USER MANUAL

version 13.3.2

MEDICAL DEVICES

THE FUTURE OF REHAB

Welcome to the future and thank you for choosing SHoW Motion.

SHoW Motion is the most innovative product for the functional evaluation of both Upper and Lower Body.

SHoW Motion incorporates wearable technology, novel measurement protocols and easy reporting of human body kinematic and muscle activity through an end-user software interface that guide the user throughout the entire process.

SHoW Motion brings functional evaluation of upper extremities to a new level in rehabilitation.
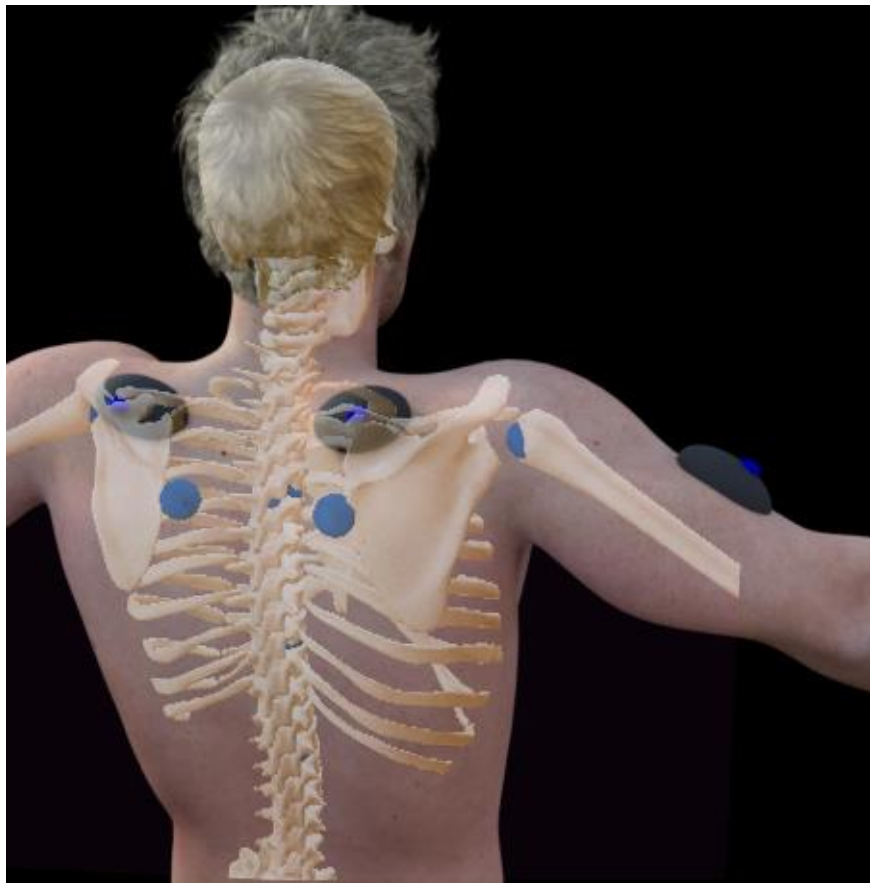
DISCLAIMER

This manual is intended to be informative document and not as lonely source of training for the product usage.

For proper training, please contact our support and assistance team at the following:

info@ncs-company.com

Technical assistance is provided by our team. Each detected problem should be reported to the address previously provided. Our team will provide technical assistance regarding all aspects of the supplied device, including the replacement of any damaged parts as indicated in the "Replaceable parts" section of the manual. These substitutions can only take place through our service center.

INTRODUCTION

Visual observation in rehabilitation is the current technique for the identification of signs of alterations in patients due to an injury, muscolo-skeletal deficiency or impairment, rather than results of surgical treatment.

The current state of art in physiotherapy does not allow to:

- dynamically track joint kinematics by evaluating how the joint is moving and in which phase of the movement an alteration occurs
- an objective evaluation which can represent patient trend in time
- available data to share among operators
- provide a direct feedback to patients

Upper and lower body functional evaluation are challenging especially in situations where it is not possible to verify hypothesis regarding limb status due to the complexity of bones and muscles forming it (as in specific shoulder scenarios, such as scapula dyskinesia).

SHoW Motion provides for the first time ever a way to measure, track, follow, compare the range of motion of anatomical articulations (such as shoulder and elbow for upper limb and hip and knee for lower limb) during the rehabilitation treatment, taking into account all clinical constraints related to easiness, quickness and portability,

MAIN FEATURES

SHoW Motion is based on the most innovative and accurate wireless motion tracking technology available in the market. By means of validated motion analysis protocol, SHoW Motion enables the analysis of upper and lower limbs joint kinematics in physiotherapy settings.

The novel characteristics of SHoW Motion with respect to other methods available in the market are:

- Quick and easy representation of both Upper and Lower Body coordination pattern, including scapula-humeral rhythm
- 3D visual feedback representation for involvement of patient and rapid feedback to the operator
- Integrated methods for the analysis of movement phases
- Optimized and simple rules based-set-up to speed-up sensors positioning
- Anatomical and functional calibration of body segments
- Automatic synchronization of motion sensors with surface EMG electromyography device
- Automatic data processing and report creation
- Non invasive and portable
- Flexible in configuration
- Based on golden standard motion sensors and EMG probes

INTENDED USE

The product is intended to be used as instrumentation for the kinematic analysis of the movement using inertial sensors. Product provides comparison capabilities of data collected that makes use of novel interpretation methods. However, the product does not implement decision-making algorithms. The ultimate decision on subject status from the legal and medical point of view, are left to the physician or the user and in any way they cannot come directly as output from the product and related software.

- The product can be used in combination with other medical devices such as surface electromyography
- The use of hardware sensors in order to complete the analysis based on SHoW Motion typically requires a maximum of 1 hour

Intended user

The intended user is a practitioner working in the clinical or sports medicine field, with knowledge regarding the specific body district area for which the product is used. User must receive an adequate training soon after the first installation of the product and its first use.

Intended person as subject of the analysis

The intended subject to be analyzed using SHoW Motion is a person able to understand and follow the user instructions in all steps of the procedure.

> **WARNING: in case of subjects with pacemakers or similar, do not place the wireless receivers near the subject's body.**

Fields of application

The flexible nature of SHoW Motion provides several fields of application:

- Monitoring rehabilitation treatment in Physiotherapy
- Pre/post surgery functional evaluation and follow-up
- Ergonomics evaluation at work place
- Sports medicine

Use of Hardware and Software

- In order to use the product, the combined use of software and wearable sensors is necessary
- For the purpose of usage, only specific hardware models and versions are compatible, such as WISE (NCS Lab, Carpi, Italy) for motion tracking, GTWY (NCS Lab, Carpi, Italy) for wireless transmission and Wave Plus (Cometa Systems, Milan, Italy) for muscle activity measurement.
- Only by using the above sensors usability and success in the analysis is guaranteed
- The use of motion tracking hardware is intended only by using the following accessories:
  - Transparent double-sided skin tape or similar (Fixomull, BSN Medical GmbH. Germany)
  - Surface EMG electrodes (Kendall or similar)[1]

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[1] Only within the expiration time the quality of this accessory can be guaranteed

Location

- The product is intended to be used in physiotherapic settings, including small physiotherapic offices where no surgical equipment or other electrical medical devices are provided

- During training of personnel and system configuration by the manufacturer, location will be chosen together with the customer according to his needs. In the event where the location needs to be changed by the customer, please contact our support and assistance.

- The recommended operating temperature is between -0ºC and +35ºC, with a maximum relative humidity of 75% and atmospheric pressure from 700 hPa to 1060 hPa. Operating outside this temperature range may decrease performance or damage the devices.

- The device must be stored and transported respecting the temperature range from -20 ºC and +45ºC, relative humidity from 30 % to 75%, and atmospheric pressure from 700 hPa to1060 hPa.

WARNING: Do not modify this device without the authorization of the manufacturer

SYSTEM CONFIGURATION

The picture below illustrates the 3 different main configurations available in SHoW Motion.

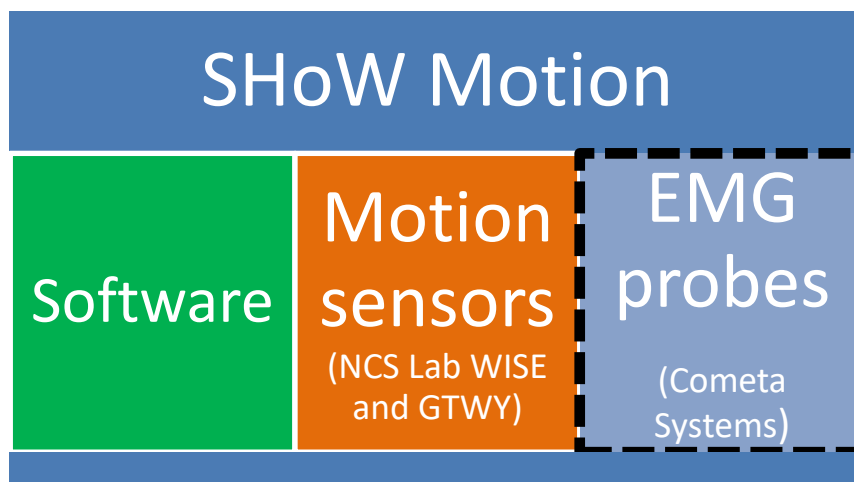**CONFIGURATION 1: SHoW Motion software**

SHoW Motion software can be used as stand-alone system when opening patient database, playing back previously recorded analyses, generating specific reports or comparisons. In this configuration there is no need to connect with the hardware sensors

CONFIGURATION 2: SHoW Motion software + Motion Sensors

SHoW Motion software can be used to control motion sensors hardware in order to track kinematics of upper/lower body by means of the ISEO/Outwalk protocol. The number of sensors used will depend on the specific product package that you have purchased and on the specific analysis you want to perform. It is highly recommended to follow the instructions provided in section BASIC INSTRUCTIONS for the best use of wireless receiver.

CONFIGURATION 3: SHoW Motion software + Motion Sensors + EMG Probes

SHoW Motion software can be used to control motion sensors hardware and EMG probes as well in order to track kinematics of upper/lower body and muscle activity. The number of motion sensors and muscles that can be tracked will depend on the specific product package that you have purchased. In this configuration, one wireless receiver is used to control Motion sensors, whilst a second wireless receiver is used to control EMG Probes. For best usage of the wireless receivers together, the two receivers must be placed at least 1 meter far from each other both horizontally and vertically.

In the following table, a summary of where different parts of SHoW Motion are fundamental is provided:

SYSTEM PART	TYPE
SHoW Motion Software	FUNDAMENTAL for calibration, data recording, data visualization, Report creation
WISE sensors + Wireless receiver (GTWY)	FUNDAMENTAL for motion recording and data transmission
Cometa EMG Probes + Wireless receiver	FUNDAMENTAL for muscle activity recording
Velcro straps	FUNDAMENTAL for motion recording

Fixomull skin tape	FUNDAMENTAL for motion recording
Surface EMG electrodes	FUNDAMENTAL for muscle activity recording

Depending on the package of the product purchased, the kit supplied differs for the number of movement sensors and for the elastic strips (in terms of number, color and size) necessary to perform the analyzes as specified in the table below. Each kit contains 1 GTWY for receiving the data wireless transmitted from WISE sensors.

To understand the following table, remember that the positioning of the sensor on the scapula does not require the use of elastic strips.

To each sales kit is associated a reference code, shown in the table below and on the product label together with the information on the production batch.

In the "Instructions of use", there is information regarding the positioning of the sensors of movement, the fixing system and the strip-sensor identifier according to the color code.

| Reference code	N° sensors	Sensor Position (bilateral)	Joint of interest (bilateral)	N° Strips
UPPER LIMB – 5 WISE (REF SHWM01U5)	5	Thorax, Arm, Scapula	Thorax, Humerus, Scapula	3
UPPER LIMB – 7 WISE (REF SHWM01U7)	7	Thorax, Arm, Scapula, Forearm	Thorax, Humerus, Scapula, Elbow	5
LOWER LIMB – 6 WISE (REF SHWM01L6)	6	Thorax, Pelvis, Thigh, Shank	Thorax, Hip, Knee	6
LOWER LIMB – 8 WISE (REF SHWM01L8)	8	Thorax, Pelvis, Thigh, Shank, Foot	Thorax, Hip, Knee, Ankle	8

PRODUCT CONTENT

PLEASE READ CAREFULLY - A User Manual is provided with the product, serving as the main reference both for hardware and software usage. It is essential that the user and all personnel involved in the use of the product fully understand the content of the manual and follows instructions provided during all the steps of the implemented protocol.

