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— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
— with international search report (Art. 21(3))

(54) Title: ENTERAL FEEDING SYSTEM

(57) Abstract: An enteral feeding system comprises a reservoir including a quantity of an enteral feeding solution, an enteral feeding set, connectable to the reservoir, for transferring the enteral feeding solution to a patient and a pump, operationally engageable with the enteral feeding set to cause transfer of the enteral feeding solution to the patient. The pump is provided with a flow monitoring device adapted to monitor an amount of solution administered and generate flow data. A data carrier provided with nutritional data relating to the enteral feeding solution is included on the reservoir and a data reader is adapted to interrogate the data carrier to extract the nutritional data. A patient monitoring module (PMM) interfaces with the pump and with the data reader to receive the flow data and the nutritional data and calculate real time delivery of individual nutrients on the basis of the flow data and the nutritional data. As a result of the direct interrogation of the data carrier and the provision of this data to the PMM, the burden of manually entering data is reduced and accuracy is improved.
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ENTERAL FEEDING SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to the enteral feeding of patients and to systems for performing such feeding. The invention further relates to an enteral pump and enteral feeding set and to a method of controlling and monitoring of enteral delivery.

2. Description of the Related Art

[0002] For certain patients it is necessary to provide for their nutrition by enteral feeding. Enteral feeding generally refers to the delivery of a nutritionally complete feed, containing carbohydrates, proteins, fibre, fat, water, minerals and vitamins, directly into the stomach. In certain cases this may also be delivered to the duodenum or jejunum. Generally, delivery is via a naso-gastric tube, although it will be understood that other placements, including surgical e.g. percutaneous placements may be considered for long term care. Enteral feeding is to be distinguished from parenteral feeding which involves delivery of essential nutrients directly into the blood stream, bypassing completely the body’s digestive apparatus.

[0003] Various enteral feeding solutions may be provided according to the specific nutritional requirements of the patient. These are usually pre-packaged in sterile reservoirs having an appropriate product label indicating the nutritional content. Feeding solutions may also be made up locally e.g. by a hospital pharmacy. Delivery takes place using a dedicated pump, usually a peristaltic type pump that acts on a section of the feeding tube to transfer the solution. Pumps may be portable or static and may be provided with various provisions for ensuring correct delivery and for monitoring the delivered volume. One such pump is known from WO201244860.

[0004] During feeding, it is desirable to closely monitor the nutritional intake status and fluid balance of the patient. In certain cases it is absolutely critical to be able to accurately monitor this throughout the enteral feeding therapy. At present, patient monitoring involves the healthcare professional manually collecting data from the product label and adding this information to the electronic medical record. Because of the nature of enteral feeding and the wide variation of the compositions from one solution to the next, each label contains a considerable quantity of data. The calculation
of administered macro-nutrients (minerals, vitamins, spore elements, fat, proteins, etc.) as well as calories is then performed manually by integrating this information into a spreadsheet or other calculation method. This is time consuming and subject to mistakes. As a result, the fluid balance as well as the nutritional intake of the patient may be incorrectly monitored, which can have dangerous consequences for particular patients.

[0005] It would therefore be desirable to provide improved systems and devices which would facilitate the enteral feeding of patients and their correct monitoring and which may improve patient safety and user convenience.

10 BRIEF SUMMARY OF THE INVENTION

[0006] According to the invention there is provided an enteral feeding system comprising: a reservoir including a quantity of an enteral feeding solution; a data carrier provided with nutritional data relating to the enteral feeding solution included in the reservoir; an enteral feeding set, connectable to the reservoir, for transferring the enteral feeding solution to a patient; a pump, operationally engageable with the enteral feeding set to cause transfer of the enteral feeding solution to the patient, the pump being provided with: a flow monitoring device adapted to monitor an amount of solution administered and generate flow data; a data reader, adapted to interrogate the data carrier to extract the nutritional data; and a patient monitoring module (PMM) adapted to interface with the pump and with the data reader to receive the flow data and the nutritional data, whereby real time delivery of individual nutrients can be calculated on the basis of the flow data and the nutritional data. As a result of the direct interrogation of the data carrier and the provision of this data to the PMM, the burden of manually entering data is reduced and accuracy is improved. Furthermore, by providing this data to the PMM, together with the flow data, the PMM can calculate the actual amount of a given nutrient received at any point in time without requiring a user to calculate the amount based on the fraction of a reservoir delivered.

