(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 September 2012 (20.09.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/123693 A1

(51) International Patent Classification:
G05B 19/4099 (2006.01)

(21) International Application Number:
PCT/GB2012/000205

(22) International Filing Date:
1 March 2012 (01.03.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1104328.8 15 March 2011 (15.03.2011) GB

(71) Applicants *(for all designated States except US)*: **FRIPP DESIGN & RESEARCH LIMITED** [GB/GB]; Advanced Manufacturing Park Tech Centre, Brunel Way, Sheffield S60 5WG, South Yorkshire (GB). **THE UNIVERSITY OF SHEFFIELD** [GB/GB]; Western Bank, Sheffield S10 2TN, South Yorkshire (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **VAN NOORT, Richard** [GB/GB]; The University of Sheffield, Western Bank, Sheffield, South Yorkshire, S10 2TN (GB). **YATES, Dr Julian** [GB/GB]; The University of Sheffield, Western Bank, Sheffield, South Yorkshire, S10 2TN (GB). **FRIPP, Tom** [GB/GB]; Fripp Design & Research Limited, Advanced Manufacturing Park Tech Centre, Brunel Way, Sheffield, South Yorkshire, S60 5WG (GB). **WILD-GOOSE, David** [GB/GB]; The University of Sheffield, Western Bank, Sheffield, South Yorkshire, S10 2TN (GB).

(74) Agents: **FRANKS & Co LIMITED** et al.; 15 Jessops Riverside, Brightside Lane, Sheffield, S9 2RX (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,

[Continued on next page]

(54) Title: METHOD AND SYSTEM FOR PRODUCING PROSTHESES

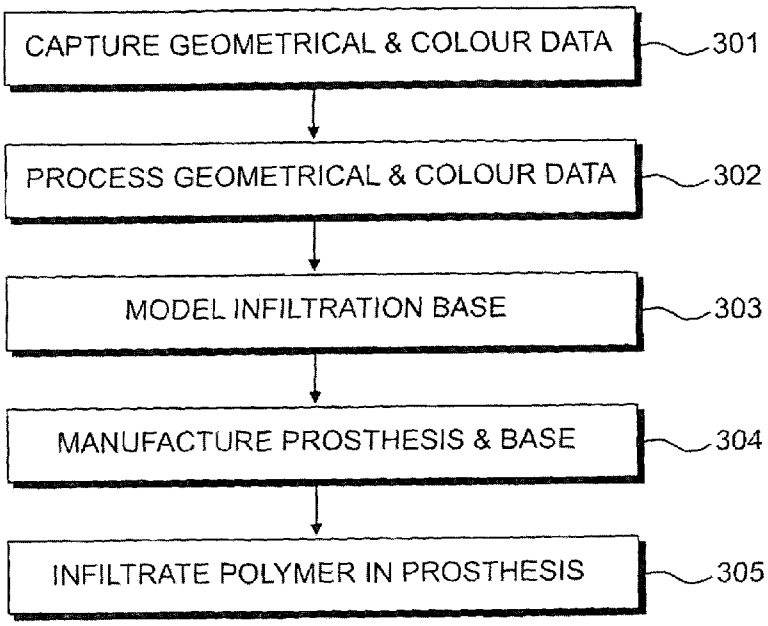


Figure 3

(57) Abstract: A method and a system are disclosed for manufacturing prostheses. Geometrical and colour data are acquired from a patient with an image processing apparatus. The acquired data is processed into a sequence of commands for a material processing apparatus. The material processing apparatus produces a prosthesis structure according to the sequence of commands, and a substantially resilient material is infiltrated in the prosthesis structure.

WO 2012/123693 A1

OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

METHOD AND SYSTEM FOR PRODUCING PROSTHESES

Field of the Invention

[0001] The present invention relates to improvements in the production of prostheses. More particularly, the present invention relates to an improved method and system for producing soft tissue prostheses.

Background of the Invention

[0002] A prosthesis is an artificial device, typically used to replace a body part either lost through trauma or illness, or malformed or missing as a congenital defect. Cosmetic prostheses have long been used to disguise injuries and disfigurements, and recent developments have permitted the creation of lifelike limbs and appendages made from resilient materials such as silicone polymer or PVC.

[0003] Many such prostheses, for instance craniofacial prostheses such as artificial noses and ears, can now be manufactured with the appearance of their real counterpart, complete with matching skin tone, veins, even individual melanin-based markings like freckles or moles, and are often referred to as soft tissue prostheses.

[0004] Anaplastologists are individuals with the required skills and knowledge to manufacture and customise soft tissue prostheses, and use manual moulding techniques with polymeric organosilicones, typically polydimethylsiloxane (PDMS), to produce prostheses capable of mimicking both the appearance and the flexibility of their real counterpart.

[0005] Accordingly, the level of detail of a cosmetic prosthesis is proportional to its manufacturing time, and therefore its cost, with the most realistic prostheses being extensively customised and particularly onerous, and standard off-the-shelf prostheses not being as detailed.

Confirmation Copy

[0006] Techniques have recently been developed for simplifying the manufacture of prostheses, by introducing rapid prototyping technologies in the field of anaplastology.

[0007] WO01/77988 discloses a method of rapid design and manufacture of biomedical devices, which includes capturing patient-specific diagnostic imaged data, converting the data to a digital computer file, transmitting the converted data via a computer network to a remote manufacturing site, converting the computer file into a multi-dimensional model and then into machine instructions, and constructing a biomedical device according to the instructions.

[0008] WO03/040787 discloses another method of rapid design and manufacture of biomedical devices, wherein patient information and patient-specific radiological data is captured and transmitted via a computer network to a design and/or manufacturing site. A multi-dimensional digital model is created from the radiological data and patient information and modified through communications interchanges between a clinical/diagnostic site and the design/manufacturing site. The digital model is eventually approved, then converted into machine instructions for constructing the biomedical device, or used in a best fit selection of biomedical devices from a pre-existing set of biomedical devices or machine instructions.

[0009] However, these techniques still require extensive infrastructural requirements, particularly specialist and expensive medical imaging devices, and the prostheses produced with same still require manual finishing or customising by a skilled prosthetic technician in order to achieve a sufficiently realistic appearance. These techniques also fail to address the issue of matching the colour of the prosthesis to the skin tone of the patient, which is particularly important for soft tissue prostheses, especially craniofacial soft tissue prostheses.

[0010] An improved method of rapid design and manufacture of soft tissue prostheses is required, for overcoming at least some of the shortcomings associated with the prior art techniques.

Summary of the Invention

[0011] According to a first aspect of the present invention, a method of manufacturing a prosthesis is provided, which comprises the steps of acquiring geometrical and colour data with an image processing apparatus; processing the acquired data into a sequence of commands for a manufacturing apparatus; producing a prosthesis structure with the manufacturing apparatus according to the sequence of commands; and infiltrating a substantially resilient material in the prosthesis structure.

[0012] Preferably, the image processing apparatus comprises at least two digital cameras, whereby the acquisition of geometrical and colour data includes capturing a multi-dimensional image of a patient to which the prosthesis is destined. More preferably, the image processing apparatus comprises three cameras, whereby the acquisition of geometrical and colour data includes capturing a three dimensional image of the patient to which the prosthesis is destined.

[0013] Alternatively, the image processing apparatus comprises a medical imaging apparatus of the computed tomography variety, for instance X-ray Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Magnetic Resonance Imaging (NMRI) or Magnetic Resonance Tomography (MRT). Certain such medical imaging apparatuses are known to have image data processing functions apt to build a volume of the anatomical region being scanned, by combining individual images in a stacked structure or the like, resulting in geometrical and colour data representative of the three dimensional image of the patient to which the prosthesis is destined, for instance surface-rendered and volume-rendered.

[0014] Preferably, processing the acquired data further includes processing the acquired geometrical data into a three dimensional model. Preferably still, processing the acquired data also further includes converting the acquired colour data for matching the prosthesis colour to the patient skintone.

[0015] When the acquired colour data is RGB or RGBA, the colour data conversion preferably further includes subjecting the RGB or RGBA data to at least one multiple – order polynomial regression. More preferably, the colour data conversion further includes subjecting subjecting the RGB or RGBA data to a multiple – order polynomial regression specific to the image processing apparatus, for obtaining CIE XYZ colourspace data. The obtained CIE XYZ colourspace data is then preferably subjected to a polynomial regression for obtaining RGB data compatible with the manufacturing apparatus.

[0016] Preferably, processing the acquired data further includes generating at least one texture from colour data.

[0017] Alternatively, the image processing apparatus comprises a data processing terminal and the acquisition of geometrical and colour data includes a selection of the geometrical and colour data from a database storing data representative of prostheses and skin tones.

[0018] Preferably, the manufacturing apparatus comprises a data processing terminal interfaced with a rapid prototyping device, and the prosthesis structure is produced by the rapid prototyping device as a layered structure.

[0019] The rapid prototyping device may advantageously be a three dimensional printer, whereby processing the acquired data into a sequence of commands further includes the definition of printing commands, and the production of the prosthesis structure further includes printing the structure in layers according to the printing commands.

[0020] Preferably, the layered structure is made from starch or amylum in powder form, consisting substantially of amylose and amylopectin molecules in proportions, depending on the source, of 20 to 25% amylose and 75 to 80% amylopectin.

[0021] Alternatively, the layered structure is made from silica. The silica may also be in powder form.

[0022] Preferably, the infiltration of a substantially resilient material in the prosthesis structure further includes placing the prosthesis structure and the substantially resilient material in a pressure chamber, and pressurising the chamber.

[0023] Preferably, a base is produced for forming an edge to the prosthesis structure, apt to match tissue surrounding an adaptation site of the prosthesis on the patient. The resilient material is allowed to run off the prosthesis structure onto the base and to solidify into a feathered edge.

[0024] Preferably, the chamber is pressurised at 1 bar at least, for a duration of at least 5 minutes. When the prosthesis structure is made of starch, with a wall thickness of substantially 14 millimetres or less or, alternatively, when the prosthesis structure is made of silica, with a wall thickness of substantially 8 millimetres or less, the chamber is preferably pressurised at substantially 3 bars at least, for a duration of at least 25 minutes.

[0025] Preferably, the substantially resilient material is an elastomer. The elastomer may be selected from the group comprising silicone polymers, chlorinated polyethylene elastomers, polycarbonaturethane (PCU) and polyether polyurethanes. The elastomer is preferably a silicone polymer, selected from the group comprising Silskin™ 25, Ideal™, Silskin™ 2000, Elastosil™ M3500, Silastic™ MDX4-4210 and A-2000™.

[0026] According to another aspect of the present invention, there is provided a system for manufacturing a prosthesis, the system comprising an image processing apparatus for acquiring geometrical and colour data; means for processing the acquired data into a sequence of commands; a manufacturing apparatus for producing a prosthesis structure according to the sequence of commands; and mean for infiltrating a substantially resilient material in the prosthesis structure.

