

See discussions, stats, and author profiles for this publication at: https://www.researchgate.net/publication/8125966

Popovic MR, Keller T. Modular transcutaneous functional electrical stimulation system. Med Eng Phys

ARTICLE in MEDICAL ENGINEERING & PHYSICS · FEBRUARY 2005

Impact Factor: 1.83 · DOI: 10.1016/j.medengphy.2004.08.016 · Source: PubMed

CITATIONS 64

reads 83

2 AUTHORS:



Milos R Popovic

University of Toronto

230 PUBLICATIONS 2,707 CITATIONS

SEE PROFILE



Thierry Keller Tecnalia 109 PUBLICATIONS 1,848 CITATIONS

SEE PROFILE

Modular Transcutaneous Functional Electrical
Stimulation System

Milos R. Popovic[†], PhD and Thierry Keller[‡], PhD

15	† Institute of Biomaterials and Biomedical Engineering, University of Toronto and
16	Toronto Rehabilitation Institute, Canada
17	

3 4 5 wiss i ederar institute of i termology Zurien and i aractite, 5 witzerian	8	‡ Swiss	Federal	Institute	of Tech	nology	Zurich	and]	ParaCare,	Switze	erland
---	---	---------	---------	-----------	---------	--------	--------	-------	-----------	--------	--------

18	‡ Swiss Federal Institute of Technology Zurich and ParaCare, Switz
19	
20	
21	
22	
23	
24	
25	Corresponding Author:
26	
27	Dr. Milos R. Popovic
28	Assistant Professor
29	Rehabilitation Engineering Laboratory
30	Institute of Biomaterials and Biomedical Engineering
31	University of Toronto
32	4 Taddle Creek Road, Room 407
33	Toronto, Ontario, M5S 3G9, Canada
34	Phone: +1-416-978-6676
35	Fax: +1-416-978-4317
36	E-mail: milos.popovic@utoronto.ca
37	http://www.utoronto.ca/IBBME/Faculty/Popovic_Milos/index.html
38	

2 Abstract

4	A new multipurpose programmable transcutaneous electric stimulator, Compex Motion,
5	was developed to allow users to design various custom-made neuroprostheses,
6	neurological assessment devices, muscle exercise systems, and experimental setups for
7	physiological studies. Compex Motion can generate any arbitrary stimulation sequence,
8	which can be controlled or regulated in real-time using any external sensor or laboratory
9	equipment. Compex Motion originated from the existing Compex 2 electric stimulator,
10	manufactured by a Swiss based company, Compex SA. The Compex Motion stimulator
11	represents a further evolution and expansion of the ETHZ-ParaCare functional electrical
12	stimulation system. This stimulator provides all the advanced FES application and control
13	features and can be easily incorporated into any standard rehabilitation program. Compex
14	Motion has successfully been applied as a neuroprosthesis for walking, reaching and
15	grasping in more than 100 stroke and spinal cord injured patients. This system has also
16	been used to strengthen muscles and to investigate muscle properties in able-bodied
17	subjects. Compex Motion is a multipurpose FES system specially designed to promote
18	sharing and exchanging of stimulation protocols, sensors, and user interfaces. To the best
19	of our knowledge an FES system that has similar capabilities does not exist yet.
20	

1 1. Introduction

2

3 For more than three decades, implanted and transcutaneous functional electrical 4 stimulation (FES) systems have been applied successfully to improve or restore body 5 functions such as grasping, standing and walking. [1-25] A detailed description of the 6 existing FES systems for walking and grasping can be found in [26]. The majority of 7 these devices were developed to provide only one treatment, or to restore a single body 8 function. If users wanted to use a FES system designed for grasping to carry out various 9 other tasks, such as walking, the user would be required to modify either the stimulator's 10 hardware or software, or both. Since such alterations were often impractical, many 11 researchers and practitioners in the FES field were forced to develop their own 12 stimulators. Consequently, numerous FES systems were developed, but only a few ever 13 reach wider rehabilitation communities or were ever used by more than a handful of 14 users. [26] This is especially evident in the case of programmable and sophisticated FES 15 systems. Thus, the majorities of sophisticated FES systems have been in a "prototype 16 phase of development" and can only be administered to patients if strong technical 17 support is ensured. As a result, successful FES programs only exist in those rehabilitation 18 centers that could afford to have significant technical support. Centers, which lacked such 19 support, often abandoned FES programs shortly after a period of experimentation with 20 this technology. Consequently, FES technology has had very limited impact on 21 rehabilitation programs; and strong FES programs were found in very few rehabilitation 22 centers worldwide.

1	Many researchers in the FES field currently believe that neuroprostheses should
2	be used primarily as prosthetic devices. In other words, they feel that patients should have
3	their own FES systems to be used at home in activities of daily living. Although this
4	approach does have its merit, especially in the case of patients with a complete spinal
5	cord injury (SCI), recent studies have indicated that a significant stroke and SCI
6	population could also benefit from FES when applied during early rehabilitation. [27-29,
7	35-37] In particular, it was found that patients, who were subjected to intensive FES
8	treatment post injury, recovered grasping or walking functions faster and better than
9	patients who did not receive any FES treatment. Both stroke and incomplete SCI patients
10	have disabilities that affect different body functions and very few patients have identical
11	disabilities, thus FES therapies need to be tailored to the patients' individual needs.
12	Furthermore, since patients often recover some body function as a result of FES therapy,
13	it is necessary to continuously adjust the FES therapy to reflect the evolving needs of the
14	patient. Since stroke and SCI patients often required individualized and custom-made
15	FES protocols, there is an obvious need for a surface FES system that is affordable,
16	flexible, reliable, portable, and programmable.
17	One of the main obstacles that hinders the technological advancements in the FES
18	field occurs as a result of the complex and time consuming validation and testing
19	procedures involved in this technology. Furthermore, any stimulation protocols
20	developed and tested in one rehabilitation centre cannot be easily transferred or shared
21	with other centers due to incompatibilities between FES systems. Also, protocols

22 developed by companies manufacturing FES systems are typically designed to provide

23 treatments to address problems in a large population of patients and are not aimed at

