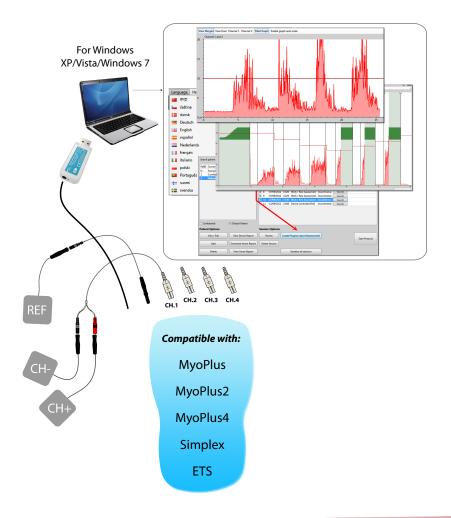
PelviTec[®] Software Manual



English



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Please note!

The PC software and hardware are constantly being updated and improved, therefore the information in this manual might not be up to date at the time of usage.

Please use the link below to get the latest information:

www.pelvitec.emgsoft.info



Software Features and Benefits

- Easy to install and operate on PC or Laptop with Microsoft Windows Operating System.
- Assessment and training tool. Designed for the Clinician in mind. Can be used by the Patient for the home training.
- PC Database System for Patients Sessions and Home Compliance storage.
- Data from the device is sent one way to the PC/Laptop using the safe radio or fibre optic connection. This ensures the Patient cannot get the electrical surge from the PC/Laptop connected to the mains. One way Unit->PC connection also excludes any possibility of interference in the functionality of the EMG/STIM device by the complex PC system.
- Individual structured patient EMG template design.
- Structured protocols for consistency of patient evaluation.
- Ability to use Markers on a select graph area where some additional measurements could be performed.
- Comprehensive treatment and printed Progress Reports.
- Download & Maintenance of the Home Compliance data from EMG unit.
- Displays stimulation time and EMG between STIM Work periods which is particularly useful for the correct using of Stimulation.
- Designed to be used for a wide range of physiotherapy applications.



Benefits from EMG and ETS

EMG Biofeedback therapy techniques throughout the world are increasingly being used for neuromuscular re-education and rehabilitation. Using EMG, both health professionals and patients themselves can evaluate various maladies.

EMG Biofeedback is currently being successfully used to treat a growing number of conditions. The high efficacy levels of treatment using EMG Biofeedback is due to the active participation of the patient. Patients are empowered by being able to control and facilitate their own ongoing progress throughout the therapy process. The instant feedback shown on a display screen further encourages and motivates the patient to continue the therapy sessions.

EMG Biofeedback Training

In order for a muscle or system of muscles to substantially improve in condition towards improved strength, endurance, speed, comfort and control, it is usual that a regime of consistent daily training be followed, most likely consisting of at least 20 minutes of sustained activity involving at least 40 cycles of contraction and release. The Software includes training protocols. In these protocols a training template can be drawn up or selected from memory. A statistical record of each completed assessment session can be stored and plotted as one of the graphs of a progress report.

EMG Triggered Stimulation (ETS) enables the patient to trigger Neuromuscular Stimulation as soon as the Patient reaches an automatically or manually adjusted EMG level called ETS Target Threshold. The patient must achieve a pre-set EMG threshold level and hold it above this threshold to trigger the stimulation cycle. At the end of each work period the device reverts to the EMG rest mode and Stimulation cannot be re-triggered until the next work period begins. ETS is known to be very motivating, particularly for patients who have difficulty in achieving anything more than very weak voluntary muscle contractions.

This relatively new feature of using ETS can be particularly effective when treating and evaluating pelvic floor muscles and stroke conditions.



Installation

General Notes:

One Software kit allows you to install it on as many computers as you need, including the LAN network installation. One kit allows you to use one installation at a time, the data adaptor is your hardware licence key for connection. For example: you can install the Software on your personal laptop and use it at home, also you can install the Software on an office PC. You can choose to which Software installation you would like to connect your portable EMG device at one time, while both installations can work and show the database at the same time (you connect just to one installation at a time).

The Installation process takes a bit longer then one would expect, up to 20 minutes, depending on the computer performance. This is due to the necessary graphical and driver environment to be installed prior to application install. The actual application itself takes less then a minute to be installed.

Minimum System Requirements:

- Windows XP / Vista / 7 operating systems.
- 1 free USB port for Data Link Adaptor.
- 500 MB spare hard drive, PC Monitor 800 x 600 px or wider.
- NOTE! If you are thinking of buying the dedicated laptop, we recommend Windows 7, good graphical card, earthed power adaptor for less EMG interference (3 pin on the actual adaptor, not 2).

Accessories provided:

- 1 x Software Installation (version 5.0 or above)
- 1 x Data Adaptor. This is a USB stick which your software application will use to receive the data from your device. This is either the Fibre Optic USB Adaptor together with the fibre optic cable, or the Radio USB Adaptor.

Quick Installation Guide:

(Please follow this chapter for the first time installation or if you want to upgrade from the previous version).

- 1. Before Installation or Upgrade, please make sure the Data USB Adaptor is not connected to the computer. Please exit any running applications.
- 2. Insert the provided Installation CD into the CD/DVD ROM drive. If you've downloaded the link, unzip it onto your desktop and run Setup.exe.



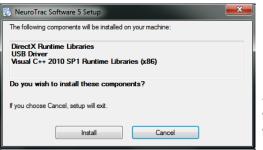


Figure 1a: Run setup. exetoinstallgraphical, environmental and USB drivers.

- 3. Please follow on-screen instructions to install drivers:
- <u>Optional USB driver</u> (SILICON LABS) If you have similar driver already installed, please choose "Maintain or Upgrade the existing driver". Don't restart system yet.
- <u>Microsoft Visual C++ Environment</u> Install or re-install it. When all the drivers are installed, you will see the actual application installation screen (Figure 1b).

NeuroTrac Software 5	lf you
	after
Select Language	insta
🔚 English 🔹	brow
Choose type of installation	sour
Server Terminal	Insta
	l

If you don't see figure 1b after the drivers installation, browse your installation source and doublecklick: Installers\...msi

Figure 1b: Install the application on single laptop/PC or in network environment.

