Fine-wire Electrode Usage Guide

1. Check the expiration date (which may be formatted as yyyy-mm-dd, yyyy-mm or yymmd) on the fine-wire needle packaging and verify that the fine-wire sterilized packaging is intact. Follow local site procedures and discard any packages that have expired, or are not sealed and intact.

2. Prepare the subject for the insertion by cleaning and sterilizing the insertion area as appropriate for the intended test, taking all necessary precautions to prevent infection and or contamination.

3. Remove the fine-wire electrode from the package and visually inspect both ends of the electrode wire without touching or contaminating the wires or needle. This may require holding the electrode against a light surface under a bright light and using a magnifying glass. Both of the hooked ends should be insulated to within 2mm of the tip with the remaining wire being exposed - the bare ends should be staggered, not in contact with each other, and snug against the point of the needle. There should be no kinks throughout the length of the wire that might cause the wire to break when removed from the subject after the test. The opposite ends of the wires should have approximately 6mm of uninsulated, exposed wire for connection to the recording interface.

4. Refer to your anatomical guides as appropriate, locate the desired insertion point and insert the needle into the muscle smoothly to the desired depth to place the hooked wires into the target muscle.

5. Carefully withdraw the needle, leaving the fine-wire pair in place within the muscle and connect the uninsulated, free ends of the wires to the inputs of your recording system. If possible, gently flex the limb controlled by the muscle to allow the wires to be seated in the muscle. Use small pieces of tape to secure the wires at the insertion site and against the skin to minimize any movement of the wires, or strain at the insertion point during testing. This helps to minimize signal artifact and noise.

6. You may optionally check the wire placement within the muscle by applying a stimulation pulse using a suitable approved nerve stimulation device. Always start with a low stimulation level and gradually increase the level while observing the target muscle - if the wire is placed correctly then a small twitch will be observed in the correct muscle when it is stimulated. Direct electrical stimulation must be kept to a minimum as the small area of the electrode tip may cause significant current density (250mA/mm²/sec) resulting in calcification and inflammation.

Motion Lab Systems pre-amplifiers can withstand stimulation pulses without problems but if you are using another system then you should check with the manufacturer to ensure that a stimulation pulse will not damage their equipment.

7. Connect an external ground reference electrode to the subject and perform the EMG test, visually monitoring the EMG signal quality during the test if at all possible.

8. After the EMG test has been completed, the recording equipment should be disconnected from the subject. The fine-wire electrode wires can then be removed with a gentle, smooth and steady pull. This will usually bring the electrodes out painlessly as the wires are so fine and delicate that they offer little resistance to their removal.

9. Immediately inspect the wires after removal to ensure that the wires have been removed intact from the subject - the wires are nominally 200mm in length ±3.125mm. Occasionally small parts of the wire will remain in the muscle after a test but provided that the wire fragments are small (less than a couple of millimeters) this is not normally a cause for concern.

10. Swab the wire removal site with a sterilizing solution, apply a suitable sterile covering if necessary and dispose of the used needle and wires in accordance with local safety policies.

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IMPORTANT NOTICE

These fine-wire electrodes are only supplied for clinical human use under the direction of a physician, and should only be used with equipment that has FDA 510(k) CFR Sec. 890.1375 for clinical use.

If in doubt, you should ask the equipment manufacturer to provide a copy of their 510(k) approval letter from the FDA for the system that you are using to confirm that the equipment can be safely used for human clinical use.

A diagnostic electromyograph is defined by the FDA as:

> A diagnostic electromyograph is a device intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease. [21CFR890.1375]

Note that almost all EMG systems that claim to have “US FDA 510(k) clearance” without specifying the CFR section have only received approval to be marketed for biofeedback use (CFR Sec. 882.5050). Biofeedback systems are not approved or designed for clinical studies, medical, or other diagnostic functions on human beings.

A biofeedback device is defined by the FDA as:

> A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters. [21CFR882.5050]

All Motion Lab Systems EMG systems and EMG pre-amplifiers incorporate the safety features necessary for intrinsically safe use of fine-wire electrodes with human beings and have received US FDA 510(k) clearance (Code of Federal Regulations Sec. 890.1375) for sale in the USA for use as a diagnostic electromyograph for medical purposes.

If your EMG system was not manufactured by Motion Lab Systems then it is recommended that you obtain written confirmation from the manufacturer that your system has the necessary regulatory approvals and safety features before using fine-wire electrodes on human beings.