Abstract:

A method and system for detecting the onset of seizures comprising a measuring unit (1) having one or more sensors for detecting the electromyographic signal of one or more muscles of the user. The sensors are connected to a pre-processing module (3) comprising a high-pass filter which filters out noise and motion artefacts related to normal muscle activities. The pre-processing module is connected to a feature extraction module (4) comprising a threshold detector which counts the number of crossings with a hysteresis within a predetermined time window. The feature extraction module is connected to a classification module (5) which compares the extracted features to a first and second threshold and generates an event signal if the extracted features are above the first and second threshold.

Fig. 1
METHOD FOR DETECTING SEIZURES

Technical field

The invention relates to a system for detecting the onset of seizures, such as epileptic seizures, comprising a measuring unit having at least one sensor configured to detect an electromyographic signal generated by a muscle on the body of a user, and a data processing unit configured to process and analyse the detected signal and generating an event signal if the analysed signal is above at least one threshold value.

The invention also relates to a method for indicating the onset of seizures, such as epileptic seizures, comprising the steps of detecting one or more electromyographic signals generated by at least one muscle on the body of a user by means of a measuring unit, processing and analysing the detected signal by means of a data processing unit which generates an event signal if the analysed signal is above at least one threshold value, and triggering an event based on the event signal.

Prior art

Today there is a need for a way to improve the detection of seizure onsets in order to improve treatment or to alert caretakers or the patient of a seizure in order to prevent potential dangerous situations associated with a seizure. Seizures, such as epileptic seizures, can occur as partial or generalized seizures or a combination of both, where generalized seizures can occur as tonic, clonic, or tonic-clonic seizures. In a tonic-clonic seizure it starts with a tonic phase which then develops into a clonic phase.

Different methods or algorithms for detecting seizure onsets are described in the literature. An example of such is disclosed in WO 2008/131782 A1 which detects epileptic seizures by evaluating a sensed EMG signal over a number of time windows, if the sensed EMG signal is over a threshold value within the first time window, where the threshold value is determined according to the maximum voluntary contraction of the user. The algorithm has the
user. The algorithm has the disadvantage that the parameters have to be adjusted to each individual person in order to reduce the number of false positives and accurately detect the seizure.

US 2007/0142873 A1 describes an adaptive method and system for detecting seizures by sensing iEEG signals which is used in a feedback loop to administer a drop or give a simulate to counteract the seizure. The parameters used to detect the seizures are determined by using a time consuming and very complex data process, where the system performs several measurements with different parameter settings from which the best parameter settings are selected. This system requires the desired signals to be captured by multiple channels in order to accurately detect the signals and to reduce the number of false positives. Furthermore, this method uses an invasive procedure to place the iEEG sensors on the body.

WO 2007/079181 A2 describes an epileptic seizure detection method and system comprising a sensor unit having multiple intracranial EEG electrodes connected to a processor unit in which a prediction algorithm is implemented. The prediction algorithm determines the probability of having a seizure within the near future by combining multiple features extracted from the sensed EEG signals. The processor unit may comprise any number of components used to process the signals, but it does not disclose an exemplary embodiment of the prediction algorithm. Furthermore, this method requires the signal to be measured at multiple locations in order to predict seizures and uses a training module/process to adjust the parameters used to predict seizures.

US 2004/0230105 A1 describes a method and system for predicting epileptic seizures which may use an EMG sensor to detect a biomedical signal connected to a processor which processes the signals using a segmentation algorithm. Various features are then extracted and analysed in a prediction algorithm using a set of FEVEVI models to predict a seizure. The method uses an automatic training algorithm to adjust the parameters of each FEVEVI model.

This system uses a complex and time-consuming method to detect seizures which are not suited for implementation in a small battery powered device attached to the body of a user.
attached to the body of a user. Furthermore, this method requires the detection of multiple signals at multiple locations and the adjustment of the parameters for each individual user.

Object of the invention

The invention solves these problems of the closest prior art by providing a method indicating the onset of seizures characterized in that the detected signal is filtered by means of a high-pass filter, the number of crossing between an amplitude of the filtered signal and a hysteresis value is counted, and the count is compared to a first threshold value and the event signal generated if the count is above the first threshold value.

This method can be implemented as a generic algorithm in a seizure detection or monitoring device without having to calibrate the parameters for each individual user first. The seizure detection method has a low false detection rate and a short latency, so that seizures can be detected faster and more accurately. Furthermore, this enables seizures to be detected by using only one measuring channel, thus reducing the complexity of the detection system and the number of components needed to detect seizures.