<u>Terminal Installation</u>: Select your language of installation and press "Terminal" to install on single computer. This is the most common option for single use.



Server Installation: This installation allows many users from the same LAN (Local Area Network) to get access to this database from any computer where Terminal is installed. Other Terminals may read, update and record sessions on this database. This multiple access will not cause any interruptions with your access to the server database installed on this computer. The Server computer (this one) should be running and connected to the LAN, also the Software should be opened to allow others to access the database. Many users will not interfere with each other and will use the database simultaneously. If you don't plan a multiple access to your database, it is better to install Terminal on your computer, since Server installation uses more computer resources (CPU & RAM) than Terminal installation.

If you are planning ahead to install Server, you should consult and perform the installation with the IT personnel of your organisation. Verity Medical Ltd. or the authorised distributor cannot support you with the issues of your particular network infrastructure.

Configuration		×
		😹 English
Configuration		
Choose method for storing data		
Store data on local or remote file system	Connect to existing	NeuroTrac Server
Enter path of folder in which you want to stor	e data (leave empty for d	efault)
		!Browse!
	ОК	Cancel

Figure 1c: Start the new database or connect to the existing one.

4. Data storage Configuration.

Just after the Installation, when you first run the Software, the Database configuration appears (Figure 1d).

<u>Store data on local or remote file system</u> - use it for Terminal Installation, when you install or upgrade your installation.

<u>Connect to existing Software Server</u> - use it for Terminal Installation, when you want to read and update the database installed on another Server.

Click OK. The installation is completed.



First run, Upgrading from previous Version

Edit Registration details:

Please complete the registration form.

The obligatory fields are indicated and will be asked again if you skip them. The registration details will be displayed in the footer section of various printed reports that are in the Software.

Here you can insert your own logo and select the color theme for the user's interface.

Upgrade or create new Login/Password:

After the registration the user will be prompted to create login/password, which will protect the access to the Patient Database.

If you want to upgrade the previous Software version, select: Import database (Figure 3).

You can always Import Database later on, by logging in to the software and selecting:

<u>Setup->Programme Setup -></u> <u>Import database</u>.

ATTENTION! After Import, whatever you've created with the newest version: sessions, logins, Patient data: all will be overwritten with the Imported data! You will be logging in with the same login and password as your previous installation.

🐝 Edit Registration De	tails 🗾						
Name	Johnny						
Business Name	Stewart						
Department	Physiotherapie						
Address	22 Alwil Road Devon's Ford Southampton						
Post code	SO53 8AQ						
Country	United Kingdom						
Telephone number	+44 2380 397 686						
Fax number							
Logo	LOGO						
Branding Colour	Select Colour						
	OK Cancel						

Figure 2: Registration



Figure 3: New user Login/Password or Upgrade

Login, Auto-Connection

Login:

This screen appears every time you doubleclick the Software Icon on your desktop.



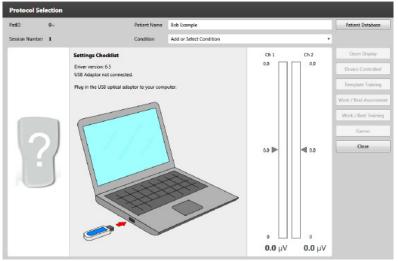


Figure 4: Login / password

Figure5: First Screen will guide you through data connection. This is also a protocol selection menu, once you have your device connected you use this screen to select the treatment.

Auto-Connection:

New and Improved auto-connection function will find the data stream from your connected unit automatically or will display the status of connection problem. Please follow on-screen instructions.

- 1. Remember, your EMG unit has the Data enable/disable function, please make sure it is enabled (PC-LK ON, SDAT ON, DON).
- 2. Make sure you've plugged in the USB adaptor and connected the fiber optic cable linking the EMG device and the adaptor.

When the connection is established, the device name and the selected mode will be displayed.



Software Quick Start

- 1. Install and register the Software (page 5).
- 2. Make sure the connection is established and you can see a picture of the connected device.
- Select File->Patient Database (page 11) Here you can select the Patient, create the new one, review Patient's treatment history.
- 4. Double-click the Patient name to start the Session. Select the appropriate session (pages 12-26). After the session is finished the results will be saved to the database.

Available Protocol Sessions:

- **Open Display** Use only for EMG. This protocol could be used as a tool for a quick look into the pathology condition. Also useful for relaxation visualisation (page 12-13).
- **Device Controlled** (which means your device has all the controls over the session, the PC simply displays and stores the data). Use with any programme. The main use is for ETS graphical display. Also very useful for storing any running programme data and statistics on PC (pages 14-15).
- **Template Training** Use only for EMG. Use your mouse to draw a line on the PC screen and follow the line with your EMG (pages 17-18).
- **Work/Rest Training** Use only for EMG. This is for the Patient's home or clinical exercises of contraction and relaxation (pages 19-22).
- Work/Rest Assessment Use only for EMG. This protocol allows checking the muscle performance on a regular basis and compare the progress the Patient is doing over longer periods of time. (pages 19-22).
 For example: do the Assessment once every week, then after two month, create a Progress Report from the stored eight Work/Rest Assessment sessions. (page 23).
- 5. **Review the graph and statistics of the sessions** created in point 4 (page 29).
- 6. **Download the Home Compliance** from your device and review the statistics of Patient's home use (pages 29-30). The Clinician LOCKs the device with the selected programme, the Patient will use the device at home, and these statistics are being saved on a daily basis. The Software can download and review the Patient Home Compliance stored and sent from your device. Please check in your device manual if your device model supports Home Compliance download to the Software.



Patient database

\sim		^{iames Set} nt Dat	up Language Help						
Search PatID 0~	patient Surname	First name Bob		Session 1 2	Date 05/09/2012 05/09/2012		Protocol Open Display Open Display	Condition Incontinence Incontinence	View (0)
0~ 1 2	Example Cornflake Oxfarm			3 4 5 6	07/09/2012 07/09/2012 07/09/2012 07/09/2012	15:09 15:14	Device Controlled EMG Work / Rest Assessment Work / Rest Assessment Work / Rest Assessment		There is an option to
				7 8 9	07/09/2012 07/09/2012 07/09/2012 07/09/2012	15:26 15:29	Work / Rest Assessment	Incontinence Incontinence	View (0) View (0) View (0)
				11	12/09/2012	15:08	Device Controlled EMG	Incontinence	session.
	fidential nt Option :		Default Patient	Sessio	n Options				You can associate th
	View / Edit		View Device Report		eview	Create	Progress report (Assessme	nt)	files like the picture of limb, e-mail from
	Add Delete		Download Home Report View Home Report	Delete	e Session		Deselect all sessions		the Patient etc., with
									the session record.

