3 Channel ECG Recorder
Model: 3000sl

November, 2017

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®-*s*/ ECG Recorder. Model: 3000-*s*/

The myPatch®-*s*/ ECG Recorder records ECG through the myPatch®-*s*/ ECG electrode (accessory to myPatch®-*s*/ ECG Recorder).

The myPatch®-*s*/ ECG Recorder acquires ECG signals and stores them internally. The device interfaces to a myPatch®-*s*/ ECG electrode and the myPatch®-*s*/ USB Cable. The myPatch®-*s*/ ECG Recorder is rechargeable and reusable. The myPatch®-*s*/ ECG Recorder contains internal non-volatile storage that stores the ECG data until it is manually deleted.

The myPatch®-*s*/ ECG Recorder contains embedded software appropriate for recording ECG, storing ECG, and for charging. When connected to a PC via the myPatch®-*s*/ USB Cable, the recorded ECG files are accessible from the recorder.

Due to the continual wearing of a Holter 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®-*s*/ ECG Recorder is connected to the myPatch®-*s*/ ECG electrode and placed on the patient.

The myPatch®-*s*/ ECG Recorder has a 2- year warranty from date of purchase.

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Copyright

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

Content

1 Package Contents

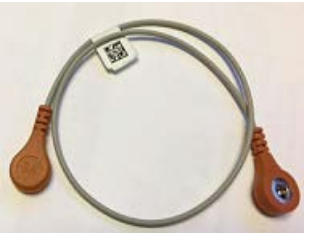
The package contains :

myPatch®-*sl* ECG Recorder with manual

Accessories Include:

myPatch®-*sl* USB Data Transfer Cable

myPatch®-*sl* Shielded Lead Wire



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2 Description

2.1 Top Side of myPatch®-*sl* ECG Recorder

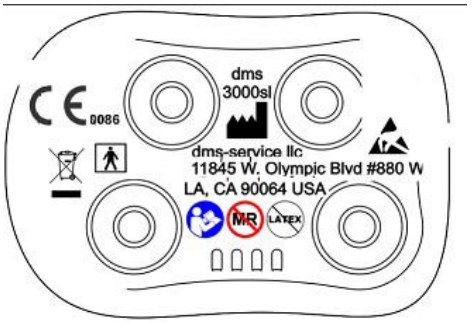
The light on the power button blinks blue when the unit is plugged into a power source. This indicates that the myPatch®-*sl* ECG Recorder is charging. When the myPatch®-*sl* ECG Recorder is fully charged, the light is a solid blue. Indicating there is enough battery power to record for 14 days (2 channels, 128 sample rate. If the Charging Diodes are flashing, the myPatch®-*sl* ECG Recorder is charging and it will not be able to record the complete 14 days (2 channels, 128 sample rate).

Power button with colored LED

The light in the power button will show the status of the myPatch®-sl ECG Recorder when powered on and not recording. The Status Diode emits a continuous or blinking green light (for 30 seconds) to indicate that the myPatch®-sl ECG Recorder is functioning and in startup mode. The light will be continuously red if it is not functioning. A yellow light indicates low battery power.

2.2 Bottom Side of myPatch®-*sl* ECG Recorder

Snaps connect to the myPatch®-*sl* electrode or to the myPatch®-*sl* USB cable.for charging or uploading the recorded ECG data.



Markings for myPatch®-sl

2.3 Side of myPatch®-*sl* ECG Recorder

UDI: Company information, device information, date of manufacture and serial number.

2.4 Top Side of myPatch®-*sl* Electrode (**myPatch®-*sl*** 3-Channel ECG Electrode)

Snaps to connect myPatch®-*sl* Holter recorder to myPatch®-*sl* 3 channel electrode.

Snap for connecting shielded snap-to-snap lead wire to electrode.

3 Important Safety Information

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

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

The myPatch®-*sl* 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 European Directive as amended 93/42/EEC concerning medical devices and 2007/47/EC. The myPatch®-*sl* 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®-*sl* ECG Recorder conforms to the Packaging and packaging waste directive 94/62/EC and Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC.

Intended Use

The myPatch®-sl ECG Recorder is a small digital Holter recorder intended for use by professionals to acquire ECG data from a patient in a clinical, point of care or at a patient setting.

The myPatch®-sl ECG Recorder uses a rechargeable lithium polymer battery and can record ECG up to 14 days (2 channels, 128 sample rate) on the torso of a patient through a myPatch®-sl ECG electrode (length or recording time is based on the sample rate and channel selection). The patient's ECG is recorded to the myPatch®-sl ECG Recorder and then transferred via the myPatch®-sl USB data transfer cable to a Holter analysis system for review by physician or other qualified personnel.