SHoW Motion is available in two main versions:

- Kinematic version - Product suitcase contains:
  - A set of inertial sensors (black-white boxes in figure)[2]
  - A 2.4 GHz wireless receiver (USB stick)
  - Recharging cables
  - One or more body interfaces[1]
  - A USB stick containing Software Package SHoW Motion
- Kinematic+EMG version – the above are augmented by:
  - A set of electromiographic probes (blue boxes in figure)[3]
  - A 2.4 GHz wireless receiver
  - A docking station with recharging capabilities
  - A set of adhesive sticks
  - A package of EMG electrodes
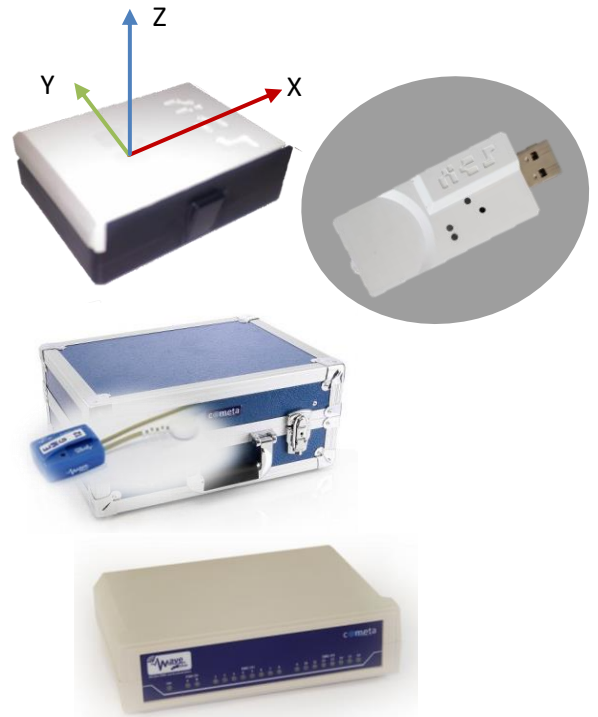
NOTES ON HARDWARE COMPONENTS

The wireless receiver of Cometa EMG Probes include several panels with status LEDs incorporated. Please refer to the respective User Manual from the manufacturer for details regarding LED indicators and needs for power connection. The hardware of the NCS Lab consists of a set of inertial sensors and a wireless receiver.

The wireless receiver has 2 LEDs. The one closest to the USB charging turns on with a steady light when the receiver is powered. The other LED flashes at high frequency when it is in configured phase, while it flashes once every 2 seconds when it is in transmission mode. To turn off the receiver, disconnect the power supply to the device. The device is reset with the extraction and subsequent insertion of the receiver to the computer. The sensor has 3 aligned LEDs. During power-up, the central LED emits 3 consecutive flashes, while in the switch-off one it emits a flash od intensity gradually smaller. When the device is transmitting, the central LED flashes. The external LEDs are on when the sensor is being recharged: the one closest to the power button lights up green, while the opposite one is red. When the device is on, the external LED closest to the button emits a steady green light. The sensor is switched on and off by pressing the side button for a few seconds.

[2] The item numerosity depends on the purchased body configuration

[3] The item numerosity depends on the purchased number of muscle channels

USAGE REQUIREMENTS

User requirements

- The right user of SHoW Motion must belong to one of the following areas:
  - Practitioner in physiotherapy
  - Practitioner in kinesiotherapy
  - Practitioner in surgery
  - Practitioner in motion analysis of human body
  - Biomedical engineer
- Each user must have received the proper training by or by means of education personnel belonging to the manufacturing Company
- The user/operator and the subject himself/herself must be able to collaborate during the procedures as these might include specific postures to assume during calibration or specific instructions need to be followed during the measurement. In other words, the product is not intended for users with problems that can limit the ability to carry out the analysis protocol described in this manual

Forbidden scenarios

- The user is recommended to not use the product on subjects in case of:
  - bleeding areas of the body
  - presence of visible injuries on the skin
- The user is recommended to not use the product in situations where:
  - motion sensors or EMG probes were accidentally open, partially broken
  - temperature by tactile inspection of sensors becomes too high and/or plastic material is changing shape or color

Contact with the skin

- Hardware included in the product (motion sensors, electromyography probes) cannot be positioned in direct contact with the naked skin. In particular:
  - Contact is possible only through the dedicated accessories as described in Section "Positioning of Sensors" of this manual
  - For most of the body districts, the use of Velcro straps is recommended; for example also when the subject is wearing specific orthopedic products (orthoses, bracing systems).
  - In general, the use of skin tape is suggested only for positioning motion sensors on sternum and scapula areas. For more information, refer to Section "Positioning of Sensors" of this manual

Usage of motion sensors hardware

- Please refer to the following section of WISE Technical Information (NCS Lab, Carpi, Italy):
  - o "Radio Frequency Exposure and Emission"
  - o "Operating Conditions"

Usage of EMG hardware

- For usage of surface EMG electromyographic products, EMG electrodes and skin adhesives, the user is forwarded to the User Manual from the specific manufacturer
- The use of EMG electromyographic hardware included is intended only together with the SHoW Motion product

Usability requirements for the accessories

Compulsory accessories to optimally operate with the hardware and software are:

- Fixomull (BSN Medical Gmbh, Germany) transparent skin tape for skin protection during motion sensor positioning. For usage of skin tape, the user is forwarded to the User Manual Instructions from the specific manufacturer of the skin tape.
- Double-sided tape (Tesa, Germany) for stable connection between motion sensors and skin tape.
- Double-sided stickers (Tesa, Germany) for stable connection between EMG probes and skin.
- Surface EMG electrodes (Kendall or similar).

WARNING: some people might result allergic to the above due to the presence of latex material, For better usage, it is recommended to inform the patient first. To limit the effect to the minimum, do not make use of such accessories for a longer time than the one required for the analysis.

ENVIRONMENT REQUIREMENTS

Environment where product is used must fulfill the following requirements:

- Never go out of the level of temperature and moisture suggested by hardware manufacturer. It is best to avoid moisture/wet surroundings. Please refer to the related User Manuals from NCS Lab and Cometa Systems for further information.

- No ferromagnetic materials (iron, heating machines, hard drivers, engines, hi-fi) should get closer to the hardware sensors, during usage or afterwards.

- At least keep 2 meters distance from the above material while operating with the system. If the office is so small that this distance cannot be maintained, make sure that the interfering furniture is not at level of subject's height. Aluminum structures in the environment do not interfere with the hardware if the hardware is not in direct contact with them.

- However, prolonged permanence (days) of motion sensors in contact with aluminum surfaces might magnetize internal components. Therefore, motion sensors are required to be located into the product suitcase. If, for any reason, this scenario have occurred recently or in the past, please go to the related section INFORMATION TO THE USER

1. For devices approved under Part 15, the user's manual or instruction manual for an intentional or unintentional radiator shall caution the user about changes or modifications to the device (Section 15.21).

2. For Class A and Class B digital devices, information to the user is required to include the following statements (Section 15.105):

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

RF RADIATOR EXPOSURE STATEMENT

This product complies with FCC and ISED radiation exposure limits set forth an uncontrolled environment.

The sensors WISE should be installed and operated with minimum distance of 0.006m between the radiator and your body. The case of the device guarantees the fulfillment of this requirement and therefore allows its direct application on the body by means of elastic bands and/or double-sided tape.

The receiver GTWY should be installed and operated with minimum distance of 0.009m between the radiator and your body.

DATA SECURITY

The privacy of the acquired data is guaranteed by an encryption system. The patient monitored with this system must have signed the consent to the processing of data.

In case of data tampering or virus interactions with the PC on which the software is installed, it is necessary to contact the technical assistance.

CONTACT INFORMATION CONTACTS

- For all other information the user is forwarded to the documentation from individual manufacturers of motion sensors and EMG sensors.

- Motion sensors hardware emits RF energy in the ISM (Industrial, Scientific, Medical) band. Please ensure that all medical devices used in proximity to this device meet appropriate susceptibility specifications for this type of RF energy (CE or FCC marked). Please refer to the section "Radio Frequency Exposure and Emission" from the WISE Technical Information (NCS Lab, Carpi, Italy).

SOFTWARE INSTALLATION

Preliminary notes

- Before every usage user must accept the following declaration:
  - "I declare that I have the proper qualification and I have received the proper training for using such product"
- PC Minimum requirements and compatible software:
  - Laptop/Desktop PC with at least quad core processor (Intel, AMD, Atom)
  - Intel Graphics HD or superior[4]
  - At least 2 USB (>2.0) ports
  - 5 GB hard disk space, necessary for the software installation and the saving of analysis and errors detected
  - 4 GB RAM memory
  - Operative system: MS Windows 7, MS Windows 8, MS Windows 8.1, MS Windows 10
- Performance cannot be guaranteed if configurations lower than the above are used
- The listed requirements allow you to use the software. The free disk space allows to save the analyzes and the error log
- The error log cannot be changed by the user in any way
- In case of installation problems, please contact our support and assistance

Installation procedure

FIRST INSTALLATION

1. Launch SHoWMotion_setup.exe and follow instructions on the screen
2. The Installer will ask the user to accept the restoring of C++ 2010 libraries
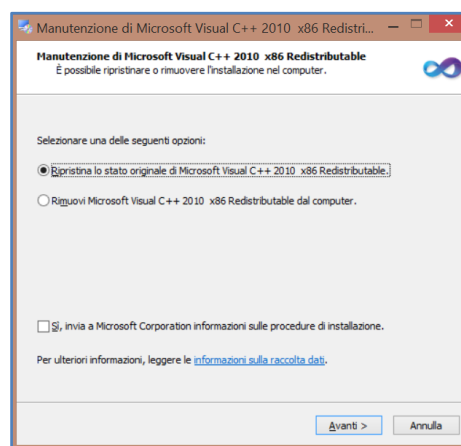
3. If necessary, the installer will also ask the user to accept installation of redistributable C++ 2012 libraries
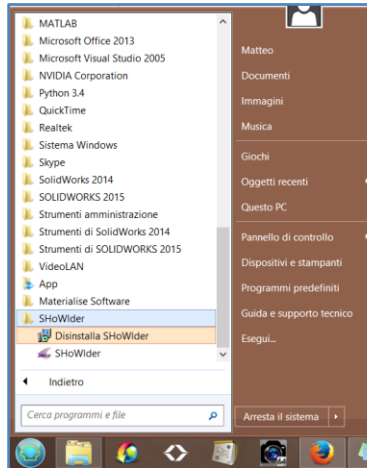

[4] Integrated graphic card is suggested for better performance

4. At this point of installation, hardware drivers are installed. Windows might ask for confirmation on drivers signature

5. Launch SHoW Motion software for the first time. The proper link can be found in the start menu


6. At first launch of the software, software license needs to be activated. In order to do this, copy the Activation License ID as shown in the picture and send it to your sales contact.
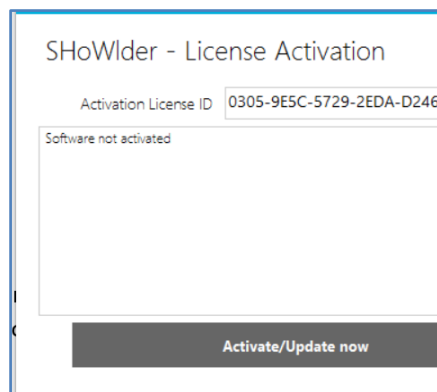

7. You will receive a license file that can only work for your personal machine. Repeat step 11 and select "Activate" to indicate where the license file is located. Once the activation has been confirmed, this procedure will not be asked anymore.
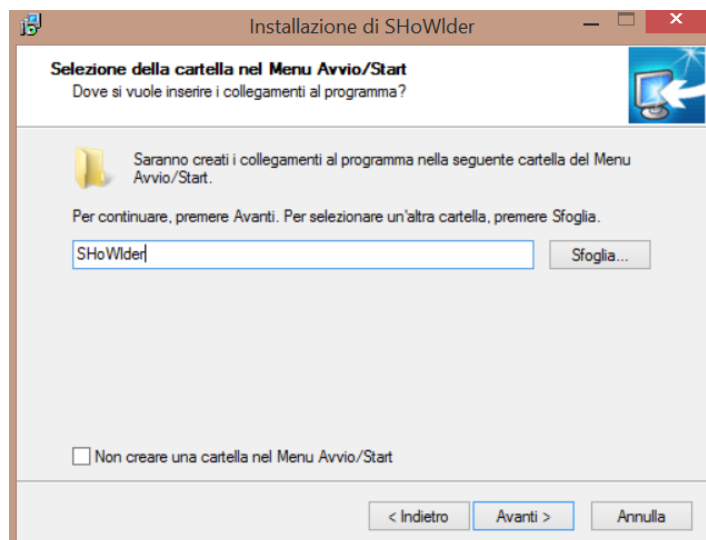
FOLLOWING INSTALLATIONS