1	customizing the protocols for individual patients beyond obvious stimulation parameters'
2	adjustments. This lack of technology and stimulation protocol sharing in the field has
3	slowed down the development of new FES treatments and technologies. One way to
4	overcome this problem is to provide researchers with a standardized, programmable,
5	reliable, and flexible electric stimulator that can be applied to diverse FES applications.
6	In particular, we believe that a system that would promote sharing of successful
7	stimulation protocols, sensors, and accessories among the FES practitioners, would be
8	instrumental in accelerating technical developments in the field.
9	In this article, Compex Motion, a new electric stimulator is presented. The
10	Compex Motion stimulator represents a further evolution and expansion of the ETHZ-
11	ParaCare FES system [6]. We have been reporting on the progress of development,
12	particularly the clinical applications of the Compex Motion system, since 2001 [26,32,34-
13	40]. However, this is the first time that we are publishing an article that describes in detail
14	the relevant technical data pertaining to the system, its advanced control features and
15	interfaces, and systems-engineering approach used to develop the device. Furthermore, in
16	this article an insight into the process of designing a neuroprosthesis using Compex
17	Motion stimulator is provided for the first time. Two actual clinical examples are used to
18	explain the process of designing neuroprostheses using Compex Motion electric
19	stimulator.
20	The Compex Motion stimulator was developed for the Swiss based company
21	Compex SA. Approximately 80 units were manufactured and are currently used in

clinical trials. Until clinical trials are completed the serial production of the unit will notbe considered.

1 2. Compex Motion Stimulator

2

3

2.1 Concept

4

5 The Compex Motion stimulator was designed to serve as a hardware platform for 6 development of diverse FES systems that apply transcutaneous (surface) stimulation 7 technology (Figure 1). One of the main design requirements for this system is that it 8 could be easily programmed, thus users with limited FES experience could generate 9 useful stimulation protocols with this system. However, the stimulator is also able to 10 provide sophisticated stimulation protocols and control features commonly used in FES 11 research. Furthermore, this system was designed to allow FES practitioners to apply the 12 same device to a number of different patients requiring unique stimulation protocols, and 13 the ability to treat patients one after the other with virtually zero "transition" time 14 between treatments. To satisfy these needs, the stimulator is programmed with graphical 15 user interface (GUI) software, which is installed on a personal computer (PC). Users can 16 program the stimulation sequence using a PC and transfer the complete stimulation 17 protocol to the stimulator by means of a serial port connection. During the transfer, the 18 stimulation protocol is programmed on a chip-card which is inserted into the stimulator. 19 Once the transfer is completed, the chip-card will contain all the relevant information 20 required to execute the stimulation protocol such as the stimulation parameters, 21 stimulation sequence, sensor data needed to be interfaced by the stimulator, signal 22 processing that needs to be carried out with the input signals from the sensors, and 23 control strategies which need to be applied to regulate the stimulation sequences. By

1	simply exchanging the chip-card, the stimulator's function can be instantaneously
2	changed to provide a different function or FES treatment.
3	
4	{Figure 1 should be placed here}
5	
6	The main hardware and software features of Compex Motion stimulator include:
7	1) portability; 2) each unit has four stimulation channels, and any number of stimulators
8	can be combined to form a multiple unit with a greater number of stimulation channels
9	(8,12,16,); 3) the pulse amplitude, duration and frequency are independently
10	controlled and can be changed during the stimulation in real-time; 4) the stimulation
11	channels are galvanically separated; 5) the stimulator is powered by a rechargeable
12	battery, thus the total stimulation duration is limited only by the battery's capacity, which
13	is eight hours of continuous stimulation; and 6) the stimulator can be interfaced and
14	controlled with any external sensor, sensory system or laboratory equipment.
15	
16	
17	2.2 Hardware
18	
19	The Compex Motion electric stimulator is a microcontroller-based system with four
20	stimulation channels, two input channels A and B, and a special purpose port C. The
21	stimulation channels are current regulated and have 3 μ s rise time for pulses with 125 mA
22	amplitudes (pulse amplitude range 0-125 mA, resolution 1 mA; pulse width range 0-
23	16 ms, resolution 500 η s - long pulse widths such as 16 ms may be used to stimulate

1	denervated muscles; and stimulation frequency 1-100 Hz, resolution 1 Hz ¹). The input
2	channels A and B can be configured as analog or digital input channels (maximum
3	sampling frequency 8 kHz, voltage range 0-5 V and resolution 20 mV). The special
4	purpose port C is used to interconnect the stimulators, to serially communicate with a PC,
5	and to trigger the stimulator using a push button. By interconnecting stimulators via port
6	C, one can expand the number of stimulation channels from four to multiples of four
7	channels. In such a configuration, one stimulator is designated as a master stimulator
8	while all other stimulators are designated as slaves. The master stimulator paces the
9	stimulation of all connected stimulators and ensures that all stimulators are synchronized
10	and maintain the same "bus frequency" during the entire stimulation protocol. The
11	Compex Motion has a dot matrix LED display that provides a visual interface between
12	the user and the stimulator (Figure 2).
13	Two special-purpose sensory systems are currently available as accessories and
14	can be used to interface with the Compex Motion stimulator to develop a sophisticated
15	neuroprostheses: the Biofeedback Sensor model 2M4456, manufactured by Compex SA
16	[30], and the Gait Phase Detection System [31]. The Biofeedback Sensor, which is a
17	typical three-electrode surface EMG (eletromyography) sensor with a preamplifier
18	combined with the real-time signal processing routine that suppresses stimulation artifact,
19	is used to measure the voluntary EMG activity of a muscle while the muscle is being
20	electrically stimulated. In essence, this signal processing routine, which is imbedded in
21	the stimulator's microcontroller, generates a single below motor threshold stimulation

¹ If the user sets the pulse width to 15ms and the stimulation frequency to 100 Hz, the GUI software will automatically reduce the pulse width to an acceptable level as a safety feature. The GUI software would display and flag this change.