Due to the continual wearing of a Holter 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 myPatch®-sl is intended for use by adults and all pediatric sub-groups.
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 the construction of the myPatch®-sl ECG Recorder.

Indications for Use

The myPatch®-sl ECG Recorder 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, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

The myPatch®-sl is intended for use by Adults and all Pediatric sub-groups.

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

The myPatch®-sl 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 ECG Recorder can be worn in wet environments and can be submerged in water up to 2 meters for 1 hour.

3.1 Limitations in Use – Contraindication

The acceptability of a recording with the myPatch®-sl 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 ECG Recorder. Do not place the myPatch®-sl ECG Recorder and Electrode on skin that is torn or has a rash.

3.2 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 ECG Recorder.

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

The myPatch®-sl ECG Recorder is not provided with physiological-type alarms. Therefore, the patient must be instructed by the medical professionals to react to any health symptoms that may arise, as he would do if he was not wearing the myPatch®-sl ECG Recorder.

The myPatch®-sl 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 ECG Recorder or attempt to adjust it.

Do not use the myPatch®-sl 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 ECG Recorder, or may result in injuries to the patient (1-MRI RF heating can induce currents in electrically conductive materials and cause a burn to the patient. 2- 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.

Do not use a defibrillator on a patient wearing the myPatch®-sl ECG Recorder, as the myPatch®-sl ECG Recorder is not protected against defibrillation shocks. Use of a defibrillator can cause the myPatch®-sl ECG Recorder to stop recording.

Portable and mobile RF communications equipment can affect the myPatch®-sl ECG Recorder. The use of mobile phones, transmitters, and similar equipment generating radio frequency emissions and placed next to the myPatch®-sl ECG Recorder is not allowed during recordings. Follow the recommendations regarding the separation distance specified in the manufacturer's declaration for EMC in this instruction manual, Table 7, Page 28.

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 myPatch®-sl ECG Recorder cannot be used for direct cardiac application.

Do not modify the myPatch®-sl ECG Recorder or the myPatch®-sl USB data transfer cable. Modification of the myPatch®-sl ECG Recorder or the myPatch®-sl USB data transfer cable can lead to electrocution, burns, and malfunction.

Use only the myPatch®-sl ECG Recorder together with myPatch®-sl ECG electrodes and myPatch®-sl USB data transfer cables supplied by dms-service llc. Use of other equipment may result in increased emissions or decreased immunity of the myPatch®-sl 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 ECG Recorder.

WARNING: It may be unsafe to use accessories (myPatch®-sl ECG electrode, snap lead wire and myPatch®-sl USB data transfer cable) other than those that are provided by dms-service llc.

Keep the myPatch®-sl ECG Recorder, the myPatch®-sl ECG electrode and the myPatch®-sl USB data transfer cable out of reach of children and pets. Danger of strangulation if the myPatch®-sl USB data transfer cable is misused.

Danger of asphyxiation if the myPatch®-sl ECG Recorder and/or accessories are swallowed.

Do not submerge the myPatch®-sl USB data transfer cable in any liquid.

Avoid contact of liquids with the internal parts of the myPatch®-sl ECG Recorder and the myPatch®-sl USB data transfer cable. This may cause electric discharge.

Store and use the myPatch®-sl ECG Recorder within the temperature ranges, pressure, and humidity specified in Section 7.4. Avoid exposing any part of the myPatch®-sl ECG Recorder to heat sources, heat radiators and fireplaces. Temperature changes cause condensation and moisture that can lead to malfunction of the myPatch®-sl ECG Recorder. Before using the myPatch®-sl ECG Recorder, allow the myPatch®-sl ECG Recorder to acclimate to ambient temperature. For reference, if the temperature difference between the myPatch®-sl ECG Recorder and the environment is above 10º C, a 20-minute wait time in an intermediate temperature is recommended.

Do not connect myPatch®-sl 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 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 ECG Recorder to the myPatch®-sl ECG electrode before placement on the patient, as this will ease the use of the myPatch®-sl ECG Recorder.

The back of the recorder has USB contact pins that are outputs. Conductive parts of electrodes and connectors should not contact other conductive parts including earth.

Do not use an obviously broken myPatch®-sl 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!

Note: dms-service does not endorse a manufacturer of standard ECG electrodes that can be used to record the 3rd channel of ECG data.

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 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 3 sizes, mpE3sl, mpE3sl-pl and mpE2sl-nl. It is recommended that the model number mpE2sl-nl is used for neonates and the mpE3sl-pl 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.

Lead Wire: The myPatch®-sl recorder has the option of recording 3 channels. Only in the 3-channel recording use do you need to use a lead wire. The snap-to-snap lead wire must be used connect from the myPatch®-sl electrode to a standard ECG electrode at the V5 position. There are 2 sizes of lead wires 6" and 13". This size to use 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 playing with the lead wire.