1. Launch SHoWMotion_setup.exe and follow the instructions on the screen:
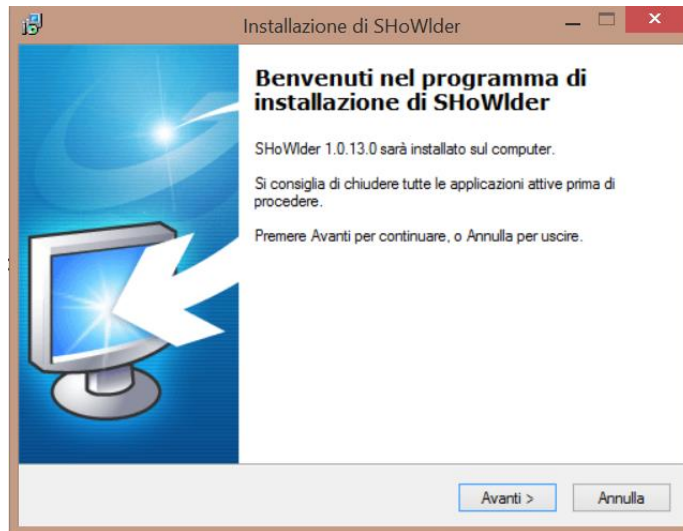
2. Select the components to be installed. Full installation is recommended:
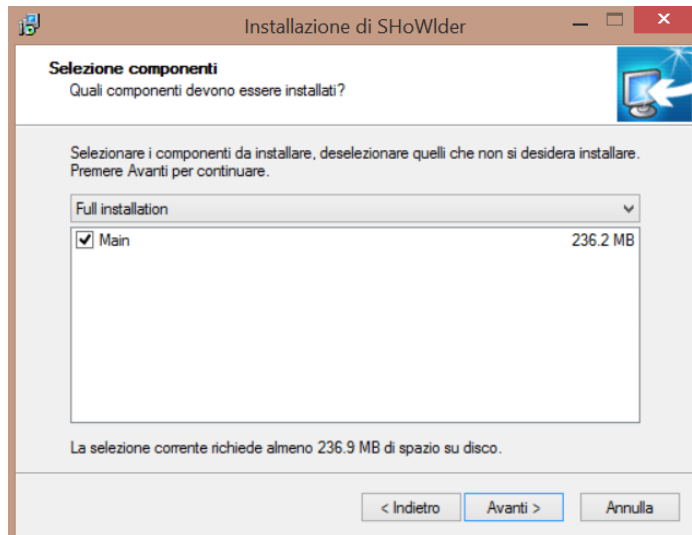
3. Select the folder where you want to install the software:

INSTRUCTIONS OF USE

PRELIMINARY VERIFICATIONS

Make sure that all sensors batteries are fully charged before each session of analysis.

- Verify to have enough free space available (at least 200 MB) on your hard drive where the software has been installed to allow correct data and error log saving after each session.

- It is convenient to start connecting wireless receivers through the USB cables before launching the software. In this way it is possible to verify that MS Windows have correctly load proper drivers for the hardware. If, for some reason, error messages appear on the screen soon after the connection of the USB cables, please refer to Section "The FCC ID of the receiver is 2ATZJ-GTWY and it is affixed in the back side of GTWY receiver as show in the figures.

The FCC ID of the sensors is 2ATZJ-WISE and it is affixed in the lower part of WISE sensors, as show in the figures.

- TROUBLESHOOTING".

- Make sure enough EMG electrodes are available for the number of muscles expected from the analysis. At least 2 electrodes are necessary for each muscle.

- Verify access to previously created database by opening the "Patient" section in the SHoW Motion software (Picture 1). For further information, please refer to Section "Load New Analysis"

Picture 1

BASIC INSTRUCTIONS

1. At the beginning of each session, open the suitcase, pick up the wireless receivers for motion sensors and EMG and position them on a flat surface so that they are at least 2 meters far each other. For best communication, it is suggested to place them at different heights with respect to each other[5]. Always use suitcase provided with the product to store sensors and accessories when these are not used.

2. Place motion sensors, EMG and related set of strap interfaces to a flat surface nearby the subject to ease the set-up

3. Connect wireless receivers via USB port as shown in the Picture 2. If USB ports number is not enough for doing this, for example if a mouse nano-receiver is used, please make use of the USB hub provided in the suitcase. It is highly recommended in this case to avoid connecting both USB cables to the same USB hub.
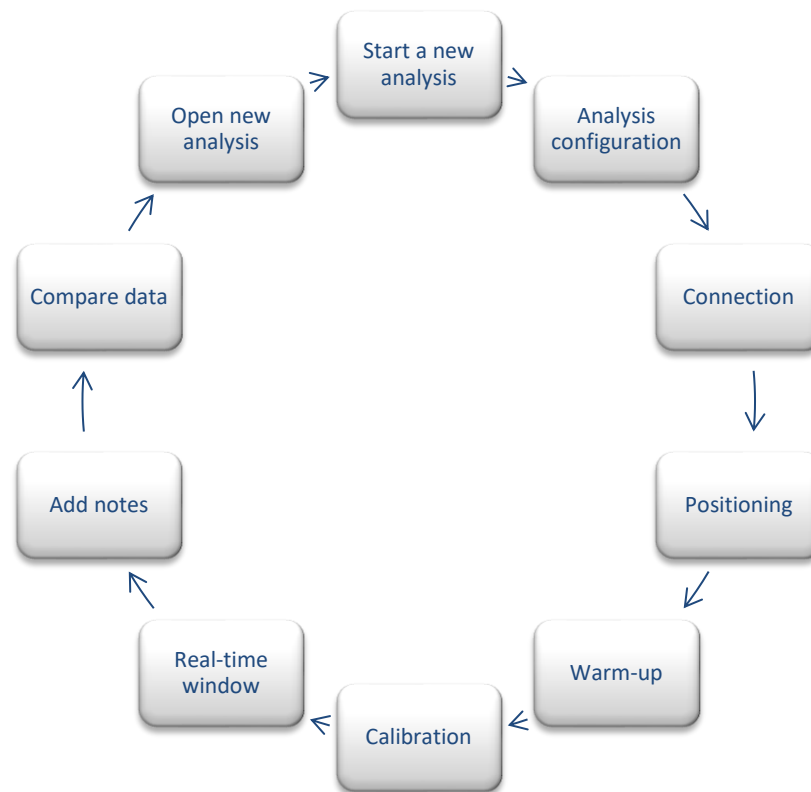

Picture 2

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[5] It is not recommended to position wireless receivers on the floor or on the ground. Please use some structure/chair or other to keep at least 1 meter distance of height from the floor

4. Turn on the EMG wireless receiver by pushing the toggle on its back. After a few seconds, LED indicators on the front will show the EMG sensors connected to the receiver. Note that only when the EMG sensors are removed from the suitcase, the connection can be established.

5. Prepare EMG sensors for the analysis by first placing skin adhesive stickers on the back of each probe. Secondly, connect 2 EMG electrodes to the extremities.

ANALYSIS FLOW-CHART

The above picture illustrates the framework used within the SHoW Motion software. During the analysis, it is always possible to go back to the previous step and repeat it. For instance, if in the real-time window the user visually recognizes that there was an inversion between two motion sensors on the upper body, it is always possible to click on "Calibration" on the left panel in order to restart calibration procedure[6].

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[6] An easy way to recognize that two sensors were switched during positioning, is given by looking at joint rotation sign: when the animation shows rotation occurring in a completely opposite direction than what the subject is performing, the two sensors might be switched

ANALYSIS PROCEDURE

Start a new analysis

To start a new session of analysis, click on the top left button to open the menu, then click on "new analysis". Right panel will change showing one list menu for each configurable parameter of the analysis (Picture 3):

- **Analysis type**: each analysis type selected automatically correspond to a subset of possible configurations, for example regarding the number of sensors to be used. Depending on the selected analysis type, all the lists below will change accordingly, presenting the available options.

- **Number of sensors**: select the number of sensors to be used for the analysis

- **Side:** select here the side of the subject that is required to be analyzed. When the number of sensors selected are enough to afford a bilateral analysis, only the option "Both" can be selected.

Picture 3

- **Patient**: click on the right button. A pop-up window will appear showing the current patient data available in the database. If database was empty, a new patient file can be created by using the "+" button and filling in the required information.

- **EMG:** the toggle is available when EMG plugin has been installed. If so, the user can either proceed without performing an EMG analysis together with the kinematics (toggle unselected) or perform an EMG analysis together with the kinematics (selected toggle). As shown in the picture 4, a list of selected muscles will be visualized.
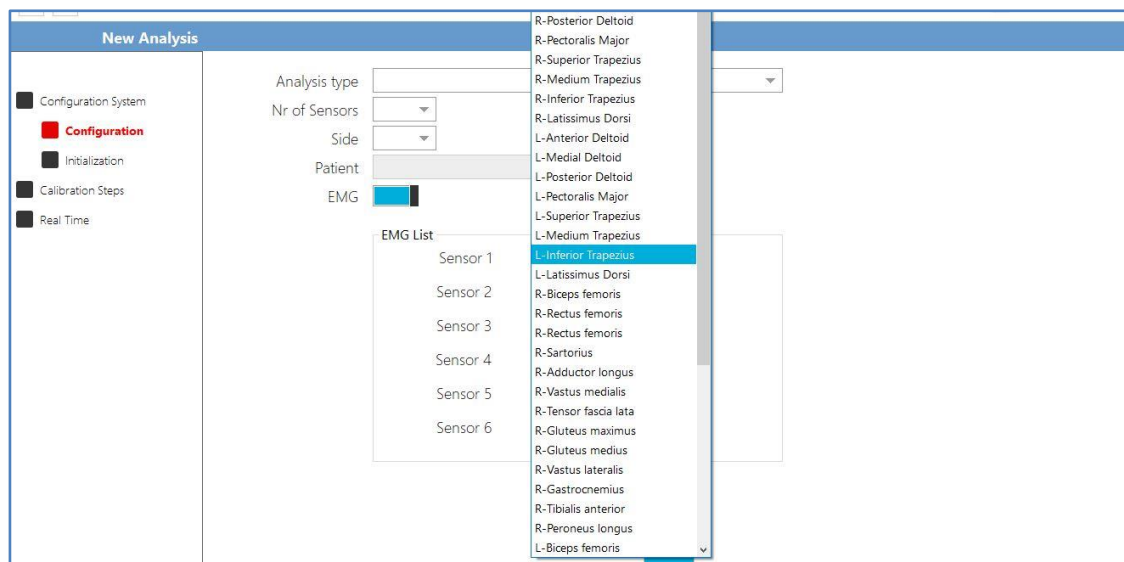
Depending on the number of EMG sensors received with the package, the user can select the corresponding muscle upon which the EMG sensors will be placed on the subject.

WARNING: at this stage make sure that the EMG wireless receiver is connected via USB and already turned on.

Click on the blue arrow to proceed to the next step.

Initialization

During initialization part, if the gateway is already inserted in the computer, extract the gateway and plug it into the USB port. If not, insert the gateway into the USB port and wait for the sensors to be activated.