[0027] Preferably, the image processing apparatus comprises at least two digital cameras, whereby the acquisition of geometrical and colour data includes capturing a multi-dimensional image of a patient to which the prosthesis is destined. More preferably, the image processing apparatus comprises three cameras for capturing a three dimensional image of the patient to which the prosthesis is destined.

[0028] Alternatively, the image processing apparatus comprises a medical imaging apparatus of the computed tomography variety, for instance X-ray Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Magnetic Resonance Imaging (NMRI) or Magnetic Resonance Tomography (MRT). Certain such medical imaging apparatuses are known to have image data processing functions apt to build a volume of the anatomical region being scanned, by combining individual images in a stacked structure or the like, resulting in geometrical and colour data representative of the three dimensional image of the patient to which the prosthesis is destined, for instance surface-rendered and volume-rendered.

[0029] Preferably, the means for processing the acquired data is adapted to process the acquired geometrical data into a three dimensional model. Preferably still, the means for processing the acquired data is further adapted to convert the acquired colour data for matching the prosthesis colour to the patient skintone.

[0028] Preferably, when the acquired colour data is RGB or RGBA, the means for processing the acquired data is adapted to subject the RGB or RGBA data to at least one multiple – order polynomial regression. More preferably, the means for processing the acquired data is adapted to subject the RGB or RGBA data to a multiple – order polynomial regression specific to the image processing apparatus, for obtaining CIE XYZ colourspace data. In this embodiment, the means for processing the acquired data is preferably further adapted to subject the CIE XYZ colourspace data to a polynomial regression for obtaining RGB data compatible with the manufacturing apparatus.

[0029] Preferably, the means for processing the acquired data is further adapted to generate at least one texture from the acquired colour data.

[0030] Alternatively, the image processing apparatus comprises a data processing terminal storing data representative of prostheses and skin tones, for selecting the geometrical and colour data therefrom.

[0031] Preferably, the processing means is a data processing terminal and the manufacturing apparatus is a rapid prototyping device adapted to produce the prosthesis as a layered structure.

[0032] The rapid prototyping device may advantageously be a three dimensional printer, the sequence of commands defines printing commands, and the three dimensional printer produces the prosthesis as a structure of printed layers.

[0033] Preferably, the layered structure is made from starch or amylum in powder form, consisting substantially of amylose and amylopectin molecules in proportions, depending on the source, of 20 to 25% amylose and 75 to 80% amylopectin.

[0034] Alternatively, the layered structure is made from silica. The silica may also be in powder form.

[0035] Preferably, the infiltration means is a pressure chamber. The pressure chamber may be adapted to infiltrate the substantially resilient material in the prosthesis structure under a pressure of at least 1 bar, for a duration of at least 5 minutes. When the prosthesis structure is made of starch, with a wall thickness of substantially 14 millimetres or less or, alternatively, when the prosthesis structure is made of silica, with a wall thickness of substantially 8 millimetres or less, the chamber is preferably pressurised at substantially 3 bars at least, for a duration of at least 25 minutes.

[0036] Preferably, the system further comprises a base for forming an edge to the prosthesis structure, apt to match tissue surrounding an application site of the prosthesis on the patient, onto which the resilient material is allowed to run off the prosthesis structure.

[0037] The substantially resilient material is preferably an elastomer. The elastomer may be selected from the group comprising silicone polymers, chlorinated polyethylene elastomers, polycarbonaturethane (PCU) and polyether polyurethanes. The elastomer is preferably a silicone polymer, selected from the group comprising Silskin™ 25, Ideal™, Silskin™ 2000, Elastosil™ M3500, Silastic™ MDX4-4210 and A-2000™.

[0038] According to a further aspect of the present invention, a method of processing image colour data is provided in a system for manufacturing a prosthesis, comprising the steps of acquiring colour data representative of a patient skintone from an image processing apparatus; transforming the acquired colour data with a first polynomial regression into an alternative colour space; and transforming the transformed colour data with a second polynomial regression to output colour data compatible with a manufacturing apparatus apt to produce a coloured prosthesis.

[0039] Preferably, the acquired colour data is RGB or RGBA and the alternative colour space is CIE XYZ. The first polynomial regression may be a multiple – order polynomial regression specific to the image processing apparatus, and the second polynomial regression may be a polynomial regression specific to the manufacturing apparatus.

[0030] Preferably, the image processing apparatus comprises a plurality of digital cameras, and the manufacturing apparatus is a rapid prototyping device, particularly a three dimensional printer. Alternatively, the image processing apparatus comprises a medical imaging apparatus of the computed tomography variety, for instance X-ray Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Magnetic Resonance Imaging (NMRI) or Magnetic Resonance Tomography (MRT). Certain such medical imaging apparatuses are known to have image data processing functions apt to build a volume of the anatomical region being scanned, by combining individual images in a stacked structure or the like, resulting in geometrical and colour data representative of the three dimensional image of the patient to which the prosthesis is destined, for instance surface-rendered and volume-rendered.

[0040] According to yet another aspect of the present invention, a method of combining a substantially resilient material with a prosthesis structure is provided, comprising the steps of producing the prosthesis structure with a rapid prototyping device; immersing the prosthesis structure in a volume of the substantially resilient material; placing the prosthesis structure immersed in the substantially resilient material in a pressure chamber; and subjecting the prosthesis structure immersed in the substantially resilient material to a predetermined pressure for a predetermined period of time.

[0041] Preferably, the rapid prototyping device is a three dimensional printer and the production of the prosthesis structure comprises a further step of printing the prosthesis structure in layers.

[0042] Preferably, the prosthesis structure is made of starch powder or, alternatively, silica powder, whereby the predetermined pressure is at least 1 bar and the predetermined period of time is at least 5 minutes. If the prosthesis structure is made of starch powder with a wall thickness of substantially 14 millimetres or less, or if the prosthesis structure is made of silica powder with a wall thickness of substantially 8 millimetres or less, the predetermined pressure is preferably at least 3 bars and the predetermined period of time is at least 25 minutes.

[0043] The substantially resilient material is preferably an elastomer. The elastomer may be selected from the group comprising silicone polymers, chlorinated polyethylene elastomers, polycarbonaturethane (PCU) and polyether polyurethanes. The elastomer is preferably a silicone polymer, selected from the group comprising Silskin™ 25, Ideal™, Silskin™ 2000, Elastosil™ M3500, Silastic™ MDX4-4210 and A-2000™.

[0044] According to still another aspect of the present invention, a computer program product is provided, which stores a computer program which, when processed by a data processing terminal, configures the data processing terminal to perform the steps of acquiring colour data representative of a patient skintone from an image processing apparatus; transforming the acquired colour data with a first polynomial regression into an alternative colour space; transforming the transformed colour data with a second polynomial regression into compatible colour data, wherein the compatible colour data is compatible with a manufacturing apparatus apt to produce a coloured prosthesis; and outputting the compatible colour data to the manufacturing apparatus for producing a coloured prosthesis matching the patient skintone.

[0045] Preferably, the image processing apparatus, the data processing terminal and the manufacturing apparatus are connected to one another over at least one network, and the respective acquisition, transformations and outputting are performed at respective network locations.

[0031] Preferably, the image processing apparatus comprises at least two digital cameras and the manufacturing apparatus comprises a rapid prototyping device. Alternatively, the image processing apparatus comprises a medical imaging apparatus of the computed tomography variety, for instance X-ray Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Magnetic Resonance Imaging (NMRI) or Magnetic Resonance Tomography (MRT). Certain such medical imaging apparatuses are known to have image data processing functions apt to build a volume of the anatomical region being scanned, by combining individual images in a stacked structure or the like, resulting in geometrical and colour data representative of the three dimensional image of the patient to which the prosthesis is destined, for instance surface-rendered and volume-rendered.

[0046] The computer program product is preferably selected from the group comprising an optical data storage medium, a magnetic data storage medium and a computer – readable file transmissible across the network.

Brief Description of the Drawings

[0047] For a better understanding of the invention and to show how the same may be carried into effect, there will now be described by way of example only, specific embodiments, methods and processes according to the present invention with reference to the accompanying drawings in which:

Figure 1 is a graphic representation of a first embodiment of the system according to the present invention, including an image processing apparatus and a plurality of network – connected data processing devices;

Figure 2 details the typical components of a network – connected data processing device shown in Figure 1;

Figure 3 details the steps of a method of producing a prosthesis with the system shown in Figure 1, including steps of and forming an infiltration base;

Figure 4 is a graphic representation of the typical components of the image processing apparatus shown in Figure 1;

Figure 5 illustrates the capture of an object with the image processing apparatus shown in Figures 1 and 4;

Figure 6 further details the image data processing step shown in Figure 3; and

Figure 7 further details the infiltration base forming step shown in Figure 3.

Detailed Description of the Embodiments

[0048] There will now be described by way of example a specific mode contemplated by the inventors. In the following description numerous specific details are set forth in order to provide a thorough understanding. It will be apparent however, to one skilled in the art, that the present invention may be practiced without limitation to these specific details. In other instances, well known methods and structures have not been described in detail so as not to unnecessarily obscure the description.

[0049] Referring now to the Figures and initially Figure 1, there is shown a first embodiment of the system according to the present invention. The system comprises a communication network 101 and at least one image processing apparatus 102 comprising a plurality of digital cameras, which is interfaced with a data processing device 103 connected to the communication network 101. The system further comprises a prosthesis manufacturing machine 104, in the example a three dimensional printer, interfaced with a data processing device 105 connected to the communication network 101. The system also comprises a pressure chamber 106, which may form part of the

prosthesis manufacturing machine 104 or be a standalone device, for instance a dental pressure bath.

[0050] Each data processing device 103, 105 has wired or wireless telecommunication emitting and receiving functionality, and means are provided for connecting the data processing devices 103, 105 to one another across the communication network 101, wherein the means may vary according to the structure of the data processing device and/or the network standard of the communication network 101.

[0051] Data processing device 103 for instance emits and receives data encoded as a digital signal over a wireless data transmission 107 conforming to the IEEE 802.11 ('WiFi') standard, wherein said signal is relayed respectively to or from the data processing device 105 by a wireless router 108 interfacing the data processing device 103 to the communication network 101, which is a Wide Area Network ('WAN'), an example of which is the Internet.

[0052] Data processing device 105 for instance emits and receives data encoded as a digital signal over a wired data transmission 109 conforming to the IEEE 802.3 ('Gigabit Ethernet') standard, wherein said signal is relayed respectively to or from the data processing device 103 by a wired router 110 interfacing the data processing device 105 to the WAN.

[0053] In the embodiment of Figure 1 therefore, the user of each data processing device 103, 105 has the use of a data communicating device configured to receive data from, and communicate data to, a remote data communicating device. This configuration is advantageous in that it allows either a single prosthesis manufacturing machine 104 to be used by one or more remote sites having a respective image processing apparatus 102, for instance the respective surgical departments of several hospitals at various geographical locations.