4 Operating Instructions

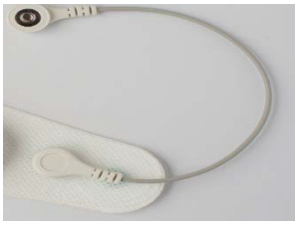
The following instruction describes the use of the myPatch®-sl ECG Recorder and must be followed point by point.

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

4.1 Start Recording

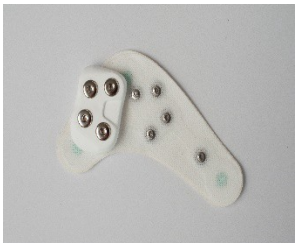
Remove the myPatch®sl Recorder from the packaging. Check battery status before use and recharge if necessary. See Section 4.3. Take the electrode out of the pouch. Place foil pouch in trash container.

Connect the download cable to the computer with the myPatch® enroll program. Delete any files that are on myPatch®sl. Enter the patient information and disconnect myPatch ®sl from the computer. See the myPatch® Utility manual for additional information.



Snap the lead wire on the snap of the electrode. Snap a standard ECG electrode on the other end of the lead wire. Perform this step if a 3rd channel of recorded ECG is desired.

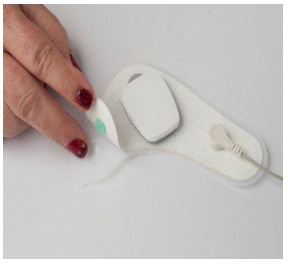
Remove or unbutton patient's shirt so the chest is exposed.
If the patient has hair where the electrode will be placed, shave the skin to remove the hair. If no hair scrub skin with soapy water or pumice prep pad. Use an alcohol wipe or cotton ball soaked in alcohol to wipe off dirt/ dead skin.



Snap the myPatch®-sl 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 one second. The button on the myPatch®-sl ECG Recorder will show a solid green light to indicate that the myPatch®-sl ECG Recorder is active. If not, consult Section 6. The green light will flash for 30 seconds indicating it is in start-up mode. Once the green lights stop flashing the myPatch®-sl ECG Recorder will go into recorder mode and is ready for normal use.



Hold the myPatch®sl 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. If there is any doubt, refer to the directions on the label of the myPatch®sl ECG electrode packaging.

Hold the myPatch®-sl -ECG electrode with the recorder in a straight up and down position. The green pad of the electrode on the patient's right side should be placed directly below the 1st rib in the center of the sternum. Take care not to touch the adhesive area. Place the electrode with the recorder on the body. Apply the standard ECG electrode attached to the lead wire to the V5 body position if you want to record three EC channels (the photo shows a 2 channel hookup).

After placement, press around the edges of the myPatch®-sl ECG electrode to improve the adherence.

If the myPatch®-sl ECG electrode is not placed correctly, connect a new myPatch®-sl ECG electrode with the myPatch®-sl ECG recorder and repeat the placement procedure.

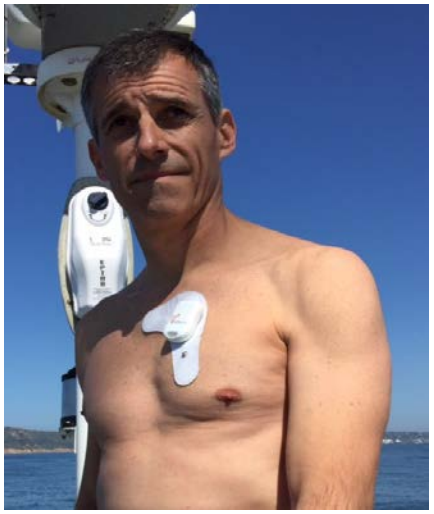
Electrode Placement Description:

RA, a modified placement of the standard Right Arm placement

LA, a modified placement of the standard Left Arm placement

LL, a modified placement of the standard Left Leg placement

V5, placed in the standard precordial lead V5 placement



Channel Descriptions

Channel 1: LL-RA=LEAD II modified
Channel 2: LL-LA=LEAD III modified
Channel 3: V5-V_w=V5

*Wilson Central Terminal (WCT), V_w=1/3(RA+LA+LL)

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 30 seconds after the solid green light on the power button disappears and will stop recording at the time selected in the Enrollment application, when the battery runs out or when the myPatch®-sl ECG Recorder's button has been held down for 4 seconds. A red light will appear to indicate the recorder is shutting down.

Tap twice in the middle of the myPatch®-sl ECG Recorder to mark an event during the recording period. A blue light will glow briefly on the power button to acknowledge the recording of the event mark.