As show in the picture 5, the software will wait for the sensors to become connected. In order to do this, motion sensors need to be waken-up form their current status. It is sufficient to raise up each motion sensor on the table. Each sensor will fell motion, therefore will start to blink as well. When all the motion sensors will start to blink at the same time like the receiving station, software will automatically confirm by a green tick on the screen. It is always possible, at this stage, to go back to the previous section or starting the positioning of sensors.
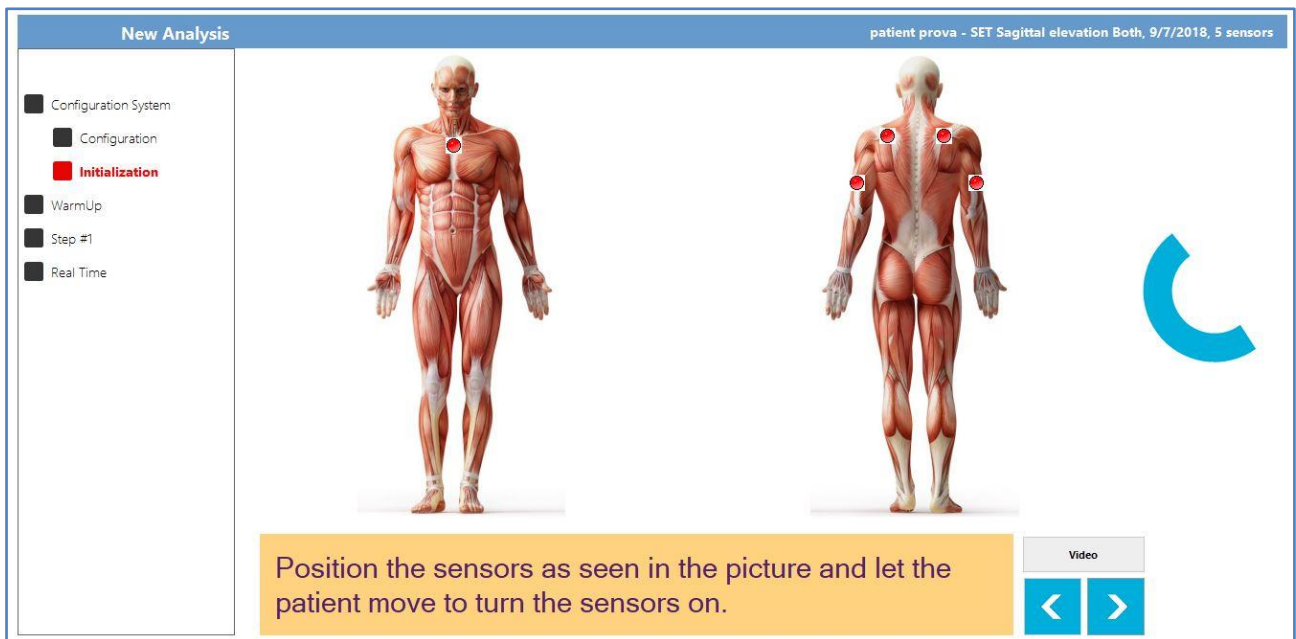
Picture 5

Positioning of sensors

A button called "video" is available for the user. When pressed the button, a dedicated movie is shown explaining the primary actions to take in order to position the motion sensors on the body of the subject. In the following pictures, stepwise procedure is described. Each sensor is provided with a colored sticker on the side, corresponding to a specific body segment. To verify this correspondence, please consult the reference material provided with the product.

Taping

Before positioning sensors, it is convenient to place skin adhesive tapes on scapula areas.

Sensors corresponding to Scapula areas need also to have a small square of double-sided tape attached on their back side.

For the remaining parts of the body, place the bands with the colored label corresponding to the adhesive placed on the sensor.

To verify this correspondence, please consult the reference material provided with the product.

Positioning of trunk sensor (upper and lower limb analysis)

Position "Trunk" sensor by first placing the trunk strap provided in the kit, around the sternum of the subject. The sensor needs to face the front of the subject with the led bottom right.

Positioning of scapula sensor (upper limb analysis)

Position "scapula" sensor on the medium aspect of the scapula spina as shown in the Picture 6. In order to perform this correctly (assuming analysis of right shoulder):

1) using your left hand, palpate Angulus Acromialis using thumb, while at the same time palpate Trigonum Spinae using medium finger.

2) Your index finger will now identify the spina of the scapula. Proceed in palpating it until you find the middle part along its length from the medium finger and the thumb.

3) Now keeping the scapula sensor in your right hand, place the sensor as shown in the Picture 6.

Picture 6

The correct positioning is made when the longer side of the motion sensor is aligned and almost parallel to the middle part of the scapula spina. If this is done properly, the sensor will not be perpendicular to the vertebral spine and the part of the sensor opposite to the side aligned will lay on the supraspinatus muscle area.

The sensor needs to be placed so that the USB connector is pointing towards the acromion.

Positioning of humerus sensor (upper limb analysis)

Position "Humerus" sensor by first placing the humerus strap provided in the kit, around the upperarm. For best results, it is highly recommended that the strap is placed around the arm so that the holder will appear at the back of the arm, around the triceps muscles.

Positioning of forearm sensor (upper limb analysis)

Position "Forearm" sensor by first placing the forearm strap provided in the kit, around the distal aspect of the forearm. The strap must be placed around the forearm so that the holder will appear at the front of the forearm, around the wrist.

Positioning of pelvis sensor (lower limb analysis)

Position "Pelvis" sensor by first placing the pelvis strap provided in the kit, around the waist. For best results, it is highly recommended that the strap is placed around the waist so that the holder will appear at the back of the waist, so that the midline of the sensor is aligned with the spine, and its Y axis is oriented along the line linking the posterior superior iliac spines (PSIS).

Positioning of thigh sensor (lower limb analysis)

Position "Thigh" sensor by first placing the thigh strap provided in the kit, around the thigh, so that the sensor is positioned laterally, within its median third, with the X axis aligned with the long axis of the femur and with the Z axis pointing laterally in the body's frontal plane.

Positioning of shank sensor (lower limb analysis)

Position "Shank" sensor by first placing the shank strap provided in the kit, around the shank, so that the sensor is positioned within the distal third, close to the lateral malleolus, with the X axis aligned with the long axis of the fibula and with the Z axis pointing laterally in the body's frontal plane.

Positioning of foot sensor (lower limb analysis)

Position "Foot" sensor by first placing the foot strap provided in the kit, around the foot, so that the base of the sensor is positioned over the dorsal surface in order to maximize its stability.

Verification of positioning stability

It is highly recommended to verify the correct positioning of sensors not only in terms of location, but also stability. To do this, perform the following:

- Trunk/Pelvis sensor: ask the subject to rise up and down arms frontally as more as possible without pain. If the trunk/pelvis sensor moves up and down according to the movement, find another stable location for the sensor (For further information, see "The FCC ID of the receiver is 2ATZJ-GTWY and it is affixed in the back side of GTWY receiver as show in the figures.

The FCC ID of the sensors is 2ATZJ-WISE and it is affixed in the lower part of WISE sensors, as show in the figures.

- TROUBLESHOOTING")
- Scapula sensor: ask the subject to rise up and down the arms laterally as more as possible without pain. If the scapula sensor is touched by the deltoid muscles or skin motion is visible, it is highly recommended to move the scapula sensor more medially, still keeping it along the spina of the scapula. (For further information, see "The FCC ID of the receiver is 2ATZJ-GTWY and it is affixed in the back side of GTWY receiver as show in the figures.

The FCC ID of the sensors is 2ATZJ-WISE and it is affixed in the lower part of WISE sensors, as show in the figures.

- TROUBLESHOOTING")[7]

- <u>Humerus/Thigh/Shank/Foot sensor:</u> after positioning, keep the entire sensor strap with one hand and try to rotate it internally towards the center of the body. If the strap will not move or fall down along the limb, the positioning is stable.

- <u>Forearm sensor:</u> after positioning, move passively the forearm of the subject so that a complete pronation and supination are performed. If the strap (and therefore the sensor) will entirely follow the movement and not slice due to the skin, the positioning is stable.

Positioning of EMG sensor

Please refer to guidelines in scientific literature regarding rules for correct positioning of EMG sensors depending on the muscles under analysis. A guide suggested for beginners is available at: http://www.noraxon.com/wp-content/uploads/2015/01/nor-19surface-emg-manual.pdf

Perform warm-up of the system

Once positioning and all verification are completed, it is possible to proceed to the next step by pressing the blue right arrow (Picture 5).

Warm-up of the system is required in order to initialize the software and make it fully ready for the analysis. During the warm-up phase (5 seconds), the subject is required to not perform motion tasks or special actions such as answering cell phone or move

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[7] Please note that positioning of sensors by verification of symmetry between left and right side of the body is not always a reliable choice. Differences in anatomy or functionality of shoulder and arms might bring to wrong assumptions. It is highly recommended to perform right and left side positioning independently from each other.

around the floor. It is also important that subject is not sitting above metal objects during this phase or walking closely to active motors or metal objects. When the subject is ready, click on the red circle at the right to start (Picture 7).

Warm-up phase of the system can easily be used in order to double-check correct positioning of motion and EMG sensors. If something is discovered during this phase, it is not necessary to restart warm-up phase.

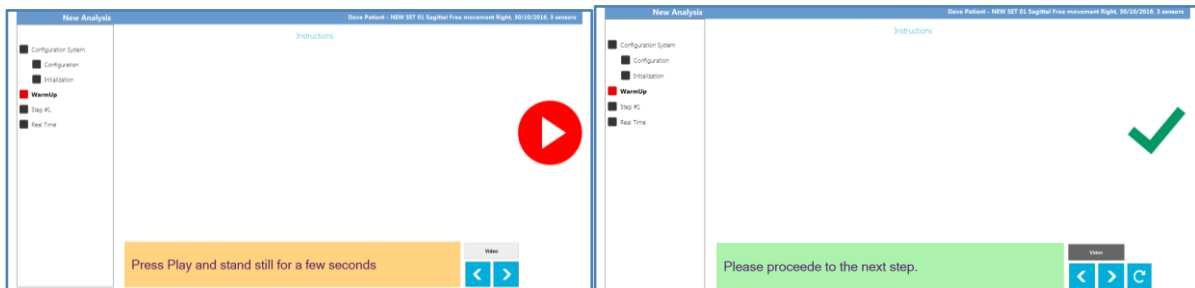It is now possible to proceed to the next step by pressing the blue right arrow (Picture 7).

Figura 7

The number and order of next steps depends on the type of analysis (upper/lower limb) and on the monitored articulations (elbow and knee requires dedicated functional calibrations).

The following chapters describe separately upper limb and lower limb calibrations steps.

UPPER LIMB Perform first calibration step (STEP #1)

During first calibration step, the subject is asked to keep an up-right posture according to ISEO protocol as described in "ABOUT MEASUREMENT PROTOCOLS". In order to accomplish this, it is important that arms are along the side of the trunk, shoulders are relaxed and elbows are 90º flexed in order to easily verify if the arms are in neutral internal-external rotation.

When the subject is ready, click on the red circle at the right. The system will automatically confirm with a green tick when the data collected is completed.

It is strictly important that during this phase the subject does not perform any movement. If the subject is not autonomously able to keep the posture, the operator can help in keeping the position.

First calibration step is compulsory, independently from the sensor configuration used or the side under examination.

When completed, it is possible to proceed to the next step by pressing the blue right arrow.

UPPER LIMB Perform second calibration step (STEP #2a)

Second calibration step is a required step only when the number of sensors used is above 5 in "Both" configuration.

During second calibration step, the subject is asked to perform a sequence of pure flexions and extensions of the elbow according to ISEO protocol as described in "ABOUT MEASUREMENT PROTOCOLS" . In order to accomplish this, it is important that arms are along the side of the trunk, their motion is limited, shoulders are relaxed and elbows flex and extend without performing any prono-supination movements. For best results, the subject should not perform full flexions or full extension and speed should be comfortable speed.

When the subject is ready, click on the red circle at the right. The user needs to stop the operation by clicking again on the red square. It is recommended that at least 5 repetitions of the same movement is performed.

It is strictly important that during this phase the subject does not perform any movement. If the subject is not autonomously able to keep the posture, the operator can help in keeping the position.

If the subject is not capable of performing the movements actively, passive mobility by the operator can also be accepted.

When completed, it is possible to proceed to the next step by pressing the blue right arrow.

UPPER LIMB Perform third calibration step (STEP #2b)

As second calibration step, also third calibration step is a required step only when the number of sensors used is above 5 in "Both" configuration.

During third calibration step, the subject is asked to perform a sequence of pure pronations and supinations of the elbow according to ISEO protocol as described in "ABOUT MEASUREMENT PROTOCOL". In order to accomplish this, it is important that arms are along the side of the trunk, their motion is limited, shoulders are relaxed and elbows maintain a flexion of 90° during pronation and supination. It is important that there are no flexion-extension movements during this phase. For best results, the subject should not perform full pronations or full supinations and speed should be comfortable speed.