1	pulse prior to executing the stimulation protocol, and measures the artifact created by that
2	pulse. Later, when the EMG signal is measured during stimulation, the previously
3	measured artifact is subtracted from the measured EMG signal to obtain the voluntary
4	EMG activity without stimulation artifacts. This signal processing algorithm and the
5	results achieved with it are discussed in [32]. The Biofeedback Sensor and the EMG
6	signal processing algorithm imbedded in the Compex Motion microcontroller are suitable
7	for all neuroprosthesis applications involving EMG real-time control, and can be used to
8	trigger stimulation sequences generated by the Compex Motion or to regulate the
9	intensity of the stimulation in real-time. The Gait Phase Detection System is a highly
10	reliable and accurate sensor suitable for real-time control of a neuroprosthesis for
11	walking. This sensory system detects, in real-time, the following gait phases with an
12	overall detection reliability above 99 %: stance, heel-off, swing, and heel-strike. Detailed
13	description of the sensor and its performances is provided in [31].
14	
15	{Figure 2 should be placed here}
16	
17	
18	2.3 Software
19	
20	The Compex Motion software consists of two independent, but related software
21	packages. The first software package is a graphical user interface (GUI) developed with
22	LabView software and installed on a PC. The GUI is used to program stimulation
23	protocols, which are later downloaded via serial port connection (port C) to a

1	programmable chip-card inserted in the stimulator's "card read-and-write" module. The
2	second software package was developed using assembler for the Motorola HC11
3	microcontroller. This software package is imbedded in the microcontroller's external
4	memory and is used to execute stimulation sequences programmed on the chip-card. By
5	inserting a programmed chip-card, and by turning on the stimulator, the software written
6	in assembler reads the content of the chip-card and without a delay, executes the
7	stimulation protocol. Since the chip-card has a memory capacity of only 2048 bytes, the
8	complete stimulation protocol could not be directly programmed on the chip-card.
9	Instead, a coding system was developed such that the complete stimulation protocol,
10	sensory interfaces and signal processing routines are represented as a set of primitives
11	and parameters that are stored on the chip-card. The microcontroller's software reads the
12	content of the chip-card, reconstructs the stimulation protocol, and executes it in form of
13	a just-in-time interpreter.
14	
15	
16	2.3.1 Microcontroller's software
17	
18	The microcontroller's software was developed using the timer controlled multitasking
19	features of the Motorola HC11 microcontroller. This software was written using
20	assembler because of the limited memory space and computational power of the
21	microcontroller. The majority of the basic low level microcontroller subroutines such as
22	the serial port communication, stimulation pulse generation, and display driver routines,

23 were adopted from the previous generation of the same stimulator, the Compex 2 version.

11

1 Other, higher level routines, which are responsible for reconstruction of the stimulation

- 2 protocol from the chip-card memory content, data acquisition, data processing, and LED
- 3 display, were developed from scratch.
- 4 With the exception of the display routines and the serial communication routines,
- 5 all other subroutines were controlled using timers in real-time. Three different timers
- 6 were used to control execution time for every subroutine. The timer concept allowed the
- 7 stimulator to process multiple tasks in real-time using a single processor. Special care
- 8 was taken to ensure that all tasks were completed before time elapsed on the timer.
- 9 Hence, all subroutines were executed in a predefined time period. In Table 1, main

10 subroutines and corresponding timer frequencies are provided.

Routine	Timer frequency	Called every
battery scan	1 kHz	1 ms
watchdog		10 ms
control frequency		100 ms
slow A/D scan		10 ms
pulse sequence interpreter (timed mode)		100 ms
look-up table routine (timed mode)		10 ms
battery check		1000 ms
stimulation frequency	1-100 Hz	8-1000 ms
pulse sequence interpreter (pulse mode)		8-1000 ms
look-up table routine (pulse mode)		8-1000 ms
fast A/D scan	8 kHz	250 µs
EMG processing		100 ms

- 12
- 13 **Table 1:** Processing times and timer rates for various subroutines.
- 14

1 2.3.2 Graphical user interface software

2

3 The GUI software applies a "drag-and-drop" technique to program the stimulation 4 sequences. This is done by sequentially placing icons called primitives on a time line that 5 describes the chronology of the tasks that will be carried out by a single stimulation 6 channel (an example provided in Figure 3). There are four such time lines, and each time 7 line defines tasks that will be executed by a corresponding stimulation channel. 59 8 primitives describe tasks that can be carried out by the stimulator. These 59 primitives are 9 sorted out into the following main groups: pulse width primitives (12 primitives), pulse 10 amplitude primitives (6 primitives), pulse frequency primitives (6 primitives), sequence 11 control primitives (10 primitives), user interface primitives (17 primitives) and general 12 purpose primitives (8 primitives). These primitives are either global or local. The local 13 *primitives* represent tasks that affect only channels in the time lines they appear. One can 14 distinguish local primitives from other primitives by their dark blue background color. In 15 general, *global primitives* represent tasks that affect all active stimulation channels. The 16 global primitives are subdivided into global primitives that need to appear in all active 17 time lines (GPA) and global primitives that need to appear in only one time line (GPO). 18 GPAs can be distinguished from other primitives by their dark green background color. 19 GPAs are used to synchronize activities carried out by all active stimulation channels. 20 GPOs can be distinguished from other primitives by their violet background color. GPOs 21 are used to execute a task that affects all active stimulation channels or the stimulator. 22 It is important to mention that the stimulation channels and their time lines were 23 designed such that each channel is executed independently. In other words, a stimulation

1	protocol carried out in one time line does not have to be related to a stimulation protocol
2	in any of the remaining three time lines. However, in certain instances it is necessary that
3	the stimulation channels execute their programs simultaneously and in a synchronized
4	fashion. In these circumstances, a user can apply one of the following GPAs to
5	synchronize stimulation protocols performed by different stimulation channels:
6	synchronize, user interaction, user branch, fast trigger, or synchronized push button
7	triggering. The main property of GPAs is that once one of them appears in any of the
8	four time lines, the simulator "freezes" the stimulation parameters for that channel and
9	waits until the identical GPA appears in all four time lines. Once the same GPA is
10	reached in all four time lines, the stimulator is allowed to proceed with the following
11	stimulation primitives in all four time lines, if the condition indicated by the GPA is
12	satisfied. An example how the user interaction and user branch GPAs are used to
13	synchronize muscle contractions to generate hand opening and closing functions is
14	provided in Subsection 3.1 and displayed in Figure 7, items (1) , (2) , (4) and (5) .
15	

{Figure 3 should be placed here}

1 <u>The main features of the GUI software are:</u>

2

3 1. The GUI software specifies the chronology of the stimulation sequences that 4 needs to be executed, and specifies all the relevant stimulation parameters for 5 each stimulation channel. In particular, it allows a user to specify pulse 6 amplitude and pulse width for each stimulation channel independently. The 7 GUI also defines the interfaces which the stimulator should support. More 8 specifically, it specifies properties of a sensor that the stimulator will interface 9 and the type of signal the user should generate with the sensor to trigger or 10 regulate the stimulator's output. 2. 11 The Compex Motion stimulator allows users to control the pulse amplitude

12and the pulse width independently. By programming how the pulse width13should change as a function of time during the stimulation, the user defines14the stimulation patterns generated by the stimulator. By programming how the15pulse amplitude should vary as a function of time during the stimulation, the16user defines the intensity of the stimulation during therapy. This feature17allows one to decouple the control of the stimulation patterns and the18stimulation intensity.