According to one embodiment, a predetermined number of time windows, such as overlapping time windows, are applied to the filtered signal, and the number of crossings within each time window is counted. This enables the length and shape of the time windows to be selected so that the detection system has a sufficiently short latency. This also enables the overlap of the time windows to be selected so that the data analysis is improved.

According to one embodiment, the number of time windows, which has a count above the first threshold value, is compared to a second threshold value, and the event signal is generated if the number of time windows is above the second threshold value. This enables the first and second threshold values to be selected so that all seizures are detected while reducing the number of false positives to a minimum and ensuring a short latency for the detection system. This also enables the first and second threshold values to be determined according to the seizure characteristics detected at that measuring position in order to more accurately detect the seizures.
According to one embodiment, at least a measuring unit detects the muscle activities of one or more muscles on the body of the user or another signal characteristic of a seizure, and at least a second data processing unit processes and analyses the detected signal from the second measuring unit and generates an output signal indicating if the detected signal is above a third threshold value or not. According to a specific embodiment, the output signals are transmitted to an evaluation module which generates the event signal if two or more of the output signals have a high value or if a weighted sum of the output signals is above a fourth threshold value. This improves the detection of seizures by comparing the detected signal to other signals which are detected at different locations, thus reducing the number of false positives.

According to one embodiment, the event signal is transmitted to an alarm unit which generates an alarm or an alarm message based on the event signal. This enables the algorithm to inform or alert the user or an external caretaker that a seizure is occurring so that the necessary actions can be taken.

The invention also solves these problems by providing a system for detecting the onset of seizures characterized in that the data processing unit comprises a pre-processing module having a high-pass filter configured to filter out signals having a frequency below a predetermined cut-off frequency, a feature extraction module which is connected to the pre-processing module and configured to count the number of crossings between an amplitude of the filtered signal and a predetermined hysteresis value, and a classification module which is connected to the feature extraction module and configured to compare the count to a first threshold value and generate the event signal if the count is above the first threshold value.

This enables the detection system to be implemented as a generic detection system which does not require the parameters for the algorithm to be calibrated for each individual user. This also enables the system to detect seizures by using only one measuring channel, thus reducing the complexity of the detection system and the number of components needed to
ponents needed to detect seizures. This seizure detection system has a low false detection rate and a short latency so that seizures can be detected faster and more accurately.

According to a specific embodiment, the cut-off frequency is above 100Hz, preferably between 100-200Hz. This enables the system to filter out most of the noise and motion artefacts, which do not relate to the seizure, before analysing the detected signal.

According to a specific embodiment, the hysteresis value is between ±0-500µV, preferably ±20-250µV. This enables the hysteresis value to be selected so that low-level noise and motion artefacts, which are not removed by the pre-processing module, have no or a minimum effect on the counts. The threshold detector mainly detects the frequency of the filtered signal if the hysteresis has a low value, whereas the threshold detector detects both the frequency and the amplitude of the filtered signal if the hysteresis has a high value.

According to one embodiment, the feature extraction module is configured to apply a predetermined number of time windows to the filtered signal and is configured to count the number of crossings within each time window. According to a specific embodiment, a first time window overlaps a second time window, and the overlap is between 0-95%, preferably between 50-75%. According to another specific embodiment, the time windows have a length between 0.25-2 sec. This enables the length of the time windows to be selected so that the detection system has a sufficiently short latency. This also enables the overlap of the time windows to be selected according to the shape of the time window so that the data analysis is improved.

According to one embodiment, the classification module is further configured to compare the number of time windows, which have a count above the first threshold value, with a second threshold value and generate the event signal if the number of time windows is above the second threshold value. According to a specific embodiment, the first threshold is between 100-400, preferably between 240-300, and the second threshold is between 1-40, preferably between 10-25. This enables the first and second threshold values to be selected so that all seizures are detected while reducing the number of false positives to a minimum and ensuring a short latency for the detection system. This also enables the first and second
This also enables the first and second threshold values to be determined according to the seizure characteristics detected at that measuring position in order to more accurately detect the seizures.