Figure 6: Patient Database

The Patient Database stores the Patient records with the sessions history. The list of names on the left side represents the Patient names. On the right column of the database there is the list of finished sessions of the selected patient. The Default Patient (highlighted as bold) is the Patient whose details will be loaded automatically after the user loads the Software again.

One Patient should be selected as a default Patient (tick below the patients list), this patient will be selected automatically any time you run the software. The default patient **name** is highlighted with bold font on the list of the patients.

Select another patient if needed, before proceeding to the protocol. You can also decide later for whom you wish to save the record: when you see the statistics and the graph, use the drop-down menu to select under which name you wish to save this session.

The database allows to **Add/Edit or Delete** the Patient records (name, surname, date of birth etc.)

The Software operator can select the Patient and **Review the Session** by double-clicking the session record or selecting the session from the right column of the database and click the Review button.



Open display

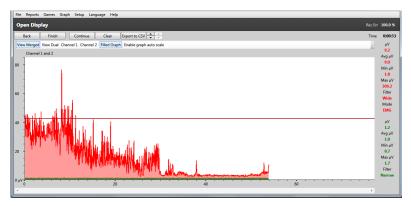


Figure 7: Open Display - relaxation test.

Applications and Protocols:

The Open Display is a basic Software function to start with. In general practice it is good to use this protocol when you need to assess a Patient for the first time. For experienced EMG practitioner this protocol is very helpful to identify a level of muscular and neurological activity, relaxation ability and the range of motion.

General suggestions when examining the EMG graph:

- The muscles in good shape will contract immediately and reach higher EMG volumes (above 100 μV for biceps, 40 μV for pelvic floor).
- A good first examination is to contract and relax rapidly, five times (see figure 8). Here the most important is to observe timings and amplitude performance.
- The relaxation examination may be performed by 3 sec of contraction, followed by relaxation. The relaxation period should be observed, how quick and how low one can relax, how steady the relaxation is.
- The muscle in good shape will keep the high level of EMG during 5 sec of constant contraction and then will relax immediately. A weak or overtrained (overstimulated) muscle will relax slowly.
- When zooming in and looking on a period of 2-5 seconds of graph, the major spikes on the graph represents the number of motoneurons being recruited. More means better enervation and muscular control.



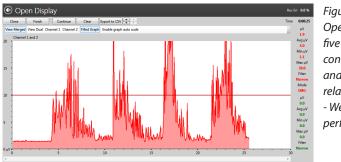


Figure 8a: Open Display: five rapid contractions and relaxations - Weak performance

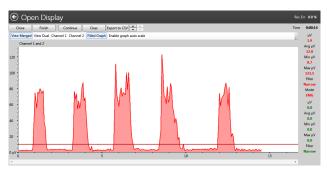


Figure 8b: Open Display: five rapid contractions and relaxations - Strong performance (sharp edges, low steady relaxations, higher amplitude).

Open Display Protocol - Quick Start:

- 1. Get the device ready: Make sure your device is in EMG mode, don't press START button on the device. There is only one operation your device is doing: sending the EMG data to the Software. All the available controls you can find on the software display.
- 2. Select Open Display: Press Open Display button from the Protocol selection menu (figure 5).
- **3. Complete Open Display Session:** Start an Open Display session by pressing the Start button (figure 7) on the upper left corner of the Software screen (not on the device!).
- 4. Save Open Display Session: Press Stop and the statistics will be displayed. Read how to analyse the Statistics on pages 28-34). After pressing the Save button on the Statistics screen (figure 8) the session will be saved for the currently selected Patient. You can review the statistics and the graph later (select the Patient and double-click the session record).



Device Controlled

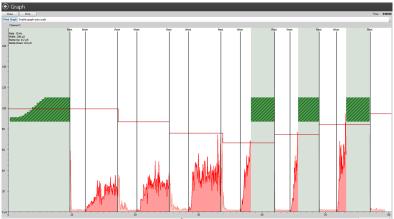


Figure 9: Device Controlled - for monitoring the ETS and EMG between STIM work periods.

Applications and Protocols:

The Device Controlled session is advised to be used with any programmes controlled by the device. The name "Device Controlled" means the session is fully controlled by the keypad of the unit, not the buttons of the PC Software.

The main use is for ETS graphical display. The Device Controlled protocol is also useful for storing any running programme data and statistics on PC: Select the desired programme on your device, connect to PC and press the Device controlled. Start the session on the device, control it on the device. All the data will be displayed as a graph on PC. After the session on your device os finished, the statistics will be sent and you can store the whole information, both the graph and the statistics on PC.

The color PC screen allows a much clear visualsation of the EMG or ETS performance, threshold volume, Work/Rest prompts which gives much more advanced graphical experience than watching a small device display. When the patient observes their EMG reaching the threshold, it influences better Patient muscle response. As a graphical tool it encourages the Patient to work longer and consistently to reach higher target thresholds faster. Make sure the relaxation is sufficient during the rest time, a good relaxation is below 4uV after every stimulation, a relaxation below 1 uV shows the excellent neuromuscular control.



EMG between stimulation: some models of stimulators with EMG functionality shows the biofeedback in between the stimulation periods.

By analysing the EMG between STIM periods the Software Operator monitors the muscle response to stimulation. The warmed up and not overstimulated muscle will relax faster! This functionality uncovers a number of processes which occur in the muscles just after stimulation.

Device controlled protocol - Quick Start

1. Get the device ready: As the Protocol name suggests, the PC Software here is controlled by the device and the main purpose of this Protocol is to visualise ETS and record the device sessions. This means that the software works only as a monitor of the device session and it creates a record of the statistics calculated by the EMG device. In contrast, all other protocols just using the EMG data stream only from the unit and organise the session by the Software. Also no other protocol stores the statistics calculated by the unit.

This Protocol if fully controlled by the keypad of the device and no start/ stop/changing threshold etc. is allowed on the PC Software, for any controls please use the device keypad.

