Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/SB/424 (12-11)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Ronald E. Massie	Nonprovisional Application Number (if known):	
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, examination fee, and any required excess claims and application size fees are filed with the request or have been already been paid.

2. The application contains or is amended to contain no more than four independent claims and no more than thirty total claims, and no multiple dependent claims.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed oath or declaration under 37 CFR 1.63 is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Mark Brown/	Date 09/14/2012
Name (Print/Typed) Mark Brown	Practitioner Registration Number 30,361

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.*

☑ *Total of 1 forms are submitted.

Dentsply Sirona Inc. – Exhibit 1004

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Filer:	Mark E. Brown/Autumn Winegar
Attorney Docket Number:	2932.2

Filed as Small Entity

Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	95	95
Utility Search Fee	2111	1	310	310
Utility Examination Fee	2311	1	125	125
Request for Prioritized Examination	2817	1	2400	2400
Pages:				
Claims:				
Claims in excess of 20	2202	4	30	120
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Publ. Fee- early, voluntary, or normal	1504	1	300	300
Processing Fee, except for Provis. apps	1808	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**3480**

Electronic Acknowledgement Receipt

EFS ID:	13755535
Application Number:	13619356
International Application Number:	
Confirmation Number:	4681
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Customer Number:	63151
Filer:	Mark E. Brown/Autumn Winegar
Filer Authorized By:	Mark E. Brown
Attorney Docket Number:	2932.2
Receipt Date:	14-SEP-2012
Filing Date:	
Time Stamp:	18:21:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$3480
RAM confirmation Number	8533
Deposit Account	503424
Authorized User	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	2932-2Declaration.pdf	125731 ebfa4ba3ef3dc0e94169b9dd8f558972b41ef180	no	3
Warnings:					
Information:					
2	Power of Attorney	2932-2POA.pdf	75540 0271f9b309341b6fc9fac6b18b22918b45e5f6c3	no	1
Warnings:					
Information:					
3		2932-2ContApplFinal091212.pdf	116694 656b1ef3673034ffff25c3d2399915ce912f49ea	yes	15

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	9
Claims	10	14
Abstract	15	15

Warnings:					
Information:					
4	Drawings-only black and white line drawings	Figs1-2.pdf	23854 cc1245e2c1d1675d21a9462fbb9c34e0e0c94301	no	2
Warnings:					
Information:					
5	TrackOne Request	sb0424.pdf	140630 d2043da7e86c30f7f8741cf732f06a0e98f5b25d	no	2
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	42057 2f8d0727780d99bc798944d4ba0c7536e5640105	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	524506

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New International Application Filed with the USPTO as a Receiving Office

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PTO/SB/81 (01-09)
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Application Number	
Filing Date	
First Named Inventor	Ronald E. Massie
Title	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
Art Unit	
Examiner Name	
Attorney Docket Number	2932.2

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☑ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: **63151**

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

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OR

☑ The address associated with Customer Number: **63151**

OR

☐ Firm or Individual Name	Law Office of Mark Brown, LLC				
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City	Kansas City	State	Missouri	Zip	64112
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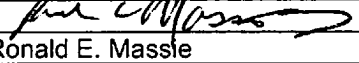
I am the:

☑ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____.

SIGNATURE of Applicant or Assignee of Record

Signature		Date	9-14-12
Name	Ronald E. Massie	Telephone	816-268-8950
Title and Company	Inventor		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of and claims priority in Serial No. 13/367,150, filed February 6, 2012, which is a continuation of Serial No. 09/452,348, filed December 1, 1999, now U.S. Pat. No. 6,381,301, and claims priority in Serial No. 12/250,423, filed October 13, 2008, now U.S. Pat. No. 9,126,112, which is a continuation-in-part of Serial No. 11/932,809, filed October 31, 2007, now U.S. Pat. No. 8,073,101, which is a continuation-in-part of Serial No. 11/224,472, filed September 12, 2005, now U.S. Pat. No. 7,839,970, which is a continuation of Serial No. 10/351,567, filed January 24, 2003, now U.S. Pat. No. 6,944,262, which is a continuation-in-part of Serial No. 10/134,153, filed April 27, 2002, now abandoned, which is a continuation of Serial No. 09/452,348, filed December 1, 1999, now U.S. Pat. No. 6,381,301, which are all incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates generally to dental and orthopedic diagnosis and treatment, and in particular to a densitometry modeling system and method.

2. Description of the Related Art

[0003] The field of dental diagnostics is generally concerned with locating pathologies in the dental structure, i.e., the teeth and the surrounding tissue and bone. Three of the most common pathologies are: 1) caries associated with decay; 2) fractures; and 3) apical abscesses. The system and method of the present invention are primarily, but not exclusively, concerned with detecting these pathologies and with orthopedics.

[0004] Early detection of dental pathologies is very important in minimizing damage. Conventional diagnosis procedures are generally performed using dental X-rays (both fixed beam and scanning beam), explorers, and other conventional equipment.

[0005] Incipient caries, particularly those located beneath the enamel surface, often go undetected with conventional equipment. When such caries are finally found, considerable damage to tooth structure may have already occurred. Subsurface, incipient caries are located almost entirely within the enamel layer of the teeth. They are sometimes referred to as "smooth surface" caries and are particularly difficult to locate using conventional diagnostic equipment and procedures. By the time such incipient caries are located, the extent of the damage is often 17% to 23% greater than it would appear to be on a conventional X-ray negative.

[0006] Dental fractures can result from bruxism (teeth grinding), trauma, etc. Dental structure which is weakened by various causes, such as decalcification, is particularly susceptible to fractures. Fractures can assume various configurations, including craize line patterns. Fracture patterns and configurations can be particularly difficult to locate using conventional X-ray equipment and procedures. For example, fractures which are generally parallel to the X-ray beam are often undetectable on an X-ray negative. Undetected, and hence untreated, fractures can provide direct paths through the enamel layer of the teeth whereby bacteria can invade the dentin and pulp layers. Pathologies in the dentin and pulp layers are often associated with considerable pain and tooth loss.

[0007] Apical abscesses comprise yet another dental condition which can be difficult to diagnose with conventional equipment, particularly in the early stages. Advanced apical abscesses can cause considerable pain because they involve the neurovascular bundles located in the root canals. Early detection of apical abscesses can lead to appropriate, early-

stage treatment, thus avoiding advanced disease processes with resultant pain, swelling, and/or space involvement which left untreated could ultimately result in death.

[0008] Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications. For example, U.S. Patents No. 4,188,537; No. 4,259,583; No. 4,823,369; No. 4,856,038; and No. 5,214,686 all relate to dental X-ray diagnosis utilizing scanning techniques and are incorporated herein by reference.

[0009] In the medical field, densitometry procedures are used for measuring bone morphology density (BMD) by utilizing scanning X-ray beam techniques. Examples are shown in U.S. Patents No. 5,533,080; No. 5,838,765; and Re. 36,162, which are incorporated herein by reference. Medical applications of densitometry include the diagnosis and treatment of such bone diseases as osteoporosis.

[00010] The availability of relatively fast computers with large memories at reasonable costs has led to the digitalization of X-ray images for mapping BMD models in various formats. For example, BMD images use color to identify varying densities. Digital BMD patient models are also used for comparison purposes with standard models and with patients' own prior BMD histories. Age correction factors can be applied to patients' models for diagnosing and monitoring the onset and progress of such medical conditions as osteoporosis and the like. The present invention utilizes such densitometry modeling and mapping techniques for dental applications.

[0010] In addition to pathology detection and diagnosis, the present invention has applications in monitoring osseointegration. Osseointegration occurs at the interface between bone structures and prostheses, such as implants and replacement joints. For example, dental implants osseointegrate with patients' dental structure. The application of tomographical

densitometry techniques to osseointegration monitoring can provide the dental or medical practitioner with important information in evaluating the effectiveness of implant procedures.

[0011] Heretofore there has not been available a system or method for applying the technology of densitometry to dental and medical applications such as the detection of caries and decalcification and the monitoring of osseointegration in connection with dental and medical prostheses.

SUMMARY OF THE INVENTION

[0012] In the practice of the present invention, a dental and orthopedic densitometry modeling system utilizes a controller with a microprocessor and memory. An input device inputs data to the microprocessor for controlling the operation of the modeling system and for providing a database including densitometry parameters for comparison with a patient's densitometry model. The controller controls the operation of X-ray equipment, which is adapted for scanning patients' dental and orthopedic structures along preprogrammed scan paths. The X-ray output is processed by the microprocessor for creating a densitometry model, which can be output in various formats. In the practice of the method of the present invention, a patient and the X-ray equipment are positioned relative to each other. A controller is preprogrammed with a scan path and with data corresponding to the patient. The X-ray equipment emits and detects X-ray beams at first and second energy levels to provide densitometry output. The densitometry output is digitized and merged to provide a tomographic model, which can be compared to predetermined parameters unique to the patient. The model can be output in various formats, including a visual image color-coded to depict varying dental and orthopedic structure densities.

PRINCIPLE OBJECTS AND ADVANTAGES OF THE INVENTION

[0013] The principle objects and advantages of the present invention include: providing a dental and orthopedic diagnostic application for densitometry; providing such an application which includes a method for modeling dental and orthopedic structure using densitometry; providing such a method which includes dual-energy, X-ray emission and detection; providing such a method which includes providing a color-coded output model showing dental density; providing such a method which detects incipient caries; providing such a method which is adapted for detecting decalcification beneath the surface of the dental enamel layer; providing such a method which employs scanning X-ray techniques; providing such a method which utilizes commercially available tomography equipment; providing such a method which detects dental fractures; providing such a method which detects dental apical abscesses; providing such a method which detects dental pathologies at the micron level; providing such a method which facilitates the monitoring of decalcification in dental structures for determining appropriate treatment; providing such a method which is adaptable for monitoring osseointegration; providing such a method which can be practiced with relatively minor changes to existing densitometry equipment; and providing such a method which is economical in operation and particularly well adapted for the proposed usage thereof.

[0014] Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

[0015] The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Fig. 1 is a schematic, block diagram of a dental and orthopedic densitometry modeling system embodying the present invention.

[0017] Fig. 2 is a flowchart of a dental and orthopedic densitometry modeling method embodying the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Introduction and Environment

[0018] As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

II. Dental Densitometry Modeling System 2

[0019] Referring to the drawings in more detail, the reference numeral 2 generally designates a dental and orthopedic densitometry modeling system embodying the present invention. The system 2 includes a controller 4 with a microprocessor 6 connected to a digital memory device 7. The hardware components of the controller 4, i.e., the microprocessor 6 and the memory device 7, can comprise any of a number of suitable hardware devices which are commercially available and are suitable for this application. In addition to various programable logic devices (PLDs) and special-purpose microprocessors, general purpose, commercially available personal computers can be utilized in the controller 4. The controller

4 can be programmed in any suitable manner utilizing any of a variety of commercially available programming languages and software development systems.

[0020] The microprocessor 6 is adapted to receive input from one or more input devices 8, such as a keyboard, a pointing device (e.g., a mouse), a communications link, or another computer. Without limitation on the generality of useful data which can be input via the input device(s) 8, such data can include: 1) a patient's dental and orthopedic records, including previous tomographical densitometry models; 2) baseline tomographical densitometry models, which can be adjusted to accommodate for such factors as age, gender, size, weight, etc.; and 3) a preprogrammed scan path for the X-ray equipment.

[0021] The microprocessor 6 controls a positioning motor 10 which is operably connected to X-ray equipment 12 and is adapted for moving same through three axes of movement. Examples of X-ray equipment adaptable for use with the present invention are disclosed in U.S. Patents No. 5,533,080; No. 5,838,765; and No. Re. 36,162, which are incorporated herein by reference. The X-ray equipment 12 includes an X-ray beam source 14 and a detector array 16. The X-ray beam can be suitably collimated to assume any suitable configuration, such as fan, pencil, cone, etc. With the scanning technique disclosed, a restricted (i.e., collimated) beam is preferred. The source and the detector array 14, 16 are adapted for positioning on either side of a patient's dental/orthopedic structure 18.

[0022] Analog signals from the detector array 16 are output to an analog-to-digital (A/D) convertor 20, from which digitized signals are transmitted to a merger device 22 for merging into formats suitable for processing and analyzing by the microprocessor 6. The microprocessor 6, using data from the merger device 22, creates a tomographical densitometry model 24 which is transmitted to an output device or devices 26. Without limitation on the generality of useful output devices 26, it can comprise a monitor, a display,

a printer, a communications link, and/or another computer. For example, a color printer can be utilized to provide a color-coded graphical representation of the tomographical densitometry model 24. The color coding can correspond to densities, thus identifying potential problem areas where decalcification has occurred and resulted in lower density. The tomographical densitometry model 24 can also be useful for monitoring osseointegration, since the density of the dental/orthopedic structure 18 (tissue and bone) in the vicinity of an implant 28 or other prostheses can provide an important diagnostic tool for the use of the dental or medical practitioner in assessing the effectiveness of an implant or prosthetic procedure. The tomographical densitometry model 24 is also entered into the computer's memory device 7.

III. Dental and Orthopedic Densitometry Modeling Method

[0023] Fig. 2 is a flowchart of a dental and orthopedic densitometry method embodying the present invention. The method steps include positioning a patient and positioning the X-ray equipment relative to the patient, i.e., with the patient's dental/orthopedic structure to be examined located between the X-ray source 14 and the detector array 16.

[0024] Diagnostic parameters are input to the system and can comprise, for example, the patient's prior tomographical densitometry models and standardized models. The tomographical densitometry models can be corrected and/or adjusted to account for a patient’s age, gender, physical characteristics, etc. The input diagnostic parameters can be stored in the computer's memory device. A scan path for the X-ray equipment is preprogrammed in the computer.

[0025] The scanning procedure is commenced by collimating a first energy band beam, detecting emissions from same with a detector array, and converting the analog output

of the detector array to a digital signal. The digital signal is output for storage in the computer. The steps of collimating the energy band beam and detecting, digitizing and storing same are repeated for a second energy band beam. The Bisek et al. U.S. Patent No. Re. 36,162 discloses the use of dual-energy X-ray beams in medical densitometry applications. As discussed therein, dual-energy densitometry can result in a more accurate patient model.

[0026] The X-ray equipment then traverses the preprogrammed scan path and the first/second energy band steps are repeated until the scanning procedure is complete. The digitized detector array output is merged and compared to the diagnostic parameters which are stored in the computer's memory. The dental/orthopedic densitometry is tomographically modeled and output, for example to a monitor or printer for converting the model to a visual image. The visual image is output in a visible form for use by dental and medical practitioners.

CLAIMS

What is claimed as new and desired to be secured by Letters Patent is:

1. A system for tomographically modeling a dental structure, the system comprising:

a controller with a microprocessor and a memory device connected to the microprocessor, said controller being adapted for storing computed tomographic models of a dental structure;

an input device connected to the microprocessor;

a positioning motor connected to the microprocessor and responsive to commands from said microprocessor;

X-ray equipment including an X-ray source, a detector array, and a restricted beam device;

a convertor for converting a signal from said detector array, said convertor being connected to said detector array and to said microprocessor; and

an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor.

2. The system according to claim 1, wherein said restricted beam device comprises a dual-energy level restricted beam device.

3. The system according to claim 1, wherein said tomographic model received by said output device is a 3D tomographic model.

4. The system according to claim 1 wherein:

said x-ray source travels along a single axis; and

said x-ray source simultaneously rotates around said single axis.

5. The system according to claim 1, wherein:

said controller is adapted for storing a first tomographic model and a second tomographic model;

said first tomographic model is a preexisting, commercially available standard model;

said second tomographic model is a current patient model; and

said controller is further adapted to compare said first tomographic model with said second tomographic model.

6. The system according to claim 1, wherein:

said controller is adapted for storing a first tomographic model and a second tomographic model;

said first tomographic model is a preexisting patient model;

said second tomographic model is a current patient model; and

said controller is further adapted to compare said first tomographic model with said second tomographic model.

7. The system according to claim 1, wherein said X-ray source emits an X-ray beam comprising a cone configuration.

8. The system according to claim 7, wherein said restricted beam device comprises a dual-energy level restricted beam device.

9. The system according to claim 7, wherein said tomographic model received by said output device is a 3D tomographic model.

10. The system according to claim 7 wherein:

said x-ray source travels along a single axis; and

said x-ray source simultaneously rotates around said single axis.

11. The system according to claim 7, wherein:

said controller is adapted for storing a first tomographic model and a second tomographic model;

said first tomographic model is a preexisting, commercially available standard model;

said second tomographic model is a current patient model; and

said controller is further adapted to compare said first tomographic model with said second tomographic model.

12. The system according to claim 7, wherein:

said controller is adapted for storing a first tomographic model and a second tomographic model;

said first tomographic model is a preexisting patient model;

said second tomographic model is a current patient model; and

said controller is further adapted to compare said first tomographic model with said second tomographic model.

13. A tomographic modeling system comprising:

a controller with a microprocessor and a memory device connected to the microprocessor, said controller being adapted for creating, storing, and comparing 3D digital tomographic models of an object without the use of fiducial markers of said object;

an input device connected to the microprocessor;

a positioning motor connected to the microprocessor and responsive to commands from said microprocessor;

X-ray equipment including an X-ray source, a detector array, and a restricted beam device;

a convertor for converting a signal from said detector array, said convertor being connected to said detector array and to said microprocessor; and

an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor.

14. The system according to claim 13, wherein said restricted beam device comprises a dual-energy level restricted beam device.

15. The system according to claim 13, wherein said controller is adapted to compare a pre-existing tomographic model with a current tomographic model.

16. The system according to claim 13, wherein:

said x-ray source travels along a single axis; and

said x-ray source simultaneously rotates around said single axis.

17. The system according to claim 13, wherein said X-ray source emits an X-ray beam comprising a cone configuration.

18. The system according to claim 17, wherein said restricted beam device comprises a dual-energy level restricted beam device.