According to one embodiment, the system comprises at least a second measuring unit which is configured to detect the muscle activities of one or more muscles on the body of the user or another signal characteristic of a seizure, and at least a second data processing unit which is connected to the second measuring unit and configured to process and analyse the detected signal and configured to generate an output signal indicating if the detected signal is above a third threshold value or not. According to a specific embodiment, the data processing units are connected to an evaluation module which is configured to generate the event signal, if two or more of the output signals have a high value or if a weighted sum of the output signals is above a fourth threshold value. This improves the detection of seizures by comparing the detected signal to other signals which are detected at different locations, thus reducing the number of false positives.

According to one embodiment, the event signal is transmitted to an alarm unit which is configured to generate an alarm or an alarm message based on the event signal. This enables the detection system to inform and alert the user or an external caretaker that a seizure is occurring, thereby allowing the person to take proper action. This also enables the alarm unit to be integrated into the unit which can be easily attached to or placed on the body of the user.

The invention also describes the use of the method or system to detect seizures having tonic activity, such as tonic-clonic seizures.

The drawings

The embodiments of the invention will now be described with reference to the drawings, in which

Fig. 1 shows a first embodiment of the seizure detection system according to the invention, and
Fig. 2 shows a second embodiment of the seizure detection system according to the invention.

Description of exemplary embodiment

Figure 1 shows a first embodiment of the detection system which comprises a measuring unit 1 having one or more sensors 1a for sensing the muscle activities generated by one or more muscles, i.e. the skeletal muscles, on the body of a user. The sensors 1a may be configured as electromyographic sensors. The sensors 1a may be integrated into the measuring unit 1, which may be attached or fixed to the body by using an adhesive agent or a fixating band or strap, or alternatively may be placed at different measuring positions and connected to the measuring unit 1 by a wired or wireless connection. The sensors 1a may be connected to a controller and a memory module, and data from the sensors may be stored in the memory module before being transmitted to a data processing unit 2 either periodically, continuously or on request from the data processing unit 2. In a preferred embodiment the measuring unit 1 uses a single measuring channel to detect the electromyographic signal. This enables the sensors to be easily placed at the measuring positions without using any invasive procedures.

The detected data are then transmitted via a wired or wireless connection to the data processing unit 2 which processes and analyses the data. The data processing unit 2 may be an external device or integrated into the measuring unit 1. The detected data are transmitted to a pre-processing module 3 comprising filter means for filtering out noise and motion artefacts which relate to normal muscle activities. The filter means may be configured as a high-pass filter with a predetermined cut-off frequency which filters out most of the noise and motion artefacts not related to the seizure. Studies have shown that all or most of the data relating to the seizure are situated in a frequency band above 100Hz, while all or most of the noise and motion artefacts are situated in a frequency band of 0-20Hz. The cut-off frequency may be selected as any frequency between the upper frequency of the lower frequency band and the lower frequency of the upper frequency band, i.e. between 20-200Hz, preferably between 100-200Hz. The cut-off frequency may be selected according to the desired order of the high-pass filter. The pre-processing module 3 may comprise a biasing circuitry which removes any bias so that the filtered signal is symmetric around zero. In a
removes any bias so that the filtered signal is symmetric around zero. In a preferred embodiment the cut-off frequency for the filter means is selected to be 150Hz or 170Hz.

The filtered data are then transmitted to a feature extraction module 4 which extracts one or more predetermined features. The feature extraction module 4 applies a number of predetermined time windows to the filtered data. The time windows may be configured as overlapping time windows with a predetermined overlap and length. The time windows may be shaped as a rectangular, a triangular, a cosine, a sine or another type of window where the overlaps have a rectangular, a triangular or another shape. In order to improve the data analysis, the time windows may have an overlap between 0-95%, preferably between 50-75%. The length of the time windows is selected so that the detection system has a sufficiently short latency, i.e. the length may be between 0.25-2 sec. In a preferred embodiment the time window is selected to have an overlap of 75% and a length of 1 sec.

The feature extraction module 4 uses a threshold detector to count the number of crossings, i.e. the zero-crossings, between the amplitude of the filtered signal and at least one predetermined threshold value within each time window. The threshold detector may be configured as a threshold detector with a predetermined hysteresis value, i.e. a positive and a negative threshold value. The hysteresis value may be selected so that low-level noise and motion artefacts, which are not removed by the pre-processing module 3, have no or a minimum effect on the counts. The hysteresis value may be selected within a range of ±0-500µV, preferably within ±20-250µV. In a preferred embodiment the threshold detector has a hysteresis value of ±50µV or ±100µV. If the hysteresis has a low value, the threshold detector mainly detects the frequency of the filtered signal, while the threshold detector detects both the frequency and the amplitude of the filtered signal if the hysteresis has a high value.