[0054] Alternative embodiments will be readily envisaged by skilled persons without exercising any inventive step, for instance wherein the communication network 101 is a Local Area Network ('LAN') and the image processing apparatus 102, the data processing devices 103, 105 and the prosthesis manufacturing machine 104 are

proximate one another or, in still simpler alternatives, wherein the image processing apparatus 102 and the prosthesis manufacturing machine 104 are both interfaced to a same data processing device 103, or even interfaced directly to one another when they incorporate suitable data processing and communicating capacities.

[0055] The invention provides a local or distributed system, which allows the capturing of a multidimensional image with colour information of the soft tissue appendage or body part to prosthesis, and/or of the prosthesis adaptation site, of a prosthesis recipient. The system processes the multidimensional image with colour information into processing instructions for the prosthesis manufacturing machine 104, which outputs a coloured three dimensional prosthesis structure according to same. The system then infiltrates a substantially resilient material in the coloured three dimensional prosthesis structure, whereby the prosthesis is ready for fitting. There follows a detailed description of relevant features and aspects of the embodiment shown in Figure 1 and their respective methodology.

[0056] A typical hardware architecture of each data processing device 103, 105 is shown in Figure 2 in further detail, by way of non-limitative example. Each data processing device 103, 105 is a computer terminal configured with a data processing unit 201, data outputting means such as video display unit (VDU) 202, data inputting means such as a keyboard 203 and a pointing device (mouse) 204 and data inputting/outputting means such as a wired network connection 105E or wireless network connection 105F, a magnetic data-carrying medium reader/writer 206 and an optical data-carrying medium reader/writer 207.

[0057] Within data processing unit 201, a central processing unit (CPU) 208 provides task co-ordination and data processing functionality. Instructions and data for the CPU 208 are stored in memory means 209 and a hard disk storage unit 210 facilitates non-volatile storage of the instructions and the data.

[0058] A network interface card (NIC) 211 provides a wired or wireless connection to the network 101. A universal serial bus (USB) input/output interface 212 facilitates connection to the keyboard and pointing devices 203, 204. All of the above devices are connected to a data input/output bus 213, to which the magnetic data-carrying medium reader/writer 206 and optical data-carrying medium reader/writer 207

are also connected. A video adapter 214 receives CPU instructions over said bus 213 for outputting processed data to VDU 202.

[0059] All the components of terminal 201 are powered by a power supply unit 215, which receives electrical power from a local mains power source and transforms same according to component ratings and requirements.

[0060] With reference now to Figure 3, an initial step 301 in the production of any prosthesis is capturing the physical attributes of the affected area of trauma. This step has traditionally been performed by anaplastologists taking an impression or mould of the affected area of trauma, using a putty or wax, in order to create a physical model which mirrors it. This prior art process can prove physiologically and/or psychologically painful, uncomfortable and time-consuming, particularly with prosthesis recipients having scarred or delicate skin. Further the area of soft tissue being recorded may be distorted under the weight and pressure of the impression material and technique used.

[0061] Alternative methods and systems have been developed more recently, which capture a live subject digitally, however they differ in the crucial characteristic of speed of capture: particularly accurate systems use one or more laser beams for target surface tracking and/or measurement, however at the expense of an increased capture period, and with the disadvantage that capturing image data from a live prosthesis recipient, apt to move even minutely during the process, introduces extensive artefacts in the captured image, which then requires correspondingly extensive data processing for repairing or completing the image data, for it to be useable.

[0062] With reference now to Figure 4, the image processing apparatus 102 implements three dimensional photogrammetry, which uses a plurality of digital cameras 401 calibrated to understand their respective locations relative to one another and capture large areas of geometry and colour detail simultaneously, within hundredth of seconds or even milliseconds. This technique mitigates disadvantages associated with length of capture, and advantageously also captures skin tone data at the same time. This capture may be undertaken pre-operatively, post-operatively or post-trauma. In a pre-operative situation, advantageously, an exact geometrical copy of the affected area may be produced with matching skin tone. Alternatively, in a post-operative or post-trauma situation, the geometry may need to be generated.

[0063] Accordingly, the image processing apparatus 102 is a digital photogrammetry apparatus capable of generating coloured three dimensional surface data from physical objects, and operates with the array of medical-grade colour digital cameras 401 and, optionally, one or more laser projectors 402. Such an apparatus is for instance a 3dMDface™ or 3dMDcranial™ image processing apparatus manufactured and distributed by 3DMD™ Imaging Equipment, Inc. of Atlanta, Georgia, USA. The multiple cameras view an object or patient from respective angles and identify geometric variations as a result of their position relative to one another.

[0064] The data processing device 103 interfaced with the image processing apparatus 102 receives captured colour image data over a data communication link 403 and is configured by appropriate instructions, for instance a computer program 404 such as the 3dMDpatient™ computer program produced and distributed by 3DMD™ Imaging Equipment, Inc. of Atlanta, Georgia, USA, to process the captured image data into geometrical and colour data, from which calculations can be made for measuring distances between points 405 on the object surface 406.

[0065] The 3dMDface™ apparatus 102 of the example is claimed to be capable of generating a digital three dimensional model with an accuracy of 0.2mm to 0.5mm. Previously published data has confirmed this level of accuracy, however the datasets for same have been limited to straight line measurements in the horizontal, vertical and anterior-posterior plane (Aldridge et al, 2005; Wong et al, 2007).

[0066] The inventors have therefore carried out a series of tests on two volunteers to confirm the level of accuracy over anatomical data, which comprises contours and complex surfaces 406, to ensure three-dimensional measurements are sufficiently accurate for generating prostheses therewith.

[0067] Arbitrary points 407 were selected on each volunteer's face. Straight line measurements were taken between two points 407A, 407B in different planes on the face, and images captured as three dimensional data. Previous reports have used anatomical landmarks to identify distances that could be considered 'constant', however, it is known that there can be significant intra-operative and inter-operative variation when pinpointing these landmarks for measurement. Rather, paper markers used as reference

points were placed on the skin in order to mitigate this potential variation. Measurements were then taken between the points using a pair of digital dial callipers and recorded.

[0068] After collection of the data, a three-dimensional camera image was taken of the face with the 3DMD system. The camera image was processed by the 3DMD system to extract relative measurements, taken from reference point to reference point along the shortest route. The following results are based on the actual tests, not the graphical depiction shown in Figure 4 by way of example only.

Results Test Subject I

Calliper Reading +1 / -1mm	3D Camera Reading	Delta
33.6	33.832	-0.232
12.9	13.185	-0.285
85.8	87.104	-1.404
	Average:	-0.607

Results Test Subject II

Calliper Reading +1 / -0.5mm	3D Camera Reading	Delta
33.9	34.103	-0.203
19.9	20.192	-0.292
102.2	103.071	-0.871
	Average:	-0.455

[0069] The results of the series of tests indicate an approximate error of ± 0.5mm. A further series of tests upon organic and inorganic subjects demonstrates that the camera system retains an accuracy of between 0.2 and 0.6 mm. From the series of tests, the inventors have noted that the largest individual error occurred in the same plane on the face (lower face) of each of the two volunteers measured. Due to the nature of the surface data captured and measured, this suggests that the error was associated with the data reading from the digital callipers, since all other datasets are equal within 0.1mm, a variation which is satisfactory for the application requirements, as a person viewing a prosthesis is unlikely to notice a change in geometry of between 0.2 mm and 0.5

mm, and this accuracy is unlikely to cause discomfort to the patient given the soft, flexible nature of the material being used for the production of the prosthesis.

[0070] The inventors have also carried out a series of tests for determining an optimum number of cameras 401 for the image processing apparatus 102, by observing the accuracy of geometrical capture over anatomical data, which comprises contours and complex surfaces 406, with, respectively with a two-camera apparatus and a three-camera apparatus.

[0071] With reference now to Figure 5, a prosthetic ear 501 was selected as anatomical data with complex contours and surfaces. A first image set captured by the two-camera apparatus, consisting of two views of the ear, each by a respective camera 401, identified areas 502 of the captured data having missing data, in the form of missing vertices and colour information, and corresponding generally to those portions of the complex contours and surfaces outside or masked to the two camera's combined field of view 503. Thus, three dimensional models obtained with a two-camera apparatus, whilst not unusable with the system and method of the present invention, would nevertheless require additional data processing for repairing or completing the model, for instance with digital modelling and model stitching, in order to produce a part suitable for production.

[0072] A second image set was captured by a three-camera apparatus, consisting of three views of the ear, two by the same cameras 401 as hitherto described and a third by an additional camera 401 (shown in dashed line in Figure 3) facing the ear. Fewer areas 504 of the captured data were identified as having missing data, in the form of missing vertices and colour information, and corresponding generally to those very few remaining portions of the complex contours and surfaces outside or masked to the three camera's combined field of view 505. Thus, three dimensional models obtained with a three-camera apparatus require little to no additional data processing for repairing or completing the model. It is expected that still better results would be obtained by

an image processing apparatus 102 having still further cameras 401, however the opportunity of adding cameras 401 should be weighed against their individual costs and the respective increases in apparatus setup complexity and data processing requirements.

[0073] Advantageously, the image data obtained by either the two-camera or the three-camera apparatus further includes a high – resolution two dimensional image with colour information, which is stored in the same file container as the captured geometrical data defining the three dimensional model.

[0074] In an alternative embodiment, which is particularly advantageous for prosthesis recipients having lost the body part or appendage before the image data could be captured, and for whom a replica prosthesis cannot be produced from the missing original body part or appendage, a plurality of preconfigured three dimensional models are stored in a database processed by terminal 103 or 105. The database effectively implements a library of three dimensional models of body parts and appendages, one of which the prosthesis recipient may select on the basis of prosthesis location characteristics and further cosmetic considerations. A high – resolution two dimensional image with colour information of the trauma area is again captured from the prosthesis recipient, which is stored in the same file container as the geometrical data defining the three dimensional model selected from the library, whereby the selected library prosthesis may still be produced with a matching skin tone.

[0075] Further to capturing the physical attributes of the affected area of trauma, a next step 302 in the production of the prosthesis is converting the captured or selected geometrical data and the captured colour data into a digital prosthesis ready to be produced by the prosthesis manufacturing machine 104.

[0076] Prosthesis may be releasably secured to the underlying tissue of the trauma area with a variety of anchoring techniques, including for instance ball joints, magnets, clips and the like. Such fixtures require integration into

prostheses prior to dispatch for patient fitting. Thus, a relevant fixture is preferably implemented during the data conversion for finalising the digital prosthesis. Upon selecting a relevant fixture type and model, a three dimensional model of same is located on the surface of the three dimensional prosthesis model. The required anchor point is built in reverse onto the surface. For instance, in the case of a magnetised fixture, a blind hole for housing a magnet attachment is built by extruding a cylinder of the correct diameter and depth at the rear surface of the prosthesis, the extrusion consisting of modifying the arrangement of model vertices substantially at the location of the extruded cylinder.