19. The system according to claim 17, wherein said controller is adapted to compare a pre-existing tomographic model with a current tomographic model.

20. The system according to claim 17, wherein:

said x-ray source travels along a single axis; and

said x-ray source simultaneously rotates around said single axis.

21. A system for tomographically modeling a dental structure, which system comprises:

a controller with a microprocessor and a memory device connected to the microprocessor, said controller being adapted for creating, storing, and comparing 3D digital tomographic models of a dental structure without the use of fiducial markers of said dental structure;

an input device connected to the microprocessor;

a positioning motor connected to the microprocessor and responsive to commands from said microprocessor;

X-ray equipment including an X-ray source, a detector array, and a restricted beam device;

a convertor for converting a signal from said detector array, said convertor being connected to said detector array and to said microprocessor; and

an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor.

22. The system according to claim 21, wherein said restricted beam device comprises a dual-energy level restricted beam device.

23. The system according to claim 21, wherein said X-ray source emits an X-ray beam comprising a cone configuration.

24. The system according to claim 23, wherein said restricted beam device comprises a dual-energy level restricted beam device.

ABSTRACT OF THE DISCLOSURE

A dental and orthopedic densitometry modeling system includes a controller with a microprocessor and a memory device connected to the microprocessor. An input device is also connected to the microprocessor for inputting diagnostic procedure parameters and patient information. X-ray equipment including an X-ray source and an X-ray detector array are connected to a positioning motor for movement relative to a patient's dental or orthopedic structure in response to signals from the microprocessor. The output consists of a tomographical densitometry model. A dental/orthopedic densitometry modeling method involves moving the X-ray equipment across a predetermined scan path, emitting dual-energy X-ray beams, and outputting an image color-coded to correspond to a patient's dental or orthopedic density.

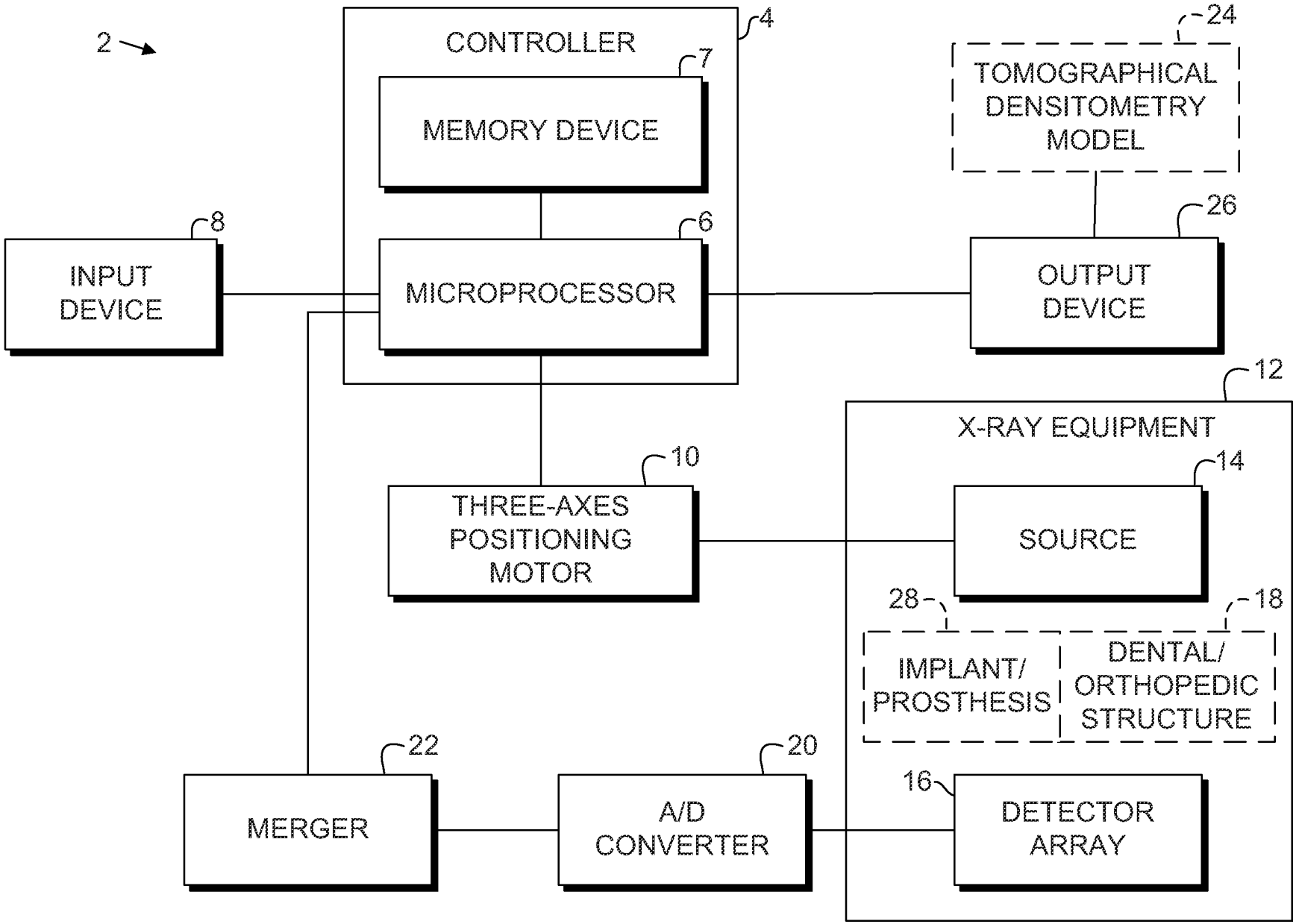

2
CONTROLLER
4
MEMORY DEVICE
7
MICROPROCESSOR
6
INPUT DEVICE
8
TOMOGRAPHICAL DENSITOMETRY MODEL
24
OUTPUT DEVICE
26
X-RAY EQUIPMENT
12
THREE-AXES POSITIONING MOTOR
10
SOURCE
14
28
IMPLANT/ PROSTHESIS
18
DENTAL/ ORTHOPEDIC STRUCTURE
MERGER
22
A/D CONVERTER
20
16
DETECTOR ARRAY

Fig. 1

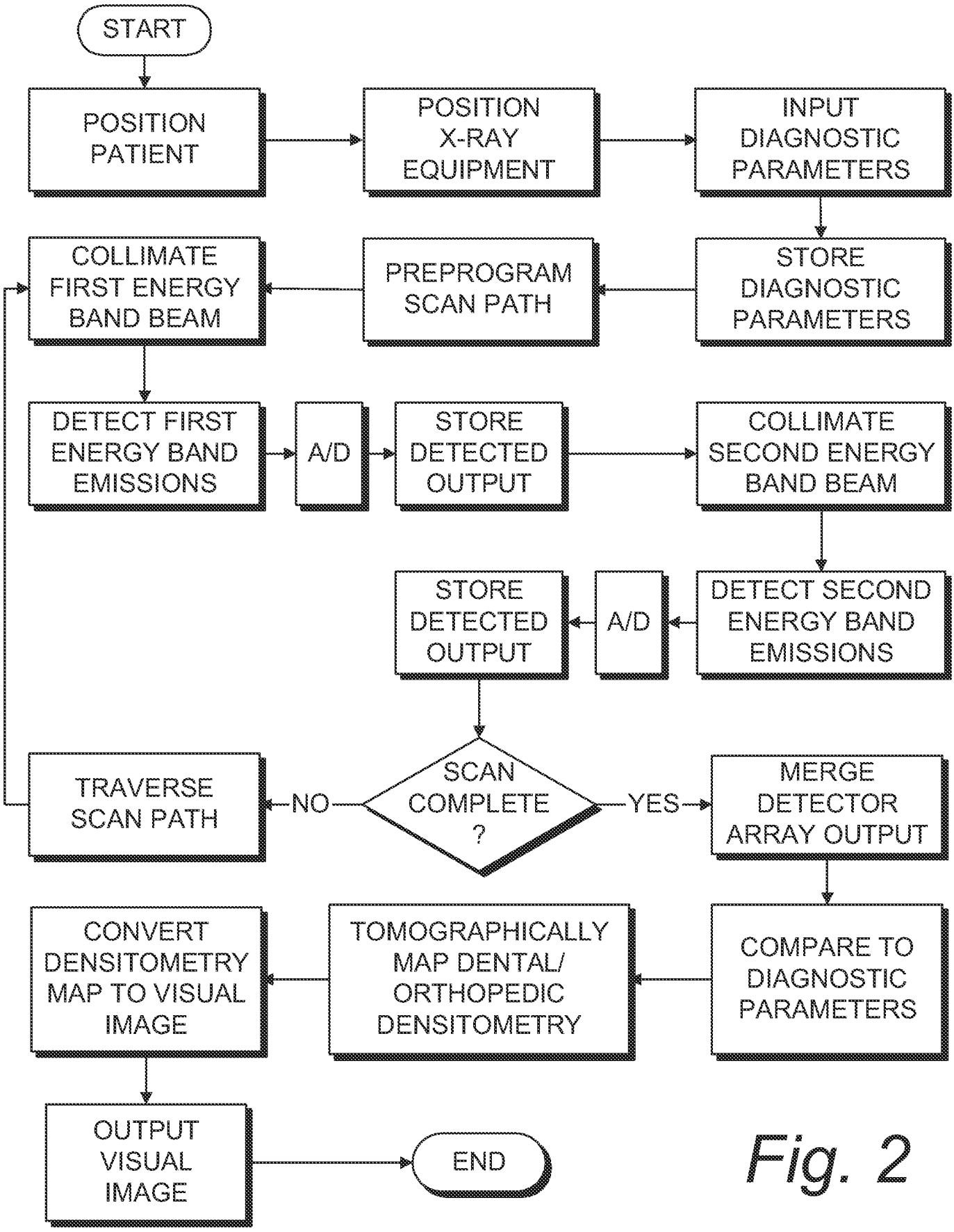

START
POSITION PATIENT
POSITION X-RAY EQUIPMENT
INPUT DIAGNOSTIC PARAMETERS
STORE DIAGNOSTIC PARAMETERS
PREPROGRAM SCAN PATH
COLLIMATE FIRST ENERGY BAND BEAM
DETECT FIRST ENERGY BAND EMISSIONS
A/D
STORE DETECTED OUTPUT
COLLIMATE SECOND ENERGY BAND BEAM
DETECT SECOND ENERGY BAND EMISSIONS
A/D
STORE DETECTED OUTPUT
SCAN COMPLETE ?
NO
TRAVERSE SCAN PATH
YES
MERGE DETECTOR ARRAY OUTPUT
COMPARE TO DIAGNOSTIC PARAMETERS
TOMOGRAPHICALLY MAP DENTAL/ ORTHOPEDIC DENSITOMETRY
CONVERT DENSITOMETRY MAP TO VISUAL IMAGE
OUTPUT VISUAL IMAGE
END

Fig. 2

PTO/SB/01 (04-09)
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☑ Declaration Submitted With Initial Filing OR ☐ Declaration Submitted After Initial Filing (surcharge (37 CFR 1.16(f)) required)

Attorney Docket Number	2932.2
First Named Inventor	Ronald E. Massie
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

I hereby declare that: (1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention titled:

DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

(Title of the Invention)

the application of which

☑ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Authorization To Permit Access To Application by Participating Offices

☑ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified patent application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the above-identified patent application is filed to have access to the above-identified patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the above-identified patent application with respect to: 1) the above-identified patent application-as-filed; 2) any foreign application to which the above-identified patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified patent application; and 3) any U.S. application-as-filed from which benefit is sought in the above-identified patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

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DECLARATION — Utility or Design Patent Application

Claim of Foreign Priority Benefits

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application number(s) are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ The address associated with Customer Number: 63151 OR ☐ Correspondence address below

Name
Mark Brown/Law Office of Mark Brown, LLC

Address
4700 Belleview Ave., Suite 210

City	State	Zip
Kansas City	MO	64112

Country	Telephone	Email
US	816-268-8950	uspto@midwestip.com

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NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Ronald E.	Massie

Inventor's Signature  Date 9/14/12

Residence: City	State	Country	Citizenship
Lake Ozark	MO	US	US

Mailing Address
24 North Shore Drive

City	State	Zip	Country
Lake Ozark	MO	65049	US

☐ Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/619,356

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	95		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	310		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	125		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	24 minus 20 =	* 4	x 30 =	120	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 125 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	650		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/619,356	09/14/2012	2882	950	2932.2	24	3

CONFIRMATION NO. 4681

63151
LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

FILING RECEIPT

OC000000056831902

Date Mailed: 10/03/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Ronald E. Massie, Lake Ozark, MO;

Applicant(s)

Ronald E. Massie, Lake Ozark, MO;

Power of Attorney: The patent practitioners associated with Customer Number 63151

Domestic Priority data as claimed by applicant

This application is a CON of 13/367,150 02/06/2012
which is a CON of 09/452,348 12/01/1999 PAT 6381301
and is a CON of 12/250,423 10/13/2008 PAT 8126112 *
which is a CIP of 11/932,809 10/31/2007 PAT 8073101
which is a CIP of 11/224,472 09/12/2005 PAT 7839970
which is a CON of 10/351,567 01/24/2003 PAT 6944262
which is a CIP of 10/134,153 04/27/2002 ABN
which is a CON of 09/452,348 12/01/1999 PAT 6381301
(*)Data provided by applicant is not consistent with PTO records.

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If Required, Foreign Filing License Granted: 09/28/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/619,356**

Projected Publication Date: Perfected

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Preliminary Class

378

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/619,356	09/14/2012	Ronald E. Massie	2932.2

CONFIRMATION NO. 4681

63151
LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

POA ACCEPTANCE LETTER

OC000000056831852

Date Mailed: 10/03/2012

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/14/2012.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/lphan/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/619,356

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	98		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	310		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	125		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	24 minus 20 =	* 4	x 31 =	124	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 125 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	657		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/619,356	09/14/2012	2882	950	2932.2	24	3

CONFIRMATION NO. 4681

63151
LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

FILING RECEIPT

OC000000056831902

Date Mailed: 10/12/2012

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Inventor(s)

Ronald E. Massie, Lake Ozark, MO;

Applicant(s)

Ronald E. Massie, Lake Ozark, MO;

Power of Attorney: The patent practitioners associated with Customer Number 63151

Domestic Priority data as claimed by applicant

This application is a CON of 13/367,150 02/06/2012
which is a CON of 09/452,348 12/01/1999 PAT 6381301
and is a CON of 12/250,423 10/13/2008 PAT 8126112 *
which is a CIP of 11/932,809 10/31/2007 PAT 8073101
which is a CIP of 11/224,472 09/12/2005 PAT 7839970
which is a CON of 10/351,567 01/24/2003 PAT 6944262
which is a CIP of 10/134,153 04/27/2002 ABN
which is a CON of 09/452,348 12/01/1999 PAT 6381301
(*)Data provided by applicant is not consistent with PTO records.

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If Required, Foreign Filing License Granted: 09/28/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/619,356**

Projected Publication Date: 01/24/2013

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Preliminary Class

378

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OCT 16 2012

OFFICE OF PETITIONS

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.:13/619,356

1. THE REQUEST FILED September 14, 2012 IS **GRANTED.**

The above-identified application has met the requirements for prioritized examination

A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;

C. filing a **request for continued examination**;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Kimberly Inabinet at 571-272-4618. In his/her absence, calls may be directed to Brian W. Brown at 571-272-5338.

/ Kimberly A. Inabinet/
[*Signature*]

Petitions Examiner, Office of Petitions
(Title)

PTO/SB/08a(04-07)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known	
Application Number	13/619,356
Filing Date	September 14, 2012
First Named Inventor	Massie, Ronald E.
Art Unit	2882
Examiner Name	Ho, Allen C.

Sheet	1	of	3

Attorney Docket No: 2932.2

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Art Unit	2882
Examiner Name	Ho, Allen C.

Sheet	2	of	3	Attorney Docket No: 2932.2

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Art Unit	2882
Examiner Name	Ho, Allen C.

Sheet	3	of	3

Attorney Docket No: 2932.2

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [2]
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EP0180482

Publication Title:

Bone Evaluation method.

Abstract:

Abstract not available for EP0180482 Data supplied from the esp@cenet database - Worldwide

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(54) Bone Evaluation method.

(57) A method for evaluating bone comprising the steps of: (a) determining a bone pattern (i) by measuring the photodensity of an X-ray photograph from the long shank bone of a limb or (ii) by photon absorption metory from the long shank bone of a limb; (b) smoothing and symmetrizing the bone pattern to modify the same; (c) determining at least one index selected from the group consisting of an index of the bone cortical width (MCI), a bone width (D), a maximum bone density (GSmax), a minimum bone density (GSmin), a bone mineral content (ΣGS), and an average bone density (ΣGS/D or ΣGS/D²); and (d) evaluating the bone based on the at least one index.

The bone evaluation also can be carried out by determining a bone density distribution, from the modified bone pattern obtained above, by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex. The bone evaluation can further be carried out by first obtaining modified patterns in a plurality of portions of the bone at a constant distance and, then, by determining a bone density distribution in each portion from the modified bone pattern in each portion by setting the above-mentioned bone model in each portion. The bone density distribution in each portion is classified, by color, based on the density values, and the X-ray image or photon absorption metory image is converted to the image of the bone density distribution.

EP 0 180 482 A2

0180482

BONE EVALUATION METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a bone evaluation method. More specifically, it relates to a bone evaluation method in which a bone pattern is determined by measuring the photodensity of X-ray photographs of the long shank bone of a limb or by photon absorption metory from the long shank bone of a limb, the resultant bone pattern is modified, and the bone is evaluated based on the resultant modified bone pattern.