Stimulation programs developed with the GUI software can be stored as
 specially formatted binary files. These files can be stored, uploaded, edited,
 and exchanged among users (Figure 3, item 4). This feature allows one to
 create libraries of stimulation protocols that can be used with various subjects
 and can be shared among FES practitioners. We believe that this feature will

1		allow less experienced users to benefit from already established stimulation
2		protocols developed by other FES practitioners.
3	4.	The software also allows users to use different, arbitrary pulse width ramp-up
4		and ramp-down profiles. These profiles are used to change the pulse width
5		during the stimulation protocol. They can be linear or nonlinear. The ramp-up
6		and ramp-down profiles can be stored as specially formatted text files
7		allowing one to create libraries of ramp-up and ramp-down profiles that can
8		be used with various stimulation protocols and can be shared among FES
9		practitioners. The ramp-up and ramp-down profiles can be edited both
10		graphically and numerically, and the stored profiles can be uploaded when
11		needed. Each stimulation channel (time line) can have two different ramp-up
12		or ramp-down profiles. One can, for example, use the ramp-up and ramp-
13		down profiles to compensate for the nonlinear muscle recruitment properties.
14		[33]
15	5.	The GUI software allows users to define the pulse shapes with the following
16		three settings: (1) monophasic or biphasic pulses, (2) monopolar or bipolar
17		pulses, and (3) alternating or non-alternating pulses (Figure 3, item 2). [33]
18		Any combination of these three settings is possible. This feature allows the
19		user to select the most appropriate stimulation pulse profile for a given
20		application.
21	6.	Stimulation protocols developed with the GUI software can be stored as files
22		on a PC (as discussed in item 3) and can be stored on memory chip-cards
23		which are inserted in the stimulator's "card read-and-write" module. An

1		important feature of the GUI is that the content of the chip-card can be
2		uploaded and displayed using the GUI software (Figure 3, item 4). This
3		feature allows the user to review and edit the content of the chip-card.
4		Furthermore, stimulation protocols developed with the GUI can be displayed
5		so that users can visualize pulse widths and amplitudes that will be generated
6		by all four stimulation channels as a function of time (Figure 4). This feature
7		allows users to review stimulation protocols and to edit the protocol (if
8		necessary) before it is applied to the subject.
9	7.	One can preset the default pulse widths, pulse amplitudes and pulse frequency
10		to all four stimulation channels (Figure 3, items 3 and 6). When the stimulator
11		is turned on, the default pulse widths and amplitudes are assigned to the
12		stimulation channels. Each stimulation channel can have a different default
13		pulse width and amplitude. As for the pulse frequency, only one default value
14		can be set for all stimulation channels, because all stimulation channels have
15		the same stimulation frequency. The default values can be changed during the
16		stimulation protocol. However, the less experienced users might prefer to use
17		only one pulse width, amplitude and frequency setting, which the default
18		setting feature is offering.
19	8.	The stimulator can be interfaced with any sensor or sensory system via input
20		channels A, B and C. These inputs can be digital or analog. Digital inputs are
21		primarily used to trigger the stimulation sequences which can be done using
22		one of the following primitives: fast trigger, synchronized push button trigger,
23		and non-synchronized push button trigger. The analog inputs can be used

1	either to trigger the stimulation sequences or to regulate stimulation amplitude
2	in real-time. Analog inputs can be used to trigger the stimulator if user
3	interaction primitive is applied. This primitive is programmed to trigger a
4	stimulation sequence if an analog signal with specified shape is presented to
5	one of two analog input channels A and B. Shapes of the triggering signal can
6	be arbitrarily selected as long as the following conditions are met: the signal's
7	duration does not exceed 25 s, the voltage range remains between 0 and 5 V,
8	and the signal does not have more than two points of inflexion (i.e. curve may
9	have maximum two "bellies", or two "valleys", or combination of a "belly"
10	and a "valley"). A programmer can specify to which input channel (A or B)
11	the command will be delivered to and how the input signal's shape should
12	look like (Figure 5 shows an example of an analog signal that has one belly
13	and a valley, and is used to trigger the stimulator). When a subject generates
14	the specified input signal with a sensor, the user interaction primitive produces
15	a trigger command that initiates or terminates certain stimulation protocol.
16	The stimulator allows up to seven different trigger conditions, i.e. seven
17	distinct analog signals that trigger user interaction primitives. The triggering
18	control can be used, for example, to initiate the stimulation patterns, to
19	terminate stimulation, and to choose between two different stimulation
20	patterns. Sensors such as EMG sensors, force sensitive resistors, gyroscopes,
21	foot switches, and push buttons have already been successfully applied as
22	analog input signals to trigger the stimulator. [6,26,31]

1		The regulation of the stimulation amplitudes with the analog inputs is
2		accomplished using "pulse amplitude look-up tables". Users can select: (1) the
3		stimulation channels that will have their amplitudes controlled by the "pulse
4		amplitude look-up tables"; (2) the analog input channels (A and/or B) that will
5		be used to measure the analog inputs; (3) the signal processing that will be
6		applied to the input signals; and (4) the functions that describe individual
7		relationships between the analog input signal and the stimulation amplitude.
8		These "relationship" functions can be arbitrarily selected and are represented
9		as look-up tables that have 64 values. Each stimulation channel can have a
10		different look-up table, i.e. different function representing input-output
11		relationship. Sensors such as the EMG sensors, sliding resistors,
12		potentiometers and a voice recognition system have already been successfully
13		implemented with this control strategy to regulate stimulation intensity in real-
14		time. [6,26,31]
15	9.	User can pre-set a maximum allowable pulse width and pulse amplitude for
16		each stimulation channel. These values can vary between different stimulation
17		channels. The purpose for setting maximum values is to ensure that the
18		stimulator will not generate pulses in which amplitudes and widths exceed
19		maximum specified values, regardless of how high the pulse amplitude and
20		pulse width are programmed with the primitives in the time lines. This
21		important safety feature prevents inexperienced FES practitioners from
22		stimulating subjects with pulses that are excessively high or are above the
23		normal sensitivity threshold.