[0077] Thereafter, the three dimensional model is subjected to a procedural modelling technique, for instance constructive solid geometry, wherein the prosthesis is constructed as a digital solid model of geometrical primitives by means of Boolean operations performed upon the three dimensional model with a Computer – Assisted Design ('CAD') application processed by the terminal 105 associated with the prosthesis manufacturing machine 104. The CAD application is for instance FreeForm® distributed by SensAble Technologies, Inc. of Wilmington, Massachussets, USA.

[0078] Whilst processing of a three dimensional model with a procedural modelling technique will be known to those skilled in the relevant art, an important aspect of the system and method according to the present invention is the inclusion of colour data in the digital solid model, for producing a coloured prosthesis with the prosthesis manufacturing machine 104, wherein the colour corresponds to a skin tone matching that of the prosthesis recipient. Both the image processing apparatus 102 and the prosthesis manufacturing machine 104 process and outputting colour information within their own, respective RGB colour space. It is therefore not possible to reproduce skin tone accurately without colour correction. The colour data must therefore be manipulated prior to producing the prosthesis with the prosthesis manufacturing machine 104, according to the method described hereafter.

[0079] For accurately reproducing captured skin tone, respective colour profiles have been developed for the imaging and prosthesis manufacturing apparatuses 102, 104 in order to transform colour data between apparatus - dependent RGB colour space (for example camera RGB, printer RGB and display RGB) and device - independent colour space (for instance CIE XYZ or CIE LAB tristimulus values of a corresponding uniform colour space). For each colour image data captured by a camera 401, a colour transformation process is performed by transforming camera RGB to CIE XYZ tristimulus values, and a new reproduction image is generated by transforming CIE XYZ tristimulus values back to either display RGB or printer RGB for, respectively, a target display 40X or prosthesis manufacturing machine 104.

[0080] With reference now to Figure 6, at step 601 the three dimensional photogrammetry system 102 is used to capture both facial geometry (including the area of trauma) and skin texture as hitherto described. The colour skin textures are recorded in two or three two dimensional images and are referred to as the original image from here on in. Each pixel of the original facial image is recorded in terms of camera RGB and is used for colour processing.

[0081] At step 602, camera RGB in each pixel of the original skin image is transformed to CIE XYZ or CIE LAB tristimulus values by a forward camera colour characterisation model (or Camera Colour Profile for a specific three dimensional photogrammetry system 102).

[0082] To develop the forward camera colour characterisation model, a wide range of training colours are used. Both CIE XYZ tristimulus values and camera RGB are measured for these training colours. Training colour charts consisting of a large amount of training colours are captured by the imaging apparatus 102, then the camera RGB is identified for each training colour sample. The same samples in the training chart are also measured by a spectrophotometer to obtain the corresponding CIE XYZ tri-stimulus values. By using camera RGB and CIE XYZ tristimulus values for these training colours, a

mathematical model, entitled a "Forward Camera Colour Characterisation Model" (FC3M), can be developed to transform camera RGB to CIE XYZ tri-stimulus values for skin colours.

[0083] The relationship between camera RGB and CIE XYZ is normally non-linear. The general method for predicting this relationship is by using a polynomial regression. However, different orders of the polynomial model will affect the performance significantly. Moreover, the respective performance of different cameras 401 can also differ significantly. For instance, a second order polynomial model may achieve the best performance for one type of camera 401, whereas a third order polynomial may be required to achieve the best performance for another type of camera 401. The selection of training samples will also affect the overall model performance significantly. Therefore, specific models should preferably be developed for specific imaging apparatuses 102.

[0084] At step 603, CIE XYZ or CIE LAB tristimulus values in each pixel of the original skin image is transformed back to printer RGB values, using a reverse printer colour characterisation model (or Printer Colour Profile for a specific prosthesis manufacturing machine 104), to generate a new reproduction image for the prosthesis manufacturing machine 104 to produce the prosthesis with the matching skintone therewith.

[0085] To develop the reverse printer colour characterisation model, a wide range of training colours are output with the prosthesis manufacturing machine 104. Both input printer RGB and CIE XYZ tri-stimulus values (for output of manufactured colour samples) are obtained for each of the training samples. Sets of training colour charts consisting a large amount of training colours are used. Their respective RGB data are sent to the prosthesis manufacturing machine 104 and corresponding CIE XYZ are measured with a spectrophotometer, for each sample manufactured by the target prosthesis manufacturing machine 104. By using CIE XYZ tristimulus values and printer RGB data for these training colours, a second mathematical model, named a

"Reverse Printer Colour Characterisation Model" (RPC2M), is developed to convert CIE XYZ tri-stimulus values to Printer RGB for skin colours or tone. Three dimensional interpolation and polynomial regression are used to develop printer characterisation. So long as the skin tone represents only a small portion of the whole colour gamut of the prosthesis manufacturing machine 104, a polynomial regression is used.

[0086] At step 604, the printer RGB values are used to generate a texture file for the digital solid model, onto which it is mapped for replacing the original skin colour texture generated from the camera RGB.

[0087] At step 605, the textured digital solid model is further processed for adding in fine details such as skin pores, veins, wrinkles, individual melanin-based markings like freckles or moles, and the like. The step 605 may be performed with a specialist image processing application, for instance 3-Matic® distributed by Materialise NV of Leuven, Belgium. The digital coloured model of the prosthesis is now ready to be produced by the prosthesis manufacturing machine 104 in a hard material.

[0088] Further to constructing the detailed and textured digital solid model of the prosthesis, a next step 303 in the production of the prosthesis is forming an edge to the prosthesis structure, apt to match tissue surrounding the application site of the prosthesis on the patient. The edge of a traditional prosthesis is formed during the moulding process from mould flash. This operation creates a very fine and transparent 'feathered' edge, which is suitable for bonding the prosthesis to the surrounding tissue seamlessly. In order to replicate this feature in a rapid – manufactured prosthesis, a base is produced with the prosthesis manufacturing apparatus 104, hereafter referred to as an infiltration platform, which will be used during the infiltration step of the overall method as described hereafter.

[0089] Reference is now made to Figure 7, which details method steps for producing the infiltration platform with a specialist rapid prototyping application,

for instance Magics™ distributed by Materialise NV of Leuven, Belgium. At step 701 the captured geometrical data for the prosthesis is selected and a border having a width of approximately 40mm is defined about the patient site receiving the prosthesis. At step 702, the border is isolated by removing the remaining data, leaving only the border area defined over a substantially planar surface. At step 703, the underside of the surface corresponding to the area is offset by approximately 0.2mm, and the offset surface is configured with a thickness of approximately 2mm. At step 704, the underside of the substantially planar surface is extruded in order to define a level underside for the infiltration platform. The digital model of the infiltration platform is now ready to be produced by the prosthesis manufacturing machine 104 in a hard material.

[0090] Further to constructing both the digital solid model of the prosthesis and the infiltration base, a next step 304 in the production of the prosthesis is manufacturing the actual prosthesis structure and the actual infiltration structure with the prosthesis manufacturing machine 104.

[0091] The infiltration platform may be constructed using any number of known layered fabrication methods, the essential requirements being that the infiltration platform must be hard and geometrically accurate. As previously described, in this embodiment, a three – dimensional printing technique is used and the prosthesis manufacturing machine 104 is a three dimensional printer, for example manufactured and distributed by the Z Corporation® of Burlington, Massachusetts, USA.

[0092] The infiltration platform is built by the printer in a three dimensional layered production process using silica, for example a zp150 silica powder and zp60 binder solution bonding the layers. The output infiltration platform structure is immersed in a bath of low viscosity cyanoacrylate and left to dry in order to produce the final part. Post processing of the infiltration platform may follow, for instance for finishing the semi-rough surface by sand blasting or hand sanding. It will be readily understood by skilled persons that alternative production methods,

such as Fused Deposition Modelling® (FDM®) also known as Fused Filament Fabrication (FFF), and Stereolithography (SLA) are eminently suitable for this aspect of the method.

[0093] The prosthesis is also built by the printer in a three dimensional, coloured layered production process using starch, for example a zp15e starch powder and zb58 binder solution bonding the layers.

[0094] Further to constructing the layered prosthesis structure, a next step 305 in the production of the prosthesis is infiltrating the prosthesis structure with a substantially resilient material, in the example an elastomer in the form of liquid silicone polymer.

[0095] A variety of elastomers are considered suitable for use with the method and system of the present invention, including silicone polymers, chlorinated polyethylene elastomers, polycarbonaturethane (PCU) and polyether polyurethanes. In the specific instance of silicone elastomers, a variety of addition-cured and condensation-cured products are considered suitable for use with the method and system of the present invention, known examples of which include Ideal (Orthomax, Bradford, UK), Silskin 25 and Silskin 2000 (De Puy Healthcare, Leeds, U.K.), Elastosil M3500 (Wacker-Chemie GmbH, Munchen, Germany), Silastic MDX4-4210 (Dow Corning Corporation, Midland, MI, USA) and A-2000 (Factor II Inc., Lakeside, AZ, USA). The above is provided by way of non-limitative example only, as very many variants of the above and alternative materials used for the fabrication of prostheses exist, which are equally capable of use with the method and system of the present invention, without hindrance or undue experimentation, as will be readily understood by persons skilled in the art.

[0096] The output prosthesis structure is thus removed from the prosthesis manufacturing machine 104 and immersed in a bath of liquid silicone polymer. The bath is moved to, and held within, the pressure chamber 106, which in the example is a dental pressure bath. The dental pressure bath 106 is pressurised

at a predetermined pressure for a predetermined period of time.

[0097] At expiry of the predetermined period of time, the prosthesis structure infiltrated with silicone polymer is removed from the dental pressure bath 106 and placed onto its infiltration platform, wherein the edge of the prosthesis structure corresponds substantially to the edge defined in the infiltration platform as described in relation to Figure Y. Silicone polymer is poured onto the combined structures for final infiltration and the run-off silicone polymer is allowed to dry over both the prosthesis and the infiltration base, which controls the form of the silicone polymer feathered edge to match the surrounding tissue contours of the prosthesis recipient.

[0098] Three dimensional structures produced by the three dimensional colour printer 104 are suitable for prosthesis, provided that a sufficient degree of infiltration of the resilient surface layer is achieved for producing a robust part that can be manipulated. In the case of flexible facial prostheses, it is important that the printed structure is sufficiently infiltrated with the elastomer, because the elastomer acts as the main binder for the printed powders, whereby portions of the structure which are not infiltrated would be exceedingly fragile and likely disintegrate.

[0099] The inventors have therefore carried out a series of tests to confirm appropriate levels of infiltration and parameters for same, to ensure that prosthesis structures are sufficiently infiltrated with silicone elastomer for the resulting prostheses to be useable.