4.2 End of Recording

After the recording period or when the recording is terminated the electrode and recorder need to be removed. 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 downwards and outwards in the direction away from the myPatch®-sl 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 has not turned off, press and hold down the power button for 4 seconds on the myPatch®-sl ECG Recorder. The light will flash red and the myPatch®-sl ECG Recorder will stop recording.

Hold the myPatch®-sl 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

Connect the myPatch®-sl ECG Recorder and the myPatch®-sl USB data transfer cable. Do not force the myPatch®sl ECG recorder onto the connection of the cable. It will only snap on in one direction.

Connect the USB-end of the myPatch®-sl USB data transfer cable to a powered-on computer.

The myPatch®-sl ECG Recorder will automatically sense the cable and go into charge mode. The LED will flash blue and will turn solid blue when charged. The LED will emit a continuous blue light to indicate that the myPatch®-sl ECG Recorder is completely charged. If the LED is flashing blue, the myPatch®-sl ECG Recorder is charging and it will not be able to use a fully charged battery. Allow recharge of the myPatch®-sl ECG Recorder before use, approximately 1 1/2 hour.

NOTE: Once myPatch®-s 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 myPatch®-sl charging over 24 hours, please remove myPatch®-sl from charge and plug myPatch®-sl back into the charging source. myPatch®-sl may need to charge for another 10 minutes or so. Make sure you see a solid blue light prior to hooking up the patient.

4.4 Copy Recorded Data to Computer

Connect the myPatch®-sl ECG Recorder and the myPatch®-sl USB data transfer cable. Do not force the myPatch®sl ECG recorder onto the connection of the cable. It will only snap on in one direction.

Connect the USB-end of the myPatch®-sl USB data transfer cable to a powered-on computer.

The file location of the myPatch®-sl .cdm file will show on your screen.
The CDM utility software will copy the folder from the recorder and transfer it to a format the Holter analysis software can read OR your Holter analysis software will identify the file and prepare it for loading
See your Holter Analysis Operators Manual or CDM myPatch®-sl Utility Software Interface Manual for instructions on how to load myPatch®-sl to your Holter program.

5 Cleaning, Maintenance, and Disposal

The myPatch®-sl 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 ECG Recorder was developed

5.1 Cleaning

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

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 ECG Recorder and the myPatch®-sl USB data transfer cable in the provided packaging to keep all items protected from shock and vibration and to keep the device free of debris. The packaging material provides enough protection against small accidental impacts.

The manufacturer is not responsible for malfunction or damage to the myPatch®-sl 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 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 ECG Recorder that prevents normal operation, please contact your distributor, 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 ECG Recorder and the myPatch®-sl USB data transfer cable have no user-serviceable parts. The myPatch®-sl ECG Recorder requires no calibration. The myPatch®-sl is a sealed device and not serviceable.

5.5 Disposal of Electrical and Electronic Devices

Never dispose of the myPatch®-sl ECG Recorder, the myPatch®-sl ECG electrode or the myPatch®-sl USB data transfer cable 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.

The myPatch®-sl ECG Recorder was tested and certified at Nemko in Carlsbad, CA. dms-service llc opted for a water submersion test of 2 meters for a period of 1 hour. The myPatch®sl ECG Recorder passed the test and has received the classification of IP68. This means that the case of the device is dust-tight and is protected against complete continuous submersion in water of 2 meters for 1 hour.

6 Troubleshooting

6.1 The myPatch®-sl ECG Recorder Does not Start

6.1.1 Make sure that the myPatch®-sl 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 ECG Recorder is correctly connected to the myPatch®-sl ECG Electrode, see Section 4.1
6.1.3 Make sure that the myPatch®-sl ECG Recorder is fully charged and ready, see Section 4.3

6.2 The myPatch®-sl ECG Recorder-Drive Is not Visible on the Computer

6.2.1 Make sure that the myPatch®-sl ECG Recorder is connected correctly to the USB-end of the myPatch®-sl USB Cable
6.2.2 Make sure that the computer is connected correctly to the USB-end of the myPatch®-sl USB data transfer cable

6.3 The Blue LED Charge Light is not Turned on at the myPatch®-sl ECG Recorder when Connected to the Computer

6.3.1 Make sure that the myPatch®-sl ECG Recorder is not placed in direct sunlight, as this make reading the light LEDs difficult
6.3.2 Make sure that the myPatch®-sl ECG Recorder is connected correctly to the snap-end of the myPatch®-sl USB Cable
6.3.3 Make sure that the USB-end of the myPatch®-sl USB data transfer cable is connected to a powered-on computer.