2. Description of the Related Art

The so-called MD method has heretofore known as a method for evaluating bone, for example, growth conditions of human bone, aging degree of human bone, or kinds of bone diseases such as osteoporosis and osteomalacia, as disclosed in, for example, "Kotsu Taisha" (i.e., Bone Metabolism) 13, pp 187-195 (1980) and 14, pp 91-104, (1981). According to the MD method, the photodensity of X-ray photographs is measured at the middle site of a metacarpal bone with a microdensitometer and various indices such as an index of the bone cortical width (MCI), a bone width (D), a maximum bone density (GSmax), a minimum bone density (GSmin), a bone mineral content (ΣGS), and an average bone density (ΣGS/D) are determined. The degree of osteanabrosis is thus evaluated based on the above-determined indices.

Another known method for evaluating bone is so-called photon absorption metory. According to this method, a γ-ray is used instead of an X-ray and the amount of the γ-ray transmitted through bone is measured by a detector, followed by a quantitative treatment.

However, in the MD method, various indices such as the maximum bone density (GSmax) and the bone cortical width (MCI) sometimes do not reflect the actual

bone conditions and, therefore, the desired evaluation of bone based on these indices becomes difficult. For example, although it is believed that the maximum bone density (GSmax) is an index representing the bone density of a bone cortex, the GSmax values will vary in accordance with the diameter of the bone and the bone cortex width even where the bones have the same bone density. Furthermore, when the bone is not homogeneous, exactly what the GSmax values represent becomes unclear.

On the other hand, it is known only that the bone mineral content (BMC) can be determined by a conventional photon absorption metory method.

SUMMARY OF THE INVENTION

Accordingly, the objects of the present invention are to eliminate the above-mentioned disadvantages of the conventional bone evaluation methods and to provide a novel bone evaluation method capable of reliably evaluating bone by using indices directly reflecting the conditions of bone with good reproducibility.

Other objects and advantages of the present invention will be apparent from the following description.

In accordance with the present invention, there is provided a method for evaluating bone comprising the steps of:

(a) determining a bone pattern (i) by measuring the photodensity of an X-ray photograph of the long shank bone of a limb or (ii) by photon absorption metory from the long shank bone of a limb;

(b) smoothing and symmetrizing the bone pattern to modify the same;

(c) determining at least one index selected from the group consisting of an index of the bone cortical width (MCI), a bone width (D), a maximum bone density (GSmax), a minimum bone density (GSmin), a bone mineral content (ΣGS), and an average bone density ($\Sigma GS/D$ or $\Sigma GS/D^2$); and

(d) evaluating the bone based on the at least

one index.

In accordance with the present invention, there is also provided a method for evaluating bone comprising the steps of:

(a) determining a bone pattern (i) by measuring the photodensity of an X-ray photograph of the long shank bone of a limb or (ii) by photon absorption metory from the long shank bone of a limb;

(b) smoothing and symmetrizing the bone pattern to modify the same;

(c) determining a bone density distribution by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex from the modified bone pattern; and

(d) evaluating the bone based on the bone density distribution.

In accordance with the present invention, there is further provided a method for evaluating bone comprising the steps of:

(a) determining a bone pattern in each portion (i) by measuring the photodensity of an X-ray photograph, at a constant distance, of the long shank bone of a limb or (ii) by photon absorption metory from each portion of the long shank bone of a limb;

(b) smoothing and symmetrizing the bone pattern to modify the same;

(c) determining a bone density distribution in each portion by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex from the modified bone pattern;

(d) classifying, by color, the bone density distribution in each portion based on the density values in each bone density distribution;

(e) converting the X-ray image of the shank

bone of the limb, or the image obtained from the photon absorption metory, to the image of the bone density distribution; and

(f) evaluating the bone based on the image of the bone density distribution.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be better understood from the description set forth below with reference to the accompanying drawings, wherein:

Fig. 1 illustrates a bone pattern obtained from the photodensity of the X-ray photograph according to an MD method;

Fig. 2 illustrates the symmetrization of the bone pattern according to the present invention;

Fig. 3 illustrates the smoothing of the bone pattern according to the present invention;

Fig. 4 illustrates each index determined from the modified bone pattern obtained by the present invention;

Fig. 5 illustrates the bone model corresponding to the modified bone pattern obtained by the present invention;

Figs. 6(a) and (b) illustrate the cross-sectional quadratic moment and the cross-sectional quadratic polar moment;

Figs. 7(a), (b), and (c) illustrate the classification, by color, of the bone density distribution to convert the X-ray image to the image of the bone density distribution; and

Figs. 8(a) and (b) illustrate an example of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The first aspect of the present invention will now be explained.

When bone is evaluated, a bone pattern is first determined in the step (a) by measuring the photodensity of an X-ray photograph of the long shank bone of a limb

or by photon absorption metory from the long shank bone of a limb.

As the long shank bone of a limb, the use of bones covered with soft tissues having a thin and average thickness is preferable. Examples of such bones are the first through fifth metacarpal bones, especially the mid-shafts of the second metacarpal bones. The X-ray photograph can be taken by any conventional X-ray photographic method and the desired bone pattern can be obtained by measuring the photodensity of the resultant X-ray photograph. For example, the bone pattern can be determined according to a conventional MD method. That is, the photodensities of the X-ray photographic image are measured, together with the X-ray photographic image of an aluminum step wedge consisting of, for example, 20 steps each having a minimum height of 1 mm (i.e., from a lowest height of 1 mm, to a total height of 20 mm) or aluminum slope, with a densitometer. Thus, the aluminum step wedge is placed besides bones to be examined and the X-ray photographic image is taken of the bones and wedge together. The photodensity is preferably measured between the nearest end and the farthest end of the bone. The photodensities thus measured are plotted at an enlarged scale on a graphical paper graduated with an optical density (OD) and the optical absorbance (OD) in each point of the bone is converted to the corresponding aluminum step of the aluminum step wedge (i.e., GS value) to obtain the bone pattern as shown in Fig. 1 (see "Kotsu Taisha" (Bone Metabolism) 13, pp 187-195 (1980); ibid 14, pp 91-104 (1981); and ibid 14, pp 319-325 (1981)). Alternatively, the bone pattern can be obtained by reading the X-ray photographic image of the bone, together with the X-ray photographic image of the aluminum step wedge or aluminum slope, by a TV camera.

Furthermore, the bone pattern can be determined from the long shank bone of a limb by photon absorption

metory. According to the photon absorption metory method, a γ-ray is used instead of an X-ray and the amount of the γ-ray transmitted through the bone is measured by a detector (see "Jin to Toseki" (i.e., Kidney and Dialysis) Vol. 6, No. 1, pp 49 (1979) and "Science" Vol. 142, pp 230 (1963)). In this method, the cross-section of the long shank bone of a limb is scanned by a γ-ray and the count numbers of the γ-ray transmitted through the bone are drawn as an image as shown in Fig. 1.

The bone pattern obtained above is then modified in step (b) by smoothing and symmetrizing the bone pattern. The symmetrization of the bone pattern will now be explained with reference to Fig. 2. That is, the center line (a) is drawn in the bone pattern (i.e., the solid line in Fig. 2) obtained by the above-mentioned step (a). The GS values (i.e., GSx_1 and GSx_2) at the positions having an equal distance X from the center line are determined and the average of the GS values GSx (i.e., $GSx = (GSx_1 + GSx_2/2)$ is plotted as the GS values at both the positions having an equal distance X from the center line. This procedure is repeated by changing the distance X. Thus, the symmetrized bone pattern (i.e., the dotted line in Fig. 2) is obtained.

The symmetrized bone pattern thus obtained is then smoothed or standardized. The smoothing of the symmetrized bone pattern will now be explained with reference to Fig. 3. That is, the bone pattern symmetrized above is equally divided in width. For example, a portion of the bone pattern is divided into five sections Xi_1 , Xi_2 , Xi_3 , Xi_4 , and Xi_5. Then, the GS values at these points (i.e., $GSxi_1$, $GSxi_2$, $GSxi_3$, $GSxi_4$, and $GSxi_5$) are determined and the average of these GS values is calculated. The average GS value is designated as a GS value at the point Xi_3. This procedure is repeated and the resultant average GS values in each portion are plotted to obtain

the smoothed bone pattern curve. This smoothing method is carried out according to the so-called moving-average method.

Although there is no critical limitation to the order of the symmetrization and smoothing in the present invention, it is preferable to first effect the symmetrization, followed by the smoothing.

According to the above-mentioned photon absorption metory, the GS value is determined as $\ell n\ (I_0/I_i)$, wherein I_0 is a count number of the γ-ray transmitted through the bone and I_i is a count number of the incident γ-ray.

In the next step (c) of the first aspect of the present invention, various indices are determined from the modified bone pattern obtained in the above-mentioned step (b). The indices obtained in the case of the second metacarpal bone will now be explained with reference to Fig. 4. In Fig. 4, D represents a bone width, d a bone marrow width, d_1 a width of a ulnar side bone cortex, and d_2 a width of a radial side bone cortex. The index MCI can be determined according to the following equation.

$$MCI = (d_1 + d_2)/D$$

Furthermore, in Fig. 4, GSmin represents a minimum bone density. The maximum bone density GSmax is determined as an average of GSmax, in Fig. 4 (i.e., the minimum GS value in the ulnar side bone cortex) and $GSmax_2$ in Fig. 4 (i.e., the maximum GS value in the raidal side bone cortex) as follows.

$$GSmax = \frac{GSmax_1 + GSmax_2}{2}$$

It should be noted that, according to the present invention, $GSmax_1$ should be equal to $GSmax_2$ due to the above-mentioned symmetrization of the bone pattern. The index ΣGS can be obtained by integrating each

GS value and the average bone density ΣGS/D or $\Sigma GS/D^2$ can be obtained from the bone mineral density value thus obtained.

According to the present invention, the desired evaluation of bone can be effected by using at least one index selected from the above-mentioned indices, i.e., MCI, D, GSmax, GSmin, ΣGS, and ΣGS/D or $\Sigma GS/D^2$. These indices, for example, the bone cortical width index (MCI), represent the actual conditions of the bone more accurately when compared with a conventional MD method. Accordingly, a more accurate bone evaluation can be effected according to the present invention.

The practical evaluation can be carried out based on any known method. For example, the evaluation method of osteanabrosis is disclosed in "Kotsu Taisha" (Bone Metabolism) 13, 187-195 (1980).

The evaluation of bone growth can be carried out according to a method disclosed in, for example, "Kotsu Taisha" (Bone Metabolism) 14, 319-325 (1981).

The evaluation of the types of bone diseases can be carried out according to methods disclosed in, for example, Japanese Unexamined Patent Publication (Kokai) Nos. 59-8935 and 59-11840. The contents of these publications are incorporated hereinto by reference.

The second aspect of the present invention will now be explained. As mentioned above, according to the second aspect of the present invention, the bone is evaluated by (a) determining a bone pattern (i) by measuring the photodensity of an X-ray photograph of the long shank bone of a limb or (ii) by photon absorption metory from the long shank bone of a limb; (b) smoothing and symmetrizing the bone pattern to modify the same; (c) determining a bone density distribution by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex from the modified bone pattern; and (d) evaluating the bone

based on the bone density distribution.

That is, according to the second aspect of the present invention, the bone pattern is first determined from the long shank bone of a limb by the X-ray photography or photon absorption metory and the resultant bone pattern is then symmetrized or smoothed to obtain a modified bone pattern in the same manner as the steps (a) and (b) of the first aspect of the present invention.

According to the second aspect of the present invention, a bone density distribution is determined by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex from the modified bone pattern.

The procedure for determining the bone density distribution will now be explained with reference to Fig. 5. The modified bone pattern obtained above is first converted to an elliptic bone model as shown in Fig. 5. The ellipic form is an external shape of a certain cross-section of the bone. The preferable ratio of major axis/minor axis of the elliptic shape is more than 1 but not more than 1.4. In the case of a metacarpal bone, the use of an elliptic shape having a ratio of major axis/minor axis of around 1.25 is especially preferable due to good matching to the actual bone. On the other hand, in the case of portions around the humerus or forearm bone being examined, the use of an elliptic shape having a ratio of major axis/minor axis near 1 is preferable.

The elliptic bone pattern is divided in n equal sections. For example, the ulnar side of the bone pattern is divided in 100 equal sections in Fig. 5. The bone densities in each layer in Fig. 5 are designated as μ'_1 , μ'_2 , μ'_3 , ... μ'_i ... , and μ'_{100}. Furthermore, as shown in Fig. 5, the bone model is set so as to have a zonate bone cortex and the bone density in each zone is assumed to be constant. Thus, the bone

density in a phase located at the equal distance from the outer periphery of the cross-section of the bone is assumed to be the same. The length of the cross-section of the bone model at each position divided in n equal sections can be represented as follows.

$$2 \cdot I_{1,1}$$
$$2 \cdot (I_{2,1} + I_{2,2})$$
$$2 \cdot (I_{3,1} + I_{3,2} + I_{3,3})$$
$$\vdots$$
$$2 \cdot (I_{i,1} + I_{i,2} + \ldots + I_{i,j} + \ldots + I_{i,i})$$
$$\vdots$$

The values such as $I_{1,1}$, $I_{2,1}$, ... can be easily determined from the ratio of major axis/minor axis of the elliptic shape by a conventional method. From these values, the following recurrence formulae can be obtained. These formulae are in the case of the bone pattern being divided in 100 equal sections.

$$GS_1 = 2 \cdot (I_{1,1} \cdot \mu'_1)$$
$$GS_2 = 2 \cdot (I_{2,1} \cdot \mu'_2 + I_{2,2} \cdot \mu'_1)$$
$$GS_i = 2 \cdot (I_{i,1} \cdot \mu_i' + \ldots + I_{i,j} \cdot \mu_i - j+_1 + \ldots + I_{i,i} \cdot \mu'_1)$$
$$GS_{100} = 2 \cdot (I_{100,1} \cdot \mu'_{100} + \ldots + I_{100,k} \cdot \mu'_{100-k-1} + I_{100,100} \cdot \mu,_1)$$

The bone density (μ_i') in each position can be obtained by solving the above-mentioned recurrence formulae and the bone density distribution can be obtained by graphically illustrating these formulae. The dotted line in Fig. 5 illustrates the bone density distribution thus obtained. According to the present invention, when the above-mentioned recurrence formulae are solved, the bone densities of the external portions of bone cortices can be considered to be the same (i.e., $\mu'_1 = \mu'_2 = \mu'_3 = \ldots$). That is, the bone pattern of a portion in which the bone density is homogeneous in

the exterior of the bone cortex is selected and, then, the above-mentioned recurrence formulae can be solved by assuming that the bone density in the selected portion is constant. Furthermore, since both end portions of the bone pattern include large errors due to the influence of scattered light, these portions are negligible and the more correct value can be determined upon neglecting both end portions. When the present bone evaluation method is applied to such a portion that the cross-section of the bone cannot be clearly approximated by an elliptic shape (e.g., the distalis portions of radius), the symmetrization of the bone pattern according to the present invention can be omitted and the calculation can be carried out by using a bone pattern only in the radial bone side and by applying, to the bone model, only a portion which can be approximated by an elliptic shape.

When the bone pattern is determined from an X-ray photograph, the bone density (μ_i') obtained above is obtained based on a GS value, which is derived by comparing the photodensity of the X-ray image with that of an aluminum step wedge or aluminum slope. Thus, the bone density μ_i' corresponds to an X-ray diminishing coefficient. The bone density or X-ray diminishing coefficient can be determined by a ratio of the value, obtained by subtracting the X-ray diminishing coefficient (μ_s) of the soft tissue around the bone from the X-ray diminishing coefficient (μ_b) of the actual bone, to the X-ray diminishing coefficient (μ_{al}) of aluminum as follows:

$$\mu'_i = (\mu_b - \mu_s)/\mu_{al}$$

On the other hand, when the bone pattern is determined by photon absorption metory, the resultant bone density is derived by subtracting the γ-ray diminishing coefficient of the soft tissue around the bone from the γ-ray diminishing coefficient of the bone.

In order to determine an accurate bone density of

each portion of a bone, scanning such as computer tomography is required. However, according to the present method, the bone density distribution can be approximately determined by applying the modified bone pattern obtained as mentioned above to the bone model.

The bone density distribution obtained as mentioned above is an index accurately reflecting the actual bone conditions, when compared with the bone density distribution obtained by conventional MD methods. Accordingly, more objective bone evaluation can be effected by using the bone density distribution according to the present invention. For example, types of bone diseases can be determined when the bone density distribution of a patient with a bone disease is compared with that of a healthy person. Furthermore, according to the present invention, the disease conditions of renal osteodystrophy having uniform bone density can be more accurately determined and the growth degree and the aged degree of the bone can also be determined.

Furthermore, from the bone density distribution, the cross-sectional quadratic moment or cross-sectional quadratic polar moment as shown in Figs. 6(a) and (b) can be determined (see Clin. Orthop. Rel. Res., 149, 268, 1980). These indices can also represent the bone strength and, therefore, the bone evaluation according to the present invention becomes more accurate by using these indices together with the above-mentioned other indices.

The third aspect of the present invention will now be explained. As mentioned above, according to the third aspect of the present invention, the bone is evaluated by (a) determining a bone pattern in each portion (i) by measuring the photodensity of an X-ray photograph, at a constant distance, of the long shank bone of a limb or (ii) by photon absorption metory from each portion of the long shank bone of a limb; (b) smoothing and symmetrizing the bone pattern of each

portion to modify the same; (c) determining a bone density distribution in each portion by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex from the modified bone pattern; (d) classifying, by color, the bone density distribution in each portion based on the density values in each bone density distribution; (e) converting the X-ray image of the shank bone of the limb, or the image obtained from the photon absorption metory, to the image of the bone density distribution; and (f) evaluating the bone based on the image of the bone density distribution.

