-PCB
Battery capacity:Nominal voltage: Charging voltage:Weight:	600 mAh
Battery cycle life:Battery life: Charger:	3.7 V
Manufacturer:Type:	4.2 V25 g
Model:	Maximum 14 days
Battery capacity:Nominal voltage: Charging voltage:Weight:	Minimum 500 recharges
Battery cycle life:Battery life: Charger:	USB 5.0 VDC, 250 mA

7.3. Measure and Weight

myPatch@sl ECG Recorder:

Measures (W x H x L):	1 15/16" x 9/16" x 2 3/4"
Weight:	2.2 oz

7.4. Environment

Enclosure protection:	TBD
Operating conditions:  Temperature:  Pressure:  Relative humidity:	+5° C to +45° C 700 - 1060 hPa 10% - 95 % (non-condensation)
Storage conditions (including between uses):  Temperature:  Pressure:  Relative humidity:	- 25° C to +70° C 700 - 1060 hPa 10 % - 95% (non-condensation)
Transportation conditions (including between uses):  Temperature:  Pressure:  Relative humidity:	- 25° C to +70° C 700 - 1060 hPa 10 % - 95% (non-condensation)

7.5. System Requirements

The myPatch®sl-b ECG Recorder requires

7.6. Validated Accessories

The myPatch®sl ECG Recorder is used in combination with other medical accessories manufactured by dms-service llc or by other manufacturers. The replacement parts should be requested from dms-service llc or an authorized dealer only.

Accessories	Part No.	Service Life
myPatch®sl ECG Electrode	mpEsl (box of 30)	Single Use
myPatch®sl ECG Electrode, Pediatric	mpE3l-p (box of 30)	Single Use
myPatch®sl ECG Electrode, Neonate	mpE3sl-n (box of 30)	Single Use
myPatch®sl ECG Electrode, T	mpE3sl-T (box of 30)	Single Use























Note: The shelf life of the myPatch®sl ECG Electrode is 2 years from the date of manufacture.

8. Reference to Standards

TBD

9. Symbols

WIP

	Serial Number
	Date of Manufacture
	Manufacturer
	Refer to Instruction Manual
	Manual Caution
	Medical Device
	Type BF Applied Parts (recorder and electrode)
	Dispose Of Waste Electrical / Electronic
	Use By
	Lot Number
	Do Not Reuse
	Temperature Range: To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used
	Does Not Contain Natural Rubber Latex
	Does Not Contain PVC (Polyvinyl chloride) Recyclable Materials
	Recyclable Materials
	Stacking Limitation
	This way Up
	Fragile, Handle with Care
	QR-Code (Quick Response Code linking to www.dms-service.com)
	Authorised European Representative
	Humidity Range: To indicate the upper and lower limits of relative humidity for transportation and storage.
	Pressure Range: To indicate the acceptable upper and lower limits for atmospheric pressure for storage and transportation.