6.4 The LED button of the myPatch®-sl ECG Recorder Lights Red

6.4.1 If the LED Button of the myPatch®-sl ECG Recorder lights red, myPatch®-sl 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

6.5 The myPatch®-sl ECG Recorder USB Driver was not Successfully Installed

6.5.1 Make sure that the myPatch®-sl ECG Recorder is connected correctly to the snap-end of the myPatch®-sl USB Cable
6.5.2 Disconnect the USB-end of the myPatch®-sl USB data transfer Cable from the computer and reconnect to computer again
6.5.3 Make sure that the USB-end of the myPatch®-sl USB Cable is connected to a powered-on computer

7 Specifications

7.1 Type and Model

Type:	myPatch®3000sl
Model:	Internally Powered, Type BF applied parts, no functional earth terminal
Device classification (EN 60601-1): Class:	IIa
Data acquisition:	1, 2 or 3 channels ECG
Placement:	Upper Sternum
Resolution:	12 bit
CMRR (common mode rejection ratio):	Max CMRR @ 50/60 Hz = 101.67 dB Max CMRR @ 100/120 Hz = 86.67 dB Lowest CMRR @ 50/60 Hz = 76.24 dB Lowest CMRR @ 100/120 Hz = 73.29 dB
Connections:	4 Snaps myPatch®sl Connector for connection to myPatch®sl electrode
Storage medium:	8GB internal storage
Maximum data file size:	3GB cdm-file (myPatch®sl File System)
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: 1 or 2 ch 14 days, 256 Hz: 1, 2 or 3 ch 9 days 512 Hz: 1, 2 or 3 ch 5 days 1024 Hz: 2 or 3 ch 3 days

a. Battery

The myPatch®-sl ECG Recorder is powered by an integrated battery with the following specifications:

Manufacturer:	Power Stream
Type:	Rechargeable lithium-ion polymer battery
Model:	GM503040-PCB
Battery capacity:	600 mAh
Nominal voltage:	3.7 V
Charging voltage:	4.2 V
Weight:	25 g
Battery cycle life:	Maximum 14 days
Battery life:	Minimum 500 recharges
Charger:	USB 5.0 V_{DC}, 250 mA

Charging of the myPatch®-sl ECG Recorder should be performed by use of a computer via the myPatch®-sl USB data transfer cable. Use of other charging devices may damage the device and/or accessories.

The battery has an internal safety circuit.

b. Measure and Weight

myPatch®sl ECG Recorder:

Measures (W x H x D):	1.75” x 2” x .5”
Weight:	25 g

c. Environment

Enclosure protection: IP 68

Operating conditions:

Temperature:	+5° C to +45° C
Pressure:	700 - 1060 hPa
Relative humidity:	10% - 95 % (non-condensation)

Storage conditions (including between uses):

Temperature:	- 25° C to +70° C
Pressure;	700 - 1060 hPa
Relative humidity:	10 % - 95% (non-condensation)

Transportation conditions (including between uses):

Temperature:	- 25° C to +70° C
Pressure:	700 - 1060 hPa
Relative humidity:	10 % - 95 % (non-condensation)

Exceeding the recommended operating, storage, and transportation directions may result in reduction of the performance of the device and/or accessories

d. System Requirements

The myPatch®-sl ECG Recorder requires a computer with the following minimum specifications to read out the recorded data:

- Microsoft® Windows XP or Mac OS X 10.7 by Apple Inc.
- 1.5 GHz processor
- 512 MBRAM
- USB 2.0 port for connection of the myPatch®-sl USB Cable
- 1 GB of free hard-drive space

e. 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.

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Accessories	Part No.	Service Life
myPatch®sl ECG Electrode	mpE3sl (box of 30)	Single Use
myPatch®sl ECG Electrode, Pediatric	mpE3sl-p (box of 30)	Single Use
myPatch® Lead Wire, 13”	mpLW13	6 months
myPatch® Lead Wire, 6”	mpLW6	6 months

Note: The shelf life of the myPatch®-sl ECG Electrode is 2 years from the date of manufacture. The shelf life of the lead wires is 3 years.

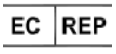
8 Reference to Standards

The myPatch®-sl ECG Recorder is manufactured for DMS-SERVICE LLC and the myPatch®-sl ECG Recorder meets the following standards and regulations:

- IEC 60601-1 ed 3.1 Consol. with am1 (2012-08) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1:2012 Chapter 14 PEMS
- IEC 60601-1-2:2014 Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 62366-1:2015 Medical Devices-Part 1: Application of Usability Engineering to Medical Devices
- IEC 60601-1-6 Usability
- IEC 60601-1-11:2015 Home Health Care Environment
- IEC 60601-2-47:2012 Ambulatory Electrocardiographic Systems
- IEC 62304:2006 Software Life Cycle
- ISO 14971:2012 Medical devices – Application of risk management to medical devices
- ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (replaces the EN 980:2008 that has DOW August 2012)

The manufacturer has declared that the equipment complies with requirements of ISO 10993-1.