[0007] Preferably, the nutritional data includes the identity and quantity of each of the nutrients in the enteral feeding solution. For an enteral feeding solution, this nutritional data can be extensive. The nutritional data may include energy content, fat content, carbohydrate content, protein content, dietary fibre content, vitamin content, mineral content, osmolarity and osmolality. Most preferably, all of these are included and present on the label. Other nutrients may also be included in the enteral feeding
solution and referenced on the label. In this context, nutrient is used generally to refer
to all of the ingredients, whether or not they may actually be metabolised or otherwise
taken up by the body. The nutritional data may also include the identity of the product,
such as by name and batch number. Alternatively, the nutritional data may comprise
merely an identification of the enteral feeding solution e.g. by name and batch number.
In that case, additional nutritional data, such as the identity and quantity of each of the
nutrients in the enteral feeding solution, may be provided or requested from another
source, based on this identification. The other source from which the additional
nutritional data may be gathered may be for example an online source such as a data
library, webserver, data centre or the like.

[0008] The data carrier may be any appropriate element capable of providing the
nutritional data to the data reader. In particular it may comprise a bar code, including
2D bar codes, datamatrix, QR-code and the like, an RFID tag or chip, and any other
suitable optical, magnetic or electronic record carrier. The data carrier may be provided
on an external package, label, card, tag or the like. Preferably, it is affixed to the
reservoir e.g. in the form of an adhesive label or directly printed onto the packaging.
The choice of data carrier may also depend on the form of the reservoir. In this context,
it will be understood that the reservoir may include any conventional form of reservoir
used for enteral feeding solutions, including both rigid and flexible containers such as
bottles, boxes, flasks, pouches, bags, tubs and the like. The data carrier may
alternatively be attached to the enteral feeding set, e.g. in the case that the reservoir and
enteral feeding set are to be replaced together.

[0009] According to an important aspect of the invention, the system is arranged to
provide at least 1000 bytes of nutritional information to the PMM. Typically 500 - 1500
bytes of data is required to adequately represent all of the nutritional data in an enteral
feeding solution. This nutritional data must be made available to the PMM in order for
it to perform its function.

[0010] According to one aspect of the invention, data compression may be used to
reduce the amount of data transmitted from the data carrier to the PMM. In one
preferred embodiment, the data carrier includes at least 30 bytes of compressed
nutritional data and the data reader is adapted to transfer this data to the PMM, which
extracts or otherwise decompresses the data to provide at least 1Kb of nutritional data.
A suitable form of data compression may involve standard codes for each of the
nutrients in the solution e.g., the text "Energy" consisting of 6 characters may be replaced by the characters AA, requiring only 2 bytes of data. Additionally, the units may be omitted from the transmission and only the values transmitted. The text: "Energy 103 kcal" can thus be converted to AA67 which is only 4 byte of data. The skilled person will understand that all of the nutritional data can be converted in this manner, reducing the space on a label required for this information and also reducing the data transmission. Other data compression methods may be used for providing the nutritional data on the data carrier and further optimization of the transmission may also be carried out. It will further be understood that in the case of data compression, the PMM will be provided with suitable decompression capability for reading and expanding the transmitted data to its full size.

[0011] In one particularly preferred embodiment, the pump and reservoir form part of an ambulatory system. In this case, the pump will be provided with its own internal energy source and may either have the PMM included within the ambulatory system or may communicate with a PMM at a remote location, e.g. by wireless means. In an alternative embodiment, the pump may be part of a stationary or bedside installation and may be physically connected for power and information exchange.

[0012] The pump may operate according to any customary method of operation suitable for enteral feeding purposes. Preferably it is arranged to have a disposable portion that is in contact with the enteral feeding solution. Most preferably the pump is a peristaltic, roller or diaphragm pump. The flow monitoring device may be any suitable means for determining the flow rate through the pump. This may include direct flow monitoring, which measures the actual flow of enteral feeding solution within the enteral feeding set, and indirect flow monitoring, which may measure the speed of operation of the pump. In one embodiment, the pump is a roller pump having a rotor and the flow monitoring device measures the number or rotations or part rotations of the rotor.

[0013] In general, the enteral feeding set will depend upon the type of pump being used. Preferably, the enteral feeding set comprises a reservoir connector for connection to the reservoir, a flexible tubing of sufficient length to bridge the distance between the reservoir and the patient, a captive pump insert which interacts with the pump to cause pumping of the enteral feeding solution, an injection gate to allow additional drug or fluid administration and a distal end connector to connect to an invasive enteral feeding
tube or any suitable patient delivery portion such as a nasogastric tube, nasoduodenal tube, nasojejunal tube, gastrostomy feeding tube, gastrojejunostomy feeding tube or jejunostomy feeding tube.