- 2. Select Device Controlled: Press Device Controlled button from the Protocol selection menu (figure 5).
- 3. Complete the Device Controlled Session: Please press the START button on the device and complete the session which you want to monitor and/or store on PC. When the statistics are displayed, you can press Save button to save the session record: the session graph and statistics. Make sure you save it for the desired person on your Patient's Database. The name is displayed on top of the screen, you can select another name before you press Save button.

If you need to brake the session on the PC Software, press Close button, in this case you will not be able to save the beginning of the session and this data will be lost. The session must be ended completely and the statistics must be sent to PC in order to save this session. After the Save button is pressed, please press ESC on the device to exit from statistics. (while the statistics are being sent, the PC Software functionality is limited).



Device Report

Any Device Controlled session recorded to the database is automatically added to the device report. This provides a unique way of storing and comparing the session results. This function is developing and the further Software versions will reveal all the potential of this functionality.



Template Training

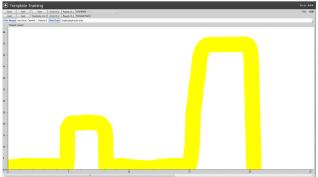


Figure 12a: Draw the template

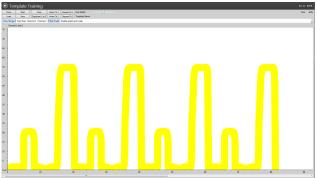


Figure 12b: Repeat (Ch A) the template

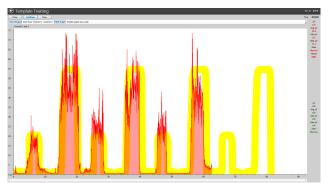


Figure 12c: The repeated template creates a pattern on your screen. This pattern can be used as a guideline for voluntary exercise. Either stay inside the pattern line or use it as threshold which outlines the relaxation and contraction border.



Applications and Protocols:

The Template Training session is advised to be used for a wide range of EMG training including Incontinence treatment and General Muscle Improvement. The idea of Template Training is to follow the guidance line (Figure 12) by the Patient's EMG graph: the Software Operator draws the line on the PC Screen and the Patient tries to keep his/her EMG within the line. The Template line can be saved (Save button on figure 12a).

Template protocol - Quick Start

- 1. Get the device ready: Make sure your device is in EMG mode, don't press START button on the device. There is only one operation your device is doing: sending the EMG data to the Software. All the available controls you can find on the software display.
- 2. Select Template Training: Press Template Training button from the Protocol selection menu (figure 5).
- 3. Complete Template Training session:
 - Draw the Template (use the PC mouse, left click and drag the mouse to draw the line on the screen) or Open the saved Template (Load button). A template, is a unique line over a certain time period like one cycle of sinusoid. You can add cycles and this way repeat the pattern (figure 12b).
 - Press Repeat Ch A button to repeat the Template.
 - Use the slide bar to thicken or thin out the template line. A thinner template is for more experienced Patients with better muscle performance. You can use thin line if you mean to use it as a demarcation line between the area of suggested contraction and area of suggested relaxation.
 - Press Start button 2 times on the upper left corner of the Software screen (not on the device!). Follow the line with your EMG (figure 12c).
- 4. Save the Template Training session: Press Stop on Template screen and the statistics will be displayed. Read how to analyse the statistics on pages 28-34.



Work/Rest Training and Assessment

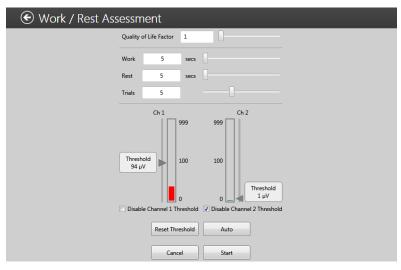


Figure 15: Work/Rest Assessment- Settings

Applications and Protocols:

Work/Rest Training is advised to be used for the Patient's daily training. First, the Patient exercises using the Work/Rest Training session themselves, then periodically the Clinician checks the Patient progress using the Work/ Rest Assessment session.

Work/Rest Training

For Training purposes, the Patient can Install the Software on home PC and exercise any time. The aim of the exercise is to follow the Work/Rest prompts displayed on the PC Software screen. The Patient must practice and contract a group of muscles as quick as he can just after the Work Prompt. During Work period - keep the high level of EMG until the Rest prompt and relax to the EMG level below $4\mu V$ as fast as possible after the Rest prompt.



Work/Rest Assessment

Work/rest Assessment is advised to be used as a periodic monitoring and a record of progress. For example, the progress of neuro-muscular rehabilitation of any kind could be evaluated by using a Work/Rest Assessment protocol performed once per week or as often as needed. Sometimes just the initial and final assessment is required.

Work/Rest Assessment works in the same way as Work/Rest Training protocol, but the Progress Report can be produced from the saved W/R Assessment sessions. Once the Assessment is finished, you can go to the Patient Database select this and any previously saved Assessment sessions by clicking the check-boxes. Using the top menu, select Reports->Progress report->Create Progress Report (pages 23-26).

How Work/Rest works:

A measure of strength, speed of contraction, stability of contraction and relaxation is made during a sequence of Work/Rest repetitions (trials). Normally 5 trials of 5 seconds work and 5 seconds of rest are used. The Patient places the electrodes on the surface of the skin over the appropriate muscle(s) or uses the Vaginal/Rectal electrode probe. Afterwards, the Patient is asked to relax and then to contract the muscle(s) to the highest level that they can comfortably repeat and hold five times following the audio prompts of "Work" and "Rest" with as little delay as possible each time. 5 repetitions are used, which will be sufficient to provide statistically significant data yet not tiring to the patient, or the last repetitions would then tend to reflect growing fatigue.

Thus the patient repetitively contracts as quickly as they can to a level that they subjectively consider to be maximal. Relaxation is very important: The muscle is relaxed when the blood can flow through the relaxed muscles, delivering the oxygen to the cells and taking out the side-products of muscle metabolism. If the muscle group cannot relax properly, the chronical muscle pain will occur.

The muscle is relaxed when the EMG is below $4\mu V$.

By carrying out the Work/Rest Assessment during the first patient visit and every one or two weeks thereafter, it is possible to track the progress of rehabilitation of the muscle or muscles, and help ensure that the training programme is effective.