The feature extraction module 4 transmits the count for each time window to a classification module 5 which evaluates the extracted features and generates an event signal if at least one of the extracted features is above a threshold value. The classification module 5 compares the count for each time window to a first threshold value and generates an event signal if the count is above the threshold value. Alternatively, the classification module 5 may compare
fication module 5 may compare the number of time windows, which has a count above the first threshold value, to a second threshold value and generate an event signal if the number of time windows is above the second threshold value. The number of time windows with a count above the first threshold value may be determined by counting the number of consecutive and/or non-consecutive time windows within a second predetermined time window.

The first and second threshold may be adjusted in order to more accurately detect the seizures. The thresholds may be determined according to the seizure characteristics detected at that measuring position.

Studies have shown that a tonic-clonic seizure generates a high number of crossings (counts) in the tonic phase, which then drops to a lower number at the beginning of the clonic phase. The first threshold value for the number of crossings may be between 100-400, preferably between 240-300. The second threshold value for the number of time windows may be between 1-40, preferably between 10-25. The first and second threshold values may be selected so that all seizures are detected while reducing the number of false positives to a minimum and ensuring a short latency for the detection system. In a preferred embodiment the first threshold value is selected to be 260 and the second threshold value is selected to be 15.

The event signal triggers an event which informs or alerts the user or an external caretaker that a seizure is occurring. The event signal may be transmitted to an alarm unit 6 by a wired or wireless connection. The alarm unit 6 may be an external device or integrated into the measuring unit 1 or the data processing unit 2. The alarm unit 6 may generate one or more types of alarms or messages, i.e. an audio, a visual, a vibrating alarm, an alarm message, or any combination thereof. The measuring units 1, the data processing units 2, and optionally the alarm unit 6 may be integrated into a single unit which can be easily attached to or placed on the body.

Figure 2 shows a second embodiment of the detection system, where the reference numbers are the same as in figure 1. The detection system comprises a number of measuring units 1, 7, 8, which are placed at different measuring positions on the body. The measuring units 7,
The measuring units 7, 8 may have the same configuration as the measuring unit 1 or different configurations. The measuring unit 1, 7, 8 comprises one or more sensors la, 7a, 8a for measuring the muscle activities generated by one or more muscles, i.e. skeletal muscles. Alternatively, the measuring units 1, 7, 8 may comprise different types of sensors, i.e. EMG, MMG or PMG, for measuring the muscle activity or may comprise at least one other sensor for measuring another type of signal related to a seizure, i.e. respiration, heart rate or galvanic skin response. The sensors may be easily placed at the measuring positions without using any invasive procedures by using an adhesive agent or a fixating band or strap. This enables the system to improve the detection of seizures and reduce the number of false positives by comparing the detected signal with other signals which are detected at different locations.

The detection system may comprise a number of data processing unit 2, 9, 10, which are connected to each of the measuring units 1, 7, 8. The data processing unit 9, 10 may have the same configuration as the data processing unit 2 or a different configuration. The data processing unit 2, 9, 10 may comprise processing means 3, 4, 11, 12 which analyses and extracts one or more features or patterns from the measured signals, and a classification module 5, 13, 14, which compares the extracted features or patterns to one or more threshold values and generates an output signal, i.e. a high or a low output signal, indicating if a seizure is present or not. The outputs of each classification modules 5, 13, 14 in the data processing units 2, 9, 10 are transmitted by a wired or wireless connection to an evaluation module 15 which evaluates the output signals and generates an event signal if a seizure is detected. The evaluation module 15 may generate an event signal if two or more of the output signals are high. Alternatively, the evaluation module 15 may apply a predetermined weighing factor to each of the output signals and generate an event signal if the sum of these weighted outputs is above a third threshold value. The event signal is then transmitted by a wired or wireless connection to the alarm unit 6 which informs or alerts the user or an external caretaker that a seizure is occurring.

The data processing units 2, 9, 10 may be arranged as parallel pipelines in a common data processing unit or as separate data processing units which are connected to the evaluation module. The evaluation module 15 may be integrated into the common data processing unit
processing unit or into one of the separate data processing units.