When the subject is ready, click on the red circle at the right. The user needs to stop the operation by clicking again on the red square. It is recommended that at least 5 repetitions of the same movement is performed.

It is strictly important that during this phase the subject does not perform any movement. If the subject is not autonomously able to keep the posture, the operator can help in keeping the position.

If the subject is not capable of performing the movements actively, passive mobility by the operator can also be accepted.

When completed, it is possible to proceed to the real-time step by pressing the blue right arrow.

LOWER LIMB Perform first calibration step (STEP #1a)

First calibration step for lower limb is the functional calibration of right knee.

During this calibration step, the subject is asked to perform a sequence of pure flexions and extensions of the right knee according to Outwalk protocol as described in "ABOUT MEASUREMENT PROTOCOLS". In order to accomplish this, the subject under investigation has to stand in the upright posture and to flex-extend the knee about five times up to 70°.

For best results, the subject should not perform full flexions or full extension and speed should be comfortable speed.

When the subject is ready, click on the red circle at the right. The user needs to stop the operation by clicking again on the red square. It is recommended that at least 5 repetitions of the same movement is performed.

It is strictly important that during this phase the subject does not perform any movement. If the subject is not autonomously able to keep the posture, the operator can help in keeping the position.

If the subject is not capable of performing the movements actively, passive mobility by the operator can also be accepted.

When completed, it is possible to proceed to the next step by pressing the blue right arrow.

LOWER LIMB Perform second calibration step (STEP #1b)

Second calibration step for lower limb is the functional calibration of left knee.

During this calibration step, the subject is asked to perform a sequence of pure flexions and extensions of the left knee according to Outwalk protocol as described in "ABOUT MEASUREMENT PROTOCOLS". In order to accomplish this, the subject under investigation has to stand in the upright posture and to flex-extend the knee about five times up to 70⁰.

For best results, the subject should not perform full flexions or full extension and speed should be comfortable speed.

When the subject is ready, click on the red circle at the right. The user needs to stop the operation by clicking again on the red square. It is recommended that at least 5 repetitions of the same movement is performed.

It is strictly important that during this phase the subject does not perform any movement. If the subject is not autonomously able to keep the posture, the operator can help in keeping the position.

If the subject is not capable of performing the movements actively, passive mobility by the operator can also be accepted.

When completed, it is possible to proceed to the next step by pressing the blue right arrow.

LOWER LIMB Perform third calibration step (STEP #2)

During third calibration step of lower limb, the subject is asked to keep an up-right posture according to Outwalk protocol as described in "ABOUT MEASUREMENT PROTOCOLS". In order to accomplish this, the subject is asked to stand still in orthostatic position: upright with the back straight, looking forward, knee center aligned to the anterior superior iliac spine and the line from the 2nd metatarsal head to the calcaneus of the right foot parallel to the same line of the left foot.

When the subject is ready, click on the red circle at the right. The system will automatically confirm with a green tick when the data collected is completed.

It is strictly important that during this phase the subject does not perform any movement. If the subject is not autonomously able to keep the posture, the operator can help in keeping the position.

When completed, it is possible to proceed to the real-time step by pressing the blue right arrow.

Launching real-time window (UPPER and LOWER LIMB)

At this stage all calibration steps have been accomplished. It is therefore possible to start to measure, visualize and record every upper body motion by means of the real-time window. Real-time windows offers both a visual feedback in terms of 3D animation and more quantitative information regarding kinematics behind motion.

Real-time window is divided into two parts, left and right panels (Picture 8). By means of the panels is possible to visualize 3D animation of the subject while moving, related graphical data and even compare current measurement in real-time with previously recorded data.
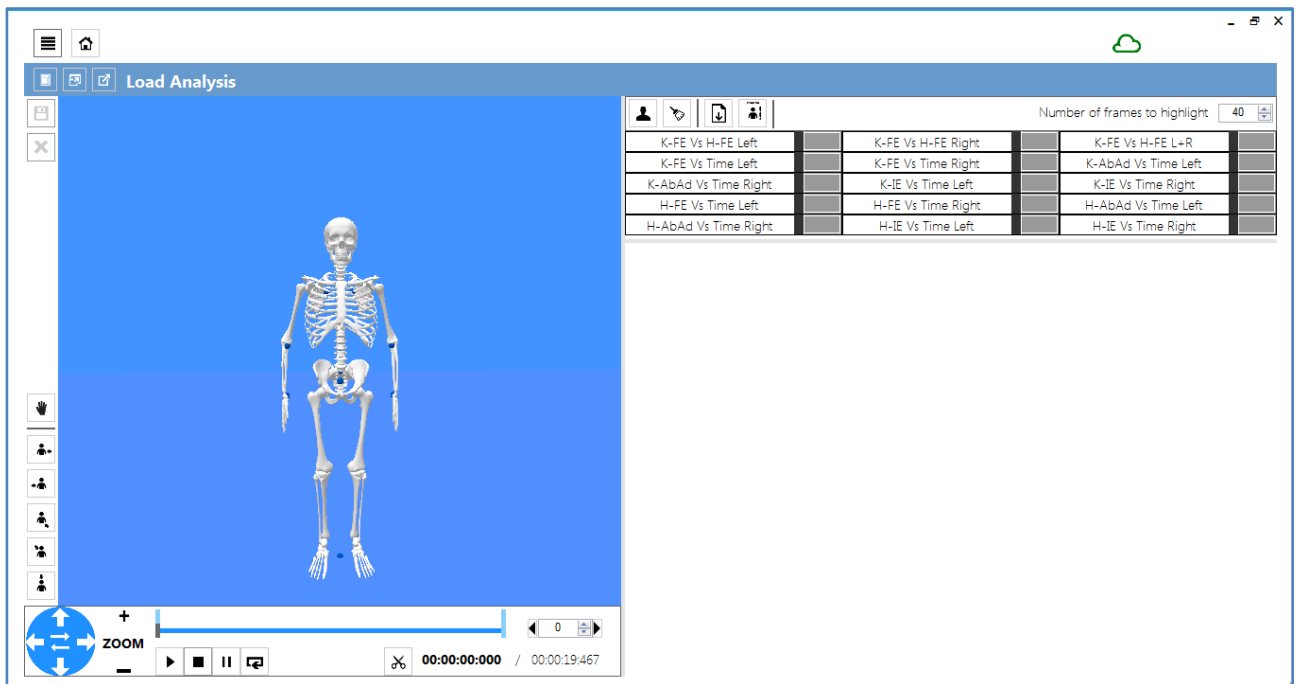
Picture 8

Controls in the left panel

Left panel contains a dedicated window incorporating a 3D environment where full skeleton can visualize in real-time. When the user presses the play button, 3D animation of the skeleton will follow subject motion, depending on the number of sensors/segments available in the configuration selected at the beginning.

Left panel also contains stop and record controls. Record is a radio button that needs to be active in order to apply recording. When record button is not active and play button is pressed, real-time visualization will be saved after stop button is pressed. In order to allow saving of data at the end of the measurement, first activate record button and then press play.

Other commands on the left panel allow the user to:
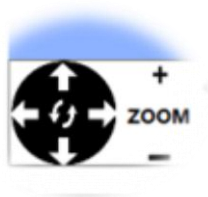
- Zoom in and out
- Pan the screen
- Rotate

It is also possible to rotate the 3D view and zoom in and out respectively by using left mouse button and mouse roll.

WARNING: before every press of the PLAY button it is necessary that the subject assumes a neutral pose as described in the previous picture 8

3D skeleton animation feedback

3D animation can be used for several purposes:

- Provide the user with a direct feedback on motions performed by the subject

- Provide the subject with a direct feedback regarding the type of measurement, how motion is performed and concept behind the analysis, enhancing therefore subject involvement
- Verifying correctness of measurement

By the 3D animation is always possible to verify that skeleton shows reasonable representation of bones. If this does not happen:

- please check that sensors positioning was correct. If this is case, go back to the calibration section and restart it
- please check that there are no new interferences around (see section "Environment Requirements")
- if strange continuous motion on the screen is visible, restart from warm-up step
- if none of the above work, please contact support and assistance

Controls in the right panel

Right panel allows the user to select the type of graphical visualization during real-time measurement. Right panel also contains buttons for the selection of trials to be compared with current data measurement.
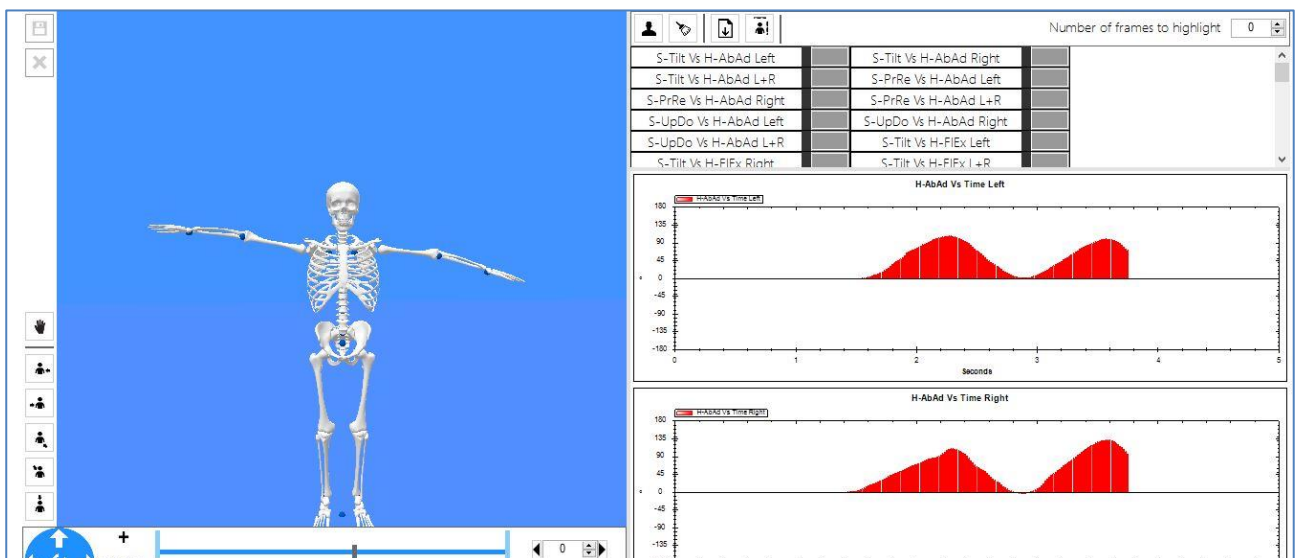
Picture 9

Compare data using real-time window

In order to directly compare data during real-time, go to the right panel, click on the ⬛ icon. A pop-up list will be shown so that you can select one of the previous recorded trials.

When confirmed, data will automatically be loaded and each graph in the right panel will contain the selected data as background. All the real-time measurements, hereinafter, will therefore be overlapped to the selected data. It is always possible to load data, either after pressing the play or the stop button.

Add notes to patient measurements

If the record button was active, by stopping the analysis a new pop-up window will appear asking the user to add notes before saving. The user can enter any kind of information within the allowed space. The entered text will be written to the "note" section of the trial in the database. It is always possible to enter or change that note later on, directly opening the database.

Inter-joint coordination plot

In the Picture 10, an example of data visualized in the right panel is shown. The graph was selected among the available list of titles by clicking on the corresponding toggle button. Each title refers to a couple of joint degree of freedom which will be visualized in the abscissa and ordinate axes of the graph. For example, the graph selected in the picture 11 is called "Up-Do Vs Fl-Ex".
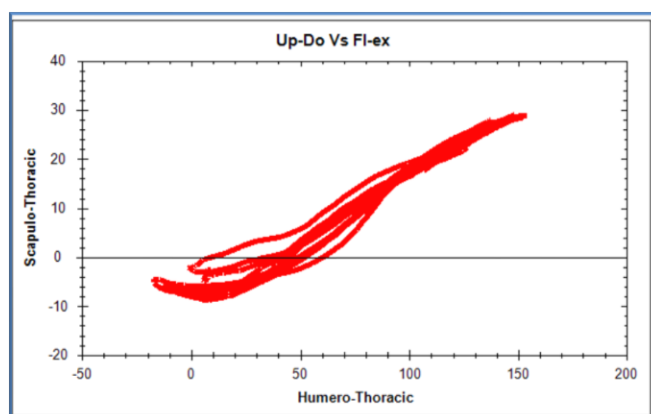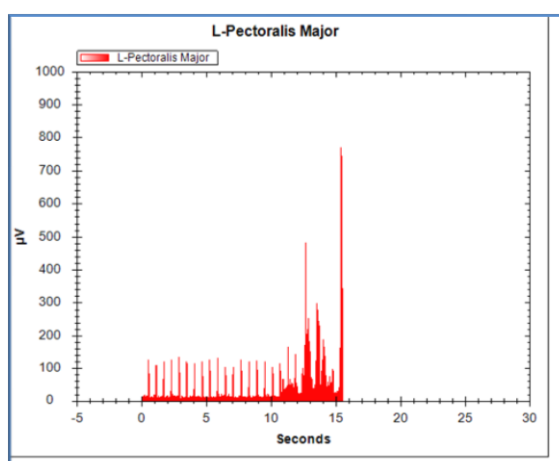

Picture 10

This refers to a inter-joint coordination plot where abscissa contains the degrees of flexion(+) and extension (-) of the humero-thoracic joint while ordinate will contain degrees of Upward(+) and Downward(-) rotation of the scapula-thoracic joint. This corresponds to the so-called "Scapulo-humeral Rhythm", that is for how many degrees the scapula rotates at a certain elevation of the arm. While the subject is moving, all the sequence of repetitions are overlapped together in the same graph.