According to the third aspect of the present invention, the bone density distribution is determined in the same manner as in the above-mentioned second aspect of the present invention, provided that the bone patterns of a plurality of portions are determined by measuring the photodensity of an X-ray photograph of the long shank bone of a limb in each portion at a constant distance or by photon absorption metory from each portion of the long shank bone of a limb. Thus, the bone density distribution in each portion is determined. This will now be further explained with reference to Figs. 7(a) and (b).

Fig. 7(a) schematically shows the X-ray photographic image of the second metacarpal bone, in which the shaded parts exhibit the shadow of the X-ray. According to the third aspect of the present invention, the X-ray photographic images are divided in a constant distance portions and the bone pattern is determined in each portion. The constant distances are generally 2 mm or less. Especially, the diaphysis portions of periphery bones can be preferably used for the evaluation. The bone density distribution in each portion is determined in the same manner as in the case of the above-mentioned second aspect of the present invention. Fig. 7(b)

schematically illustrates the bone density distribution thus obtained. In the third aspect of the present invention, the resultant bone density distribution is classified by color depending upon the values of the bone density (μ'). For example, a portion having a high bone density (or a normal portion) is colored with a reddish color and a portion having a decreasing bone density (or a light or medium atrophic portion is colored with pink, yellow, or blue zone, and a portion having an extremely low bone density (or highly atropic portion) is colored with a bluish color. This colored classification is carried out in each bone density distribution.

The color classified bone density distribution is then used to convert the X-ray photographic image of the long shank bone of a limb to a color classified image of the bone density distribution, as schematically illustrated in Fig. 7(c). These procedures can be usually carried out, with a computer, by graphic display. In the case of the bone pattern being determined by photon absorption metory, the bone pattern in each portion is similarly obtained and, then, the bone density distribution and the color classified image can be obtained in the similar manner as mentioned above.

In addition, the above-mentioned steps (a) to (c) of the third aspect of the present invention are effected by the conventional MD method determining a bone density distribution (see "Kotsu Taisha" (Bone Metabolism) 14, pp 91-104, 1981). The resultant bone density distribution is then subjected to the steps (d) to (e) of the third aspect of the present invention. Thus, the bone pattern derived from, for example, an X-ray photographic image of the long shank bone of a limb is converted to the color classified image of the bone density distribution, and the bone can be evaluated based on the resultant image.

The color classified image obtained in the manner

described above represents not only one cross-section of the bone, but also the bone density distribution of the entire bone. Consequently, bones can be more accurately and more practically evaluated by the color classified image. For example, in the case of senile osteoporosis, it is observed according to the present invention that the bone cortex becomes thinner and a substantial uniform decrease in the bone density occurs from a juxtaposition to a distalis position. In the case of rheumatoid arthritis, extensive osteanabrosis is observed around the joints or articulatioes.

As explained above, the present invention provides a bone evaluation method obtained by improving a conventional MD method. According to this method, the conditions of the bone can be more accurately and objectively evaluated and, therefore, the present invention is very significant in the bone evaluation field.

EXAMPLES

The present invention will now be further illustrated by, but is by no means limited to, the following Examples.

Example 1

A bone density distribution was obtained from an X-ray photograph of the second metacarpal bone of a woman aged 62 with osteoporosis according to the above-mentioned third aspect of the present invention. The result is as shown in Fig. 7. When the bone density was determined, the bone density of the external portion of the bone cortex was assumed constant.

The bone pattern shown in Fig. 8(a) was obtained from the measurement by densitometry. The curve (i) in Fig. 8(a) illustrates the bone pattern obtained by converting the bone width to 10 mm. The curve (ii) in Fig. 8(b) illustrates the modified bone pattern obtained by symmetrizing and smoothing the bone pattern, and the curve (iii) in Fig. 8(b) illustrates the bone density

distribution.

Example 2

Bone density distributions of 19 males and 18 females, ranging in age from 20 to 40, were determined in the same manner as in Example 1.

The bone densities (μ') of the external bone cortex thus obtained are as follows:

Index	Male (N = 19)			Female (N = 18)		
	Average	Standard deviation	Variation (%)	Average	Standard deviation	Variation (%)
μ'	0.39	0.030	7.80	0.41	0.024	5.86

CLAIMS

1. A method for evaluating bone comprising the steps of:

(a) determining a bone pattern (i) by measuring the photodensity of an X-ray photograph of the long shank bone of a limb or (ii) by photon absorption metory from the long shank bone of a limb;

(b) smoothing and symmetrizing the bone pattern to modify the same;

(c) determining at least one index selected from the group consisting of an index of the bone cortical width (MCI), a bone width (D), a maximum bone density (GSmax), a minimum bone density (GSmin), a bone mineral content (ΣGS), and an average bone density (ΣGS/D or $\Sigma GS/D^2$); and

(d) evaluating the bone based on at least one said index.

2. A method as claimed in claim 1, wherein said long shank bone of a limb is the mid-shaft of a second metacarpal bone.

3. A method for evaluating bone comprising the steps of:

(a) determining a bone pattern (i) by measuring the photodensity of an X-ray photograph of the long shank bone of a limb or (ii) by photon absorption metory from the long shank bone of a limb;

(b) smoothing and symmetrizing the bone pattern to modify the same;

(c) determining a bone density distribution by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex from the modified bone pattern; and

(d) evaluating the bone based on the bone density distribution.

4. A method as claimed in claim 3, wherein said long shank bone of a limb is the mid-shaft of a second

metacarpal bone.

5. A method as claimed in claim 3, wherein the ratio of the major axis to the minor axis of the elliptic bone cross-sectional external shape is more than 1 but not more than 1.4.

6. A method for evaluating bone comprising the steps of:

(a) determining a bone pattern in each portion (i) by measuring the photodensity of an X-ray photograph, at a constant distance, of the long shank bone of a limb or (ii) by photon absorption metory from each portion of the long shank bone of a limb;

(b) smoothing and symmetrizing the bone pattern of each portion to modify the same;

(c) determining a bone density distribution in each portion by setting a bone model having an elliptic bone cross-sectional external shape, a zonate bone cortex, and a bone density decreasing portion in the inside of the bone cortex from the modified bone pattern;

(d) classifying, by color, the bone density distribution in each portion based on the density values in each bone density distribution;

(e) converting the X-ray image of the shank bone of the limb, or the image obtained from the photon absorption metory, to the image of the bone density distribution; and

(f) evaluating the bone based on the image of the bone density distribution.

7. A method as claimed in claim 6, wherein said long shank bone of a limb is the mid-shaft of a second metacarpal bone.

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Fig. 1

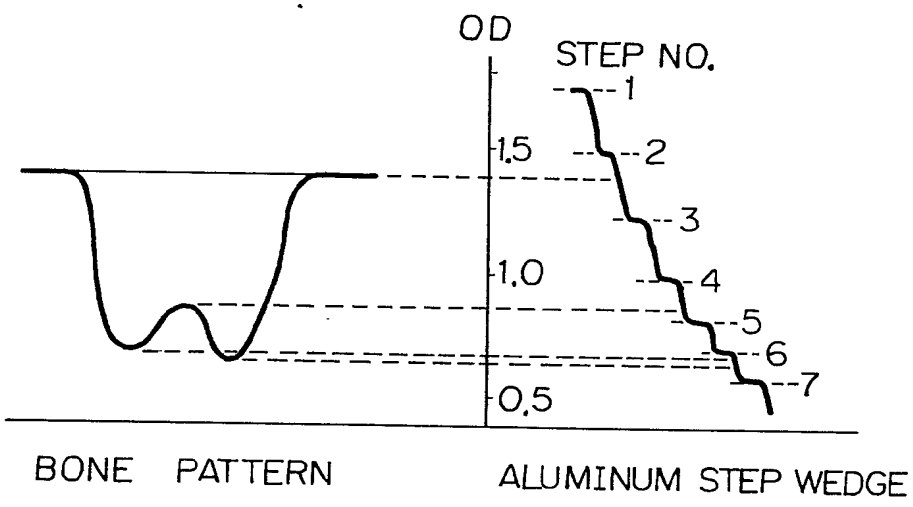
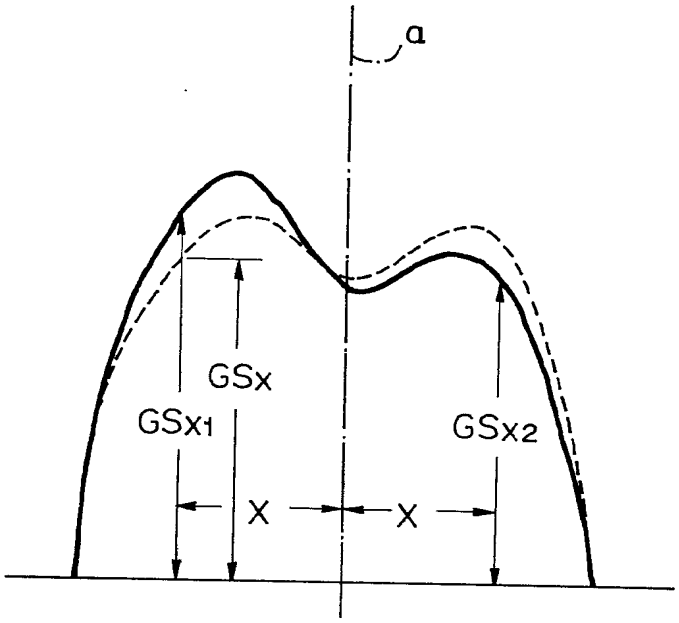


Fig. 2



$$GS_X = \frac{GS_{X1} + GS_{X2}}{2}$$

Fig. 3

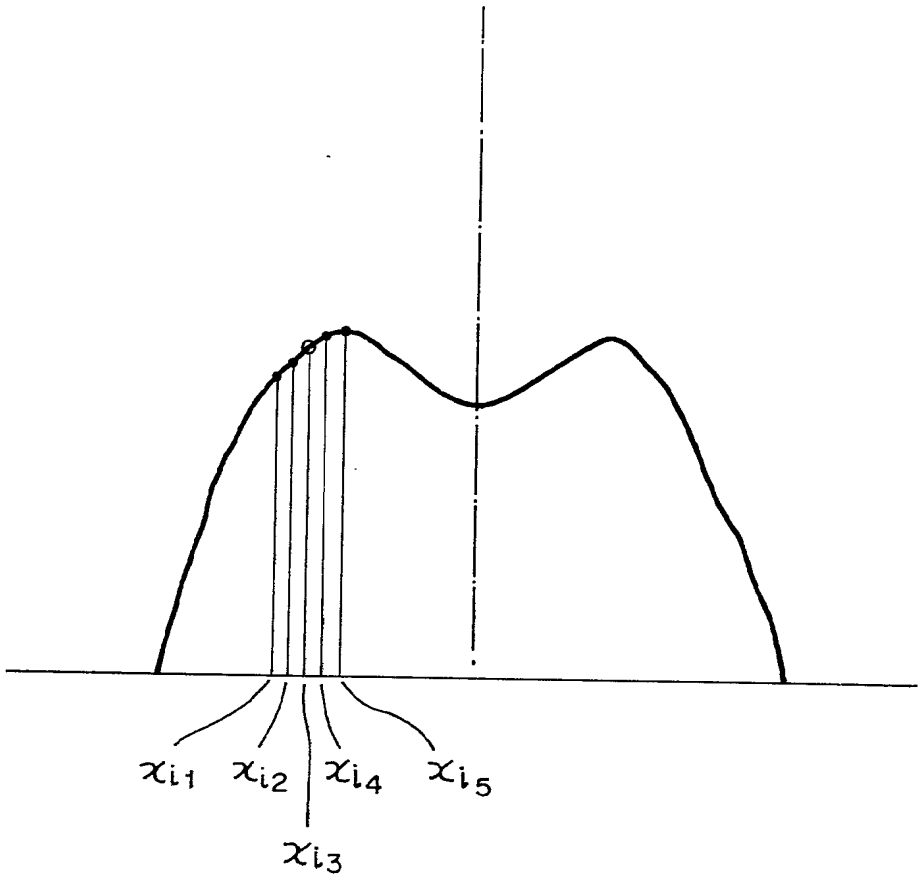


Fig. 4

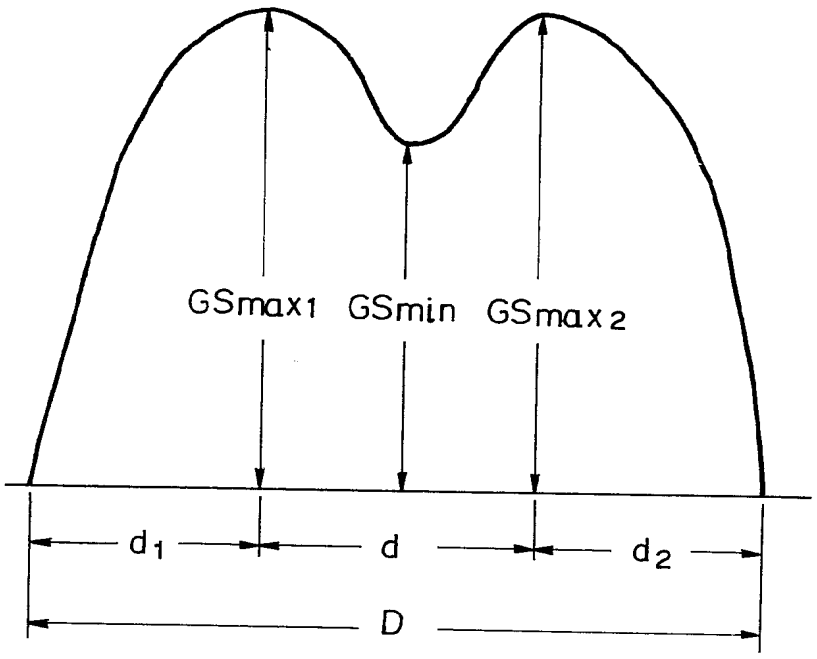


Fig. 5

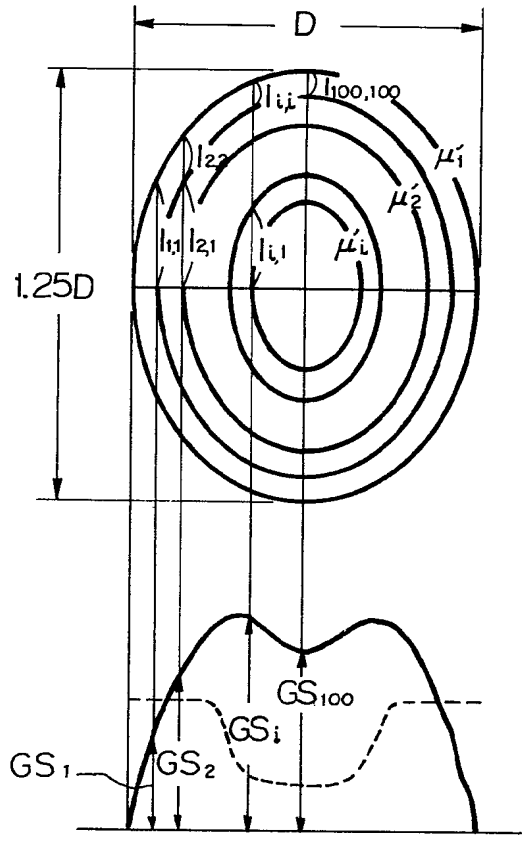
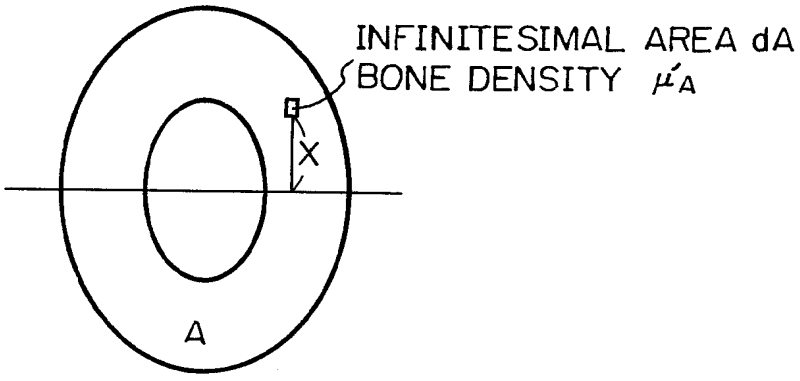

D
1.25D
$l_{i,i}$
$l_{100,100}$
$l_{2,2}$
$l_{1,1}$
$l_{2,1}$
$l_{i,1}$
μ'_1
μ'_2
μ'_i
GS_{100}
GS_i
GS_1
GS_2