The described method in figure 1 and 2 for detecting the onset of seizures can be implemented as a generic algorithm in a detection or monitoring system, which only uses a single EMG measuring channel to detect seizures. This enables the generic algorithm to be implemented in a small detection or monitoring device without having to calibrate the parameters, i.e. the threshold values, for each individual user first. This reduces the complexity of the detection system and reduces the number of components needed to detect seizures.

The described detection system may comprise an adaptive update module (not shown) which updates the threshold values each time the system has detected a seizure. This enables the first and second threshold values for the number of counts and time windows to be adjusted so that the system is able to detect the seizures more accurately. This in turn will reduce the number of false positives and also reduce the latency for the system.

Example

Electromyographic measurements were conducted on six different persons of different ages and genders as shown in table 1. The persons all had at least one tonic-clonic seizure which was verified by other measurements, including video and ECG measurements.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age</th>
<th>Seizures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tabel 1

The EMG sensors were placed on the left deltoid muscle with the active electrode on the center of the muscle and the reference electrode placed on the acromioclavicular joint. The EMG signal was sampled with a sampling rate of 1024Hz. The measured EMG signals were
EMG signals were pre-processed with a high-pass Butterworth filter with an order of 20 and a cut-off frequency of 150Hz and analysed with time windows with a length of 1 sec. and an overlap of 75% and a hysteresis value of ±50µv. The first and second threshold chosen for each of the test subjects can be seen in table 2.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Counts</th>
<th>Window</th>
<th>Sensitivity</th>
<th>Latency</th>
<th>FDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>0,</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>0,</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>8,00;</td>
<td>0,</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>0,</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td>7,00;</td>
<td>0,</td>
</tr>
</tbody>
</table>

Tabel 2

As shown in table 2 the described detection system has a sensitivity of 100%, meaning that it detected all the seizures. The detection system has a false detection rate (FDR) between 0-0.1885 per hour and a latency between 7-10.5 sec.
CLAIMS

1. A system for detecting the onset of seizures, such as epileptic seizures, comprising
- a measuring unit (1) having at least one sensor configured to detect an electromyographic
  signal generated by a muscle on the body of a user, and
- a data processing unit (2) configured to process and analyse the detected signal and
  generate an event signal, if the analysed signal is above at least one threshold value
  characterized in that
  - the data processing unit (2) comprises a pre-processing module (3) having a high-pass
    filter configured to filter out signals having a frequency below a predetermined cut-off fre-
    quency,
  - a feature extraction module (4) which is connected to the pre-processing module and
    configured to count the number of crossings between an amplitude of the filtered signal and
    a predetermined hysteresis value, and
  - a classification module (5) which is connected to the feature extraction module (4) and
    configured to compare the count to a first threshold value and generate the event signal if
    the count is above the first threshold value.

2. System according to claim 1, characterized in that the cut-off frequency is above
   100Hz, preferably between 100-200Hz.

3. System according to claim 1 or 2, characterized in that the hysteresis value is between
   ±0-500 μV, preferably between ±20-250μV.

4. System according to any one of claims 1 to 3, characterized in that the feature ex-
   traction module (4) is configured to apply a predetermined number of time windows to the
   filtered signal and is configured to count the number of crossings within each time window.

5. System according to claim 4, characterized in that a first time window overlaps a
   second time window, and that the overlap is between 0-95%, preferably between 50-75%.
6. System according to claim 4 or 5, characterized in that the time windows have a length between 0.25-2 sec.

7. System according to any one of claims 4 to 6, characterized in that the classification module (5) is further configured to compare the number of time windows which have a count above the first threshold value, with a second threshold value and generate the event signal if the number of time windows is above the second threshold value.

8. System according to claim 7, characterized in that the first threshold is between 100-400, preferably between 240-300, and the second threshold is between 1-40, preferably between 10-25.

9. System according to any one of claims 1 to 8, characterized in that the system comprises at least a second measuring unit (7, 8) which is configured to detect the muscle activities of one or more muscles on the body of the user or another signal characteristic of a seizure, and at least a second data processing unit (9, 10) which is connected to the second measuring unit and configured to process and analyse the detected signal and configured to generate an output signal indicating if the detected signal is above a third threshold value or not.

10. System according to claim 9, characterized in that the data processing units (2, 9, 10) are connected to an evaluation module (15) which is configured to generate the event signal if two or more of the output signals have a high value or if a weighted sum of the output signals is above a fourth threshold value.

11. System according to any one of claims 1 to 10, characterized in that the event signal is transmitted to an alarm unit (6) which is configured to generate an alarm or an alarm message based on the event signal.