1	10.	In the absence of a chip-card, the stimulator is unable to perform any function.
2		By simply changing the chip-card, the user can instantly change the function
3		of the stimulator. This feature allows users to apply the same device to a
4		number of different subjects requiring unique stimulation protocols.
5	11.	The stimulator also facilitates real-time EMG signal processing with a
6		stimulation artifact suppression algorithm that can be used for EMG
7		neuroprosthesis control (see Subsection 2.2 for details). It is important to
8		mention that two EMG sensors can be used simultaneously to
9		command/trigger one simulator. One EMG sensor would be attached to input
10		channel A and the other to input channel B. The user can program the
11		stimulator such that raw EMG readings, or integrated EMG readings, or
12		differences of either raw or integrated EMG readings, are used to
13		control/trigger the stimulator. The EMG signal can be used to control the
14		stimulator in the same manner as all other analog signals, as discussed in
15		item 8.
16	12.	The stimulator can operate in either time-based or pulse-based mode. In time-
17		based mode, the pulse amplitude, width and frequency can be changed
18		(refreshed) every 100 ms. During the time frame of 100 ms, between two
19		consecutive "parameter refreshment instances", the above values remain
20		constant. In pulse-based mode, the pulse amplitude, width and frequency can
21		be changed (refreshed) within the time period that is the reciprocal value of
22		the stimulation frequency. In other words, each time a stimulation pulse is
23		generated, a new set of pulse amplitude, width and frequency can be set. In

11	3.	Example of a Neuroprosthesis Application
10		
9		
8		{Figure 5 should be placed here}
7		
6		{Figure 4 should be placed here}
5		
4		standard FES protocols and treatments.
3		used for research purposes, while the time-based mode is more appropriate for
2		a different amplitude, width and frequency. The pulse-based mode is primarily
1		pulse-based mode, one can have a stimulation pattern such that each pulse has

12

13 To date, more than 100 SCI and stroke patients have used the Compex Motion system. 14 The system was primarily used as a neuroprosthesis for reaching, grasping and walking. 15 It was also used by a few patients to treat shoulder subluxation and to strengthen muscles. 16 The Compex Motion stimulator has also been used to investigate muscle properties in 17 animal studies at ParaCare. Two examples of Compex Motion applications are presented 18 in this section. One example describes a neuroprosthesis for grasping that was applied to 19 a C5 complete SCI patient in 2002. The second example describes a fully automated 20 neuroprosthesis for walking applied to C6 to C7 incomplete SCI patient in 2001. Other 21 successful applications of the Compex Motion stimulator can be found in [26,32,35-40] 22 as well as the comparison to other commercially available stimulators.

3.1 Neuroprosthesis for grasping

3

2

4 A neuroprosthesis for grasping had been developed for a 22-year-old, C5, complete, SCI 5 male patient. This patient had been admitted to the Toronto Rehabilitation Institute FES 6 program two months after sustaining a SCI. The subject's left arm was chosen for the 7 neuroprosthesis application since muscles in his left arm were not denervated and the 8 patient was also able to place his left hand in almost any point in the arm's work space. 9 The patient had good voluntary control of the left shoulder and biceps muscle, while his 10 left triceps muscle was graded level 3. The patient had significant difficulty using his 11 right arm and could voluntarily cover only 30 to 40 % of the right hand's workspace. 12 Prior to his SCI, this patient was right handed. When the patient was admitted to the FES 13 program he had ASIA score A. 14 This patient was fitted with a neuroprosthesis that allowed him to perform both 15 lateral and palmar grasps on demand (Figure 6). Channel No.1 was used to stimulate the 16 *flexor digitorum superficialis muscle* and the *flexor digitorum profundus muscle* to 17 generate finger flexion. Channel No.2 was used to stimulate the *flexor pollicis longus* 18 *muscle* to generate thumb flexion. Channel No.3 was used to stimulate the *median nerve* 19 to produce thumb opposition (two small self-adhesive electrodes placed on the skin along 20 the tendon of the flexor carpi radialis muscle were used to generate this function; distance 21 between electrodes was 2 cm). Channel No.4 was used to stimulate the *extensor* 22 *communis digitorium muscle* to generate hand opening. The patient used a push button to 23 command the neuroprosthesis. By continuously pressing a push button for less than 0.5 s,

1	the patient would issue user interaction A command (UI-A in Figure 7). By holding the
2	push button longer than 1 s continuously, the patient would issue user interaction B
3	command (UI-B in Figure 7). The user interaction A was used to command the lateral
4	grasp, while the user interaction B was used to command the palmar grasp. By generating
5	the user interaction A or B command, the neuroprosthesis would instantaneously produce
6	the lateral or palmar grasp, respectively. Once the hand was closed, it remained closed
7	until the patient pressed the push button for the second time. By generating the user
8	interaction A command while the hand is closed, the patient produces hand opening.
9	This neuroprosthesis was successfully used by the patient for more than three
10	months at the Toronto Rehabilitation Institute, Canada as part of an ongoing study.
11	Patient was able to grasp and manipulate variety of objects in activities of daily living.
12	
13	{Figure 6 should be placed here}
14	
15	{Figure 7 should be placed here}
16	
17	
18	3.2 Neuroprosthesis for walking
19	
20	A neuroprosthesis for walking was developed for a 31-year-old, male, C6 to C7
21	incomplete, SCI patient. The patient suffered from a unilaterally dominated paraplegia of
22	the left leg, while his right leg was fully functional. The patient had significant deficits in
23	hip and knee flexion and, because of that, he could not walk and had to use a wheelchair

to ambulate in ADL. The patient was readmitted to the ParaCare FES program five years
after SCI. The same patient used our manually controlled ETH-ParaCare neuroprosthesis
for walking in 1997. [6] When the patient was readmitted to the FES program at ParaCare
he had ASIA score C.
The patient was fitted with a fully automated neuroprosthesis for walking
(Figure 8). This system applied a Gait Phase Detection System (GPDS) to signal different
gait phases during locomotion.[31] The left foot was instrumented with the GPDS that
allowed the Compex Motion stimulator to automatically sequence electrical stimulation
according to the patient's foot position during walking and his overall walking speed.
Channel No.1 was used to stimulate <i>peroneal nerve</i> to elicit the flexion reflex. Channel
No.2 was used to contract the <i>tibialis anterior muscle</i> to help with the foot clearance
during swing phase (Figure 9). The stimulation started at the detection of the heel-off

phase of the gait (user interaction A or UI-A) and terminated at the detection of the heel-

strike phase of the gait (user interaction B or UI-B).