The same considerations apply to other inter-joints coordination cases, as hip-knee for lower limbs.

EMG data plot

Graphical information is also available when an EMG system is combined with motion sensors. The right panel will include an additional list of graphs which can be selected in order to visualize signals coming from each EMG probe, in other words muscle activity against time for each selected muscle.
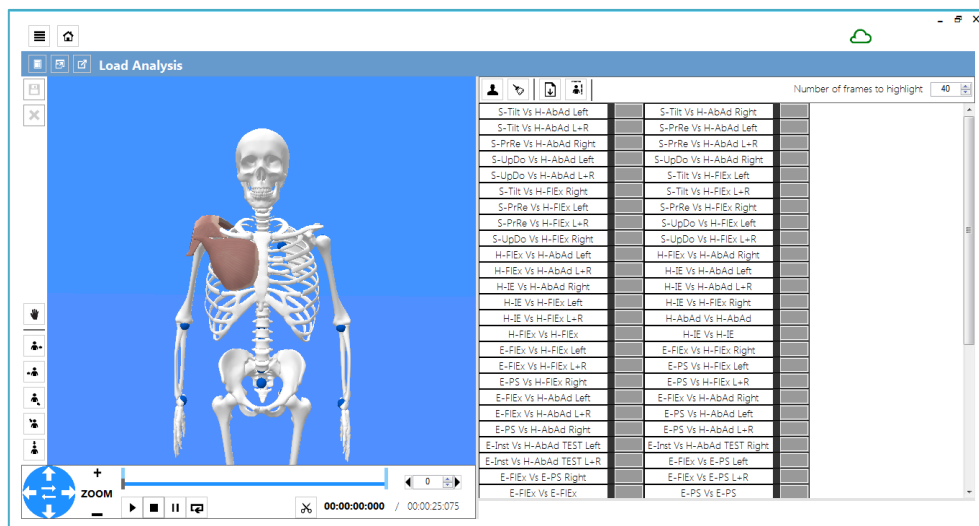

Picture 11

As shown in the Picture 11 above, EMG muscle activity is plot against time. Muscle activity is provided as µV, according to the amplification method of the EMG manufacturer. During real-time, the plot against time will scroll to the left showing data frame by frame.

3D animation using EMG

Direct information regarding muscle activity is also available in the 3D animation window when an EMG system is associated with motion sensors. Each muscle selected at the beginning of the analysis will be visualized on the screen as a pink surface having corners corresponding to conjunction points of muscles with bones.

Surfaces representing muscles will change their geometry depending on the motion of bones (moved thanks to motion sensors data), together with their color due to the muscle contraction instantaneously measured by using EMG. The higher the intensity of the muscle contraction the darker will get the color of the surface. In other words, color is modulated by means of µV of activity measured by EMG on the specific muscle.

In the Picture 12, the example shows correspondence between dark red color of the surface representing the left pectoralis major muscle and the peak of µV in the EMG signal shown in the graph.
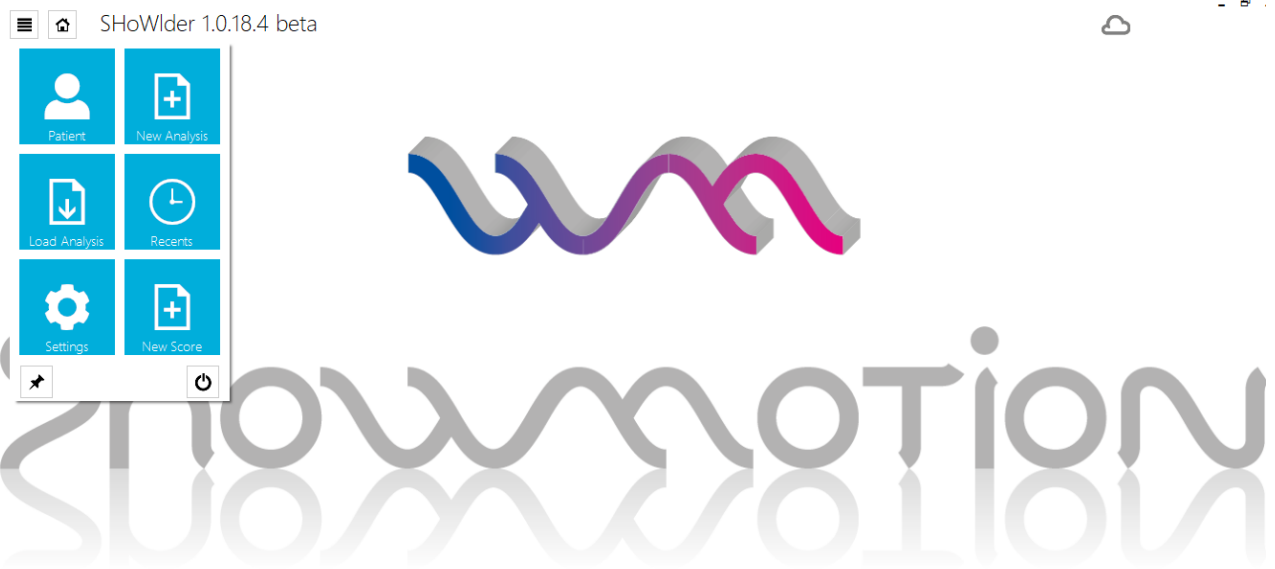

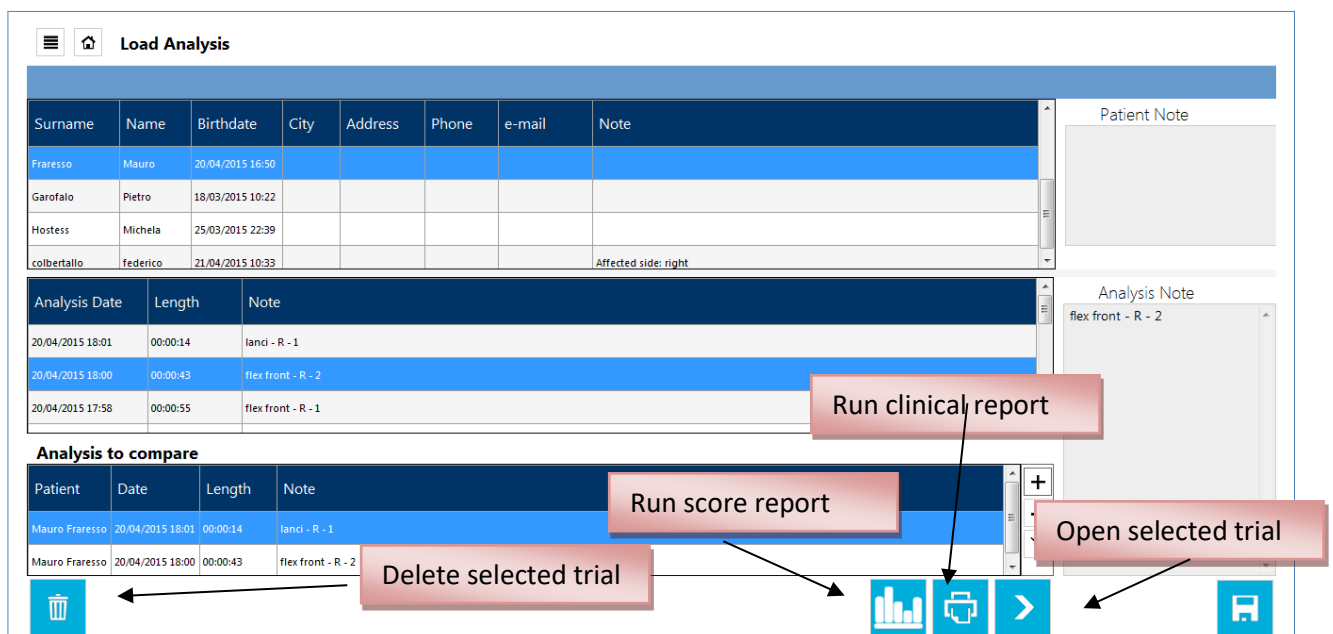**Picture 12**

Load a new analysis

After real-time analysis it is always possible to open a trial which was recorded previously, visualize 3D animation and plot data, exactly in the same way as in real-time.

To do this, click on the top-left button on the interface and select "Load Analysis" (Picture 13).

Picture 13

This will open a new window called "Load Analysis" containing the list of subjects trials available in the database. Clicking on a subject allows to visualize and change Patient Note, while clicking on a trial allows to visualize and change the Analysis Note. The buttons at the bottom of the window serve as commands to interact with the database, as shown in the Picture 14.

Picture 14

After opening a recorded trial, a screen very similar to the real-time window will appear. The main difference regards the replacement of the record button with the pause button. The play, stop and pause buttons can be used to scroll the recording like with a video file. The selected graph in the right panel will be refreshed with all the dataset available until the frame where the cursor mouse is. It is of course possible to rotate the 3D environment and control it like in the real-time view.

Report creation

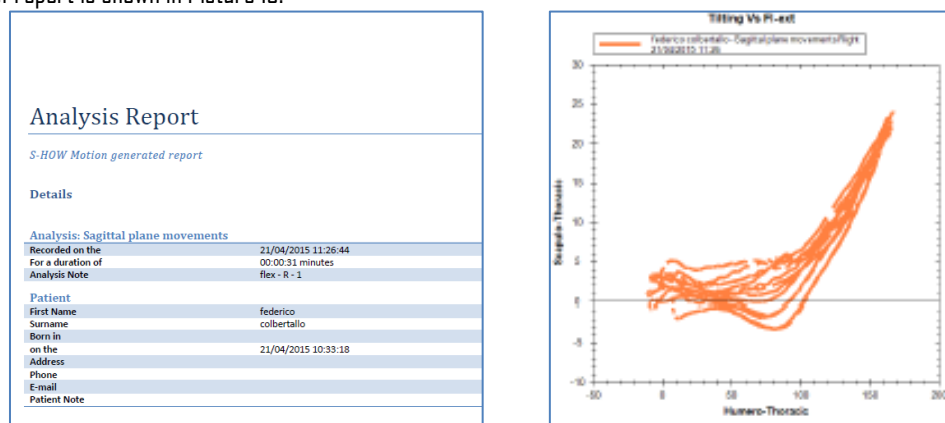Selecting a trial from the database and clicking on [printer icon] button will automatically generate a PDF format report of the entire trial containing:

- Patient information and related notes
- Graphs available with kinematics information (including inter-joint coordination)
- Graphs with EMG information for all the muscles analyzed

An example of report is shown in Picture 15.

Picture15

Segmentation report creation

Kinematics data included in real-time window and graphs in the clinical report contain the full set of repetitions of movement performed by the subject.

SHoW Motion offers a novel functionality which allows to split motion into different phases and generate proper scoring for each of them and for each degree of freedom.

Selecting a trial from the database an clicking on button [bar chart icon] will automatically generate a PDF format report starting from the entire trial.