[0014] The PMM may be implemented either as software or hardware or a combination thereof, to the extent that it can perform the required function of interfacing with the pump and with the data reader to receive the flow data and the nutritional data in order to calculate the real time delivery of individual nutrients on the basis of the flow data and the nutritional data. It can also be located at any position in the system or may be distributed. As indicated above, the PMM may in one embodiment be remotely located from the pump and communication may take place through an appropriate communication channel, such as wirelessly or over the internet. Alternatively, the PMM may be integrated within the pump itself, e.g. as a module forming part of a controller of the pump.

[0015] In addition to the PMM, the enteral feeding system may further comprise a patient data monitoring system (PDMS) arranged to store patient data relating to the patient and to a plurality of further patients. The PMM is preferably arranged to interface with the PDMS to update the patient data and the skilled person will understand that it may have all of the necessary drivers required to interface therewith. Updating may take place on the basis of the real time delivery of the various individual nutrients as calculated by the PMM. In one particular embodiment, the PDMS is arranged to calculate the real time delivery of individual nutrients on the basis of the flow data and the nutritional data and further on the basis of library data received from an electronic library external to the system. The library data may be provided to the PDMS or may be provided directly to the PMM. In general, the latter may be preferred and the library may be dedicated to a particular PMM including information related to the specific pump and enteral feeding solutions. According to one embodiment, the library data comprises data relating to the identity and quantity of each of the nutrients in the enteral feeding solution and the library data is received in response to a request for data based on the nutritional data. It will also be understood that the PDMS may itself be connected to a further library for the provision of other data such as clinical data from other locations within an institution or from a healthcare provider or doctor.

[0016] According to the invention, the system may be provided with a display for displaying the calculated real time delivery of the individual nutrients. The display may
form part of the PDMS although other display locations may also be provided. Preferably the display and its associated drivers allows for real time monitoring of all or any of the individual nutrients, individually or together. Preferably the display allows a graphical representation of both delivery rate and cumulative delivery over a time period. Because significant variations can occur between the relative quantities of different nutrients, the display may provide for logarithmic representation of the respective nutrients or use different axes for different nutrients.

[0017] According to a further aspect of the invention, the pump comprises an occlusion detector arranged to allow operation of the pump up to an occlusion pressure of at least 50 KPa, preferably at least 60 KPa and most preferably at least 80 KPa. In general, enteral feeding solutions are relatively viscous and the pump must exert considerable pressure in order to pump the solution to the body, even when no occlusion occurs. In the event that the enteral feeding set is bent or blocked, excess pressure may occur and in order to avoid false alarms, the occlusion detector may be set to a relatively high value before an alarm is given. Values as high as 200 Kpa (2 bar) may even be permitted. The enteral feeding solution may have a viscosity of at least 0.1 Pa.s but preferably will have a viscosity of between 1 Pa.s and 250 Pa.s, measured at shear rate of 100 s⁻¹ at 20 °C, for example using the AR 2000 EX by TA-instruments.

[0018] The invention also relates to a method of data management in an enteral feeding system, comprising: extracting nutritional data from a data carrier relating to the nutritional composition of an enteral feeding solution; delivering the enteral solution to a patient; monitoring delivery of the enteral feeding solution to generate flow data based on an amount of solution delivered; and calculating a real time delivery of individual nutrients on the basis of the flow data and the nutritional data.

[0019] The method may also include displaying the real time delivery of a plurality of individual nutrients on a display of a patient data monitoring system (PDMS). In this manner, a care giver can at any moment determine the state of administration of the relevant nutrient.

[0020] Additionally, the method may comprise decompressing the nutritional data received from the data carrier prior to calculating the real time delivery, whereby the real time delivery is calculated on the basis of the decompressed data.