[00100] A set of cubes, each having an edge measuring 20 mm, were printed both in silica and in starch with the Z-Corporation printer 104. The cubes were infiltrated with a silicone polymer, Silskin 25, under both conditions of standard air pressure and 3 bar pressure in the dental pressure bath 106. The length of time for the infiltration ranged from 5 to 25 minutes. Each sample was

sectioned into two equal parts and a dye was used to identify those areas that had not been infiltrated with the silicone polymer. A total of 44 measurements were taken for the penetration depth for each specimen.

[00101] The results indicate that both pressure and duration influence the degree of infiltration of the polymer in the sample cubes. Under air pressure, the depth of infiltration is approximately 1 mm and the duration has little influence. Under a pressure of 3 bars, a greater depth of infiltration was achieved, after a duration of 20 to 25 minutes, of approximately 7 mm for the the starch cubes and of approximately 5 mm for the silica cubes.

[00102] The results clearly indicate that pressurisation has a positive influence on the depth of penetration of the silicone polymer, and that the depth of penetration in starch is higher than in silica. Prostheses produced with the printer 104 can be infiltrated from all sides, and a maximum depth of infiltration is believed to be approximately 14 mm for starch prosthesis structures, and 8 mm for silica prosthesis structures. Thus, so long as the thickness of a starch prosthesis structure is approximately 14 mm or less, or so long as the thickness of a silica prosthesis structure is approximately 8 mm or less, full infiltration of the structure with the silicone polymer can be achieved.

[00103] Prostheses produced with this embodiment differ from those produced with prior art methods by an anaplastologist. Prostheses produced manually by the anaplastologist consist essentially of silicone polymer, and it is known that silicone is not entirely biocompatible and, in some patients, can cause significant tissue irritation and inflammation. As silicone polymer is already used in the manufacture of prostheses, any new material, or combination of materials, should be at least as biocompatible. Prostheses produced with this embodiment contain a combination of silicone polymer and starch or silica powder. This combination is required for a method of manufacture which outputs customised prostheses quickly and efficiently, and which would otherwise not be possible using silicone polymer alone. The silicone polymer acts as the binder for the

starch or silica powders and, although the respective materials used may be considered relatively inert and safe, there is a question as to their potential biocompatibility when combined.

[00104] The inventors have therefore carried out a series of tests to confirm the biocompatibility of infiltrated prosthesis structures, to ensure their application to recipients is unlikely to result in any cutaneous reaction.

[00105] Biocompatibility was assessed using an in-vitro human skin tissue model, EpiDerm, obtained from the MatTek Corporation of Ashland, Massachusetts, USA. EpiDerm cell lines are manufactured as ready-to-use, normal (non-transformed or diseased), human cell-derived, fully differentiated, three dimensional, organotypic in-vitro tissue equivalents, for use in biocompatibility and irritability testing. The EpiDerm model consists of cultured normal, human-derived epidermal keratinocytes, which form a three dimensional, multilayered, highly differentiated model of the human epidermis, thus providing a useful in-vitro means to assess the potential toxicity of any compound or material. Protocols for using the EpiDerm model in tests for assessing cytotoxicity and irritancy, including MTT assay and LDH assay tests used by the inventors, are clear and well documented.

[00106] The MTT assay is a test for determining the live cell number and activity following exposure to a stimuli. The MTT assay is a colorimetric assay that relies on the enzymatic reduction of a yellow tetrazolium salt, 3-(4, 5-dimethylthiazol-2-yl)-2, 5-diphenyltetrazolium bromide (MTT), to a purple Formosan derivative in metabolically active cells. The Formosan can then be analysed using a colorimetric signal at 570 nm. The outcome is a linear optical density value that is directly proportional to the cell number and activity.

[00107] The lactate dehydrogenase (LDH) assay is a test for assessing cytotoxicity resulting from exposure to chemical compounds or other toxic products. LDH is a soluble cytosolic enzyme that is released following loss of

cellular membrane integrity from either apoptosis and/or necrosis. The assay measures LDH concentrations using a two-step coupled reaction. In the first step, the LDH released catalyzes the reduction of NAD+ to NADH and H+ by oxidation of lactate to pyruvate. In the second step, the newly formed NADH and H+ are used to catalyze the reduction of a tetrazolium salt (INT) to highly-coloured Formosan derivative which absorbs strongly at 490-520 nm. Again this is an optical density value that is linear and directly proportional to the level of cell death/inactivity.

[00108] Both of these assays were undertaken to assess the biocompatibility of the combination of silicone polymer and starch of prostheses. In addition to the assays performed, histological examination was also undertaken to evaluate the effect of direct contact between the prosthesis material and the EpiDerm model. This further examination allows visualization of any potential disruption/destruction of the cells within the in-vitro skin model, by way of subjective assessment only as no quantitative calculations can be undertaken. All tests were undertaken by an operator who was blind to the samples provided.

[00109] The results of the MTT assay indicate that there was no demonstrable difference in the optical density observed either between the samples tested, consisting of a silicone polymer sample and a silicone polymer /starch sample, or between the samples and the control tissue.

[00110] The results of the LHD assay indicate that there was a difference in the optical density observed between the samples tested at 24 hours, with the silicone polymer sample producing a higher optical density than both the control tissue and the silicone polymer /starch sample, but no difference between the control tissue and the silicone polymer /starch sample by that time. No difference was observed between either of the samples or the control tissue following exposure at 12 hours.

[00111] Following histological examination of the specimens, subjective assessment of the tissue samples indicates that, at 24 hours, with the silicone polymer sample there was a significant disruption of the cellular architecture with vacuolation throughout the stratum spinosum and stratum basal leading to loss of tissue characteristics/atypia and, with the silicone polymer /starch sample, there was no disruption of tissue architecture throughout the full thickness of the tissue, and no evidence of vacuolation or atypia.

[00112] The embodiments in the invention described with reference to the drawings comprise a computer apparatus and/or processes performed in a computer apparatus. However, the invention also extends to computer programs, particularly computer programs stored on or in a carrier adapted to bring the invention into practice. The program may be in the form of source code, object code, or a code intermediate source and object code, such as in partially compiled form or in any other form suitable for use in the implementation of the method according to the invention. The carrier may comprise a storage medium such as ROM, e.g. CD ROM, or magnetic recording medium, e.g. a floppy disk or hard disk or via one of the secure "file transfer protocol (FTP) sites available. The carrier may be an electrical or optical signal which may be transmitted via an electrical or an optical cable or by radio or other means.

[00113] In the specification the terms "comprise, comprises, comprised and comprising" or any variation thereof and the terms include, includes, included and including" or any variation thereof are considered to be totally interchangeable and they should all be afforded the widest possible interpretation and vice versa.

[00114] The invention is not limited to the embodiments hereinbefore described but may be varied in both construction and detail.

Claims

1. A method of manufacturing a prosthesis, comprising the steps of:

acquiring geometrical and colour data with an image processing apparatus;

processing the acquired data into a sequence of commands for a manufacturing apparatus;

producing a prosthesis structure with the manufacturing apparatus according to the sequence of commands; and

infiltrating a substantially resilient material in the prosthesis structure.

2. The method according to claim 1, wherein the image processing apparatus comprises at least two digital cameras and the step of acquiring geometrical and colour data comprises the further steps of capturing a multi-dimensional image of a patient to which the prosthesis is destined.

3. The method according to claim 2, wherein the image processing apparatus comprises three cameras and the step of acquiring geometrical and colour data comprises the further steps of capturing a three dimensional image of the patient to which the prosthesis is destined.

4. The method according to claim 1, wherein the image processing apparatus comprises a medical imaging apparatus selected from the group comprising X-ray Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Magnetic Resonance Imaging (NMRI) or Magnetic Resonance Tomography (MRT).

5. The method according to any of claims 1 to 4, wherein the step of processing the acquired data comprises the further step of processing the acquired geometrical data into a three dimensional model.

6. The method according to any of claims 1 to 5, wherein the step of processing the acquired data comprises the further step of converting the acquired colour data for matching the prosthesis colour to the patient skintone.

7. The method according to claim 6, wherein the acquired colour data is RGB or RGBA and the step of colour data conversion comprises the further step of subjecting the RGB or RGBA data to at least one multiple – order polynomial regression.

8. The method according to claim 6, wherein the colour data is RGB or RGBA and the step of colour data conversion comprises the further step of subjecting the RGB or RGBA data to a multiple – order polynomial regression specific to the image processing apparatus, for obtaining CIE XYZ colourspace data.

9. The method according to claim 8, comprising the further step of subjecting the CIE XYZ colourspace data to a polynomial regression for obtaining RGB data compatible with the manufacturing apparatus.

10. The method according to any of claims 1 to 9, wherein the step of processing the acquired data comprises the further step of generating at least one texture from colour data.

11. The method according to claim 1, wherein the image processing apparatus comprises a data processing terminal and the step of acquiring geometrical and colour data comprises the further step of selecting the geometrical and colour data from a database storing data representative of prostheses and skin tones.

12. The method according to any of claims 1 to 11, wherein the manufacturing apparatus comprises a data processing terminal interfaced with a rapid prototyping device, and the step of producing the prosthesis structure

comprises the further step of producing the prosthesis as a layered structure with the rapid prototyping device.

13. The method according to claim 12, wherein the rapid prototyping device is a three dimensional printer, the step of processing the acquired data into a sequence of commands comprises the further step of defining printing commands, and the step of producing the prosthesis structure comprises the further step of printing the structure in layers.

14. The method according to claim 12 or 13, wherein the layered structure is made from a starch or amylum powder.

15. The method according to claim 14, wherein the powder comprises 20 to 25% amylose and 75 to 80% amylopectin.

16. The method according to claim 12 or 13, wherein the layered structure is made from a silica powder.

17. The method according to any of claims 1 to 16, wherein the step of infiltrating a substantially resilient material in the prosthesis structure comprises the further steps of placing the prosthesis structure and the substantially resilient material in a pressure chamber, and pressurising the chamber.

18. The method according to claim 17, comprising the further steps of producing a base for forming an edge to the prosthesis structure, apt to match tissue surrounding an application site of the prosthesis on the patient; and allowing the resilient material to run off the prosthesis structure onto the base.

19. The method according to claim 17 or 18, wherein the pressurising is at least 1 bar for a duration of at least 5 minutes.

20. The method according to any of claims 1 to 19, wherein the substantially resilient material is an elastomer, selected from the group

comprising silicone polymers, chlorinated polyethylene elastomers, polycarbonaturethane (PCU) and polyether polyurethanes.

21. The method according to claim 20, wherein the elastomer is a silicone polymer, selected from the group comprising Silskin™ 25, Ideal™, Silskin™ 2000, Elastosil™ M3500, Silastic™ MDX4-4210 and A-2000™.

22. A system for manufacturing a prosthesis, comprising:

an image processing apparatus for acquiring geometrical and colour data;

means for processing the acquired data into a sequence of commands;

a manufacturing apparatus for producing a prosthesis structure according to the sequence of commands; and

means for infiltrating a substantially resilient material in the prosthesis structure.

23. The system according to claim 22, wherein the image processing apparatus comprises at least two digital cameras for capturing a multi-dimensional image of a patient to which the prosthesis is destined.

