



INITIALISATION OF A NEW NEUROPHYSIOLOGICAL DEVICE



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INTRODUCTION

The purchase of a new neurophysiological device is regulated by the national legislation on publically funded acquisitions and the EU directives on public purchase. The management system in our Department is based on the standard SFS-EN ISO/IEC 17025:2005. All activity on our Department is regulated and documented according to this standard.

THINGS TO BE DONE BEFORE PURCHASE

The chief physician appoints a physician and a technologist to take the responsibility for the initialisation of a new device. The technical inspection of the device is the responsibility of the hospital physicist and the laboratory device maintenance personnel. Before deciding on a purchase 2 or 3 devices from different manufactures are tested. The responsible personnel acquaint themselves with the devices and compare their features. The decision on the purchase is made after the comparison and all personnel have the opportunity to give their own opinion which might influence the final decision.

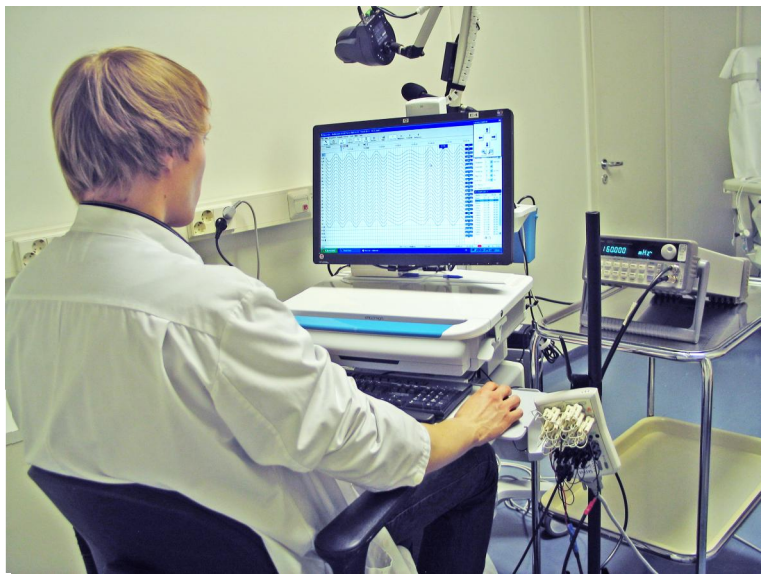


Figure 1 The calibration of a new device

MEMBERS OF THE INITIALISATION FORM

INITIALISATION OF A NEW NEUROPHYSIOLOGICAL DEVICE OR METHOD

DEVICE OR METHOD: _____
 Personnel responsible for the method:
 Personnel responsible for the initialisation:

Accepted by _____ Date _____

| | | |
|---|--|--|
| Realisation of the need of a new method based on literature, user needs or an own idea | | |
| Goals | | |
| Gathering all needed information on the device and method from literature and other laboratories etc | | |
| Timetable | | |
| Number of project: | | |
| Needed equipment and software purchase and related procedures | | |
| Electrical safety inspection | | |
| Decision on whether the laboratory needs its own reference values | | |
| Making note of general reference values and saving them to a reference value file used by the unit | | |
| Starting to write down instructions | | |
| Arranging maintenance and calibration | | |
| Teaching the use of the device Technologists: Physicians: | | |
| The first test studies | | |
| Identification codes for the test studies: Scrutinizing the instructions and writing the process description | | |
| Gathering all needed reference values | | |
| The first patient studies | | |
| Scrutinizing the instructions again | | |
| Other things to note | | |

THE INITIALISATION PROTOCOL

- the need for purchase is stated
- all needed information on devices and software is gathered
- an electrical safety inspection is made
- all needed reference values are gathered
- instructions are carefully scrutinized
- other personnel is taught to use the device
- the first patient studies are made
- the instructions are scrutinized again

THINGS INFLUENCING THE INITIALISATION SCHEDULE

- the schedules of the device supplier
- the availability of healthy persons needed for the reference value sample
- arranging space for the testing of new device
- arranging time for the responsible personnel to test the devices
- the comparison of the reference values between the old and the new device

CONCLUSION

The role of the Neurophysiology Technologist in initialisation of a new neurophysiological device is quite big. The technologist takes part in the purchase of the device, does the test studies, teaches the other personnel to use the device, writes down the instructions together with a physician and a hospital physicist and gathers all needed reference values.