12. A method for indicating the onset of seizures, such as epileptic seizures, comprising the steps of
- detecting one or more electromyographic signals generated by at least one muscle on the body of a user by means of a measuring unit (1),
- processing and analysing the detected signal by means of a data processing unit (2) which generates an event signal if the analysed signal is above at least one threshold value, and

- triggering an event based on the event signal,

 characterized in that
- the detected signal is filtered by means of a high-pass filter,
- the number of crossings between an amplitude of the filtered signal and a hysteresis value is counted, and
- the count is compared to a first threshold value and the event signal generated if the count is above the first threshold value.

13. Method according to claim 12, characterized in that a predetermined number of time windows, such as overlapping time windows, is applied to the filtered signal, and the number of crossings within each time window is counted.

14. Method according to claim 13, characterized in that the number of time windows, which has a count above the first threshold value, is compared to a second threshold value, and the event signal is generated if the number of time windows is above the second threshold value.

15. Method according to any one of claims 12 to 14, characterized in that at least a measuring unit (7, 8) detects the muscle activities of one or more muscles on the body of the user or another signal characteristic of a seizure, and at least a second data processing unit (9, 10) processes and analyses the detected signal from the second measuring unit and generates an output signal indicating if the detected signal is above a third threshold value or not.

16. Method according to claim 15, characterized in that the output signals are transmitted to an evaluation module (15) which generates the event signal if two or more of the output signals have a high value or if a weighted sum of the output signals is above a fourth threshold value.
17. Method according to any one of claims 1-7, characterized in that the event signal is transmitted to an alarm unit (6) which generates an alarm or an alarm message based on the event signal.

18. Use of the system as defined in any one of claims 1 to 11 or the method defined in any one of claims 12 to 17 to detect seizures having tonic activity, such as tonic-clonic seizures.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/04 A61B5/0488 A61B5/11

ADD.

According to International Patent Classification (IPC) or both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>WO 2008/131782 AI (COLOPLAST AS [DK]; DELTA [DK]; HOPPE KARSTEN [DK]) 6 November 2008 (2008-11-06) cited in the application abstract claims 16-18,22 page 5, line 14 - page 6, line 13 page 7, line 12 - page 8, line 8 figures 1,2,3a -----</td>
<td>1-18</td>
</tr>
</tbody>
</table>

X  Further documents are listed in the continuation of Box C.  X  See patent family annex.

* Special categories of cited documents:

*A* document defining the general state of the art which is not considered to be of particular relevance

*E* earlier application or patent but published on or after the international filing date

*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

*O* document referring to an oral disclosure, use, exhibition or other means

*P* document published prior to the international filing date but later than the priority date claimed

*"!" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

*X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

*"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

*"S" document member of the same patent family

Date of the actual completion of the international search  17 September 2012

Date of mailing of the international search report  27/09/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2

NL-2280 HV Rijswijk

Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Ol api nski, Michael

Authorized officer

Form PCT/ISA210 (second sheet) (April 2005)
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>WO 2007/034476 A2 (BIOLET LTD [IL]; KRAMER URI [IL]; SHAHAM AMOS [IL]; SHPITALNIK SHAI [IL]) 29 March 2007 (2007-03-29) paragraphs [0075], [0077]; figure 4</td>
<td>1-18</td>
</tr>
<tr>
<td>Y</td>
<td>WO 2005/018448 A1 (BRAINZ INSTR LTD [NZ]; NAVAKATI KYAN MICHAEL ALEXANDER [NZ]) 3 March 2005 (2005-03-03) page 1, lines 8-12</td>
<td>1-18</td>
</tr>
<tr>
<td>Patent document cited in search report</td>
<td>Publication date</td>
<td>Patent family member(s)</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>----------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2010137735 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2008131782 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2007208212 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2008119900 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2010023089 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2012203131 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2012053491 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 101583311 A2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1926427 A2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2007034476 A2</td>
</tr>
<tr>
<td>WO 2007143234 A2</td>
<td>13-12-2007</td>
<td>AT 444016 T</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2012659 A2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2008269835 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2007143234 A2</td>
</tr>
<tr>
<td>WO 2005018448 A1</td>
<td>03-03-2005</td>
<td>AU 2004266555 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2536516 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NZ 527751 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2008228100 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2005018448 A1</td>
</tr>
</tbody>
</table>