Fig. 6a

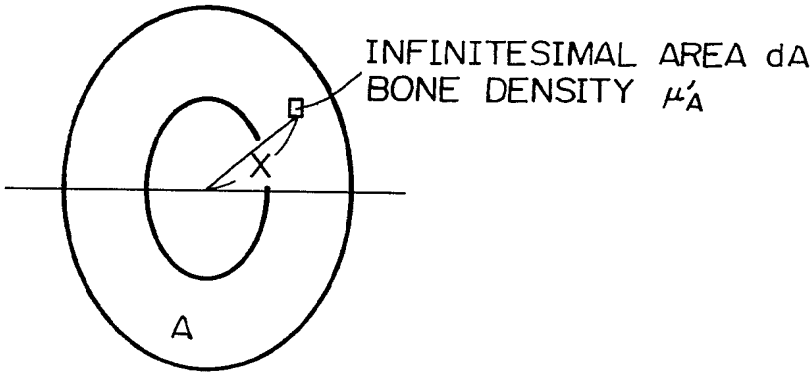
CROSS-SECTIONAL QUADRATIC MOMENT



$I = \int_A \mu'_A X^2 dA$

Fig. 6b

CROSS-SECTIONAL QUADRATIC POLAR MOMENT



$I = \int_A \mu'_A X^2 dA$

Fig. 7a

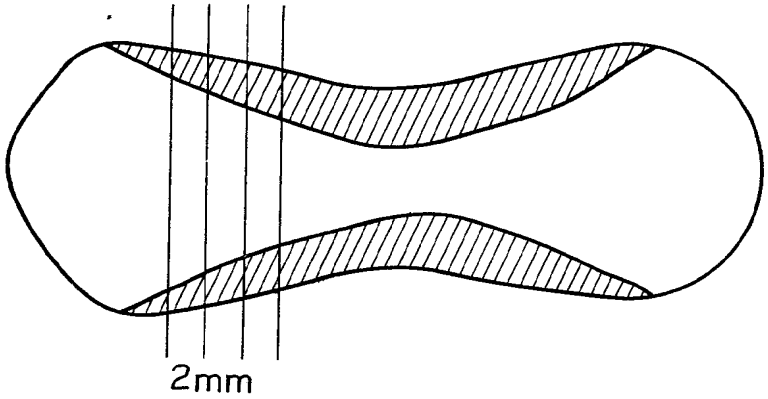


Fig. 7b

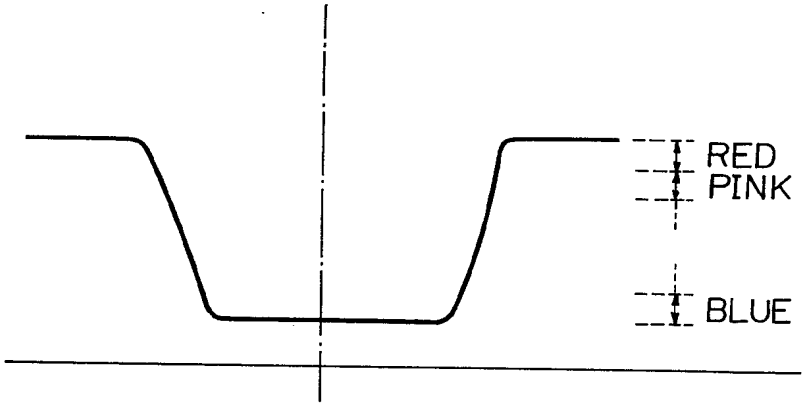


Fig. 7c

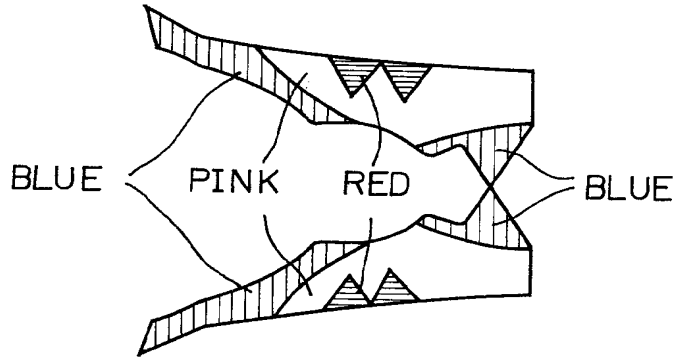


Fig. 8a

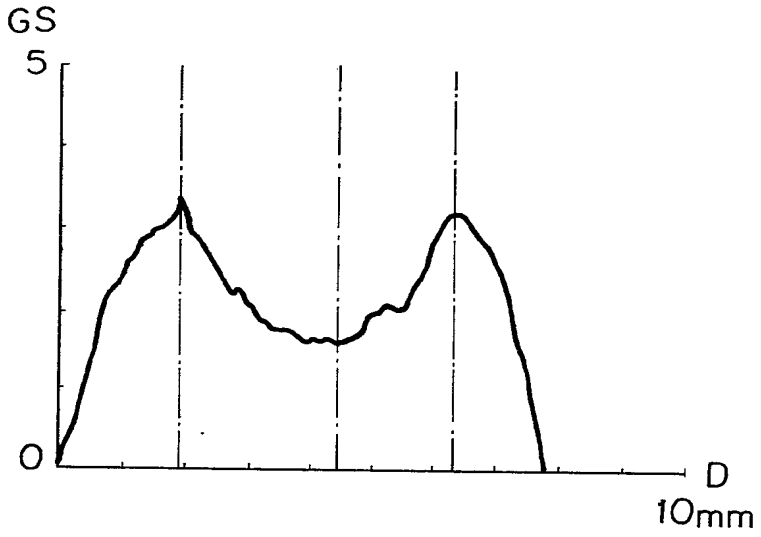
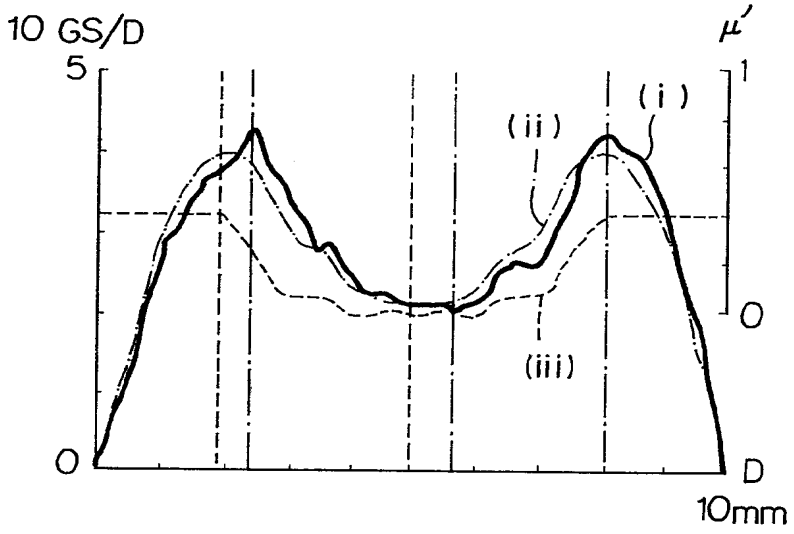


Fig. 8b



D3

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(54) Method and apparatus for improving the alignment of radiographic images.

(57) In a diagnostic process in which two images are made on an image recording medium of the same structure at the beginning and the end of a time interval during which the structure changes, a method is provided for permitting a computing device to improve the alignment of the images as reproduced in the form of pixels on a monitor screen. A particular spatial pattern of marker elements is provided, when each of the images is made, in a particular juxtaposition to the structure being imaged, so that the shadows of the elements arise on the respective images. The computing device can then rotate, translate and alter the scale of one image with respect to the other until the shadows of the elements on one image coincide as closely as possible with those on the other image.

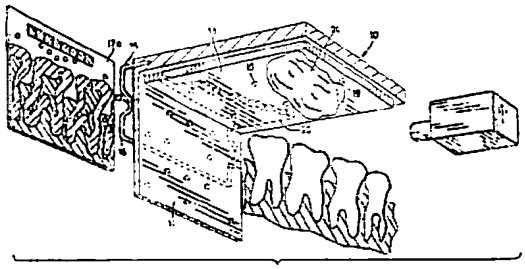


FIG 4

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Bundesdruckerei Berlin

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Description

METHOD AND APPARATUS FOR IMPROVING THE ALIGNMENT OF RADIOGRAPHIC IMAGES

This invention relates generally to the field of radiology, and has to do particularly with a method and apparatus for improving the alignment of radiographic images taken at different times of the same tissue structure, so that the images can be sequentially shown in aligned condition, whereby changes in the structure can be noted.

The present invention will be described specifically in connection with dental radiology and its use in determining on-going structural changes in teeth and related structures (such as remineralization). However, it will be understood from what follows that the principles of this invention could be applied in other areas.

It is known to utilize a computer to carry out densitometric analyses of standardized radiographs taken of the same tissue structure at different points in time, in order to detect tissue change. For example, in the dental area it is known to compare radiographs of the same tooth structure taken at different times, in order to detect remineralization in the teeth or lesions in the periodontal tissue. One technique utilized in this procedure is called subtraction radiography, wherein a computer will digitize two standardized radiographs of the same structure taken at different times, and then subtract the one from the other. If the two radiographs are identical, the result will be a uniform picture with no apparent detail. However, if the radiographs differ, for example at anatomical locations which have changed between the exposures, then the subtraction image will exhibit a different density (grey level) than the background. The above principles are well understood, and form part of the prior art. Reference may be made to an article entitled "Subtraction Radiography and Computer Assisted Densitometric Analyses of Standardized Radiographs", by Ortman et al, published in the Journal of Periodontal Research, 1985: 20:644-651.

Thus, it will be understood that, when wishing to compare radiographic images taken at different times of the same dental structure for the purpose of following changes in the structure, the ideal situation is that in which both or all of the images are made under precisely the same conditions of exposure. In other words, for every image, the relative positions of the film, the teeth and the source of X-rays would be identical. Moreover, the degree of exposure, the film characteristics, and the intensity of the X-ray source would also have to be the same from exposure to exposure. If this could be achieved consistently, then subtraction radiography could be carried out directly and the information thus generated would be highly reliable.

However, as a practical matter the perfection of alignment is generally not attained. Although a bite block of conventional nature can be utilized to ensure to a large degree that the position of the film with respect to the teeth is consistent from image to image, it will be appreciated that even a slight change in the geometric position of the source of the X-rays from image to image (further or closer, up or down, right or left) will significantly alter the scale or position of the image by an amount sufficient to interfere with analysis of structural changes by the technique of subtraction radiography. Furthermore, where the film is improperly inserted into the bite block, sequential images can be mutually rotated even where the source of the X-ray is precisely the same.

Conventionally, attempts have been made to overcome the alignment problem by utilizing external beam-image receptor alignment devices that are very cumbersome and problematic to use. Reference may be had to an article by McHenry et al, entitled "Methodological Aspects and Quantitative Adjuncts to Computerized Subtraction Radiography", published in the Journal of Periodontal Research 1987; 22: 125-132. Even with such devices, however, problems can persist in attaining perfect alignment. For example, problems arising through improper film insertion into a bite block are not overcome by the external alignment devices. And of course, such devices do not address the problem of attaining gray-scale uniformity.

In view of the difficulties and problems outlined above, it is an object of one aspect of this invention to make use of modern microprocessor capabilities to improve the alignment of radiographic images. More specifically, this invention involves the provision of a plurality of marker elements in a specific, repeatable spatial juxtaposition with respect to the animal tissues being investigated (for example the teeth), such that the radiographic images contain the shadows of the marker elements. The radiographic images thus produced are converted to arrays of pixels and stored electronically. Each pixel has a pair of geometric coordinates and also an index number identifying its grey level. The microprocessor or computing device then operates on one of the pixel arrays by first identifying the shadows of the marker elements, and then bringing the geometric coordinates of the marker element shadows on one array into substantially overlying relationship with the geometric coordinates of the marker element shadows on the other array, using translation, rotation, scaling up, scaling down, differential scaling, or a combination of these spatial transformations. By incorporating an aluminum step wedge in association with the marker elements, such that the image of the step wedge also appears on the radiograph, the computer can internally adjust the gray-scale of the various pixels in order to balance the shading in the different radiographs. This is carried out in two separate processes. First, the complete images are corrected for differences in contrast using either a pseudosigmoidal function or other parametric functions or non-parametric approaches. Then, the images of the steps of the wedge are used to construct a calibration curve to convert levels of radiographic density into equivalent weights of hydroxyapatite mineral of bone. In this

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way, changes in radiographic density can be converted into equivalent changes in bone density. Any structural changes can then be determined by subtraction radiography carried out by the computer.

Even more particularly, this invention provides a method for investigating changes in animal tissues, comprising:

at a first point in time, providing a plurality of marker elements in a specific, repeatable spatial juxtaposition with respect to the tissues, and making a first image of the tissues by exposing a first recording medium to radiation that has first passed through both the tissues and the marker elements, whereby the shadows of the marker elements appear superimposed on the first image of the tissues,

at a later point in time, providing the same plurality of marker elements in substantially the same specific, repeatable spatial juxtaposition with respect to the tissues, and making a second image of the tissues by exposing a second recording medium to radiation that has first passed through both the tissues and the marker elements, whereby the shadows of the marker elements appear superimposed on the second image of the tissues,

converting the first and second images to first and second arrays of pixels and storing the pixel arrays electronically in a memory means, wherein each pixel has a pair of geometric coordinates and also an index number identifiying its grey level,

using a computing device to improve the alignment of one array of pixels with respect to the other, wherein the computing device identifies the shadows of the marker elements in the two pixel arrays, and operates on one array in such a way as to bring the geometric coordinates of the shadows on one array into the closest possible coincidence with the geometric coordinates of the shadows on the other array, by causing said one array to undergo one or more of the operations of:

a) translation,

b) rotation,

c) scaling up,

d) scaling down,

e) differential scaling, storing the improved pixel array electronically in the memory means,

and assessing the intensity difference between pairs of corresponding pixels in the improved array and the said other array to determine whether tissue change is indicated.

Further, this invention provides, for a diagnostic process in which two images are made on an image recording medium of the same structure at the beginning and the end of a time interval during which the structure changes, a method of permitting a computing device which electronically stores the images to improve the alignment of the images as reproduced in the form of pixels on a monitor screen, each pixel having a specific grey level, the method comprising providing, when each of the images is made, a particular spatial pattern of marker elements in a particular juxtaposition to said structure so that the shadows of the elements arise on the respective images, whereby the computing device is enabled to rotate, translate and alter the scale of one image with respect to the other until the shadows of the elements on one image coincide as closely as possible with those on the other image.

Finally, this invention provides, for a diagnostic process in which two radiographic images are made on radiographic film of the same human tissues within or close to the teeth at the beginning and the end of a time interval during which tissue change occurs, a bite block for permitting a computing device which electronically stores the images to improve the alignment of the images as reproduced in the form of pixels on a monitor screen, each pixel having a specific grey level, the bite block registering repeatably with the same teeth of a given person and incorporating a specific spatial pattern of marker elements whereby when the bite block is held between the given person's teeth the elements will have a specific and repeatable juxtaposition with respect to the dental structure and the shadows of the elements will arise on the respective radiographic films, thereby enabling the computing device to rotate, translate and alter the scale of one image with respect to the other until the shadows of the elements on one image coincide as closely as possible with those on the other image.

One embodiment of this invention will be described with reference to accompanying drawings, in which like numerals denote like parts throughout the several views, and in which:

Figure 1 shows a side view and top view of digitizing apparatus for use with the method of this invention;

Figure 2 is a perspective view of a bite block for use with this invention;

Figure 3 is a cross-sectional view through the bite block shown in Figure 2, also illustrating the position of teeth with respect to the bite block;

Figure 4 is an exploded view showing the X-ray source, several teeth, the bite block of Figure 2 (inverted) and a piece of X-ray film;

Figure 5 is a face view of an exposed processed film in accordance with this invention;

Figures 5(a), (b) and (c) represent, respectively, a pre-lesion X-ray image, a post-lesion X-ray image, and a subtraction image made after spatial and intensity alignment; and

Figures 6 through 10 contain logic flowcharts giving an overview of the program steps carried out in connection with this invention.

As has been explained above, the aim of this invention is to provide a means of recording markers on diagnostic images so that images obtained on successive occasions may be analyzed and operated on by a computer or microprocessor in order to provide accurate alignment of the separate images through calculations performed by the computer. In addition to the alignment function, however, the computer can also be utilized to enhance the images, and to carry out a diagnostic analysis of the image in order to provide evidence of and quantification of changes or differences between the successive images.

Essentially, the markers are placed on the diagnostic images by interposing a plurality of marker

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elements in the beam of a diagnostic imaging system, in such a way that the shadows of the markers are recorded on the image of the anatomical structures that are of diagnostic interest. These marker images or shadows provide a permanent record, in the image, of the positional relationship between (1) the source of the diagnostic radiation for the imaging system, (2) the anatomical structures of interest, (3) the markers themselves, and (4) the recording medium for the diagnostic image.

It is important to understand that the source of the diagnostic radiation for the imaging system can take a number of forms not restricted to diagnostic dental X-rays. Any imaging system will be able to carry out the principle of this invention so long as an image of the markers is formed by the system.

While dental X-ray film is described below in connection with the specific embodiment disclosed in the drawings, it is well known to form images xerographically or even directly in the electronic components of a camera system which is sensitive to diagnostic radiation without the intermediate step of forming an image on X-ray film.

It is further to be understood that the use of markers is of general application in the head and neck region, and is not restricted to intra-oral use. Indeed, the basic principle of this invention (as set out in claim 1, for example) is not even restricted to human or animal tissues. The principle can be applied in any structure which evidences change over a time interval and of which images can be made by passing radiation through it or reflecting radiation off it (e.g., the markers could be white dots on an engine part, imaged conventionally). In the case of the human being, the teeth can be used as fixed reference points for extra-oral as well as intra-oral diagnostic imaging. Other fixed points of the skeleton of the head, such as the oral meati and the bridge of the nose, can also be used as reference points.

Turning first to Figures 2, 3 and 4, a bite block 10 constructed in accordance with this invention includes a clamp portion 12 which is connected to a wall 14 extending substantially perpendicularly therefrom. Embedded in the end of the clamp portion 12 which is connected to the wall 14 are the two ends 15 of a film clip 16. The film clip 16 includes a substantially rectangular loop of wire having two portions 17 which are offset toward the wall 14, in order to grip a film holder. In Figure 3, the film itself is shown at 17a, but of course it will be understood that the film must be protected from exposure to light up to the point of its development. For this purpose, a standard plastic envelope would typically be provided, of a kind well known in the art. Thus, the offset portion 17 of the film clip 16 would press the film envelope against the back of the wall 14, thus holding the film 17a itself in close juxtaposition with the back of the wall 14.

The clamp portion 12 has a further layer 18 superimposed thereon, the purpose of the layer 18 being to contain a plurality of reference balls 19, and a step wedge 20. The step wedge is a block of aluminum cut into discrete steps which present a radiographic "face" of 1, 2, 3, 4...8 mm thickness, forming (roughly) equal-shaped and equal-sized squares on the image. Additional reference balls 22 are embedded in the wall 14, the pattern being well seen in Figures 2 and 4.