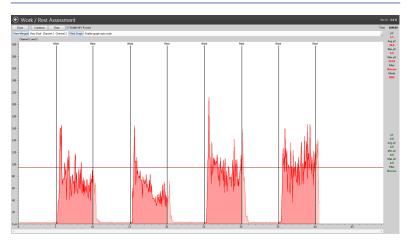


Figure 16: Work/Rest Assessment- Session

Work/Rest Assessment - Quick Start

- 1. Get the device ready: Make sure your device is in EMG mode, don't press START button on the device. There is only one operation your device is doing: sending the EMG data to the Software. All the available controls you can find on the software display.
- 2. Select W/R Assessment [Training]: Press W/R Assessment [Training] button from the Protocol selection menu (figure 5). The Settings menu will appear (figure 15).
- 3. Complete W/R Assessment [Training] Session: In the Settings menu (figure 15) the Work time, Rest time and number of Trials [only W/R Training] can be adjusted. Press <u>Start to go to the graph</u>, figure 16. Before proceeding to the actual training or assessment, make sure you've relaxed and your EMG reading in the top right of the screen is below 4uV. Without a proper relaxation the Work/Rest protocol is meaningless. When ready to do the contractions, press Start button on the top of the screen. Follow on-screen prompts, when the Work line appear - contract the muscle as high and as steady as you can, when rest line appear, relax as quick as possible to the lowest reading and keep it low during the whole rest period.



4. Save W/R Assessment [Training] Session: Finish all the Trials (repetitions) of Work/Rest and the statistics will be displayed. Read how to analyse the Statistics on page 29 - 33). Remember to fill in the Quality of Life field for W/R assessment session. The Quality of Life is determined by the Therapist's opinion of the Patient's condition. A number between 0 and 100 needs to be entered, 0 being extremely low, 100 being optimal.

After pressing the Save button on the Statistics screen (figure 17) the session will be saved for the currently selected Patient. You can review the statistics and the graph later (select the Patient and double-click the session record).



Progress Report

The Progress report is made from the saved W/R Assessment sessions.

	patient		Session	Date	Time	Protocol	Condition	Attachments	
			1	05/09/2012	17:23	Open Display	Incontinence	View (0)	
PatID	Surname	First name	2	05/09/2012	17:26	Open Display	Incontinence	View (0)	
)~	Example	Bob	3	07/09/2012		Device Controlled EMG	Incontinence	View (0)	
	Cornflake	Alice	4	07/09/2012	15:09	Work / Rest Assessment	Incontinence	View (0)	
2	Oxfarm	Jenny	5	07/09/2012	15:14	Work / Rest Assessment	Incontinence	View (0)	
			6	07/09/2012	15:15	Work / Rest Assessment	Incontinence	View (0)	
			7	07/09/2012	15:24	Work / Rest Assessment	Incontinence	View (0)	
			8	07/09/2012	15:26	Work / Rest Assessment	Incontinence	View (0)	
			V 9	07/09/2012	15:29	Work / Rest Assessment	Incontinence	View (0)	
			1 0	07/09/2012	15:30	Work / Rest Assessment	Incontinence	View (0)	
			11	12/09/2012	15:08	Device Controlled EMG	Incontinence	View (0)	
	fidential 1t Option :	☑ Default Patient	Session	n Options		4			
	View / Edit	View Device Report	Re	view	Create	Progress report (Assessme	nt)		
									Start Protoco
	Add	Download Home Report	Delete	Session					

Figure 18: Creating the Progress Report

- Create the Progress Report: First you need to create at least two W/R Assessment sessions (pages 20-21). Go to the Patient Database and select the Patient (single click his name). Select the sessions named "Work/ rest assessment" by ticking the check box in front of each session. After you've selected one or more session, the new "Create Progress Report" button appears under the list of sessions, press it and the report will be displayed (Figure 18).
- 2. Review and save the Progress Report: The First screen of the report will appear (figure 19a). This is the most important page, showing the graph comparison where many physiological trends can be identified throughout the observed time. The Progress report consists of four TABs representing different aspects of stored data (figure 19a-d). The Progress Report can be saved to the Software Database, flash memory, or can be e-mailed, which provides a great flexibility to collect or share the results of the treatment.
- 3. Open and Review the saved Progress Report: Go to the Patient Database and select from the Top menu: Reports->Progress reports ->Saved Progress Reports, select the Patient Name and the saved Report number then press the Display button.



Progress Report Figures

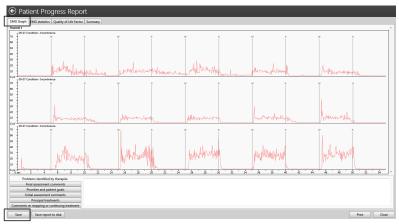


Figure 19a: Progress Report ->TAB1->Graph comparison

Please have look on Figure 19a. On this TAB all the graphs are displayed on the same time scale. Many positive trends [such as increase amplitude and stability of the contraction] as well as negative trends [such as progressing muscular instability] can be identified. By comparing the beginning of the treatment with the final neurological or muscular performance the Therapist has an additional dimension of progress proof ¹.

After you've reviewed the Progress report, please press the Save button if you want to save the progress report record. At any time in the future you may re-create the very same report as long as the Assessment sessions are in the database and not deleted.

¹ Please Note! You cannot base your Assessment only on one or all of the TABs of the Progress Report.

Whether there was a significant progress or not, the therapist cannot decide based only on tools provided. The software aims to store the records, the recorded results are based on the data which might not represent the real state of the rehabilitation progress due to variety software unrelated reasons including incorrect subject behaviour during the recordings, high electromagnetic interference on one of the session, etc. Please take into consideration all of the TABs plus the real examination of anatomical effect of a treatment, whether the limb has a proper movement, whether the patient became more continent. A proper questionnaire should be filled in in TAB4, a Quality of Life value should be properly evaluated on TAB3 by the Therapist.