As shown in the Picture 16, for the humero-thoracic joint rotation and each corresponding rotation of the scapula, a bar is generated at each level of elevation of the arm. The height of the bar corresponds to the score given at that level of elevation. The higher the score, the less scapula rotation occurred in order to reach that level of arm elevation.
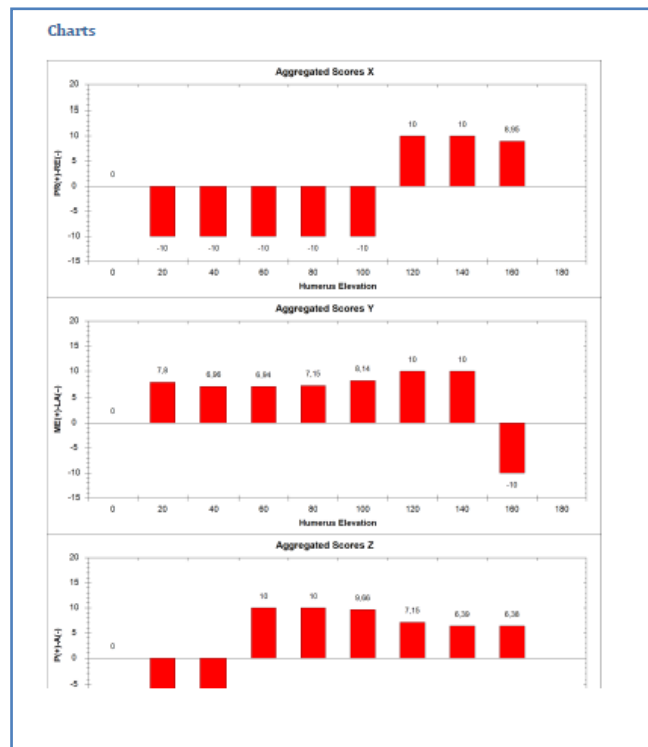
Picture 16

Alarms generated by the software

The problems detected by the software are signaled to the user with alarm messages. The generated alarms are not exclusively visual but include text. The text clearly illustrates the problems encountered and how to solve them. The user of the system must be aware of the alarms that may be generated by the software and how to manage them. If it is impossible to proceed with the analysis, contact our support team.

The following are the main possible alarms generated, ther causes and how to solve them:

>> EMG station error:

This error is caused by a wrong identification of the EMG station by the PC. It is advisable to check that the station is switched on and connected via USB cable to the PC where the software is installed. If these conditions are verified, press "OK", return to the previous screen and continue the analysis. If the problem occurs again, try changing the USB port of the PC to which the EMG station is connected.

>> The calibration step hasn't reached the configured quality limit:
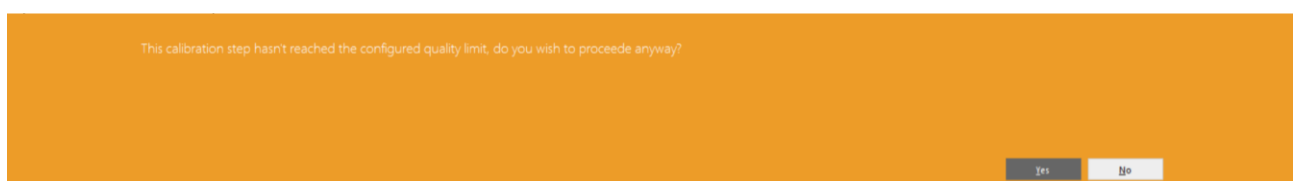
This message appears when the quality of the data received by the sensors during the functional calibration phase is not optimal. This could be caused by: i) incorrect positioning of the sensors ii) sensors have transmitted inconsistent iii) the calibration movement was not performed correctly. It is advisable to check the positioning of the sensor, press "No" and re-run the functional calibration, carefully monitoring the patient's movement and re-explaining the specific movement to be performed. In case of correct execution, the message will no longer appear. In case of repeated error in this phase, caused by the patient's difficulty in correctly executing the movement, proceed in any case to the next step by pressing "Yes". This does not prevent the analyzes from being performed, but makes them less accurate.

>> Data incoherent:

> The received data are incoherent, please repeat the step. If you keep getting this error you may need to go back to the Initialization step.

This message appears when the software detects inconsistent data. This error could be caused by: i) incorrect positioning of the sensors ii) sensors have transmitted inconsistent iii) at least one sensor is unloaded or has lost synchronization with the others. It is advisable to check the positioning of the sensors and carry out the calibration phase again. In the event of a persistent error it will be necessary to go back to the initial step and repeat all the calibration steps.

>> Errore durante il salvataggio:

Analysis not saved. Error

This message appears when the scanned data cannot be saved. This error could be caused by: i) lack of disk space ii) sensors have not transmitted data iii) at least one sensor is unloaded or has lost synchronization with the others.

We recommend that you try again to save. In the event of a persistent error, it will not be possible to save the data and it will be necessary to perform the analysis again.

ABOUT MEASUREMENT PROTOCOLS

SHoW Motion modus operandi was designed in order to fully implement:

- ISEO (INAIL Shoulder and Elbow Outpatient) protocol for tracking shoulder and elbow kinematics of upper body
- Outwalk protocol for tracking lower limb

Description of ISEO is publicly available in:

Cutti, Andrea Giovanni, Andrea Giovanardi, Laura Rocchi, Angelo Davalli, e Rinaldo Sacchetti. «Ambulatory measurement of shoulder and elbow kinematics through inertial and magnetic sensors». *Medical & Biological Engineering & Computing* 46, n. 2 (February 2008): 169–78. doi:10.1007/s11517-007-0296-5.

The main parts included in the ISEO protocol are:

- Dedicated and optimized positioning of motion sensors on the body segments
- Anatomical calibration of trunk, scapula and humerus segments
- Functional calibration of elbow

ISEO has been widely used in applied research in clinics in different fields, including the creation of reference data on scapulo-humeral rhythm for population of subjects of different age.

Please refer to the following publication for latest validation studies based on ISEO.

- Parel et al; Ambulatory measurement of the scapulohumeral rhythm: Intra- and inter-operator agreement of a protocol based on inertial and magnetic sensors; Gait & Posture; v 35(4) pp 636-640;2012
- Parel et al; Bootstrap prediction bands of scapula kinematics based on the iseo protocol; Gait & Posture; v 37 pp S29; 2013
- Parel et al; Recovering of the scapulo-humeral rhythm in patients treated for rotator-cuff tear: Are 90 days enough?; Gait & Posture, v 35 pp S22-S23; 2012
- Pellegrini; Motion analysis assessment of alterations in the scapulo-humeral rhythm after throwing in baseball pitchers; Musculoskelet Surg; v 97 pp S9-S13; 2013
- Parel et al; Intra-protocol repeatability and inter-protocol agreement for the analysis of scapulo-humeral coordination; Med Biol Eng Comput; v 52 pp 271-282; 2014
- A.G. Cutti et al; Prediction bands and intervals for the scapulo-humeral coordination based on the Bootstrap and two Gaussian methods; Journal of Biomechanics; v 47 (5) pp 1035-1044; 2014
- J. Van den Noort et al; Effect of scapula locator double calibration on measurement of scapular kinematics with inertial and magnetic sensors in scapular dyskinesis; Gait & Posture; v 42 pp S27; 2015
- J. Van den Noort et al; Measurement of scapular dyskinesis using wireless inertial and magnetic sensors: Importance of scapula calibration; Journal of Biomechanics; v 48 (12) pp 3460-3468; 2015
- A.G. Cutti et al; The Constant score and the assessment of scapula dyskinesis: Proposal and assessment of an integrated outcome measure; Journal of Electromyography and Kinesiology; v 29 pp 81-89; 2016

Description of Outwalk is publicly available in:

A. Ferrari et al; Outwalk: A new protocol to measure the 3D kinematics of gait in real-life environment using an inertial & magnetic measurement system; Gait & Posture; v 30 pp S52-S53; 2009

A. Ferrari et al; First in vivo assessment of "Outwalk": a novel protocol for clinical gait analysis based on inertial and magnetic sensors; Med Biol Eng Comput; v 48 pp1-15; 2010

PRODUCT MAINTENANCE

Hardware

Maintenance of hardware components is necessary to guarantee characteristics and performance of hardware and related measurements. In this section, a list of items to be periodically verified by the user is provided:

- **Batteries**: duration of batteries during measurement is guarantee for the entire analysis if a full charge has been accomplished. Before every use, please verify sensors where charged. The WISE is equipped with LiPo batteries, with a capacity of 240mAh. Fully charged, it has a run-time of 2.5-3.5hrs, depending on the data rate and temperature. Charging will take ~1hrs at room temperature. Do not exceed charging ambient temperature range of 0ºC to +35 ºC. Please refer to hardware manufacturer for additional technical constraints related to the environment.

- **Accuracy**: accuracy of hardware is guaranteed under the intended use and the usage and environment requirements. Please refer to hardware manufacturer for additional technical information regarding data accuracy. For further information regarding accuracy of ISEO/Outwalk protocols, visit the related Section "About Measurement Protocol".

- **Calibration**: inertial sensors might require a re-calibration of magnetic sensors incorporated. For a full re-calibration of sensors please contact our support and assistance.

- **Cleaning**: make sure that all sensors are placed in the proper slots in the suitcase after usage. If sweat, gel, residual of skin tape of double-sided adhesive are present on the sensors, use a dry rag to remove them before the placement. Sensors and probes must be put in clean areas after usage. Clean areas must have not large ranges of variation of temperatures, humidity. If for any reason after the cleaning, colors or geometry of the devices changes, please contact our support and assistance. If for any reason at the first usage after the cleaning the system shows strange behavior, please contact our support and assistance.

Charging

Motion sensors and EMG electromyographic probes contain lithium batteries which need to be charged before each use. Follow these instructions in order to provide sensors with full charging.

- Place each sensor on the charging slot of the station so that the micro USB female port get connected with the male micro USB port on the station. When the station is connected to power, charging of sensor will immediately start and sensor LED will start to blink.

- EMG probes do not require USB connection to be charged. In order to charge each EMG probe, place it on the slots available in the EMG suitcase. The suitcase needs to be connected to power in order to allow charging to start. When LED indicators of EMG probes stop to blink, EMG probes are fully charge.

> **WARNING: in case of EMG probes, LED indicators will stop blink either if the probe is fully discharged or fully charged. Make sure power cable is connected to the EMG suitcase before charging.**
>
> **It is absolutely forbidden to load the sensors while the latter are positioned on the skin of the subject.**

Software

Maintenance of software and computer where software is installed are necessary to guarantee the best experience with SHoW Motion. Your trainer and Company support team will make sure that after first installation computer is optimally configured to operate with SHoW Motion. However, it is highly recommended that:

- **Laptop PC**: your computer needs to be always connected to the power in order to avoid any data loss in database. In case of power loss and subsequent shutdown of the computer during an acquisition, the analyzes performed will not be saved and will have to be repeated.
- **Antivirus**: your computer must have a proper and valid antivirus software installed. Being installed on a Windows machine, SHoW Motion can be affected by Windows viruses like any other software installed. Make sure that antivirus is always updated
- **Firewall** software: your computer must have a proper and valid firewall software installed. Being installed on a Windows Machine, make sure that external network attacks do not interfere with software. Make also sure that firewall software is always updated
- **PC** installation of software not suggested by this user manual might corrupt Device Drivers or correct functioning of software. Please ask assistance for suggestions regarding this topic.

Database

Periodic backup of database is highly recommended due to the above suggestions. The error log cannot be deleted or modified by the user. In order to backup the entire database, please follow these instructions:

1. Copy and paste the database folder. In order to locate the database folder, click on Settings in SHoW Motion software
2. Copy the file data.sqlite available in the installation folder (typically C:/Program Files/SHoW Motion) to the same backup folder of the database copied in 1)

When creating a new database, it is strictly necessary to backup the main database information file from the previous database before starting to record on a new database, as above described.

Replaceable parts

Replaceable parts of the system requiring the intervention of the technical assistance are: battery, sensor, gateway, charging station. In the event of a malfunction, contact the technical assistance that will evaluate the replacement of one or more replaceable parts.
For hardware relating to electromyographs, refer to the manufacturer's documentation.

TECHNICAL INFORMATION

SYSTEM COMMUNICATION

Risk of communicating within the same Wi-Fi channel

- At first usage we set-up the proper channel of communication setup
- When changing environment, we recommend to ask assistance in case of you would like to switch channel of communication

HARDWARE SPECIFICATIONS

For specifications on inertial sensors, please refer to the WISE Technical Information (NCS Lab, Carpi, Italy).

For specifications on EMG probes please refer to the Wave Plus User Manual (Cometa Systems, Milan, Italy).