24. The system according to claim 23, wherein the image processing apparatus comprises three cameras for capturing a three dimensional image of the patient to which the prosthesis is destined.

25. The system according to claim 22, wherein the image processing apparatus comprises a medical imaging apparatus selected from the group comprising X-ray Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Magnetic Resonance Imaging (NMRI) or Magnetic Resonance Tomography (MRT).

26. The system according to any of claims 22 to 25, wherein the processing means is further adapted to transform the acquired geometrical data into a three dimensional model.

27. The system according to any of claims 22 to 25, wherein the processing means is further adapted to convert the acquired colour data for matching the prosthesis colour to the patient skintone.

28. The system according to claim 27, wherein the acquired colour data is RGB or RGBA and the processing means is further adapted to subject the RGB or RGBA data to at least one multiple – order polynomial regression.

29. The system according to claim 27, wherein the acquired colour data is RGB or RGBA and the processing means is further adapted to subject the RGB or RGBA data to a multiple – order polynomial regression specific to the image processing apparatus for obtaining CIE XYZ colourspace data.

30. The system according to claim 27, wherein the processing means is further adapted to subject the CIE XYZ colourspace data to a polynomial regression for obtaining RGB data compatible with the manufacturing apparatus.

31. The system according to any of claims 22 to 30, wherein the processing means is further adapted to generate at least one texture from colour data.

32. The system according to claim 22, wherein the image processing apparatus comprises a data processing terminal storing data representative of prostheses and skin tones, for selecting the geometrical and colour data therefrom.

33. The system according to any of claims 22 to 32, wherein the processing means is a data processing terminal and the manufacturing apparatus is a rapid prototyping device adapted to produce the prosthesis as a layered structure.

34. The system according to claim 33, wherein the rapid prototyping device is a three dimensional printer, the sequence of commands defines printing commands, and the three dimensional printer produces the prosthesis as a structure of printed layers.

35. The system according to claim 33 or 34, wherein the layered structure is made from a starch or amylum powder.

36. The system according to claim 35, wherein the powder comprises 20 to 25% amylose and 75 to 80% amylopectin.

37. The system according to claim 33 or 34, wherein the layered structure is made from a silica powder.

38. The system according to any of claims 22 to 37, wherein the infiltrating means is a pressure chamber.

39. The system according to claim 38, wherein the pressure chamber is adapted to infiltrate the substantially resilient material in the prosthesis structure under a pressure of at least 1 bar, for a duration of at least 5 minutes.

40. The system according to claim 39, further comprising a base for forming an edge to the prosthesis structure, apt to match tissue surrounding an application site of the prosthesis on the patient, onto which the resilient material is allowed to run off the prosthesis structure.

41. A system according to any of claims 22 to 40, wherein the substantially resilient material is an elastomer, selected from the group comprising silicone polymers, chlorinated polyethylene elastomers, polycarbonaturethane (PCU) and polyether polyurethanes.

42. A system according to claim 41, wherein the elastomer is a silicone polymer, selected from the group comprising Silskin™ 25, Ideal™, Silskin™ 2000, Elastosil™ M3500, Silastic™ MDX4-4210 and A-2000™.the substantially resilient material is a silicone polymer.

43. A method of processing image colour data in a system for manufacturing a prosthesis, comprising the steps of :

acquiring colour data representative of a patient skintone from an image processing apparatus;

transforming the acquired colour data with a first polynomial regression into an alternative colour space; and

transforming the transformed colour data with a second polynomial regression to output colour data compatible with a manufacturing apparatus apt to produce a coloured prosthesis.

44. The method according to claim 43, wherein the acquired colour data is RGB or RGBA and the alternative colour space is CIE XYZ.

45. The method according to claim 43 or 44, wherein the first polynomial regression is a multiple – order polynomial regression specific to the image processing apparatus.

46. The method according to any of claims 43 to 45, wherein the second polynomial regression is a polynomial regression specific to the apparatus apt to produce the prosthesis.

47. The method according to any of claims 43 to 46, wherein the image processing apparatus comprises a plurality of digital cameras.

48. The method according to any of claims 43 to 46, wherein the image processing apparatus comprises a medical imaging apparatus selected from the group comprising X-ray Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Magnetic Resonance Imaging (NMRI) or Magnetic Resonance Tomography (MRT).

49. The method according to any of claims 43 to 48, wherein the apparatus apt to produce the prosthesis is a rapid prototyping device.

50. The method according to claim 49, wherein the rapid prototyping device is a three dimensional printer.

51. A method of combining a substantially resilient material with a prosthesis structure, comprising the steps of:

producing the prosthesis structure with a rapid prototyping device;

immersing the prosthesis structure in a volume of the substantially resilient material;

placing the prosthesis structure immersed in the substantially resilient material in a pressure chamber; and

subjecting the prosthesis structure immersed in the substantially resilient material to a predetermined pressure for a predetermined period of time.

52. The method of claim 51, wherein the rapid prototyping device is a three dimensional printer and the step of producing the prosthesis structure further comprises printing the prosthesis structure in layers.

53. The method of claim 51 or 52, wherein the prosthesis structure is made of starch powder or silica powder, the predetermined pressure is at least 1 bar and the predetermined period of time is at least 5 minutes.

54. The method of claim 53, wherein the prosthesis structure is made of starch powder with a wall thickness of substantially 14 millimetres or less, the predetermined pressure is at least 3 bars and the predetermined period of time is at least 25 minutes.

55. The method of claim 53, wherein the prosthesis structure is made of silica powder with a wall thickness of substantially 8 millimetres or less, the predetermined pressure is at least 3 bars and the predetermined period of time is at least 25 minutes.

56. The method of any of claims 51 to 55, wherein the substantially resilient material is an elastomer, selected from the group comprising silicone polymers, chlorinated polyethylene elastomers, polycarbonaturethane (PCU) and polyether polyurethanes.

57. The method according to claim 56, wherein the elastomer is a silicone polymer, selected from the group comprising Silskin™ 25, Ideal™, Silskin™ 2000, Elastosil™ M3500, Silastic™ MDX4-4210 and A-2000™.the substantially resilient material is a silicone polymer.

58. A computer program product storing a computer program which, when processed by a data processing terminal, configures the data processing terminal to perform the steps of

acquiring colour data representative of a patient skintone from an image processing apparatus;

transforming the acquired colour data with a first polynomial regression into an alternative colour space;

transforming the transformed colour data with a second polynomial regression into compatible colour data, wherein the compatible colour data is

compatible with a manufacturing apparatus apt to produce a coloured prosthesis; and

outputting the compatible colour data to the manufacturing apparatus for producing a coloured prosthesis matching the patient skintone.

59. A computer program product according to claim 58, wherein the image processing apparatus, the data processing terminal and the manufacturing apparatus are connected to one another over at least one network, and the steps of acquiring, transforming and outputting are performed at respective network locations.

60. A computer program product according to claim 58 or 59, wherein the image processing apparatus comprises at least two digital cameras and the manufacturing apparatus comprises a rapid prototyping device.

61. A computer program product according to any of claims 58 to 60, wherein the computer program product is selected from the group comprising an optical data storage medium, a magnetic data storage medium and a computer – readable file transmissible across the network.