~	Reports Games Setup Language Help			
€	Patient Progress Report			
EMG	Graph EMG statistics Quality of Life Factor Summary			
\square		137.3 µV	137.3	
		0 µV	1.5	
		33.1 µV 0 µV	A 33.1	
statistic		33.1 µV	0.7	
EMG.1 Statistics		0.5 µV	0.4	
		0 µV	N 0.4	
		271.1 µV	271.1	
		0 µV	0.8	
		1 2 3 4 5 6 7 Session		
	Problems identified by therapist.			
	Final assessment comments			
	Priorities and patient goals			
	Initial assessment comments			
Con	Principal treatments nments re: stopping or continuing treatment			
S	ave Save report to disk			Print Close

Figure 19b: Progress Report -> TAB2 -> EMG Statistics :

On Figure 19b, the statistics are presented on a time scale as a progress chart. This visual tool allows an easier comparison of the gathered statistical values to identify progress or lack of it.

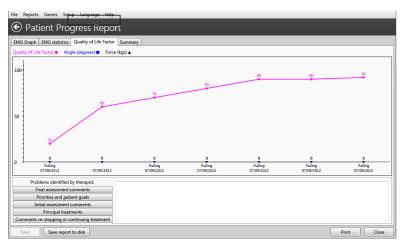


Figure 19c: Progress Report -> TAB3 ->Quality of Life Factor :

On Figure 19c an optional yet quite useful record is presented, based on the custom questionnaire: the Therapist asks questions regarding the actual health and life situation and based on the answer therapist records the value in that range of 1 (poor quality of life) to 100 (excellent quality of life).

File Reports Games Setup La	nguage Help					
• Patient Progres	s Report					
EMG Graph EMG statistics Qualit	y of Life Factor Summary					
Jenny Oxfarm PatID 2 NHS No Hospital No D of B		A	lex Therapist ID			
Dr / Consultant referral date	07/09/2012		Number of assessm	ients 7		
Initial treatment date	07/09/2012		Report date	07/09/2012		
Initial assessment date	07/09/2012		Condition	Incontinence		
Final assessment date	07/09/2012					
Referring doctor / consultant name		•	Address			
Telephone number						
Problems identified by therapist.		Init	tial assessment comments			
Too tens by the Beginning Significal Improvement after third v	veek.	To	tens by the Beginning			
Final assessment comments		Pri	ncipal treatments			
Significal Improvement after third v 90% of recovery after sixth week	veek.					
Priorities and patient goals		Co	mments re: stopping or cor	ntinuing treatment		
n/a		Th	ne maintenance NMS progra	ammes as a follow up		
Save Save report to disk]				Print	Close

Figure 19d: Progress Report -> TAB4 ->summary : Here all the text comments could be typed and then saved.

Learning Process

With the structured protocols of work / rest and trials [repetitions] which one must follow to produce a progress report, it may be possible by exchanging information with other clinicians, to quantify what are the normal and abnormal parameters for muscle characteristics. The EMG domain is a well known yet many aspects of muscular and neurological response are still uncovered or unpublished. It is a well known fact that the learning process of EMG interpretation is a long term learning curve when your knowledge becomes more useful, complete, comprehensive in time where you do EMG records and asking your more experienced colleagues for help in interpretation. You will be amazed how quickly you can learn to see what was invisible without EMG.

The EMG tools for Physiotherapists are like a GPS system for a ship or an airplane! Your Biofeedback experience is what will make you stand out from the crowd when it's time to examine the patient. Just the first 5-10 seconds of Open display of EMG and you can immediately tell "where you are" with this case. EMG is offering you a fundamental advantage when you are about to assess progress, current status, or suggest the rehabilitation.

This software is an excellent display and recording tool for your own assessments and daily practice, but it cannot substitute You - the Professional - in all the assessments and any decision making.



Home Compliance Download

Please NOTE! The home Compliance is available to be downloaded only from the devices where this option is available, please refer to the device operator's manual.

Download procedure

Use the device at home. Make sure the device records the statistics on a daily basis. Once the unit is connected and sending the statistics to the to PC Software, make sure you've recorded them before disconnecting or erasing the statistics on your device:

File	Reports	Games	Graph	Setup	Language	Help	
	Patient Da	tabase		ctio	2		
	Start Proto	ocol		CLIO	•		
	Exit				Patient	Name	Jenny Oxfarm
Sess	ion Numb	er 11			Conditi	ion	Incontinence •

Figure 20a: Select the Patient Database

File	Reports G	ames Grapi	h Setup	Language	Help					
€	Patier	nt Data	abase	9						
Search	n patient				Session		Time	Protocol		Condition
PatID	Surname	First name			1	05/09/2012		Open Display		Incontinence
0~					2	05/09/2012		Open Display		Incontinence
-	Example Cornflake	Bob Alice			3	07/09/2012		Device Controlled EM	-	Incontinence
1	Oxfarm		C		4	07/09/2012	15:09	Work / Rest Assessme	ent	
2	Oxrarm	Jenny	~~	Download Hor	me Report		-		nt	Incontinence
									nt	Incontinence
				The P	atient Hon	ne Compliance	e is Dow	nloading	nt	Incontinence
									nt	Incontinence
									nt	Incontinence
						1			nt	Incontinence
						-			L	
				1		Cancel				
Cor	fidential	V (Default Pa	lient	D	ownload Hom	ie Repo	rt		x
Patier	View / Edit		_/	vice Report	Sess	() The	e Patien	V t Home Compliance ha	IS SI	uccessfully downloaded!
	Add Delete			Home Report	De					ОК

Figure 20b: Press Download Home Report button. Press OK, then please make sure you see the report in the database, afterwards you may decide if to erase or keep the statistics on the device memory.



Review Home Compliance

Select the Patient and press View Home Report

In the Patient database select the Patient with the saved Home compliance. The picture below shows the Daily Home Compliance Report:

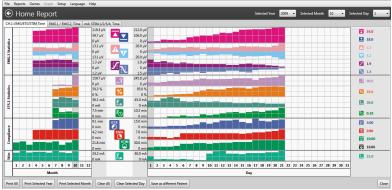


Figure 21: Daily Home Compliance

Analyse/Print off the Home Compliance

The Home Compliance downloaded statistics are organized on the Daily Report (the picture above). Select the year from the upper left corner - the Average statistics of the year will be displayed on the left. Each column on the left represents one month (averages of all days of the month). Select the month and review the statistics day by day on the middle part of the display. Select the day and review the statistics values on the right side of the display.

Please note! The device sends only the statistics and no graph data, when connected for Home compliance download. Because of this there is no option to see graph on a Home Compliance Report.