9 Symbols

	Serial Number
	Date of Manufacture
	Manufacturer
	Refer to Instruction Manual
	Caution
	Type BF Applied Parts (recorder and electrode)
	Dispose Of Waste Electrical / Electronic According To The RAEE Directive
	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
	Stacking Limitation
	This way Up
	Fragile, Handle With Care
	QR-Code (Quick Response Code linking to www.dms-service.com)
	MR Unsafe -an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	IP Rating 6x Dust Tight IP Rating x8 Protected Against Submersion up to 2 meter for 1 hour
	Regulatory European Representative for dms-service llc
	Electrostatic Discharge
	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.

Annex 1 Electromagnetic Compatibility

Table 1 - Guidance and MANUFACTURER'S declaration - IMMUNITY TEST SUMMARY

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or user of the equipment should ensure that it is used in such an environment.

Test Methods	Minimum Test Level Required as per *IEC 60601-1-2*	Criterion Level Tested	Compliance Status
IEC 61000-4-2 - Electrostatic Discharge Immunity	Air discharge up to ± 15 kV; Contact discharge up to ± 6 kV	Air discharge up to ± 15 kV; Contact discharge up to ± 8 kV *	PASS
IEC 61000-4-3 - RF Radiated Fields Immunity	Radiation field strength of 3V/m from 80 – 2500 MHz (80% AM, 1 kHz)	Radiation field strength of 3V/m from 80 – 2700 MHz (80% AM, 1 kHz), Table 9 *	PASS
IEC 61000-4-4 -Electrical Fast Transient Immunity	Power line pulses of ± 2kV direct; I/O line pulses of ± 1kV	Power line pulses of ± 2kV direct; I/O line pulses of ± 1kV	N/A*
IEC 61000-4-5 -Lightning Surge Immunity	Power line surges of ± 2kV common, ± 1kV differential mode	Power line surges of ± 2kV common, ± 1kV differential mode	N/A*
IEC 61000-4-6 -RF Common Mode Immunity	150 kHz - 80 MHz at 3 Vrms 1 kHz 80% amplitude modulated	150 kHz - 80 MHz at 7 Vrms 1kHz 80% amplitude modulated *	N/A*
IEC 61000-4-8 -Power Frequency Magnetic Field Immunity	Inductive loop at 50 Hz and 60Hz, to 3 amps (rms) per meter	Inductive loop at 50 Hz and 60Hz, to 30 amps (rms) per meter *	PASS
IEC 61000-4-11 - Voltage Dips and Short Interruptions	Voltage Dips of >95% for 0.5 cycles 30% for 25 cycles 60% for 5 cycles >95% for 250 cycles (5s)	Voltage Dips of 100% for 0.5 cycles 100% for 1 cycles 30% for 25/30 cycles 100 for 250/300 cycles *	N/A*

*EUT is Battery operated.

Table 2 - Guidance and MANUFACTURER'S declaration - EMMISIONS TEST SUMMARY

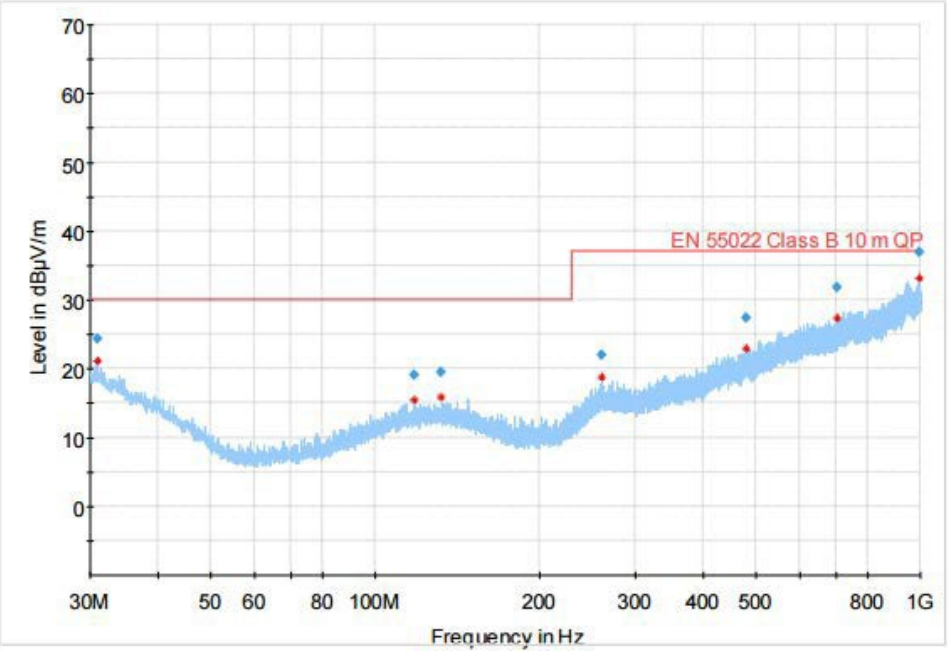
The Compliance Status is a judgment based on the calculated highest emissions to appropriate standard limits.