Also shown in Figures 2 through 4 is a quantity of bite impression material 24 which is of conventional nature and well known in the art. This material is placed on the layer 18 in a somewhat plastic condition, whereupon the patient bites the bite block, holding the teeth in contact with the material 24 until the latter has set. This leaves an impression of the specific teeth in the material 24, which permits the bite block to be precisely relocated in clamped position between the patient's teeth for a series of subsequent X-rays. Thus it will be appreciated that the bite block shown in Figures 2-4 allows for the reference balls 19 and 22 to have a specific and repeatable juxtaposition with respect to the same dental structure (teeth and periodontal tissues), and the shadows of the balls 19 and 22 will appear on each radiographic film 17a. The balls 19 and 22 are preferably of lead, although any material could be used, so long as it left a clearly discernable shadow on the radiographic film.

It will thus be appreciated that, by preparing two radiographic images on suitable film or other medium at the beginning and the end of a time interval during which the tooth structure changes (for example by remineralization, lesion or decay), it will be possible firstly to convert each image to an array of pixels each having a specific geometric position and a specific grey level, whereby a computer or microprocessor will be enabled to rotate, translate and/or alter the scale of one image with respect to the other until the shadows of the marker elements on one image substantially coincide with those on the other image.

Digitizing

To carry out the analog-to-digital conversion of each X-ray image, an apparatus was constructed for mounting the three principle components used in this process: 1. a standard (Kodak) carousel slide projector fitted with a macro-focus lens; 2. a sheet of neutral-density acetate stretched on a frame, with guide runners; and 3. an Electrohome black-and-white video camera connected to the controlling minicomputer. Seen in Figure 1, the apparatus is designed as an optical "bench" of sorts, with a projector 30 and camera 32 being fixed in position at opposite ends of the apparatus, and a display screen 34 movable along the projector-camera axis.

Each X-ray is mounted in a glass photographic slide and displayed as a 20 cm wide by 15 cm tall image back-projected on the acetate screen 34 positioned approximately 40 cm in front of the slide projector 30. In this way, the displayed size and focus of each projected image may be controlled by any manipulation of the lens controls of the projector or camera, and the positioning of the projection screen between the two devices.

Each image is digitized as a 512-row and 512-column matrix of values with a range of 0 to 255. At this resolution, it appears that the limiting step in the imaging process is the actual exposure of the

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radiographic film and the photographer's abilities and method. Two sources of variation appear to account for the majority of difficulties encountered with current clinical methods, each of which arises from the susceptibility of film radiography to errors produced by human users in a situation that does not lend itself readily to any form of controlled automation (technologically and socially). Variations in patient, film and camera positioning from exposure to exposure, and the requirements for such accurate positioning posed by the process of imaging a small area with a large device from a distance ensure that comparison of images taken at separate times (over years), by separate radiographers will be very difficult. Secondly, small (random) variations in the X-ray beam voltage on exposure, film quality and post-exposure processing induce variations in both the overall intensity and the relative distribution of the 256 possible levels of intensity that can further obscure small changes in tissue between exposures.

Image Processing

Three software processes have been developed for use with pairs of images, in order to: 1. correct spatial transformations of the tissues imaged radiographically as would be evident if the two images were superimposed (spatial alignment), 2. correct brightness and contrast differences due to the above spatial transformations and fluctuations in the radiographic beam intensity, film and processing quality (intensity alignment), and 3. compare two images which have been equalized by the above two processes so as to detect differences between them. The software interface involves the use of a video terminal and keyboard, and a monochrome graphics display and "mouse" pointer. Each process is described below, along with its associated hardward and software.

Spatial Alignment

Hardware

Spatial alignment involves matching of reference points on corresponding areas of each image so that tissue structures that remain constant (evident) on two images may superimpose exactly, or with as little error as possible. Radiographic images provide poor reference markers, as they present indistinct structural features and boundaries, which are unreliable and sensitive to camera positioning error. The alignment process described earlier introduces non-tissue markers that provide sharp, constant reference points with a marker-tissue spatial relationship that can be controlled.

As described earlier, the reference markers preferably consist of lead balls that have been embedded in two perpendicular planes of a bite block modified from those currently used to hold the radiographic film during exposure. Lead is used for maximum density, and balls are used for transformation invariance. (see Figures 2 and 3). The X-ray "shadow" produced by the balls is in effect superimposed on that produced by the imaged tissues, as seen in Figure 5, and thus can serve as artificial reference points that can be used for all exposures of the tissues of interest providing that the relationship between the reference markers and the underlying tissue is maintained for all exposures (i.e., the bite block must be seated on the same teeth in the same position).

In practice, a patient would be fitted with a bite block (or several) at the time of first consultation which would be used for all exposures of the tissues of interest (for which they were first employed). As described, the soft impression of the biting surface of the teeth to be imaged permits accurate positioning on the teeth, to maintain a constant marker-tissue relationship. The spatial arrangement of the reference points allows the best empirical alignment possible with the software algorithm used, appearing as white disks forming two concentric rectangles surrounding the region of interest (see Figure 4). We currently use a ball diameter of 1/32 inch.

Software

Once the reference and comparison images are digitized, the alignment process consists of three stages: 1. selection of reference points, 2. alignment of reference points on one image to the corresponding points on the other and, by this, all other image points, and 3. repair of image "fractures" caused by the transformations required to accomplish the alignment. Three separate software programs perform the separate stages, although they could be combined into one larger program.

Because the balls present a well-known radiographic appearance, they can be selected with ease by an operator equipped with a mouse pointer that controls a cursor on the monochrome display screen. The operator indicates (with a crosshair cursor) the centre of each reference marker to be used, and the coordinates of the selected point are stored. The sequence of markers selected must remain the same for both images, although there is no empirical effect of overall selection order.

Once reference markers have been chosen, and their spatial coordinates known, the process of alignment is started with the determination of the coordinate differences between each corresponding pair of points. Each difference (along X and Y) is squared and summed and presented to a curve-fitting algorithm that tries to minimize this difference by iterative modifications (transformations) applied to the to-be-matched (TBM) image's reference marker coordinates. The transformations used involve application of (fixed and predetermined) sequences of trigonometric functions to the TBM coordinate values, so as to produce translations along the X- and/or Y-axes, rotations around X-, Y- or Z-axes, and dilation or contraction of the X- and/or Y-axes (see Table 1). The algorithm applies differing amounts of each transformation in turn, and terminates when the lowest possible global image difference is determined (as measured by the sum of squared differences between reference-image marker and TBM-image marker centre coordinates). The parameters used for this "optimal" sequence of transformations are stored and applied to every point on the TBM image. In essence, the program

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determines the best way to shift, rotate, expand or contract the TBM image, so that its markers best superimpose on those of the "standard" image and then apply these operations to every other point on the TBM image.

Table 1: Alignment models tested Each model is composed of two or three successive transformations:

Model 1:

(1) Translation along X- and Y-axes
(2) Rotation around Z-, Y-, and X-axes

Model 2:

(1) Translation along X- and Y-axes
(2) Rotation around Z- and Y-axes
(3) Dilation (size change) of X- and Y-axes

Model 3:

(1) Perspective transformation with manipulation of
- viewing projection, and
- projection plane
(2) Rotation around Z-, Y-, and X-axes

Model 4:

(1) Translation along X- and Y-axes
(2) Dilation (size change) of X- and Y-axes
(3) Rotation around Z-axis

Because of limits on computational precision and image resolution, and differences in camera distancing from the tissues, the transformed image may contain regions for which no discrete transformed point can be calculated. For example, a TBM image that is smaller than the reference (or initial) image will require fractional expansion for proper alignment, and the floating-point coordinates used to represent each new image coordinate pair are rounded up or down to the nearest integer for display. This error would appear as a pattern of no-intensity horizontal, vertical and/or diagonal lines (solid or broken) of one unit width superimposed on the transformed image. For all transformations performed to-date (and those expected), these lines can be easily removed by writing to each no-intensity point the average of its (up to eight) nearest non-zero neighbors.

Once the spatially-transformed image has been computed, it can be stored in place of the TBM image, as it will represent the best spatial fit of that image to the reference image. The pair of images to be compared can then be further manipulated for purposes of enhancement (perhaps to increase contrast or definition), or in some cases may be amenable to immediate comparison. It has been found, however, that an additional source of image differences, unrelated to pathological differences and resulting from inadequacies in the technology and practice of film-screen radiography, often necessitate an additional stage of image equalization before proper comparison and measurement may be performed.

Intensity Alignment

Software

After spatial alignment, and before comparison, images must be equalized for variations in exposure duration, film response, and processing controls. One program controls this alignment stage with little operator intervention. The frequency distribution of intensity levels of each image is calculated and converted into a relative frequency distribution. These distributions in turn can then be converted into probability density functions for each image by calculating a cumulative frequency distribution. The probability density function determined for each image can then be transformed to fit an "ideal" (specified) distribution, and the image's new frequency distribution can be reconstituted. Currently, the ideal distribution is a pseudo-sigmoidal function with those image points in the top or bottom 5% of the frequency distribution set to their respective extremes, and the intermediate 90% of the distribution fit to a linear function with a slope of 1 (see Figure 5). An alternate distribution currently being tested is the gamma probability density function, which, when its parameters are set appropriately, assumes a shape much like that found empirically with X-ray images (i.e., a positively-skewed quasi-normal distribution of positive values), and thus can effect an initial, equalizing, fit with fewer and smaller intensity-value transformations than distributions with other forms.

Once this final phase of image equalization has been accomplished, the two images can be compared with a minimum of non-pathological image difference. Other operations can also be enacted on the images prior to comparison. Further intensity distribution manipulations may be used to highlight selected corresponding regions on each image (e.g., fitting to normal, exponential or sigmoidal curves). Image "definition" may be enhanced to show detail, or reduced to remove "grain".

Image Comparison

Subtraction of one image from another is the most straightforward process by which images can currently be compared. An informal method, involving rapid display of each of a pair of images in succession, can be used for an initial and easily-recognized visual identification of obvious differences. For quantifiable differences, however, more sophisticated methods must be employed, and this display-oriented method will not be discussed further.

One central subtraction method is currently used to perform all comparisons (on pairs of images), although several analytic software routines are available to provide parameters controlling the subtraction operation. As was done for the spatial alignment transformations, a "reference" image is selected; for comparison, the oldest of a pair of exposures would usually be considered for this role. The intensity of each comparison-image point is subtracted from the intensity of its corresponding

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point in the reference image.

The subtraction produces at each point one of three classes of values: positive, negative and zero indicating, respectively, tissue gain, tissue loss, and no tissue change (see Figure 6). The resulting "difference" image can be displayed directly (as an image of absolute differences) or coded to reflect the result of the subtraction at each point, with tissue gain appearing as high intensity (white), loss appearing as low intensity (black) and no change appearing as medium intensity (grey). Because the image equalizations performed are still subject to operator error or calculation and display limits, a certain margin of error remains that may hinder measurement of true differences. For this reason the subtraction process can be constained by limits on the amount of numeric difference between subtracted points that is considered acceptable and to be ignored by the measurement software.

Several methods can be used to determine those intensity changes that are considered to be non-significant and, conversely, those that exceed a particular threshold. The simplest, and thus first introduced, method will involve operations on the distribution of image-pair differences resulting from subtraction (centered on 0 and ranging from 0-255 positively and negatively): specifically, the use of the distribution's standard deviation (or 5th and 95th percentiles) to determine the upper and lower thresholds for "difference".

Measurement of Change

Once suitable limits on point differences have been established, only those pairs of image points that are found to differ "significantly" (gain or loss) will be considered for further analysis. It is expected that further enhancement will be required to constrain the search for significant differences to specific image regions, and to exclude areas of difference smaller than those of clinical interest (e.g., scattered unitary points).

Once the final regions of difference have been localized, their absolute difference can then be related to a recognized measure of tissue density. The step-wedge located at the top of each image can be used as a reference density with which all pathological tissue densities can be compared.

The operator, again using the mouse pointer and the screen cursor as for spatial alignment, selects the center of each grey square presented by the step-wedges of the reference and TBM images. The average of all intensities in a N x N unit square centered on the point selected by the operator is used as the intensity value of the selected point. This averaging is performed to remove noise introduced by the film's grain, and minimize intensity variations remaining after all equalizing transformations.

Once all points have been chosen, a mean value for each step-wedge density is calculated from the values presented by each image, and these values are used to determine the particular function that characterizes the relationship between step-wedge density and resulting intensity level. When this function (and its parameters) have been determined, the mean difference of the area or areas that have been marked as significantly different is then translated into a specific density of aluminum. A standard empirical relationship can then be used to translate the aluminum-density value into a value of hydroxyapatite-density, a widely-used density metric.

In Figure 5, the exposed processed film shows the shadows 40 of the lead reference balls, along with the skeletal bone 42, the individual teeth 44, and the image of the step-wedge 46.

In Figure 5, part (a) is a pre-lesion radiograph, and part (b) is a post-lesion radiograph. In the image (b), a first arrow 50 points to the bottom edge of the image, above which a demineralization location is found about one third of the way up. The arrow 52 shows a remineralization location, again about one third of the way up.

Figure 5 (c) shows an idealized subtraction image, where the black portion 54 indicates loss of tissue, whereas the white portion 56 shows tissue gain. The remainder of the image (c) shows no change.

Claims

1. For a diagnostic process in which two images are made on an image recording medium of the same structure at the beginning and the end of a time interval during which the structure changes, a method of permitting a computing device which electronically stores the images to improve the alignment of the images as reproduced in the form of pixels on a monitor screen, each pixel having a specific grey level, the method comprising providing, when each of the images is made, a particular spatial pattern of marker elements in a particular juxtaposition to said structure so that the shadows of the elements arise on the respective images, whereby the computing device is enabled to rotate, translate and alter the scale of one image with respect to the other until the shadows of the elements on one image coincide as closely as possible with those on the other image.

2. The invention claimed in claim 1, in which the structure is human teeth, in which the images are radiographic images made on photosensitive film, in which the radiation is X-radiation, and in which the marker elements are separated metallic balls incorporated in a bite block, the X-radiation passing in order through the teeth, the marker elements, and the film.

3. The invention claimed in claim 2, in which at least some of the metallic balls are all substantially in the same plane aligned with the plane of the film.

4. The invention claimed in claim 2, in which a portion of the metallic balls are all substantially in a first plane aligned with the plane of the film, and the remaining metallic balls are positioned in a second plane at right angles to the first

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plane.

5. The invention claimed in claim 2, in which the bite block incorporates an aluminum step wedge to allow the computing device to align the grey scales of the two images.

6. For a diagnostic process in which two radiographic images are made on radiographic film of the same human tissues within or close to the teeth at the beginning and the end of a time interval during which tissue change occurs, a bite block for permitting a computing device which electronically stores the images to improve the alignment of the images as reproduced in the form of pixels on a monitor screen, each pixel having a specific grey level, the bite block registering repeatably with the same teeth of a given person and incorporating a specific spatial pattern of marker elements whereby when the bite block is held between the given person's teeth the elements will have a specific and repeatable juxtaposition with respect to the dental structure and the shadows of the elements will arise on the respective radiographic films, thereby enabling the computing device to rotate, translate and alter the scale of one image with respect to the other until the shadows of the elements on one image coincide as closely as possible with those on the other image.

7. The invention claimed in claim 6, in which said marker elements are metallic balls contained within a fixed portion of the bite block.

8. The invention claimed in claim 6, in which said marker elements are lead balls of which at least a portion are all substantially in the same plane aligned with the plane of the film.

9. The invention claimed in claim 6, in which the marker elements are metallic balls, a portion of the metallic balls being all substantially in a first plane aligned with the plane of the film, and the remaining metallic balls being positioned in a second plane normal to the first plane.

10. The invention claimed in claim 6, in which the bite block incorporates an aluminum step wedge to allow the computing device to align the grey scales of the two images.

11. A method for investigating changes in animal tissues, comprising:

at a first point in time, providing a plurality of marker elements in a specific, repeatable spatial juxtaposition with respect to the tissues, and making a first image of the tissues by exposing a first recording medium to radiation that has first passed through both the tissues and the marker elements, whereby the shadows of the marker elements appear superimposed on the first image of the tissues,

at a later point in time, providing the same plurality of marker elements in substantially the same specific, repeatable spatial juxtaposition with respect to the tissues, and making a second image of the tissues by exposing a second recording medium to radiation that has first passed through both the tissues and the marker elements, whereby the shadows of the marker elements appear superimposed on the second image of the tissues,

converting the first and second images to first and second arrays of pixels and storing the pixel arrays electronically in a memory means, wherein each pixel has a pair of geometric coordinates and also an index number identifying its grey level,

using a computing device to improve the alignment of one array of pixels with respect to the other, wherein the computing device identifies the shadows of the marker elements in the two pixel arrays, and operates on one array in such a way as to bring the geometric coordinates of the shadows on one array into the closest possible coincidence with the geometric coordinates of the shadows on the other array, by causing said one array to undergo one or more of the operations of:

a) translation,

b) rotation,

c) scaling up,

d) scaling down,

e) differential scaling,

storing the improved pixel array electronically in the memory means,

and assessing the intensity differences between pairs of corresponding pixels in the improved array and the said other array to determine whether tissue change is indicated.

12. The invention claimed in claim 11, in which said animal tissues are within or close to human teeth, in which the image is a radiographic image made on photosensitive film, and in which the radiation is X-radiation.

13. The invention claimed in claim 12, in which the provision of the marker elements in a specific, repeatable spatial juxtaposition with respect to the tissues is accomplished by providing a bite block incorporating the marker elements, and arranging for the bite block to be gripped in a reproducible fashion at the same location between the same teeth prior to the making of each radiographic image.