This neuroprosthesis was successfully used by the patient for more than four weeks at the ParaCare, Switzerland as part of a physiotherapy treatment. Patient was able to walk on his own for prolonged periods of time and was able to walk distances up to 500 m. When the patient joined FES program at ParaCare he was wheelchair user.

{Figure 9 should be placed here}

{Figure 8 should be placed here}

2 **4.** Conclusions

3

4 The Compex Motion stimulator can be applied as a hardware platform to develop various 5 custom-made neuroprostheses, neurological assessment devices, muscle exercise 6 systems, and experimental setups for physiological studies. This stimulator allows users 7 to generate an arbitrary stimulation protocol that can be controlled or regulated using any 8 external sensor, sensory system, or laboratory equipment. Each stimulator has four output 9 channels, and any number of stimulators can be combined to form a multiple unit with a 10 greater number of stimulation channels. The stimulation sequences are stored on readily 11 exchangeable memory chip-cards. By replacing the chip-card, the function of the 12 stimulator is changed instantaneously to provide different functions or FES treatments. 13 The Compex Motion provides numerous features absent in other completive FES 14 systems, yet it is intuitive and easy to program and apply in rehabilitation settings. 15 Compex Motion is specially designed to promote sharing of stimulation protocols, 16 sensors and user interfaces. For example, a FES protocol developed with Complex 17 Motion in one institution can effortlessly be distributed (for example e-mailed) and tested 18 by other rehabilitation centers which have the same stimulator. This allows users to 19 collectively test and improve on existing stimulation protocols and interfaces, and to 20 standardize them if they are found to be effective and reliable. Currently, the Compex 21 Motion system is used by the following FES groups to treat patients with different 22 disabilities: the Toronto Rehabilitation Institute, Canada; Sunnybrook and Women's 23 College Health Sciences Centre, Canada; ParaCare, Switzerland; the Rehabilitation

Institute of Chicago, USA. These three teams readily exchange stimulation protocols and
 user interfaces.

Another beneficial feature of the Compex Motion system is its modularity, which provides users with an unlimited number of stimulation channels and promotes the application of complex sensory systems and user interfaces. Practitioners have the option of acquiring individual modules one at a time, rather than having to purchase a single and expensive FES system all at once.

8 Compex Motion is a non-invasive system which can easily be applied to patients 9 at different stages of recovery and rehabilitation. Implanted FES systems are geared 10 mainly for long term FES treatments and are generally viewed as prosthetic devices, 11 where as, the Compex Motion system is especially appropriate for rehabilitation 12 treatments that are administered during early rehabilitation (for example immediately 13 after stroke or SCI). In addition, the Compex Motion system can also be applied as a 14 prosthetic system which patients can use as a neuroprostheses in activities of daily living. 15 16 17 **Acknowledgements:**

18

This project was supported by Federal Committee for Technology and Innovation and the
Swiss Federal Science Foundation, both located in Bern, Switzerland.

21 We would like to acknowledge the help of our colleagues Ms. Betty Chan and

22 Ms. Zina Bezruk who reviewed the manuscript for grammatical correctness.

2 **References:**

- 3
- 4 [1] D. Popovic and T. Sinkjaer, Control of Movement for the Physically Disabled.
- 5 London, UK: Springer, 2000.
- 6 [2] N. Hoshimiya and Y. Handa, "A Master-Slave Type Multichannel Functional
- 7 Electrical Stimulation (FES) System for the Control of the Paralyzed Upper Extremities,"
- 8 Automedica, vol. 11, pp. 209-220, 1989.
- 9 [3] T. Cameron, G. E. Loeb, R. A. Peck, J. H. Schulman, P. Strojnik, and P. R. Troyk,
- 10 "Micromodular Implants to Provide Electrical Stimulation of Paralyzed Muscles and
- 11 Limbs," IEEE Tr. Biomedical Engineering, vol. 44, pp. 781-790, 1997.
- 12 [4] B. Smith, P. H. Peckham, M. W. Keith, and D. D. Roscoe, "An Externally
- 13 Powered, Multichannel, Implantable stimulator for Versatile Control of Paralyzed
- 14 Muscle," IEEE Tr. on Biomechanical Engineering, vol. 34, pp. 499-508, 1987.
- 15 [5] R. Kobetic and E. B. Morsolais, "Synthesis of Paraplegic Gait With Multichannel
- 16 Functional Neuromuscular Stimulation," IEEE Tr. on Rehabilitation Engineering, vol. 2,
- 17 pp. 66-78, 1994.
- 18 [6] M. R. Popovic, T. Keller, I. P. I. Pappas, V. Dietz, and M. Morari, "Surface-
- 19 Stimulation Technology for Grasping and Walking Neuroprostheses," IEEE Engineering
- 20 in Medicine and Biology Magazine, vol. 20, pp. 82-93, 2001.
- 21 [7] M. J. IJzerman, T. S. Stoffers, F. A. C. G. in 't Groen, M. A. P. Klatte, G. J.
- 22 Snoek, J. H. C. Vorsteveld, R. H. Nathan, and H. J. Hermens, "The NESS Handmaster

1	Orthosis: Restauration of Hand Function in C5 and Stroke Patients by Means of
2	Electrical Stimulation," Journal of Rehabilitation Sciences, vol. 9, pp. 86-89, 1996.
3	[8] A. Prochazka, M. Gauthier, M. Wieler, and Z. Kanwell, "The Bionic Glove: An
4	Electrical Stimulator Garment That Provides Controlled Grasp and Hand Opening in
5	Quadriplegia," Archives of Physical Medicine and Rehabilitation, vol. 78, pp. 608-614,
6	1997.
7	[9] S. Rebersek and L. Vodovnik, "Proportionally Controlled Functional Electrical
8	Stimulation of Hand," Archives of Physical Medicine and Rehabilitation, vol. 54, pp.
9	168-172, 1973.
10	[10] D. Popovic, M. Popovic, A. Stojanovic, A. Pjanovic, S. Radosavljevic, and D.
11	Vulovic, "Clinical Evaluation of the Belgrade Grasping System," Proceedings of the 6th
12	Vienna International Workshop on Functional Electrical Stimulation, pp. 247-250, 1998.
13	[11] W. T. Liberson, H. J. Holmquest, D. Scot, and M. Dow, "Functional
14	Electrotherapy: Stimulation of the Peroneal Nerve Synchronized with the Swing Phase of
15	the Gait of Hemiplegic Patients," Archives of Physical Medicine and Rehabilitation, vol.
16	42, pp. 101-105, 1961.
17	[12] L. Vodovnik, A. Kralj, U. Stanic, R. Acimovic, and N. Gros, "Recent
18	Applications of Functional Electrical Stimulation to Stroke Patients in Ljubljana,"
19	Clinical Orthopaedics and Related Research, pp. 64-70, 1978.
20	[13] M. Wieler, S. Naaman, and R. B. Stein, "WalkAid: An Improved Functional
21	Electrical Stimulator for Correcting Foot-Drop," Proceedings of the 1st Annual Conf. on
22	the Int. FES Society., pp. 101-104, 1996.