Test Methods	Frequency Range	Compliance Status
CISPR 11 Group 1, A Conducted Emissions	0.15 MHz – 30 MHz	N/A*
CISPR 11 Group 1, A Radiated Emissions	30.0 MHz – 1,000 MHz	PASS
IEC 61000-3-2 Power Line Harmonics	Up to the 40th Harmonic	N/A*
IEC 61000-3-3 Power Line Flicker	less than or equal to 4% Maximum Relative Voltage Change; Value of d(*t*) less than or equal to 3.3% for more than 500 ms	N/A*

*EUT is Battery operated.

Table 3: Guidance and MANUFACTURER'S declaration - RADIATED EMISSIONS <1 GHz

Client	DMS-Service LLC			
NEx #	312787	Temperature	23	˚C
EUT Name	Holter Monitor	Humidity	54	%
EUT Model	3000sl	Pressure	99.9	kPa
Governing Doc	IEC 60601-1-2	Test Location	10 Meter Chamber	
Basic Standard	CISPR 11	Test Engineer	Jose Cuevas	
Test Voltage	Battery operated	Date	7/27/2016	



Frequency (MHz)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB)
31.0415	24.29	30	5.71	1000	120	234.8	H	8	19
117.8045	19.07	30	10.93	1000	120	289.6	V	241	13
132.232	19.46	30	10.54	1000	120	352.6	V	60	13.2
260.152	22.01	37	14.99	1000	120	325	V	318	15.9
479.9405	27.4	37	9.6	1000	120	259.2	H	342	21
702.9425	31.73	37	5.27	1000	120	105.3	H	272	25

Table 4 - Guidance and MANUFACTURER'S declaration - ELECTROSTATIC DISCHARGE

This test simulates electrostatic events and evaluates the ability of the EUT to tolerate such events. testing was performed in accordance with IEC/EN 61000-4-2. All accessible enclosure surfaces and ports are evaluated unless specified as a static sensitive surface. The product specific standard sets the Level and the number of test strikes to apply

Client	DMS-Service LLC			
NEx #	312787	Temperature	22	°C
EUT Name	Holter Monitor	Humidity	51	%
EUT Model	3000sl	Pressure	1000	kPa
Governing Doc	IEC 60601-1-2	Test Location	ESD Ground Plane	
Basic Standard	IEC 61000-4-2	Test Engineer	Jose Cuevas	
Test Voltage	Battery operated	Date	7/28/2016	

Test Conditions	
Discharge Rep. Rate	1 per second
Number of Discharges	>10 per polarity, per location
Performance Criteria:	B
EUT Mode:	Recording

Contact Discharge						
Voltage: (+/- kV)	2 ☒	4 ☒	6 ☒	8 ☐	Other ☐	

Location	Comments
Vertical Coupling Plane	No susceptibility noted.
Horizontal Coupling Plane	No susceptibility noted.
Contact Locations	Device stops recording when ESD discharge ocurred on the pacient side of the 13"lead

Air Discharge						
Voltage: (+/- kV)	2 ☒	4 ☒	8 ☒	15 ☒	Other ☐	

Location	Comments
Air Locations	No susceptibility noted.
"Spark" event(s)	No spark events noted.

Compliancy			
Compliant?	Yes	Additional Comments	N/A

Table 5- Guidance and MANUFACTURER'S declaration - RADIO FREQUENCY

The radiated RF immunity test exposes the equipment under test to a calibrated uniform field of radiated electromagnetic energy. The EUT is continuously monitored while exposed to the required frequency range and field strength. The test chamber, radiating antennas, and calibrated fields meet the requirements of referenced standards. The product specific standard sets the level, duration, and the frequency range to apply.