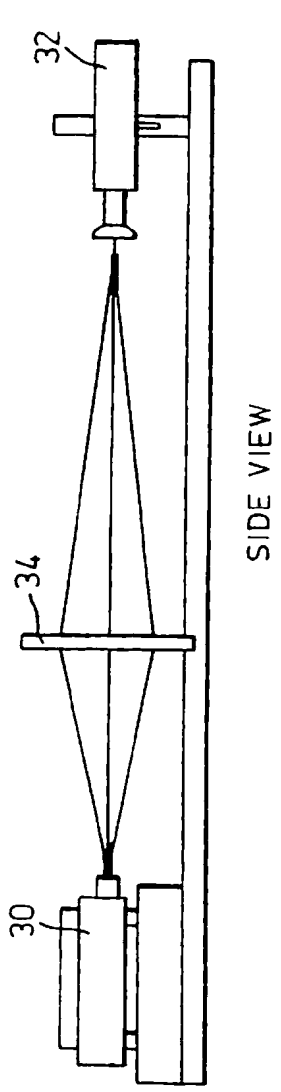
14. The invention claimed in claim 13, in which the marker elements are all substantially in the same plane aligned with the plane of the film.

15. The invention claimed in claim 13, in which a majority of the metallic balls are substantially in the same plane aligned with the plane of the film, and at least one metallic ball is positioned out of the plane of the others.

16. The invention claimed in claim 13, in which the marker elements are metallic balls.

17. The invention claimed in claim 13, in which the bite block incorporates a step wedge, and wherein the computing device utilizes the images of the step wedge on the two pixel arrays to align the grey scales of the arrays.

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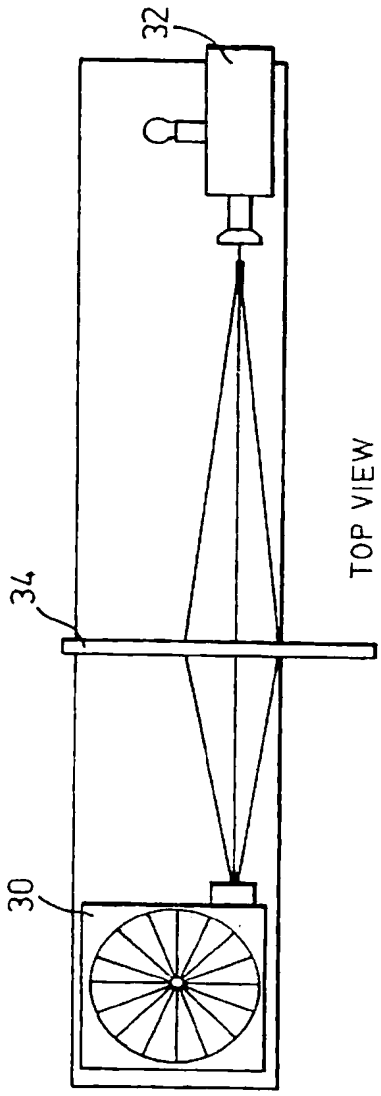


FIG.1

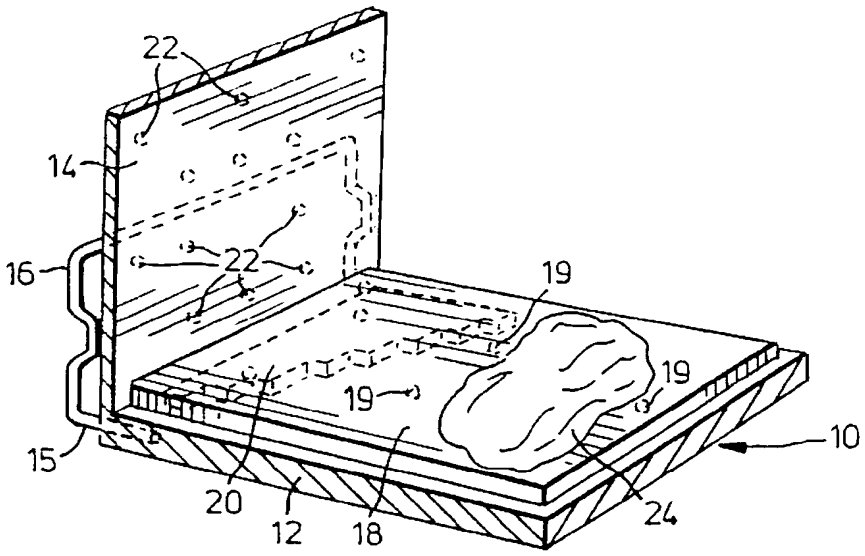


FIG.2

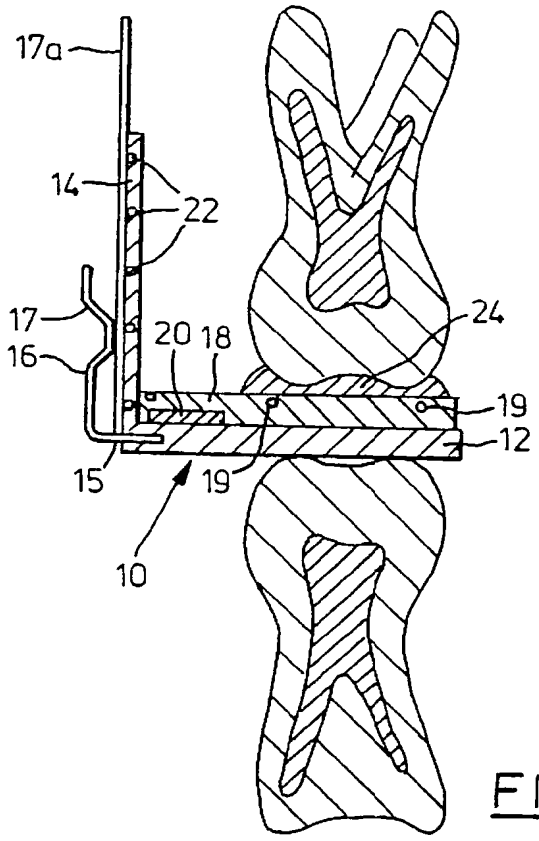


FIG.3

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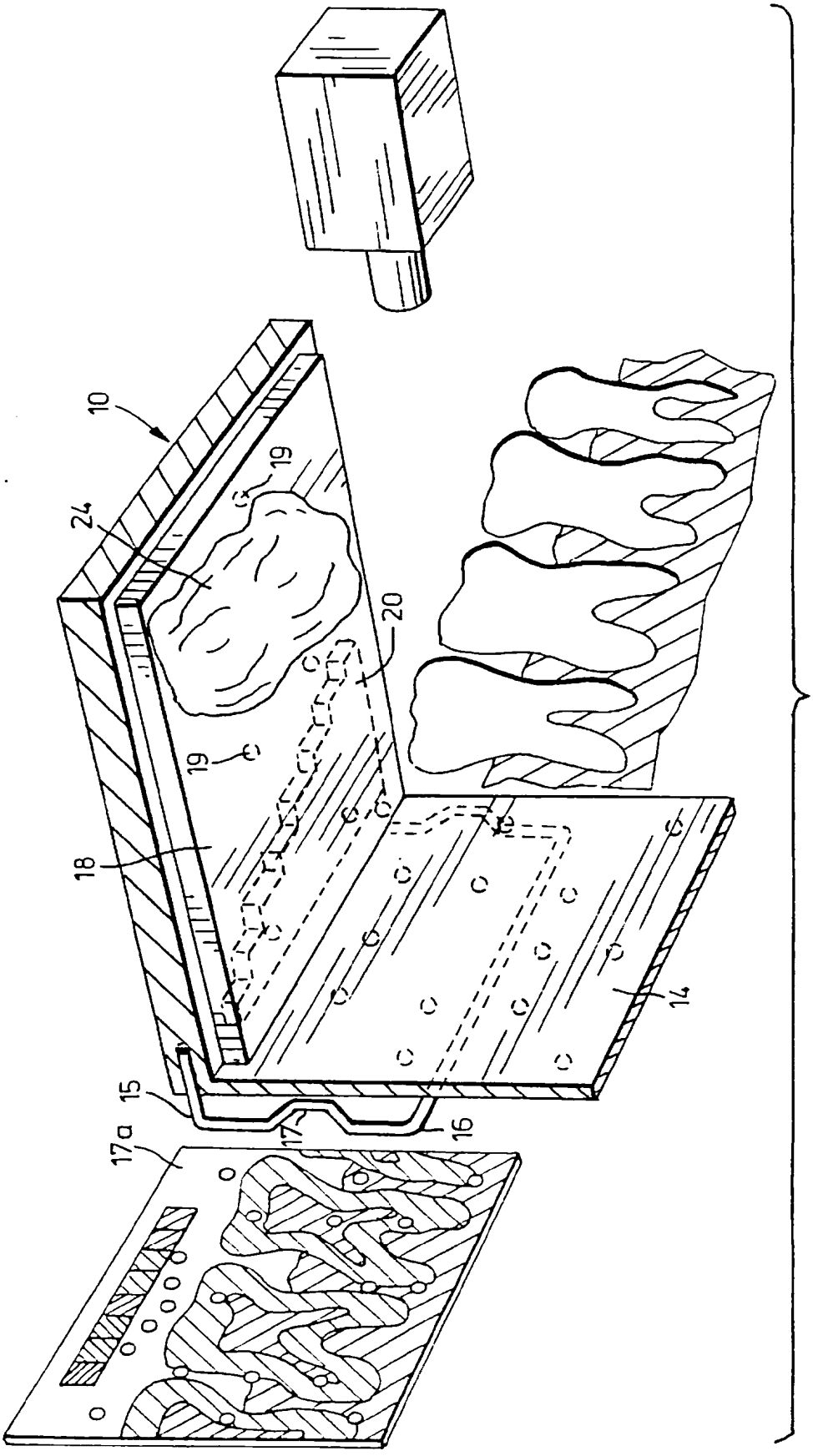


FIG.4

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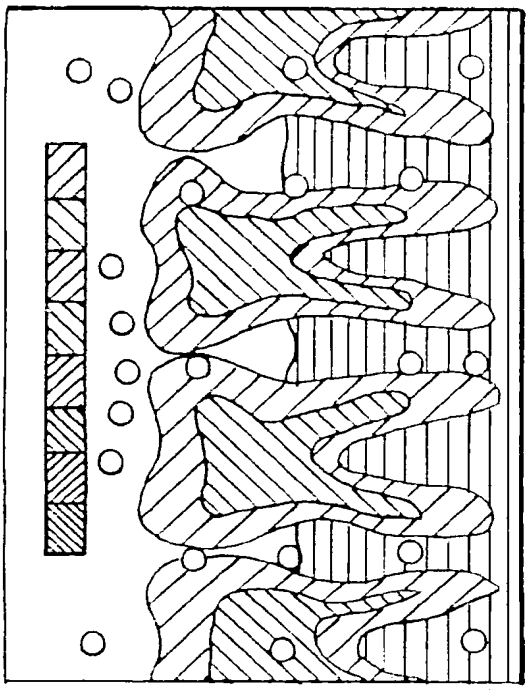


FIG. 5(a) IMAGE 1

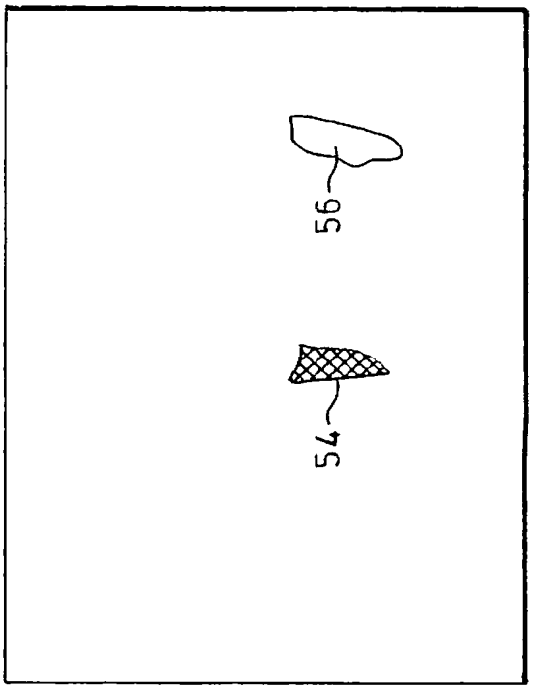


FIG. 5(c) IMAGE 3

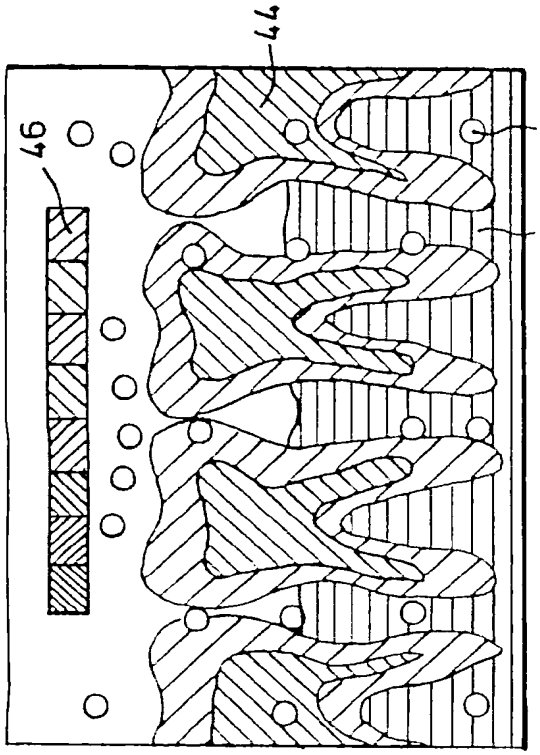


FIG. 5

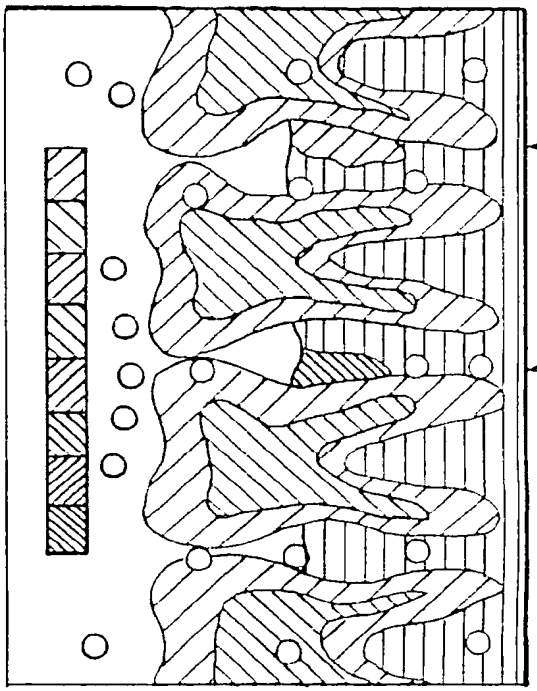
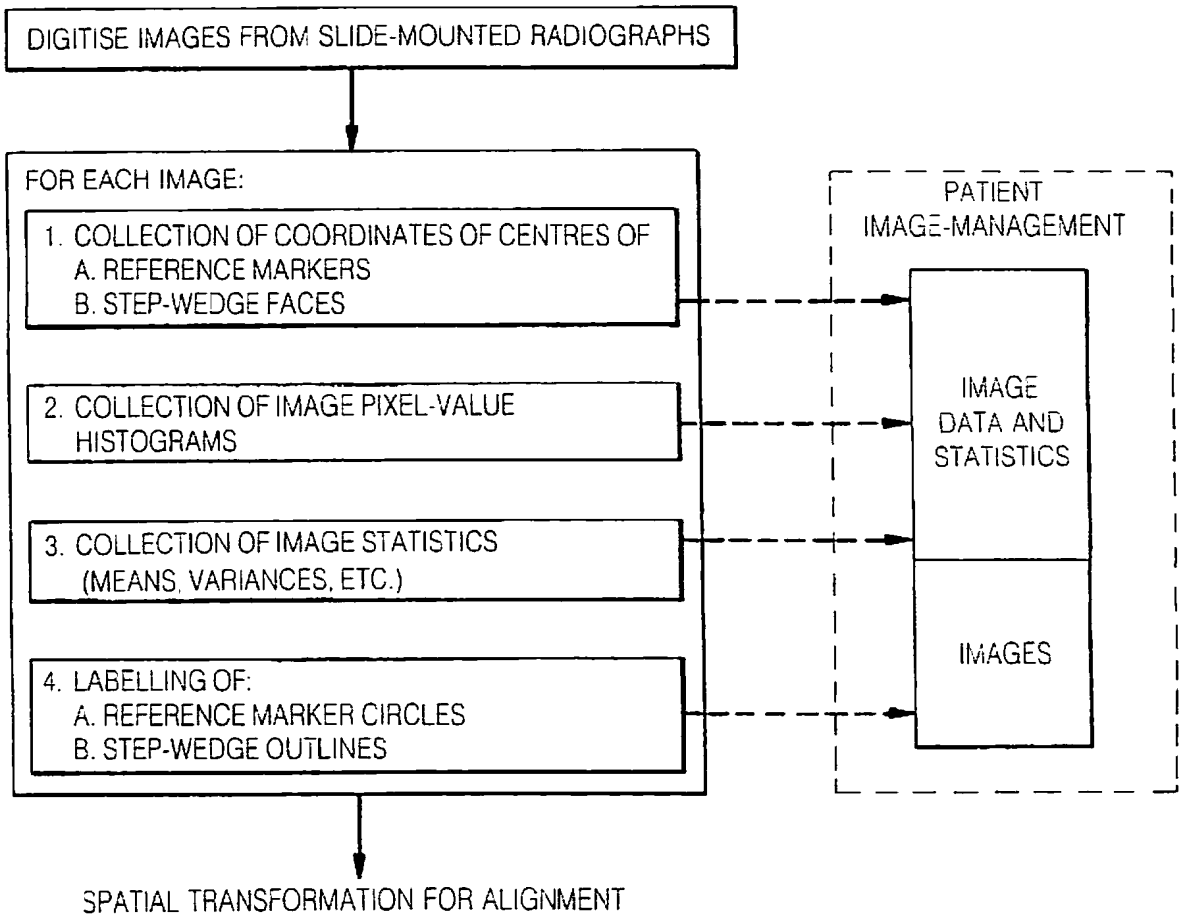