LABEL
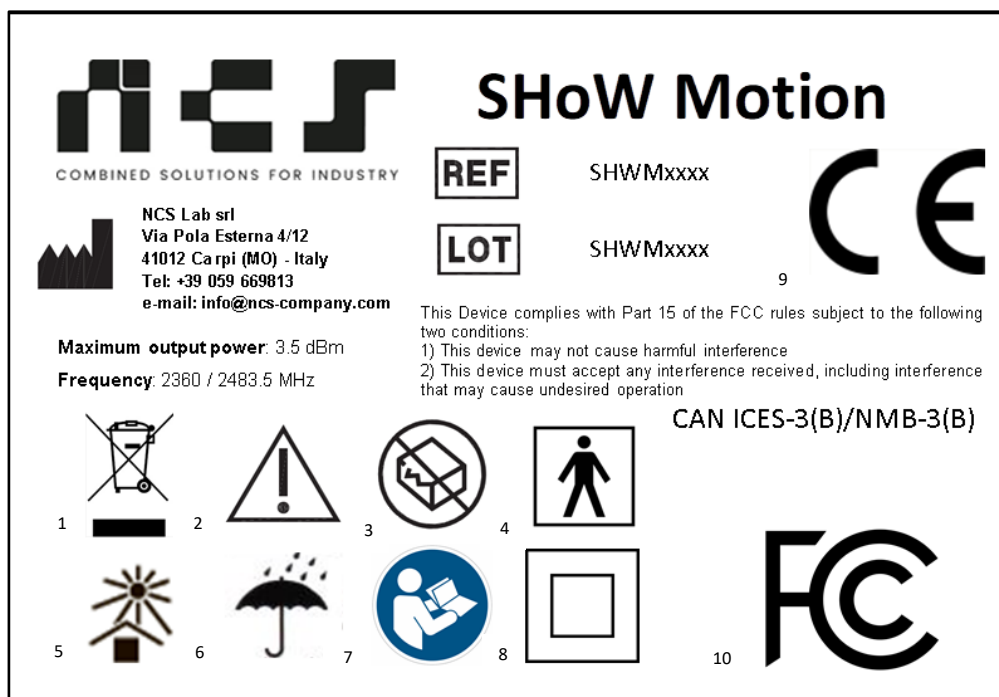
1. Equipment and battery are disposed of separately
2. Carefully read contraindications and precautions
3. Do not use if the packaging is not intact
4. Applied Part Type BF
5. Keep away from sunlight
6. Keep dry
7. Mandatory reading of the user manual
8. Insulation class: Class II device with double insulated
9. CE Marking symbol
10. FCC Marking symbol

The device has a degree of protection for enclosures of electrical equipment equal to IP20.

The WISE contains a small transmitter and a radio receiver. During communication with the gateway, radiofrequency (RF) and microwave electromagnetic fields are transmitted in the frequency range 2360-2483.5 MHz (compliant with the standard IEEE 802.15.4 PHY). The output power of the radio transmitter is a function of the temperature. It has a maximum value of 4.5 dBm at -40° C, 3.5 dBm at 25° C and 2.1 dBm at 105° C.

The FCC ID of the receiver is 2ATZJ-GTWY and it is affixed in the back side of GTWY receiver as show in the figures.

The FCC ID of the sensors is 2ATZJ-WISE and it is affixed in the lower part of WISE sensors, as show in the figures.

TROUBLESHOOTING

>> What is the installation folder of SHoW Motion after installation?

Unless the user selected a different one during the installation process, the default installation folder for SHoW Motion is C:/Program Files/SHoW Motion

>> What should I do when some updates of SHoW Motion are available?

If you receive an update that include an update of files already installed, copy and paste the update content to the installation folder. If asked, overwrite the existing files

>> Windows cannot find the proper software driver for the EMG wireless receiver. What shoulder I do?

Together with the installation software, a separate folder containing EMG Wave Plus driver is provided. This can be useful when a specific version of the operative system refuses to automatically install the driver once the USB cable has been connected. For manual installation, please enter the Device Manager (the location might change depending on your Windows machine). Search for the device which has a question mark besides. Right click on "update windows drivers" will allow to select the folder where the EMG Wave Plus driver is located. Then restart the computer.

>> A strange window appears regarding windows firewall. Is this important?

When launching the real-time analysis for the first time, Windows Firewall might ask to accept connection by the graphical 3D engine. You can either accept this or not.
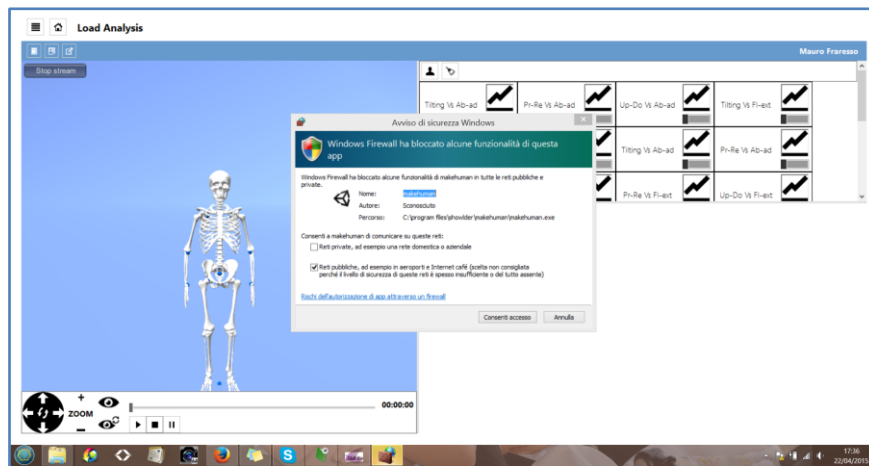
>> Hardware cannot be connected anymore after an unexpected reset

Unplug the wireless receivers from the USB port. Plug them again and restart the analysis

>> Technical assistance

Technical assistance is provided by our team.

Any problem encountered should be reported to the following email: info@ncs-company.com

Our team will provide technical assistance regarding all aspects of the supplied device and will also take care of replacing any damaged parts of the device.

The replacement of parts of the device can only take place through our service center.

INFORMATION TO THE USER

1. For devices approved under Part 15, the user's manual or instruction manual for an intentional or unintentional radiator shall caution the user about changes or modifications to the device (Section 15.21).

2. For Class A and Class B digital devices, information to the user is required to include the following statements (Section 15.105):

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

RF RADIATOR EXPOSURE STATEMENT

This product complies with FCC and ISED radiation exposure limits set forth an uncontrolled environment.

The sensors WISE should be installed and operated with minimum distance of 0.006m between the radiator and your body. The case of the device guarantees the fulfillment of this requirement and therefore allows its direct application on the body by means of elastic bands and/or double-sided tape.

The receiver GTWY should be installed and operated with minimum distance of 0.009m between the radiator and your body.

DATA SECURITY

The privacy of the acquired data is guaranteed by an encryption system. The patient monitored with this system must have signed the consent to the processing of data.

In case of data tampering or virus interactions with the PC on which the software is installed, it is necessary to contact the technical assistance.

CONTACT INFORMATION

For further information regarding system and software upgrades, software issues, troubleshooting or urgent matters while using the product, please contact NCS Lab support team: info@ncs-company.com +39 059 669813, Via Pola Esterna 4/12, 41012 Carpi (MO)

E-mails sent to the above address will be answered within 48 hours.

WARRANTY ON PRODUCT

> **WARNING: Non modification of this device is allowed**

Please refer to your sales contact for information regarding warranty contract on the product.

There are some limitations in the warranty which regard to special cases where repair cannot be guaranteed under warranty:

- Motion sensors and EMG sensors break down due to water
- Some liquid parts enter the USB port of the motion sensors and the motion sensor stops working

> **WARNING: if for any reason liquid or water enters the USB port of the motion sensors, contact our customer support immediately**

DISPOSAL OF HARDWARE

It is compulsory to follow the common procedures adopted inside of your hospital/location In order to carry out disposal of the hardware included in SHoW Motion.

SOFTWARE LICENSE AND MAINTENANCE AGREEMENT (SLAMA)

IMPORTANT - READ CAREFULLY BEFORE INSTALLING OR OTHERWISE USING SDK SOFTWARE PROVIDED UNDER THIS AGREEMENT

ARTICLE 1 – MAIN TERMS

SHoW Motion (SHOW) is an end-user software incorporating high-level methods for the quantification of motor control coordination. SHOW is provided as it is and is only intended for clinical use and applied research in clinics but not as measurement system software.

This Software License Agreement ("Agreement") is between the licensee (You) and NCS Lab s.r.l. (NCS). By installing or otherwise using the Software Product, you agree to be bound by the terms of this agreement. You must indicate your agreement to be bound by the terms of this agreement by using the ACCEPT button on installation or license activation program, or else you will not be able to install SHOW. If you do not agree to the terms of this agreement, you must discontinue installation of the software now. If you are installing SHOW on a computer not owned by you, you are bound to the terms of this agreement both in your individual capacity and as an agent of the owner of the computer, and your actions will bind the owner of the computer. You represent and warrant to NCS that you have the capacity and authority to enter into this agreement on your own behalf as well as on behalf of the owner of the computer the SHOW is being installed upon. For purposes of this agreement, the owner of a computer is the individual or entity that has legal title to the computer or that has the possessory interest in the computer if it is leased or loaned by the actual title owner.

ARTICLE 2 – TERMS AND CONDITIONS

The Software is a license to the licensee, SHOW remains property of NCS Lab srl (Carpi, Italy).

- The licensee is not authorized to copy, sublicense, and / or resell SHOW.

- Software is not intended as measurement system software but only for the quantification of motor control coordination in research and clinical settings.

- The licensee may not disassemble or re-engineer SHOW in any way.

- All updates or improvements on SHOW which is covered by this license agreement remain property of NCS Lab.

- Software SHOW installation is limited to a maximum of 1 PC/laptop.

- The licensee has the obligation to consult and gain approval of NCS Lab prior to publishing research or clinical results generated with the use of the SHOW.

ARTICLE 3 - LIMITATION OF LIABILITY

SHOW is provided as-is. NCS cannot be held responsible for situations where software may or not work on the PC/laptop selected. NCS Lab does not have any obligation to support or update the Software.

NCS Lab disclaims warranties, either express or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, non-interference, system integration, and non-infringement. NCS Lab does not warrant that the software or documentation will meet licensee's needs, or that licensee's operation of the same will be uninterrupted or error free, or that all nonconformities can or will be corrected.

NCS Lab disclaims unintended use of the SHOW functionality regarding kinematics of human motion, such as for the creation of measurement systems based on it or diagnostic tools of human/animal body parts or human/animal joints. SHOW is intended to be used only for the quantification of the motor coordination. The ultimate decision on patient status from the legal and medical points of view are left to the physician or the user and in any way they cannot come directly as output from the product and related software. The intended user of SHOW is a practitioner working in the clinical or sports medicine field, with knowledge regarding the specific body district area for which the product is used. User must receive an adequate training soon after the first installation of the software and its first use.

Regarding SHOW functionality for usage of the specific hardware models and compatible versions, such as WISE (NCS Lab, Carpi, Italy) for motion tracking, GTWY (NCS Lab, Carpi, Italy) for wireless transmission and Wave Plus (Cometa Systems, Milan, Italy) for muscle activity, NCS Lab disclaims the use of hardware different from the one specified.

IN NO EVENT SHALL NCS LAB BE LIABLE TO LICENSEE FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOST PROFITS; LOST SALES OR BUSINESS EXPENDITURES; INVESTMENTS; OR COMMITMENTS IN CONNECTION WITH ANY BUSINESS, LOSS OF ANY GOODWILL, OR FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT OR USE OF THE SOFTWARE OR DOCUMENTATION, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY, AND WHETHER OR NOT NCS LAB HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

ARTICLE 4 - APPLICABLE LAWS

This agreement shall be governed by and construed in accordance with the laws of the court of Modena which shall have exclusive jurisdiction over any disputes relating to the terms and conditions mentioned above, without regard to the conflict of law's provisions thereof.

ARTICLE 5 - ENTIRE AGREEMENT

This Agreement constitutes the sole and entire agreement of the parties as to the subject matter set forth herein and supersedes any previous agreements, understandings, and arrangements between the parties relating to such subject matter. Any modification(s) or amendment(s) to this Agreement must be in writing and signed by an authorized representative of each party.

ACKNOWLEDGMENTS

Wave Plus (Cometa Systems), WISE (NCS Lab) and GTWY (NCS Lab) are trademarks from the respective owners.