Client	DMS-Service LLC			
NEx #	312787	Temperature	24	˚C
EUT Name	Holter Monitor	Humidity	57	%
EUT Model	3000sl	Pressure	99.9	kPa
Governing Doc	IEC 60601-1-2	Test Location	RF Imm Chamber	
Basic Standard	IEC 61000-4-3	Test Engineer	Jose Cuevas	
Test Voltage	Battery operated	Date	7/29/2016	

Test Conditions	
Test Level	3 V/m
Frequency Swept	80 MHz - 2700 MHz
Selected Frequencies	N/A
Modulation	1 kHz, 80% AM modulated
Frequency Step	1%
Dwell Time	3 seconds
Performance Criteria	A
EUT Mode	Recording

Test Scans Accomplished				
Frequency (MHz)	Antenna Polarization	Compliant	Orientation	Comments
80 to 2700	Horizontal	Yes	Front	No susceptibility noted.
80 to 2700	Horizontal	Yes	Rear	No susceptibility noted.
80 to 2700	Horizontal	Yes	Side Left	No susceptibility noted.
80 to 2700	Horizontal	Yes	Side Right	No susceptibility noted.
80 to 2700	Vertical	Yes	Front	No susceptibility noted.
80 to 2700	Vertical	Yes	Rear	No susceptibility noted.
80 to 2700	Vertical	Yes	Side Left	No susceptibility noted.
80 to 2700	Vertical	Yes	Side Right	No susceptibility noted.

Compliancy			
Compliant?	Yes	Additional Comments	N/A

Frequency (MHz)	Antenna Polarization	Compliant	Orientation	Comments
380-390 MHz, 18 Hz Pulse Mod., 27 V/m	V / H	Yes	All	No susceptibility noted
430-470 MHz, 1 kHz FM, 28 V/m 10 s Dwell @ 450 MHz	V / H	Yes	All	No susceptibility noted
704-787 MHz, 217 Hz Pulse Mod., 9 V/m 10 s Dwell @ 710 MHz 10 s Dwell @ 745 MHz 10 s Dwell @ 780 MHz	V / H	Yes	All	No susceptibility noted
800-960 MHz, 217 Hz Pulse Mod., 28 V/m 10 s Dwell @ 810 MHz 10 s Dwell @ 870 MHz 10 s Dwell @ 930 MHz	V / H	Yes	All	Detection Wand goes to extended scan
1700-1990 MHz, 217 Hz Pulse Mod., 28 V/m 10 s Dwell @ 1720 MHz 10 s Dwell @ 1845 MHz 10 s Dwell @ 1970 MHz	V / H	Yes	All	No susceptibility noted
2400-2570 MHz, 217 Hz Pulse Mod., 28 V/m 10 s Dwell @ 2450 MHz	V / H	Yes	All	No susceptibility noted
5100-5800 MHz, 217 Hz Pulse Mod., 9 V/m 10 s Dwell @ 5240 MHz 10 s Dwell @ 5500 MHz 10 s Dwell @ 5785 MHz	V / H	Yes	All	No susceptibility noted

Table 6- Guidance and MANUFACTURER'S declaration - POWER FREQUENCY MAGNETIC FIELD
This test subjects devices to the fields produced by current carrying conductors of standard building power. Testing was performed in accordance with IEC/EN 61000-4-8. The EUT was exposed to 50 Hz and 60 Hz power frequency magnetic fields, to the level required by the product specific standard.

Client	DMS-Service LLC			
NEx #	312787	Temperature	23	˚C
EUT Name	Holter Monitor	Humidity	54	%
EUT Model	3000sl	Pressure	99.9	kPa
Governing Doc	IEC 60601-1-2	Test Location	Ground Plane 3	
Basic Standard	IEC 61000-4-8	Test Engineer	Jose Cuevas	
Test Voltage	Battery operated	Date	7/27/2016	

Test Conditions	
Test Level	30 amps (rms) per meter
Frequency	50 Hz and 60 Hz
Duration Per Axis	10 minutes
Performance Criteria	A
EUT Mode	**Recording**

Text Axis	Compliant	Comments
X	Yes	No susceptibility noted. 50 Hz
Y	Yes	No susceptibility noted. 50 Hz
Z	Yes	No susceptibility noted. 50 Hz
X	Yes	No susceptibility noted. 60 Hz
Y	Yes	No susceptibility noted. 60 Hz
Z	Yes	No susceptibility noted. 60 Hz

Compliancy			
Compliant?	Yes	Additional Comments	N/A

Table 7- Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and myPatch®sl.
The myPatch®sl is intended for use in an environment where radiated RF frequencies are controlled. The patient can help to prevent electromagnetic interference by maintain a minimum distance between portable/ mobile RF communications equipment and the myPatch®sl as recommended in the table below.

Maximum Transmitter Power in Watts	Separation Distance based on Frequency of the Transmitter in Meters Based on the **Formula D=0.75√P** for Frequencies 80Hz to 2.5 GHz
0.1 Watt	0.237 Meters
1 Watt	0.75 Meters
10 Watts	2.37 Meters
100 Watts	7.5 Meters
1000 Watts	23.7 Meters

This guideline may not apply in all situations as electromagnetic propagation is affected by absorption and reflection of objects. The myPatch®sl is not intended for use in or near MRI equipment.