Session and Statistics review

Session review:

To review any stored session, please open the Patient's database, select the patient and the recorded sessions will be displayed on the right column. Doubleclick the session to see the graph and statistics.

Understanding the statistics:

The statistics summarise the protocol and are very helpful for treatment results analysis. When the same statistical result (e.g. Work Average) is compared in time, you can see the important trends and developments (if the Work Average is rising in time, the overall muscular power and muscle control are progressing well).

There are many ways you can get the statistical results of your treatment, below are the most practical:

Statistics from the device LCD:

When you use the device without PC Software, the device displays the statistics on its portable screen after the session is finished. You can keep noting the statistics in an excel file or on a peace of paper, or use one of the automated PC Software methods below.

Device controlled:

When you use the device with the PC Software, the PC Software displays the graph of the session, and by the end of the session the statistics are sent to PC Software for a record (page 14 - 15).

You can revise the recorded statistics in two ways: by selecting the session from the Patient's Database, or by selecting from the top menu: Reports->Device report (page 16).

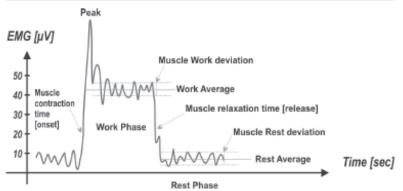
Progress Report:

This functionality is one of the most useful. You can record the Work/Rest session and then select some of them to create the Progress report (page 19 - 26). The device will not display the session, it will only send the EMG data to PC Software.

Home Report:

The user can download the daily statistics to the PC Database (page 27) and review the statistics stored by the unit when the unit was locked.





EMG Statistics



Work Average $[\mu V]$ - the overall average microvolts achieved during the all work periods of the session.

Generally the higher the Work average is, the better the muscle performance.

<u>Home Compliance</u>: the good progress is when Work average is getting higher and higher each day.



Rest Average [µV] - the overall average microvolts during all rest periods of the session.

Generally the lower the Rest average is, the better the muscle performance. It is very important how low you can relax your muscles in terms of microvolts. Below 4µV a muscle is beginning to rest. If the Rest average is above 4µV make sure you use the EMG reference lead wire! The reading above 4µV commonly means the muscle is overstimulated or tired after a longer EMG training session.

<u>Home Compliance</u>: a good progress is when the Rest average is getting lower and lower each day.



Onset Average [sec] - This is the average time taken in seconds to achieve 75% of the work average of all work segments, any values over 2 seconds are ignored.

Generally this parameter measures how fast you can contract a muscle, the shorter the Onset average time is, the better the muscle performance. Reading below 1 second can be considered normal. The time it takes to contract a muscle gives an indication on the recruitment of the fast twitch fibres. If the onset time was slow, the recruitment percentage of the fast twitch fibres would be less than if the onset time was faster.

Home Compliance: the good progress is when Onset average time is getting shorter and shorter each day.





Release Average [sec] - This is the average time taken in seconds to relax below 37.5% of the work average of all work segments, any values over 2 seconds are ignored.

Generally this parameter measures how fast you can relax a muscle, the shorter the Release average time is, the better the muscle performance.

Healthy muscle normally reverts back to a low resting EMG value in less than one second. If the muscle takes longer to revert back to rest then there will be a reason, such as muscle or nerve damage or some other underlying problem.

<u>Home Compliance:</u> the good progress is when Release average time getting shorter and shorter each day.



Work Average deviation [μ V, %] - The average deviation in microvolts of the work periods of the session, it excludes the first second of each work portion.

Generally the deviation means the average differences between EMG readings.

If a muscle shakes and contracts spasmodically, the EMG graph is sharp and wavy (high EMG deviation). If the muscle is not tired and in good shape, it doesn't tremble and stays firm in contraction, the EMG graph will be smother (low EMG deviation).

Work Deviation % = $\frac{\text{Work average deviation } [\mu V] \times 100 \%}{\text{Work Average } [\mu V]}$

If the deviation in the work phase were more than 20% then it would be considered that the muscle is becoming unstable. Home Compliance: the good progress is when Work Deviation % value is getting smaller and smaller each day.



Rest Average deviation $[\mu V, \%]$ - The average deviation in microvolts of the rest periods of the session, it excludes the first second of each rest portion.

Generally the high Rest average deviation means overstimulated or overtrained muscle or the body has difficulties in controlling the muscle because of the damage of the motor neurons.

Rest Deviation % = $\frac{\text{Rest average deviation } [\mu V] \times 100 \%}{\text{Rest Average } [\mu V]}$

This percentage is called the coefficient of variability. Deviations of over 20% normally indicate lack of muscle control and stability. <u>Home Compliance:</u> the good progress is when Rest Deviation % value is getting smaller and smaller each day.





Average peak/minimum value $[\mu V]$ - This is the maximal/minimal muscle contraction over the session. This information is less important for the overall analysis.

ETS Statistics

ETS Target [µV] - the average Target threshold used during ETS phase. The ETS Target is defined by EMG threshold, which the Patient needs to achive by voluntary muscle contraction to trigger EMG to STIM. Generally the higher the Target is, the better the muscle performance. When analysing the Target progress, compare the reading with the ETS Score for the same day. Normally, the higher the Target, the smaller the Score is. <u>Home Compliance:</u> the good progress is when the Target is getting higher and higher each day.

ETS Score [%] - how successful the Patient was reaching the threshold. If on average the Patient reached threshold immediately after Work prompt - the score is high (60-90%). If the Patient has difficulties reaching the target and it takes them several seconds to trigger from EMG to Stimulation, their ETS Score will be low (10-50%)

Home Compliance: the good progress is when Score is getting higher and higher each day.

ETS Target setting will influence the ETS Score result, for example for lower Targets it will be higher scores, if the Target threshold is variable (not stable) during the treatment, the Score result should be ignored. If you want to concentrate purely on ETS Score statistics - make the Target threshold same for the period of time you do the experiment.

Please consider one of the ETS treatment:

1. Set MANUAL (ETS target) Threshold on MyoPlus, don't change threshold during the whole time of home treatment. On the Home Compliance Report the Target Threshold result should be the same or almost the same for all days. After Home Compliance Download (page 27) - analyse the ETS Score (ignore ETS Target threshold).