- 1 [14] P. N. Taylor, P. A. Wright, J. H. Burridge, G. E. Mann, and I. D. Swain,
- 2 "Correction of bi-Lateral Dropped Foot Using the Odstock 2 Channel Stimulator
- 3 (O2CHS)," Proceedings of the 4th Annual Conference on the International Functional
- 4 Electrical Stimulation Society, pp. 257-260, 1999.
- 5 [15] D. Graupe, R. Davis, H. Kordylewski, and K. H. Kohn, "Ambulation by
- 6 Traumatic T4-12 Paraplegics Using Functional Neuromuscular Stimulation," Critical
- 7 Review Neurosurgery, vol. 8, pp. 221-231, 1998.
- 8 [16] D. Graupe and K. H. Kohn, "Functional Neuromuscular Stimulator for Short-
- 9 Distance Ambulation by Certain Thoracic-Level Spinal-Cord-Injured Paraplegics,"
- 10 Surgical Neurology, vol. 50, pp. 202-207, 1998.
- 11 [17] M. Solomonow, E. Aguilar, E. Reisin, R. V. Baratta, R. Best, T. Coetzee, and R.
- 12 D'Ambrosia, "Reciprocating Gait Orthosis Powered With Electrical Muscle Stimulation
- 13 (RGO II) Part I: Performance Evaluation of 70 Paraplegic Patients," Orthopedics, vol. 20,
- 14 pp. 315-324, 1997.
- 15 [18] M. Solomonow, E. Reisin, E. Aguilar, R. V. Baratta, R. Best, and R. D'Ambrosia,
- 16 "Reciprocating Gait Orthosis Powered With Electrical Muscle Stimulation (RGO II) Part
- 17 II: Medical Evaluation of 70 Paraplegic Patients," Orthopedics, vol. 20, pp. 411-418,
- 18 1997.
- 19 [19] D. Popovic, R. Tomovic, and L. Schwirtlich, "Hybrid Assistive System The
- 20 Motor Neuroprosthesis," IEEE Tr. on Biomedical Engineering, vol. 36, pp. 729-737,
- 21 1989.

- 1 [20] Y. Shimada, K. Sato, E. Abe, H. Kagaya, K. Ebata, M. Oba, and M. Sato,
- 2 "Clinical Experience of Functional Electrical Stimulation in Complete Paraplegia,"
- 3 Spinal Cord, vol. 34, pp. 615-619, 1996.
- 4 [21] K. Takahashi, N. Hoshimiya, H. Matsuki, and Y. Handa, "Externally Powered
- 5 Implantable FES System," Japanese Journal of Medical Electronics and Biological
- 6 Engineering, vol. 1, pp. 43-51, 1999.
- 7 [22] R. Davis, T. Houdayer, B. Andrews, and A. Barriskill, "Paraplegia: Implanted
- 8 Praxis24-FES System for Multi-functional Restoration," Proceedings of the 4th Annual
- 9 Conference on the International Functional Electrical Stimulation Society, pp. 155-158,
- 10 1999.
- 11 [23] A. Kralj, T. Bajd, and R. Turk, "Enhancement of Gait Restoration in Spinal
- 12 Injured Patients by Functional Electrical Stimulation," Clinical Othopaedics and Related
- 13 Research, pp. 34-43, 1988.
- 14 [24] R. Kobetic, R. J. Triolo, and E. B. Morsolais, "Muscle Selection and Walking
- 15 Performance of Multichannel FES Systems for Ambulation in Paraplegia," IEEE Tr. on
- 16 Rehabilitation Engineering, vol. 5, pp. 23-28, 1997.
- 17 [25] T. Bajd, A. Kralj, M. Stefancic, and N. Lavrac, "Use of Functional Electrical
- 18 Stimulation in the Lower Extremities of Incomplete Spinal Cord Injured Patients,"
- 19 Artificial Organs, vol. 23, pp. 403-409, 1999.
- 20 [26] M.R. Popovic, A. Curt, T. Keller, and V. Dietz, "Functional Electrical Stimulation
- 21 for Grasping and Walking: Indications and Limitations," Spinal Cord, vol. 39, No. 8, pp.
- 403-412, 2001.

1	[27] E. C. Field-Fote, "Combined use of Body Weight Support, Functional Electrical	
2	Stimulation, and Treadmill Training to Improve Walking Ability in Individuals with	
3	Chronic Incomplete Spinal Cord Injury," Archives of Physical Medicine and	
4	Rehabilitation, vol. 82, pp. 818-824, 2001.	
5	[28] M. Wieler, R. B. Stein, M. Ladouceur, M. Whittaker, A. W. Smith, S. Naaman, H.	
6	Barbeau, J. Bugaresti, and E. Aimone, "Multicenter Evaluation of Electrical Stimulation	
7	Systems for Walking," Archives of Physical Medicine and Rehabilitation, vol. 80, pp.	
8	495-500, 1999.	
9	[29] D. B. Popovic, M. B. Popovic, and T. Sinkjaer, "Neurorehabilitation of upper	
10	extremities in humans with sensory-motor impairment," Neuromodulation, vol. 5, pp. 54-	
11	67, 2002.	
12	[30] Instruction Manual: Biofeedback Version 2M4456. Ecublens, Switzerland:	
13	MediCompex SA, 1996.	
14	[31] I. P. I. Pappas, M. R. Popovic, T. Keller, V. Dietz, and M. Morari, "A Reliable	
15	Gait Phase Detection System," IEEE Transactions on Neural Systems and Rehabilitation	
16	Engineering, vol. 9, pp. 113-125, 2001.	
17	[32] T. Keller and M. R. Popovic, "Stimulation Artifact Removal Algorithm for Real-	
18	Time Surface EMG Applications," Proceedings 7th Vienna International Workshop on	
19	Functional Electrical Stimulation, pp. 118-121, 2001.	
20	[33] L. L. Baker, C. L. Wederich, D. R. McNeal, C. Newsam, and R. L. Waters,	
21	Neuromuscular Electrical Stimulation - A Practical Guide, 4th Edition. Downey, USA:	
22	Los Amigos Research and Education Institute Inc., 2000.	