62. A method substantially as hereinbefore described, with reference to and as shown in the accompanying drawings.

63. A system substantially as hereinbefore described, with reference to and as shown in the accompanying drawings.

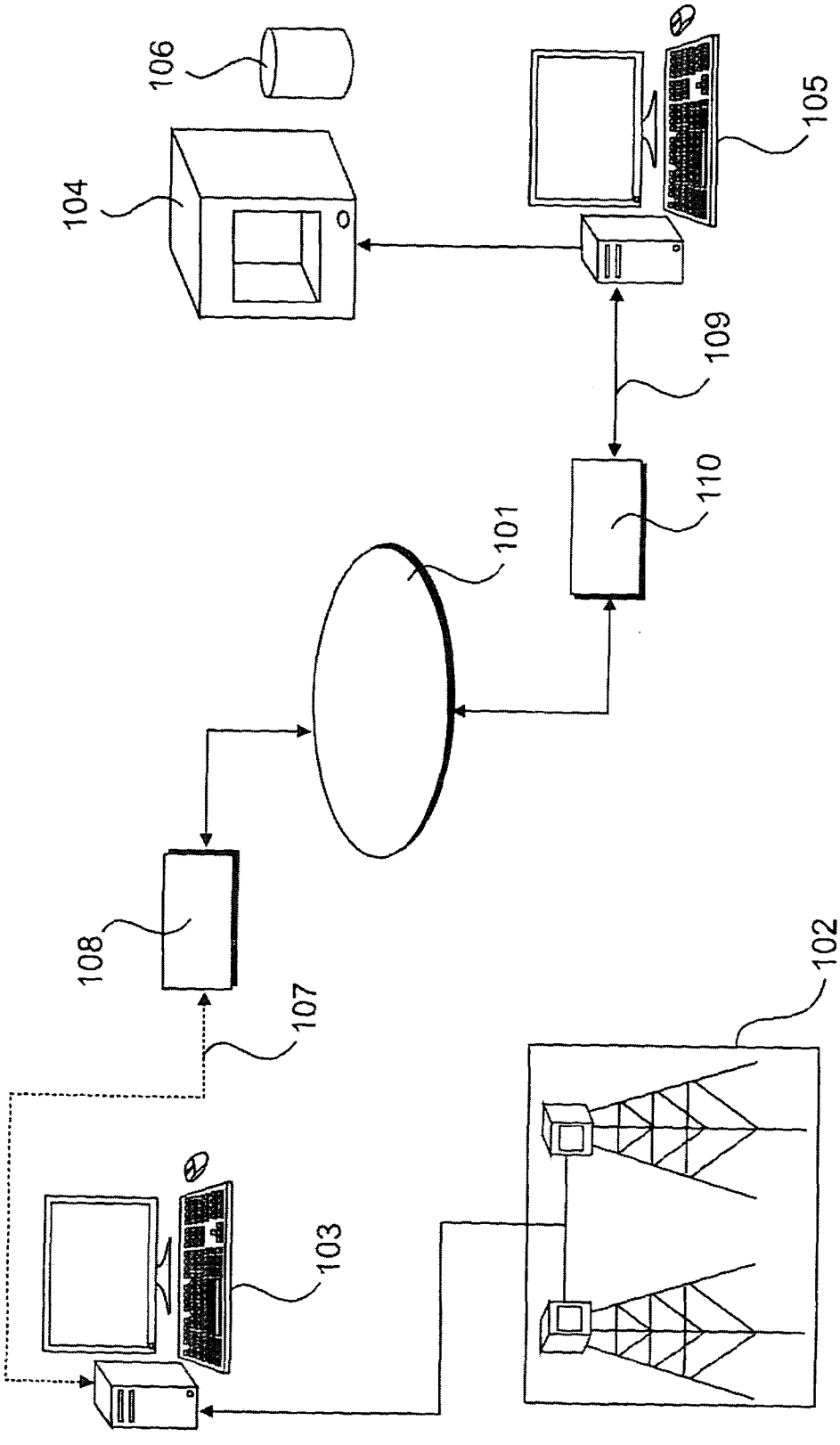


Figure 1

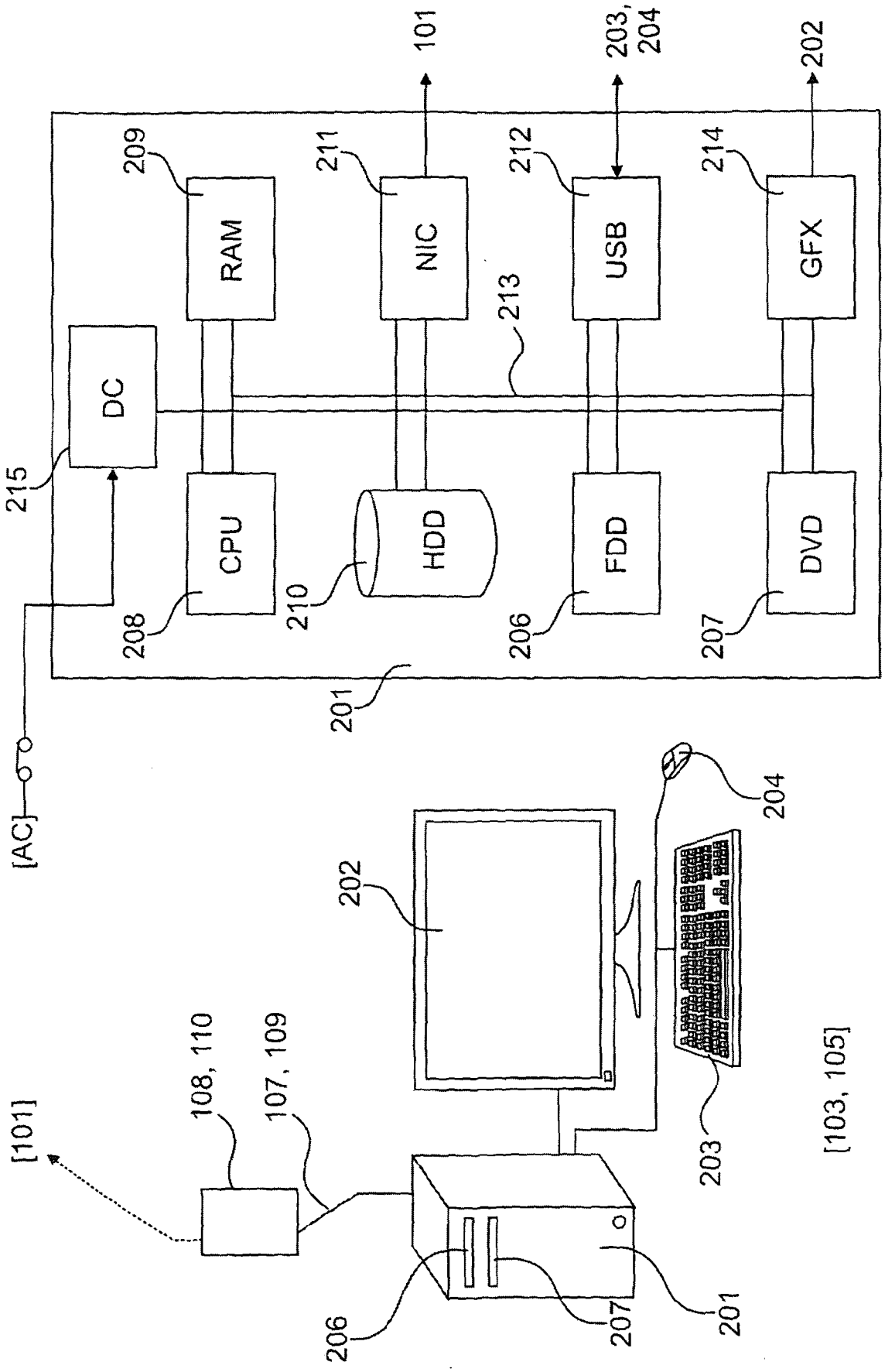

101
203, 204
202
209
211
212
214
RAM
NIC
USB
GFX
213
DC
215
CPU
HDD
FDD
DVD
208
210
206
207
201
[AC]
204
202
108, 110
107, 109
[101]
203
[103, 105]
206
207
201

Figure 2

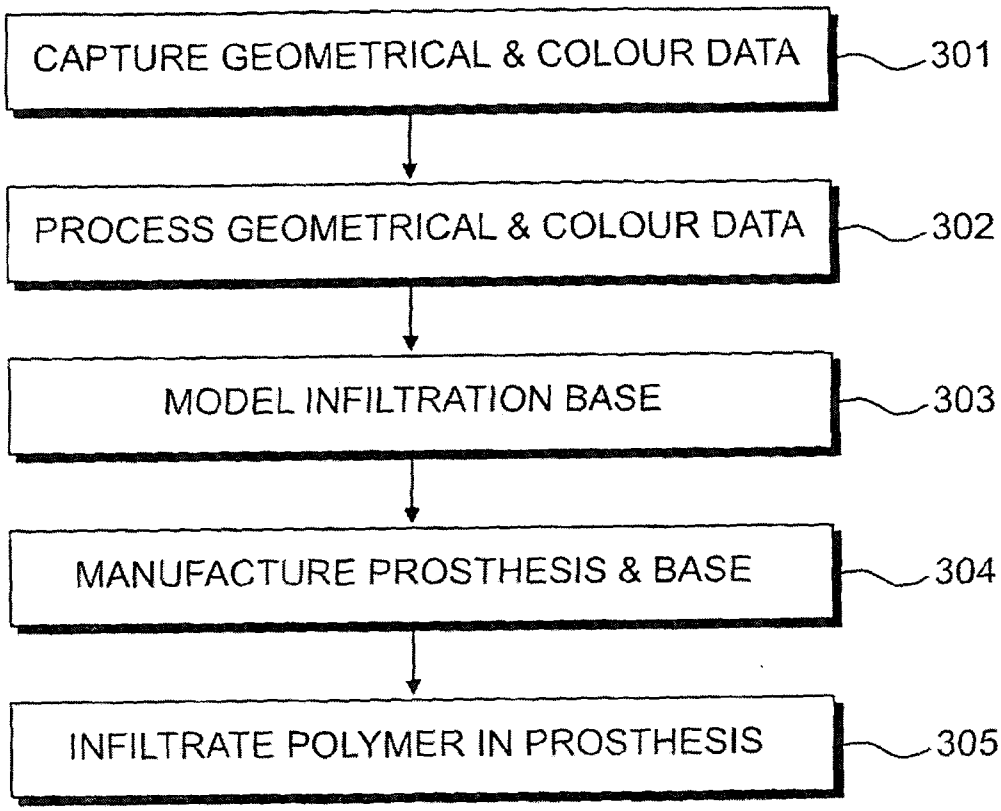

CAPTURE GEOMETRICAL & COLOUR DATA
301
PROCESS GEOMETRICAL & COLOUR DATA
302
MODEL INFILTRATION BASE
303
MANUFACTURE PROSTHESIS & BASE
304
INFILTRATE POLYMER IN PROSTHESIS
305