[0021] The invention still further relates to an enteral feeding pump for use in an enteral feeding system, comprising: a pump, operationally engageable with an enteral
feeding set to cause transfer of an enteral feeding solution from a reservoir to a patient, the pump being provided with a flow monitoring device adapted to monitor an amount of solution administered and generate flow data; a data reader, adapted to interrogate a data carrier to extract nutritional data relating to a nutritional content of the enteral feeding solution; a patient monitoring module (PMM) adapted to interface with the pump and with the data reader to receive the flow data and the nutritional data and calculate a real time delivery of individual nutrients on the basis of the flow data and the nutritional data.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The features and advantages of the invention will be appreciated upon reference to the following drawings of a number of exemplary embodiments, in which:

[0023] Figure 1 shows a schematic view of an enteral feeding system according to the present invention;

[0024] Figure 2 shows the label of Figure 1;

[0025] Figure 3 shows a screen shot of the PDMS in a first display mode; and

[0026] Figure 4 shows a screen shot of the PDMS in a second display mode.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0027] Figure 1 shows a schematic view of an enteral feeding system 1 according to the present invention. The enteral feeding system 1 comprises a reservoir 2 including a quantity of an enteral feeding solution 4. The reservoir 2 is a generally conventional flexible pouch and is releasably connected to an enteral feeding set 6 for transferring the enteral feeding solution 4 to a patient (not shown). For administration of the enteral feeding solution 4, a pump 8 is provided. The pump 8 is a Nutricia FlocareTM enteral feeding roller pump with a disposable pump insert on which a rotor 9 of the pump 8 acts. The skilled person will nevertheless understand that other forms of pump, enteral feeding set and reservoir could be used within the scope of the invention. The pump 8 is operationally engaged with the enteral feeding set 6 to cause transfer of the enteral feeding solution 4 to the patient. The pump 8 includes a flow monitoring device 10 adapted to monitor the rotation of the rotor 9 to determine the amount of enteral solution 4 administered and generate flow data based on a real time evaluation of the fluid administered. The pump 8 is also provided with appropriate sensors as may otherwise be conventional, including an occlusion sensor 12. The occlusion sensor 12 is set to a pressure value which can give warning to a user in the event of an occlusion
downstream of the pump. It will be understood that enteral feeding solutions are of relatively high viscosity and a value of around 83 KPa +/− 21 kPa is generally conventional for such sensors in order to avoid false alarms. Additional upstream occlusion sensing may also be provided.

[0028] According to the invention, the reservoir 2 is provided with a data carrier 14 provided with nutritional data relating to the enteral feeding solution 4. This is in the form of a large format 2D barcode, containing around 500-1500B of data. The data carrier 14 is provided on a label 15 carrying similar data in readable form. The skilled person will understand that other forms of data carriers could be used subject to them being able to store sufficient data representative of the enteral feeding solution 4 in the reservoir 2. Also provided is a data reader 16, adapted to interrogate the data carrier 14 to extract the nutritional data. The data reader 16 is a hand-held barcode scanner operationally connected to the pump 8 for transmission of data thereto. It is alternatively envisaged that the data reader may be in the form of an integrated scanner provided on the pump body.

[0029] Figure 1 also shows a pump controller 20, a patient monitoring module (PMM) 30, a patient data management system (PDMS) 40 and a data library 50, adapted to interface with each other as will be explained in further detail below. The pump controller 20 is integrated as part of the pump 8 and interacts with the flow monitoring device 10, occlusion sensor 12 and other sensors of the pump 8. The PMM 30, the PDMS 40 and the data library 50 are external modules, remote from the pump 8. Nevertheless, the skilled person will recognise that some or all of the functions of these modules may also be distributed elsewhere, such as within the pump 8 itself. The communication between the pump controller 20 and the external modules in the illustrated embodiment is a wired connection. It will however be understood that the communication may also take place e.g. over the internet or by dedicated secure communication methods.

[0030] In the illustrated embodiment, the PDMS 40 is provided with a display 42 and a user interface 44. It will be understood that the PMM 30 may also be provided with a display and user interface if so required e.g. for bedside use.

[0031] Figure 2 shows the label 15 of Figure 1 including the nutritional data in readable form and the data carrier 14, which incorporates the same data in compressed form. This nutritional data includes the identity and quantity of each of the nutrients in the
ental feeding solution 4, normalised per 100 ml of the solution. Although not shown, it may also include the name, expiry date, logistic information and batch number of the enteral feeding solution 4.

[0032] Figure 3 shows a screen-shot of the PDMS display 42 in a view of the minerals and trace elements display.

[0033] Figure 4 shows a screen-shot of the PDMS display 42 in a view of the total administered screen for minerals and trace elements.

[0034] Operation of the enteral feeding system 1 will be described with reference to Figures 1 to 4. In use, a user or care-giver wishing to provide enteral feeding, connects enteral feeding set 6 to a new reservoir 2 of enteral feeding solution 4. Once connected, and with the enteral feeding set 6 inserted in the pump 8, the user scans the data carrier 14 with the data reader 16. The nutritional data incorporated on the data carrier 14 is extracted from the data carrier 14 and passed to the PMM 30. PMM 30 decompresses the compressed data into the form as provided on the label 15.