2. Set AUTO (ETS target) Threshold on MyoPlus, the threshold will be adjusted automatically by the device, the better the muscle performance, the higher threshold will be set automatically by MyoPlus. After Home Compliance Download (page 27) - analyse the ETS Target Threshold (ignore ETS Score).



ETS Stim mA [mA] - This is the average stimulation level used during ETS sessions.

<u>Home Compliance:</u> You need to consider the Patient's situation to be able to judge the ETS Stim mA properly. For some Incontinence, Stroke and similar rehabilitation the Patient normally feels lack of Pain due to the damaged sensory neurons for higher mA. In this situation the progress will be considered when mA level was lower and lower due to the sensation ability improvements.

For the muscle growth, reeducation or improvement treatment, the higher mA used the better achievements were.

ETS Stim Time [mm:ss] - total time of Stimulation during ETS. Compare this time with the ETS overall Time and you will have an idea whether the EMG or STIM was used more often during the ETS sessions.

Home Compliance: These statistics are supplementary and the analysis depends on the Clinician's point of view which depends on the way the ETS treatment was performed. In some cases the ETS treatment is used to encourage reaching the threshold by voluntary contractions and the Stimulation helps to keep the muscle contracted. Sometimes ETS is used to help voluntary contractions when a Patient tries to contract muscles during the stimulation.

Time Compliance

When MyoPlus is LOCKed, it stores the session statistics and time compliance on a daily basis. Time compliance means how long (minutes, seconds) the EMG or STIM or ETS was used by the patient during the day.

EMG Time [mm:ss] - In the Home compliance report this is the total accumulated EMG time for all EMG phases of the selected day/month.

ETS Time [mm:ss] - In the Home compliance report this is the total accumulated ETS time for all ETS phases of the selected day/month.

STIM Time [mm] - In the Home compliance report this is the total accumulated STIM time for all STIM phases of the selected day/month.

STIM mA [mA] - This is the average stimulation level used during STIM sessions of the selected day/month.



Useful functions and maintenance

Additional Observations Record

The PC Software allows the Software Operator to collect additional observations which could be recorded after each Software Sessions:

Quality of life factor: This is a subjective value determined by the Therapist based on the Patient's condition and Patient's self-evaluation during the session. The quality of life factor depends strictly on the medical related problems.

As the treatment takes effect the quality of life factor progress report should show a positive trend upwards.

Angle: This records the maximum angle or movement that can be obtained by the affected / damaged limb undergoing rehabilitation. The angle is measured by the Clinician using other specially designed equipment, we do not manufacture or supply this equipment.

Note: The angle has no meaning for Incontinence protocols.

Force: This records the maximum force in Kilograms that can be obtained by the affected / damaged limb undergoing rehabilitation. The force is measured by the Therapist / Consultant using other specially designed equipment, Verity Medical does not manufacture or supply this equipment.

Language: Our Software is translated to more than 10 languages, to set your language, select from the top menu: ->Language

Graph menu: You can set up the color of the EMG and STIM graph, the default horizontal and vertical EMG scale and many other options. From the Top menu select: Setup->Programme Setup->Graph Setup.

Connection to the Device: If you think the connection to the device was lost please review page 9.

Uninstall: If at any point you wish to uninstall the Software, please follow the process outlined below:

Go to the Windows Start menu on your desktop, select Settings, then Control Panel, then Add/Remove Programs. Select your software installation and press the Uninstall button.



Markers: For any additional comments or EMG data analysis, the markers could be placed on the stored graph. Finish the session, then select on the top of the graph: Add Marker.

The Markers are very useful to highlight the artefacts which should be explained; to save the part of the graph as a Template for the Template Training; to calculate the most useful parameters of a selected area.

Backup: The Software consists of the Executable elements and the Database. If the executable needs to be re-installed, simply re-install the software from the Installation media. This will not damage any stored or personal information.

The Database keeps all the personal data like login, password, registration, patient's database and all the records. You can easily backup or restore the database:

To Backup, select from the top menu: Setup->Backup->Backup data. The programme will create the ZIP file of the database backup, you will have a choice where to store your backup. It is a very practical approach to backup on your memory stick at least every month.

To Restore, select from the top menu: Setup->Backup->restore from Backup data. The programme prompts you to select the ZIP file from which you want your database to be restored.

WARNING! When you restore, you overwrite your current database with the previously saved database. All new records of your current database will be lost and the old records from the backup will be loaded.

File F	Reports G	ames Graph	Setu	p Language	Help					
	Datio	nt Datak		Backup		•	Ba	ackup da	ta	
	Patier	ii Dalal		Programme S	etup	•				
Search	patient			User Options		•	R	estore fro	om Backup	Condition
	_			Referrer Detai	ls		9/2012	2 17:23	Open Display	Incontinence
PatID	Surname	First name		Pain Types			9/2012	2 17:26	Open Display	Incontinence
0~	Example	Bob							Device Controlled EM	G Incontinence
1	Cornflake	Alice	Conc	Conditions			9/2012	2 15:09	Work / Rest Assessme	nt Incontinence
2	Oxfarm	Jenny		Templates	Templates		9/2012	2 15:14	Work / Rest Assessme	nt Incontinence
				Diagnostics			9/2012	2 15:15	Work / Rest Assessme	nt Incontinence
			_		7	07/	09/2012	2 15:24	Work / Rest Assessme	nt Incontinence
					8	07/	09/2012	2 15:26	Work / Rest Assessme	nt Incontinence
					9	07/	09/2012	2 15:29	Work / Rest Assessme	nt Incontinence
					10	07/	09/2012	2 15:30	Work / Rest Assessme	nt Incontinence

Figure 23: Backup and Restore from the backup.

Distributor:

PelviTec BV

Radex Innovation Centre Rotterdamseweg 183-C 2629 HD Delft, Nederland

Tel: 015 - 268 25 64 E-mail: info@pelvitec.com

Customer Service:

Please contact your distributor for any customer service enquiry. Your invoice of purchase and/or the rear cover of this manual (this page) should state the name and the contact details of your distributor.

Troubleshooting:

The PC software and hardware are constantly being updated and improved, therefore the information in this manual might not be up to date at the time of usage. Please use the link below to get the latest information: *www.pelvitec.emgsoft.info*

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