Figure 3

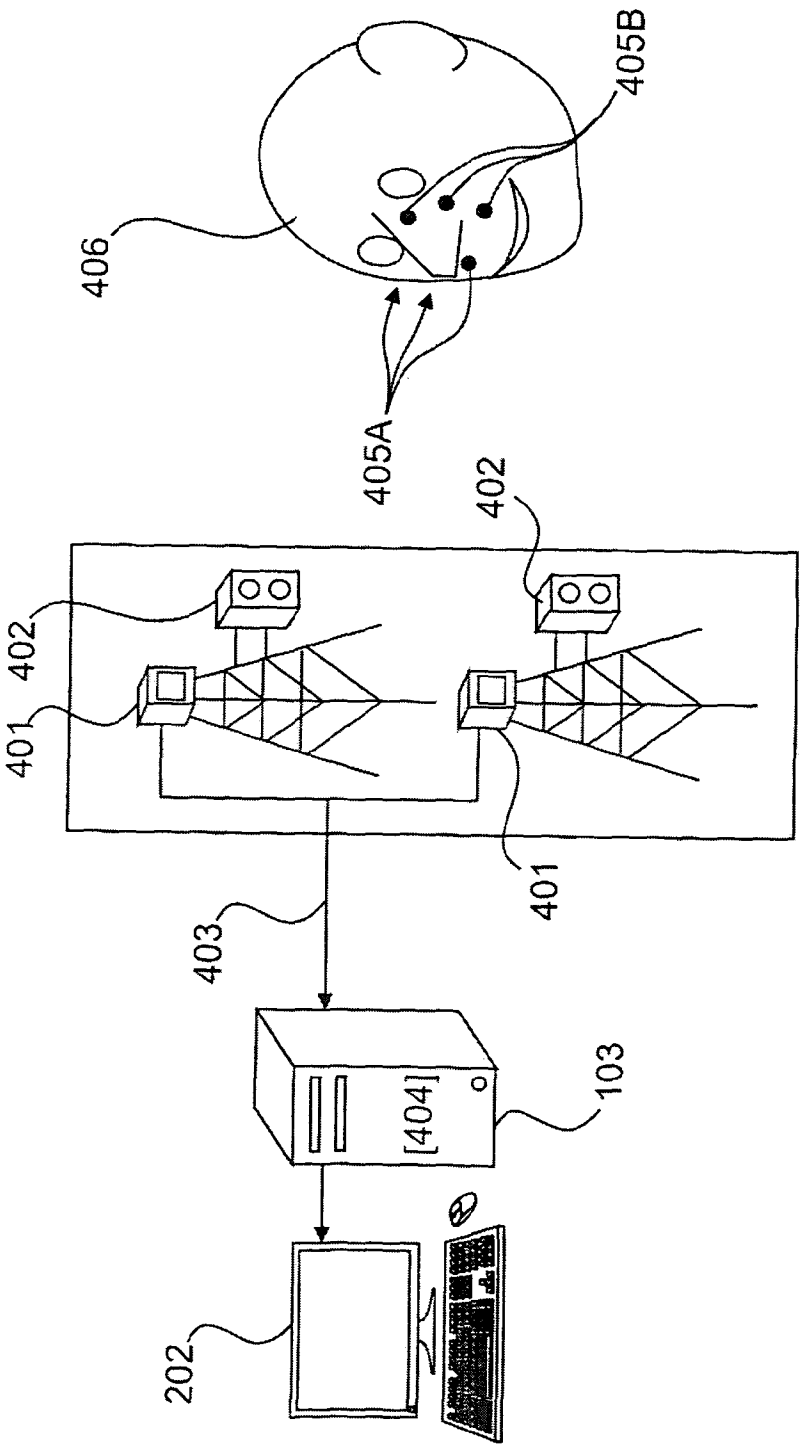


Figure 4

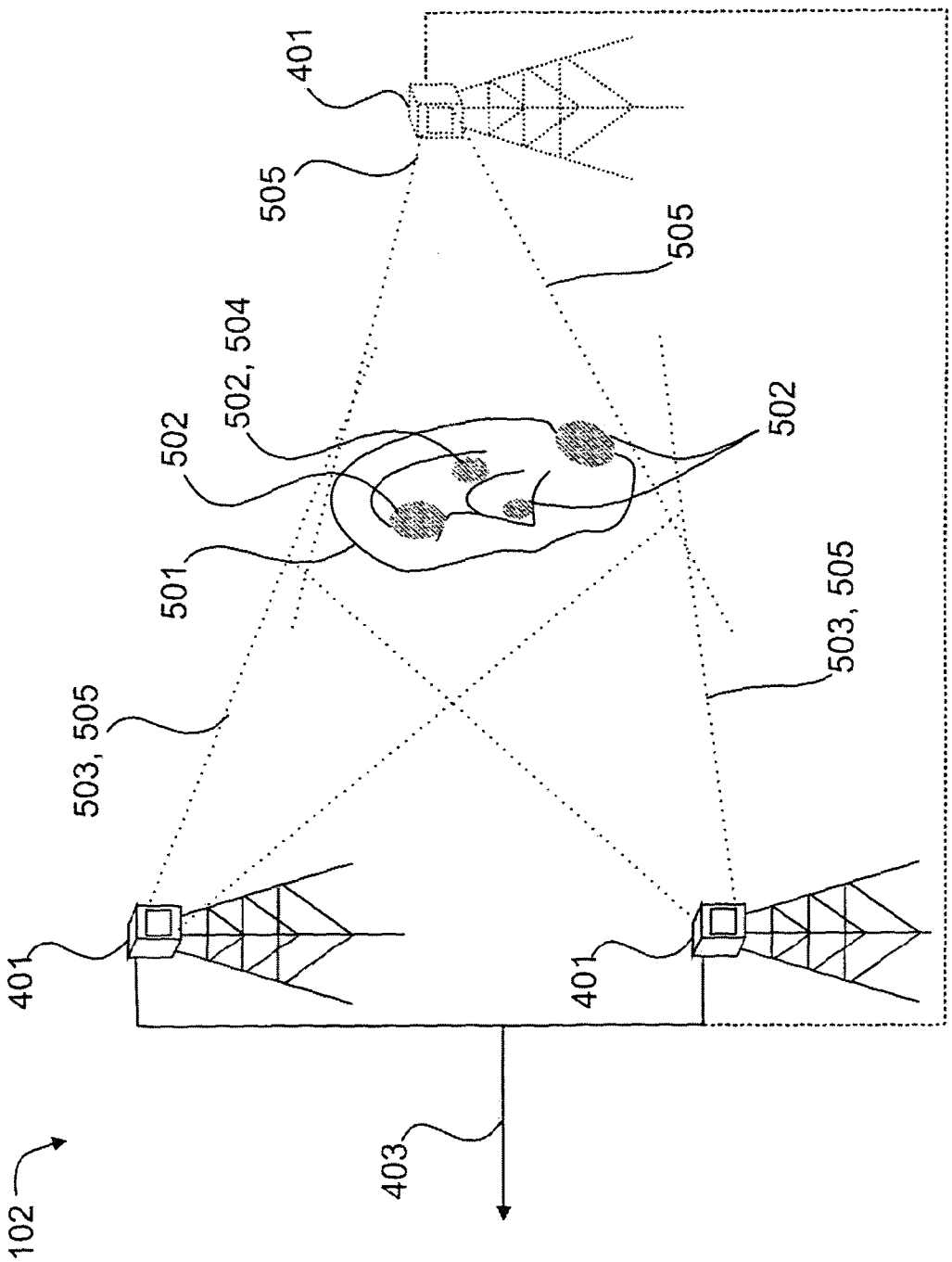


Figure 5

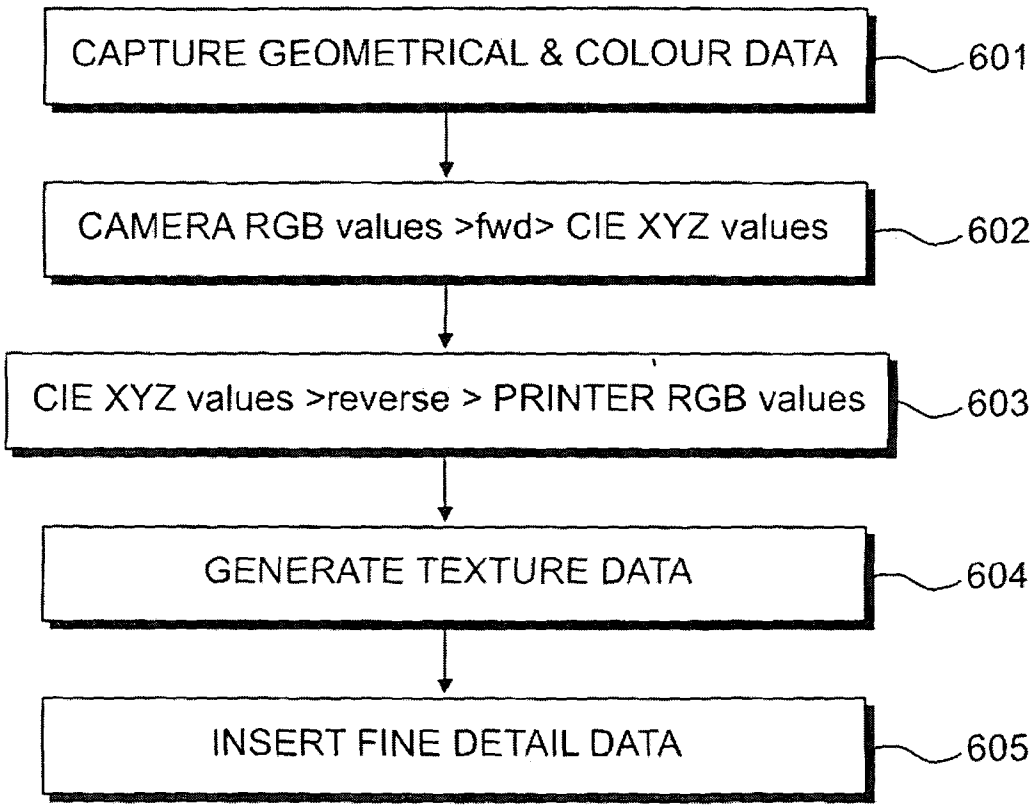

CAPTURE GEOMETRICAL & COLOUR DATA
601
CAMERA RGB values >fwd> CIE XYZ values
602
CIE XYZ values >reverse > PRINTER RGB values
603
GENERATE TEXTURE DATA
604
INSERT FINE DETAIL DATA
605

Figure 6

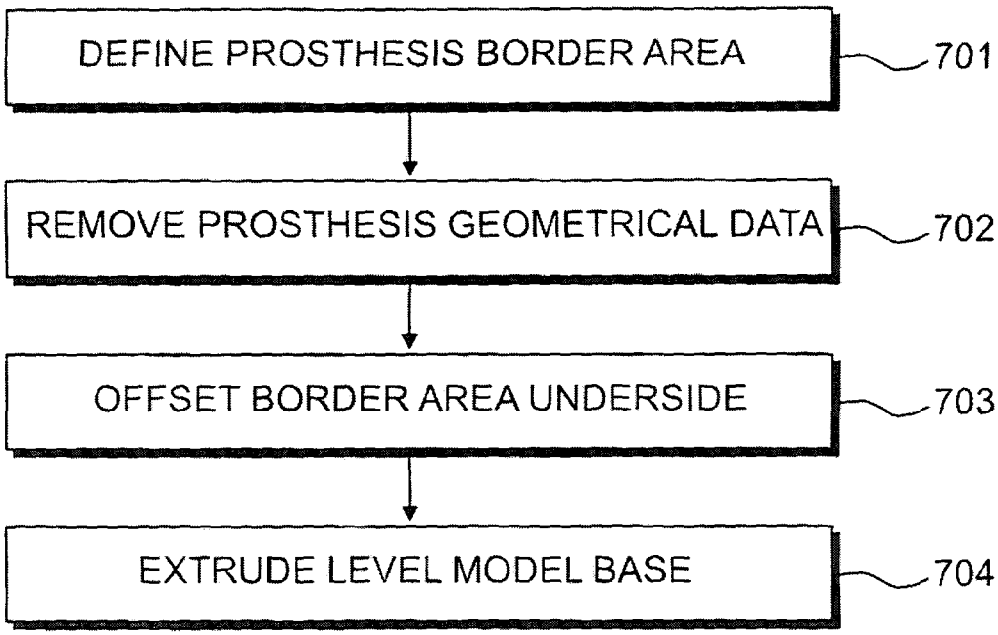

DEFINE PROSTHESIS BORDER AREA
701
REMOVE PROSTHESIS GEOMETRICAL DATA
702
OFFSET BORDER AREA UNDERSIDE
703
EXTRUDE LEVEL MODEL BASE
704

Figure 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/000205

A. CLASSIFICATION OF SUBJECT MATTER
INV. G05B19/4099
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)
G05B

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/007249 A1 (CRANLEY PAUL E [US] ET AL) 17 January 2002 (2002-01-17) paragraph [0007] - paragraph [0089]	1-50, 58-63
A	FR 2 768 967 A1 (HERMET LILIANE [FR]) 2 April 1999 (1999-04-02) page 2, line 1 - page 12, line 19; figures 1-7	1-63

-/--

[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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 May 2012	08/06/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Hauser, Leon

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/000205

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	XINGZHENG WANG ET AL: "An Optimized Tongue Image Color Correction Scheme", IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE, IEEE SERVICE CENTER, LOS ALAMITOS, CA, US, vol. 14, no. 6, 1 November 2010 (2010-11-01), pages 1355-1364, XP011373636, ISSN: 1089-7771, DOI: 10.1109/TITB.2010.2076378 page 1355 - page 1364 -----	5-11, 27-32, 43-46, 58-63

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2012/000205

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002007249 A1	17-01-2002	US 2001037070 A1	01-11-2001
		US 2002007249 A1	17-01-2002
FR 2768967 A1	02-04-1999	AT 211972 T	15-02-2002
		AU 9354698 A	23-04-1999
		CA 2304591 A1	08-04-1999
		DE 69803206 D1	21-02-2002
		DE 69803206 T2	29-08-2002
		EP 1019255 A1	19-07-2000
		ES 2172202 T3	16-09-2002
		FR 2768967 A1	02-04-1999
		JP 2001518411 A	16-10-2001
		US 6498961 B1	24-12-2002
		WO 9916629 A1	08-04-1999