[0035] The pump 8 is set into operation and under the control of the pump controller 20, commences delivery of the enteral feeding solution 4 to the patient at a nominal rate of 100 ml per hour. Flow monitoring device 10 records the flow rate based on the number of rotations of rotor 9 and generates real-time flow data which is also provided to the PMM 30. On the basis of the flow data and the nutritional data, PMM 30 calculates a real time delivery of nutrients to the patient. This delivery data may comprise a momentary rate of delivery based on the concentration of an individual nutrient in the solution 4 multiplied by the momentary flow rate. It can also include the cumulative delivery based on an integration of the flow rate over time and the relevant concentration. The PMM transmits the respective delivery data to the PDMS 40 where it is displayed to a care-giver on display 42. In addition to the delivery data received from the PMM 30, the care giver may also extract data from the data library 50 to further expand the patient record. Such data may include additional drug data or nutritional data extracted from the data library 50 on the basis of the name and batch number collected from the data carrier 14. The care-giver may also input data, such as patient data and additional drug or nutritional data, directly via the user interface 44.

[0036] In Figure 3, the rate of administration of the minerals and trace elements to patient XXXXX over time is shown. In the illustrated example, all minerals are shown on a single graph over the previous 24 hour period with a scale of mg/hour given on the y-
axis in a logarithmic scale. It can be seen that the momentary delivery rate at hour 24 for Mg is around 23 mg/hour. The care giver can also observe that at around hour 10 the delivery has been stopped and has restarted at hour 14. It will be understood that for the sake of clarity, separate displays for each nutrient may be requested, each on an appropriate scale. The user can also choose to display values for energy, proteins, carbohydrates, fats or vitamins. Alternatively, a number of nutrients may be selected from a list for display together.

[0037] In Figure 4, the user has chosen to display the momentary total cumulative delivery for minerals and trace elements. This is the total in mg of the respective nutrient delivered over the last 24 hour period. A care giver can directly determine how much of a particular nutrient has been taken and may take this into account on assessing the condition of a patient and whether any additional nutrition may be required. Thus, the invention has been described by reference to certain embodiments discussed above. It will be recognized that these embodiments are susceptible to various modifications and alternative forms well known to those of skill in the art. In particular, the particular data transferred and displayed will depend upon the treatment regime and may vary accordingly. Many modifications in addition to those described above may be made to the structures and techniques described herein without departing from the spirit and scope of the invention. Accordingly, although specific embodiments have been described, these are examples only and are not limiting upon the scope of the invention.
CLAIMS

1. An enteral feeding system comprising:
   a reservoir including a quantity of an enteral feeding solution;
   a data carrier provided with nutritional data relating to the enteral feeding solution included in the reservoir;
   an enteral feeding set, connectable to the reservoir, for transferring the enteral feeding solution to a patient; and
   a pump, operationally engageable with the enteral feeding set to cause transfer of the enteral feeding solution to the patient, the pump being provided with a flow monitoring device adapted to monitor an amount of solution administered and generate flow data;
   a data reader, adapted to interrogate the data carrier to extract the nutritional data
   a patient monitoring module (PMM) adapted to interface with the pump and with the data reader to receive the flow data and the nutritional data, whereby real time delivery of individual nutrients can be calculated on the basis of the flow data and the nutritional data.

2. The system according to claim 1, wherein the nutritional data includes the identity and quantity of each of the nutrients in the enteral feeding solution.

3. The system according to claim 1 or claim 2, wherein the data carrier is affixed to the reservoir.

4. The system according to any preceding claim, wherein the data carrier includes at least 30 byte of nutritional data and the PMM is adapted to decompress or otherwise extract the data to provide at least 1Kb of nutritional data.

5. The system according to any preceding claim, wherein the data carrier comprises a 2-D barcode.
6. The system according to any preceding claim, wherein the PMM is integrated in the pump.

7. The system according to any preceding claim, wherein the PMM is remotely located from the pump and communication takes place wirelessly.

8. The system according to any preceding claim, further comprising a patient data monitoring system (PDMS) arranged to store patient data relating to the patient and to a plurality of further patients and wherein the PMM interfaces with the PDMS to update the patient data.

9. The system according to claim 8, wherein the PDMS is remotely located from the pump and communication takes place wirelessly.

10. The system according to any preceding claim, wherein the PMM is arranged to calculate the real time delivery of individual nutrients on the basis of the flow data and the nutritional data and further on the basis of library data received from an electronic library external to the system.