1	[34] T. Keller, M.R. Popovic, I.P.I. Pappas, and P.Y. Müller, "Transcutaneous
2	functional electrical stimulator "Compex Motion," Artificial Organs, vol. 26, No. 3, pp.
3	219-223, 2002.
4	[35] M.R. Popovic, V. Hajek, J. Takaki, A.K. Bulsen and V. Zivanovic, "Restoration
5	of reaching and grasping functions in hemiplegic patients with severe arm paralysis,"
6	Proceedings of the International Functional Electrical Stimulation Society Conference,
7	pp. 79-83, 2003.
8	[36] T.A. Thrasher and M.R. Popovic, "FES-assisted walking for rehabilitation of
9	incomplete spinal cord injury," Proceedings of the International Functional Electrical
10	Stimulation Society Conference, pp. 131-134, 2003.
11	[37] M. Adams, V. Takes, M.R. Popovic, A.K. Bulsen, and V. Zivanovic, "Restoration
12	of grasping functions in patients with quadriplegia," Proceedings of the International
13	Functional Electrical Stimulation Society Conference, pp. 86-91, 2003.
14	[38] M.R. Popovic, D.B. Popovic, and T. Keller, "Neuroprostheses for grasping,"
15	Neurological Research, vol. 24, pp. 443-452, 2002.
16	[39] M.R. Popovic and T.A. Thrasher, "Neuroprostheses," To appear in <i>Encyclopedia</i>
17	of Biomaterials and Biomedical Engineering, G.E. Wnek and G.L. Bowlin, Eds.: Marcel
18	Dekker, Inc., in 2004.
19	[40] I.P.I. Pappas, T. Keller, S. Mangold, M.R. Popovic, V. Dietz, and M. Morari, "A
20	Reliable Gyroscope-Based Gait-Phase Detection Sensor Embedded in a Shoe Insole," To

21 appear in *IEEE Sensors Journal in 2004*.

- 1 Figures



- 8 Figure 1: Compex Motion stimulator, three memory chip-cards, two EMG sensors, and
- 9 two surface stimulation electrodes



- 10 channels
- 11



4 Figure 3: Main screen of the GUI software: 1) setup functions, 2) stimulation mode 5 functions, 3) default stimulation frequency setting, 4) memory chip-card functions, 5) 6 time line editing functions for stimulation channel No. 3; 6) default pulse amplitude for 7 stimulation channel No. 2, 7) upper limits for pulse width and amplitude for stimulation 8 channel No. 1, 8) time line for stimulation channel No. 2, and 9) primitive "jump to first" 9 in time line No. 1





4 Figure 4: Visualization of the stimulation program in Figure 3: items 1,3,5 and 7 are 5 stimulation amplitudes as a function of time for channels 1,2,3 and 4, respectively, and items 2,4,6 and 8 are pulse widths as a function of time for channels 1,2,3 and 4, 6

7 respectively. Time line in the figure is provided in seconds.

×

Ok

🔁 Set Trigger Criteria File name test1.txt 5.5-5.0-4.5-4.0-3.5-3.0-2.5 level2 v 2.0-1.5 -1.0-0.5 -0.0--0.5time time 1 -0.8-1.8 0.2 1.0 1.2 1.4 2.0 -0.3-0.2 0.0 0.4 0.6 0.8 1.6 2.2 2.3 s level 1 numerical/graphical entry level 2 peak/valley1 peak/valley 2 3.00 2.20 V s shorter/longer 3 time 2 shorter/longer 2 time 3 shorter/longer 1 time 1 0.70 0.30 **0.80** s 8 s 🚺 Load Criteria

2

Save Criteria

3

4 Figure 5: An example of an analog signal that is used as a triggering criterion for the 5 user interaction primitive. This figure shows GUI used to select the triggering criterion for the analog input signal, and the graphical presentation of the selected trigger signal. 6 7 The figure describes the following triggering criteria: 1) First, the signal has to increase 8 its amplitude from a level below 3 V to a level above 3 V and maintain that level for at 9 least 0.7 s (defined by level 1 and time 1 parameters and switches); 2) Then the signal has 10 to decrease to below 3 V level, while at the same time, its intensity should not decrease

1	below 2.2 V level. The signal should remain at this level for at least 0.3 s (defined by
2	level 2 and time 2 parameters and switches); 3) Then the signal's intensity has to
3	decrease below 2.2 V and has to remain below this threshold for no longer than 0.8 s
4	(defined by level 2 and time 3 parameters and switches). If the analog signal has such
5	properties, the user interaction primitive set by this GUI will trigger the stimulator.
6	Otherwise, the stimulator will wait until the subject generates the desired triggering
7	command described by this GUI.
8	
9	



Figure 6: SCI male patient, C5, complete, with the neuroprosthesis for grasping for the left hand. In figure a) the patient is performing the palmar grasp and in figure b) the lateral grasp. The electrodes placed on the arm (detailed description is provided above) were secured with the black glove/wrist-retainer that ensured that the electrodes did not move during treatment. The Compex Motion stimulator was placed in a pocket behind the patient and was attached to the wheelchair. The command push button used to trigger the simulation sequences was attached to the right armrest.



Figure 7: Grasping protocol that generates both a) lateral and b) palmar grasps on
demand. The upper part of the figure presents primitives in time lines and the lower part
represents the outputs for channels 1, 2, 3 and 4.







a)



- **Figure 8:** Patient with the neuroprosthesis for walking; a) without the neuroprosthesis b)
- 4 with the neuroprosthesis.



1

3

Figure 9: Walking protocol that allows automatic triggering of the neuroprosthesis with
the GPDS. The upper part of the figure presents primitives in time lines and the lower
part represents the outputs for channels 1, 2, 3 and 4.

UI-A is user interaction A which is generated when the GPDS detects the heel-off
phase of the gait; UI-B is user interaction B which is generated when the GPDS detects
the heel-strike phase of the gait; ch-1, 2, 3 and 4 are stimulation channels; and labels ①

- 1 to ④ are used to indicate which primitives in the time lines are responsible for certain
- 2 stimulation protocol events.