11. The system according to claim 10, wherein the library data comprises data relating to the identity and quantity of each of the nutrients in the enteral feeding solution and the library data is received in response to a request for data based on the nutritional data.

12. The system according to any preceding claim, wherein the pump comprises an occlusion detector arranged to allow operation of the pump up to an occlusion pressure of at least 50 KPa, preferably at least 60 KPa and most preferably at least 80 KPa.

13. The system according to any preceding claim, wherein the enteral feeding solution has a viscosity of at least 0.1 Pa.S and preferably between 1 Pa.S and 250 Pa.S measured at shear rate of 100 s⁻¹ at 20 °C.

14. A method of data management in an enteral feeding system, comprising:
extracting nutritional data from a data carrier relating to the nutritional composition of
an enteral feeding solution;
delivering the enteral feeding solution to a patient;
monitoring delivery of the enteral feeding solution to generate flow data based on an
amount of solution delivered;
calculating a real time delivery of individual nutrients on the basis of the flow data and
the nutritional data.

15. The method of claim 14, further comprising displaying the real time delivery of
a plurality of individual nutrients on a display of a patient data monitoring system
(PDMS).

16. The method of claim 14 or claim 15, further comprising decompressing the
nutritional data received from the data carrier.
### Nutritional Information

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy</strong></td>
<td>430 kJ</td>
</tr>
<tr>
<td></td>
<td>103 kcal</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>4.0 g</td>
</tr>
<tr>
<td><strong>Carbohydrate</strong></td>
<td></td>
</tr>
<tr>
<td>- Sugars</td>
<td>12.3 g</td>
</tr>
<tr>
<td>- Lactose</td>
<td>&lt;0.025 g</td>
</tr>
<tr>
<td><strong>Fat</strong></td>
<td></td>
</tr>
<tr>
<td>- Saturates</td>
<td>3.9 g</td>
</tr>
<tr>
<td>- Monounsaturates</td>
<td>1.0 g</td>
</tr>
<tr>
<td>- Polyunsaturates</td>
<td>2.2 g</td>
</tr>
<tr>
<td>- Docosahexaenoic</td>
<td>0.7 g</td>
</tr>
<tr>
<td>- Eicosapentaenoic</td>
<td>14.0 g</td>
</tr>
<tr>
<td><strong>Dietary fibre</strong></td>
<td></td>
</tr>
<tr>
<td>- Soluble</td>
<td>1.5 g</td>
</tr>
<tr>
<td>- Insoluble</td>
<td>0.7 g</td>
</tr>
<tr>
<td><strong>Vitamins</strong></td>
<td></td>
</tr>
<tr>
<td>- Vit. A</td>
<td>82 μg/RE/ER</td>
</tr>
<tr>
<td>- Vit. D₃</td>
<td>1.0 μg</td>
</tr>
<tr>
<td>- Vit. E</td>
<td>1.3 mg/ α-TE/ET</td>
</tr>
<tr>
<td>- Vit. K</td>
<td>5.3 μg</td>
</tr>
<tr>
<td>- Thiamin</td>
<td>0.15 mg</td>
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<tr>
<td>- Riboflavin</td>
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<td>- Biotin</td>
<td>4.0 μg</td>
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<tr>
<td>- Vit. C</td>
<td>10 mg</td>
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<tr>
<td><strong>Minerals and trace elements</strong></td>
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<tr>
<td>- Na</td>
<td>(4.4 mmol) 100 mg</td>
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<tr>
<td>- K</td>
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<td>(2.3 mmol) 23 mg</td>
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<tr>
<td>- I</td>
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<td>- Osmolarity</td>
<td>250 mOsmol/l</td>
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<td>- H₂O</td>
<td>83 ml</td>
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INTERNATIONAL SEARCH REPORT

PCT/NL2013/050727

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61J15/00 G06F9/00 A61M5/142

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61J G06F A61M

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
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Further documents are listed in the continuation of Box C. 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 relating 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

"T" 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

"Z" document member of the same patent family

Date of the actual completion of the international search
18 June 2014

Date of mailing of the international search report
26/06/2014

Name and mailing address of the ISA/
European Patent Office, P.B. 5018 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer
Kousouretas, Ioannis

Form PCT/ISA/210 (second sheet) (April 2005)
**Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 14-16 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
   
   see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.
Continuation of Box II.2

Claims Nos.: 14-16

Method of treatment Rule 39(1)(iv) PCT

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.
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