FIG. 5(b) IMAGE 2

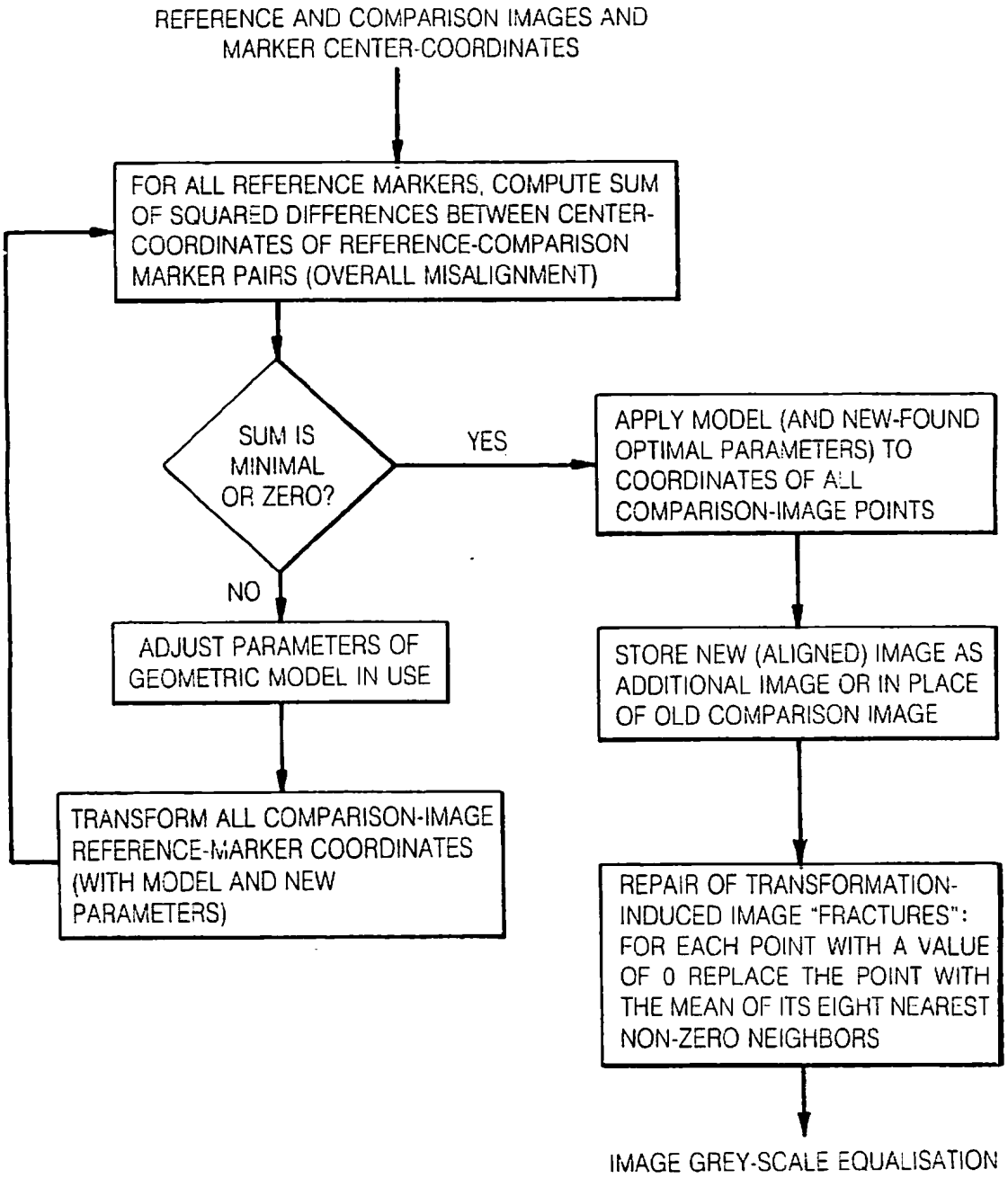
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FLOW-CHART 1: IMAGE DIGITISATION AND CHARACTERIZATION

FIG. 6

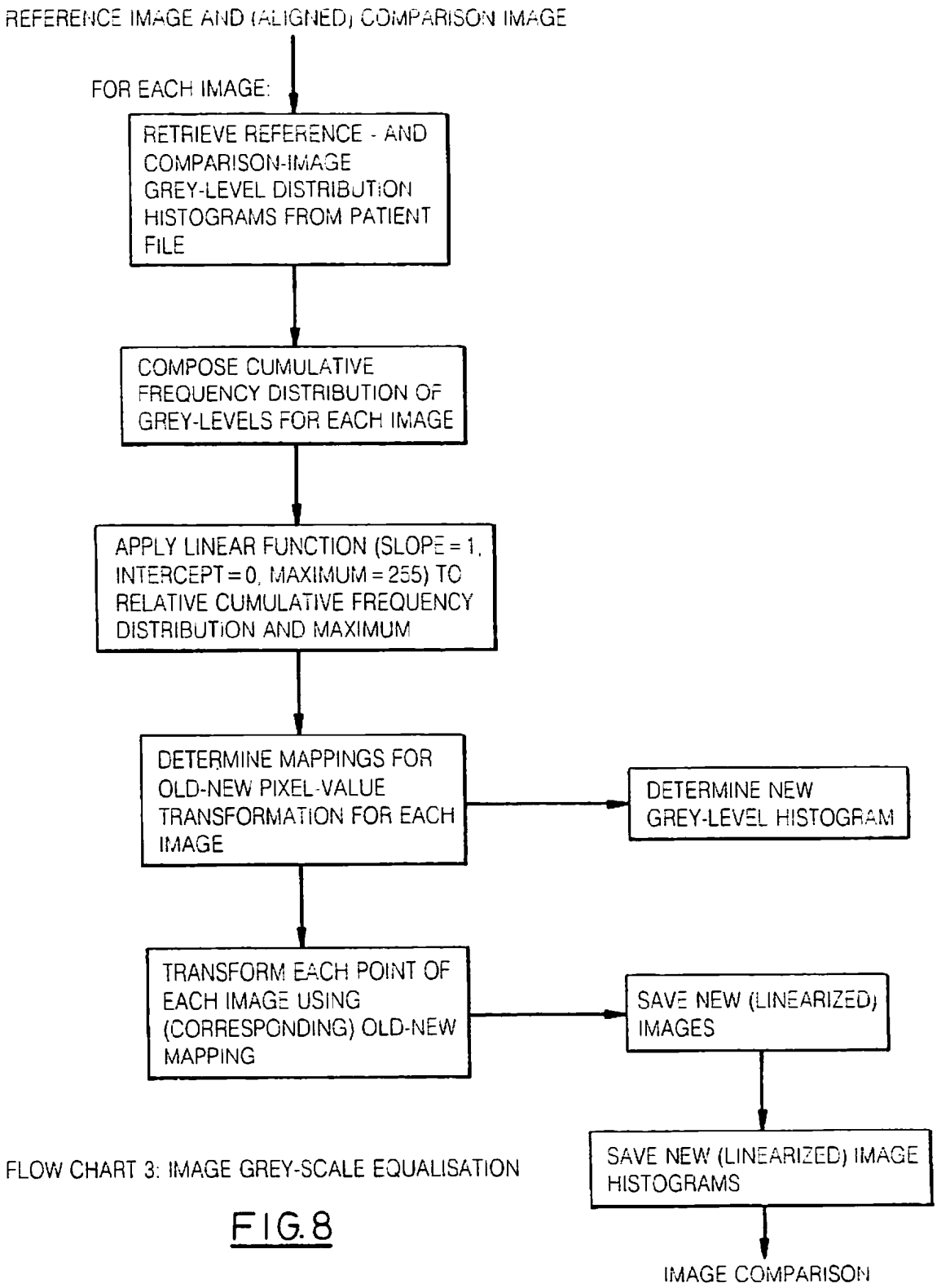
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FLOW CHART 2: SPATIAL TRANSFORMATION FOR ALIGNMENT

FIG. 7

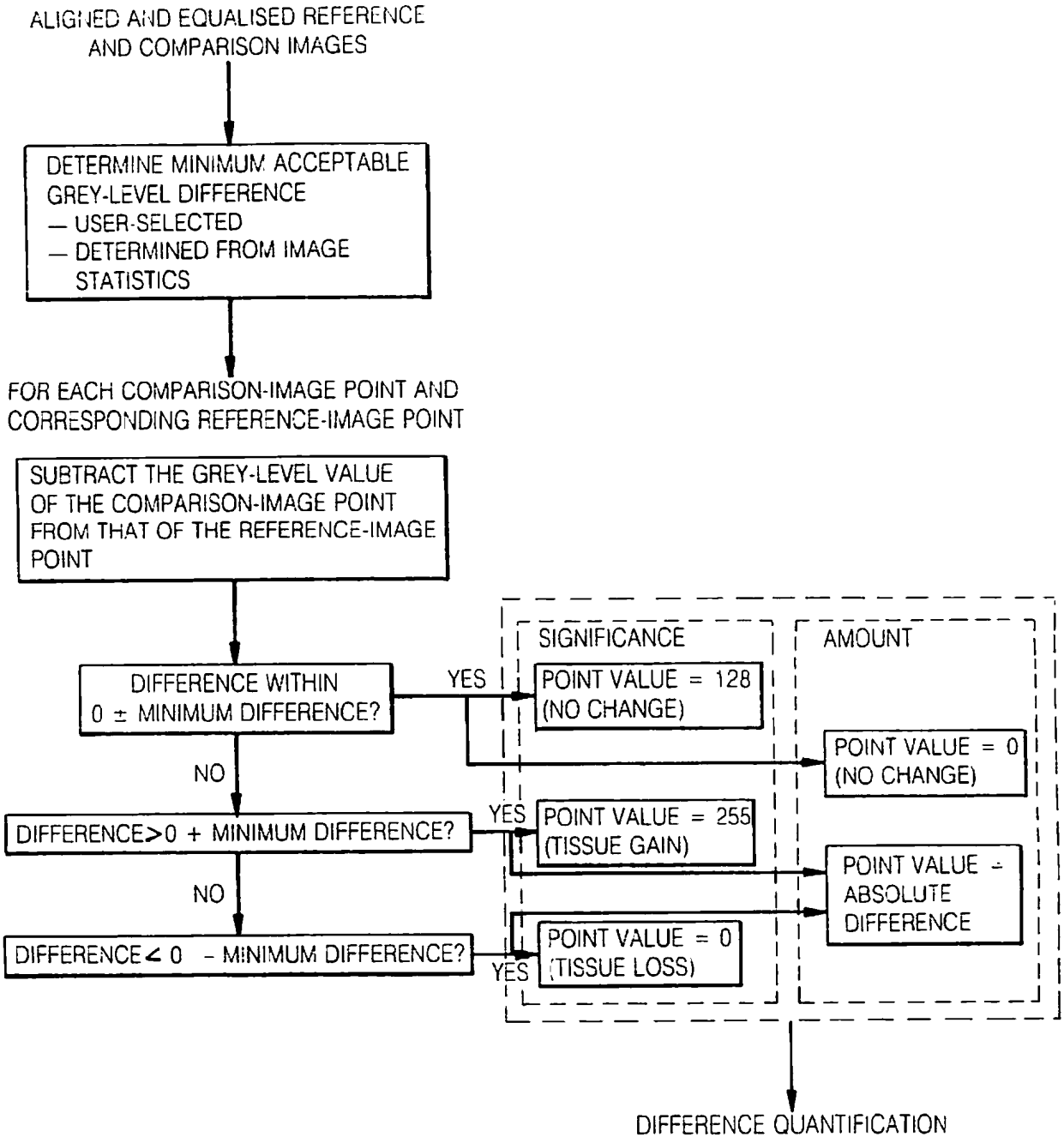
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FLOW CHART 3: IMAGE GREY-SCALE EQUALISATION

FIG.8

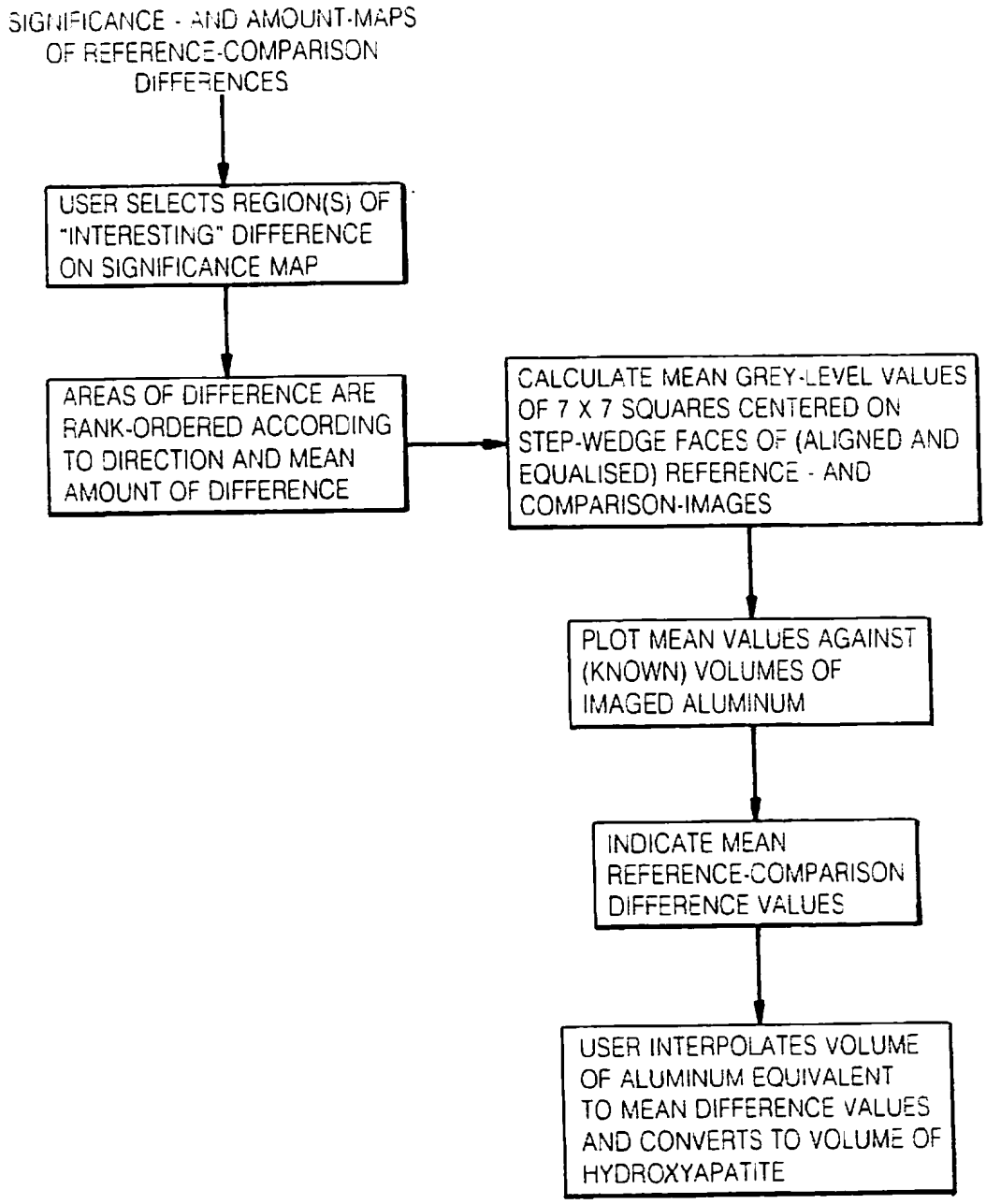
JSDOCID <EP 0314506A1_I_>



FLOW CHART 4: IMAGE COMPARISON

FIG.9

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FLOW CHART 5 DIFFERENCE QUANTIFICATION

FIG.10

ISDOCID <EP_ _0314506A1_I_>

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 88 31 0182

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Y	DE-A-2 202 428 (SCHWARTZ et al.) * Figures; page 4, line 1 - page 9, line 7 * & CA-A-939 833	1,11	A 61 B 6/14
A		2,3,6,8 ,12,14	

Y	PROCEEDINGS OF THE SOCIETY OF PHOTO-OPTICAL INSTRUMENTATION ENGINEERS, Paris, 9th-13th July 1978, vol. 166, pages 184-191, Society of Photo-Optical Instrumentation Engineers, Bellingham, Washington, D.C., US; G. SELVIK: "Röntgen stereophotogrammetry in Lund, Sweden" * Whole article *	1,11	
A	IDEM	2,6,7, 12,16	

Y	US-A-4 247 780 (WEBBER et al.) * Figures; column 3, line 27 - column 5, line 53 *	11	TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A		1,6	A 61 B G 03 B

D,A	JOURNAL OF PERIODONTAL RESEARCH, vol. 20, 1985, pages 644-651, US; L.F. ORTMAN et al.: "Subtraction radiography and computer assisted densitometric analyses of standardized radiographs" * Page 644-647, introduction: "Material and methods" *	1,2,5,6 ,10-12, 17	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	07-02-1989	CHEN A.H.

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corresponding to Ref. (3)

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(74) Agents: BIGEL, Mitchell, S. et al.; Bell, Seltzer, Park & Gibson, P.O. Drawer 34009, Charlotte, NC 28234 (US).

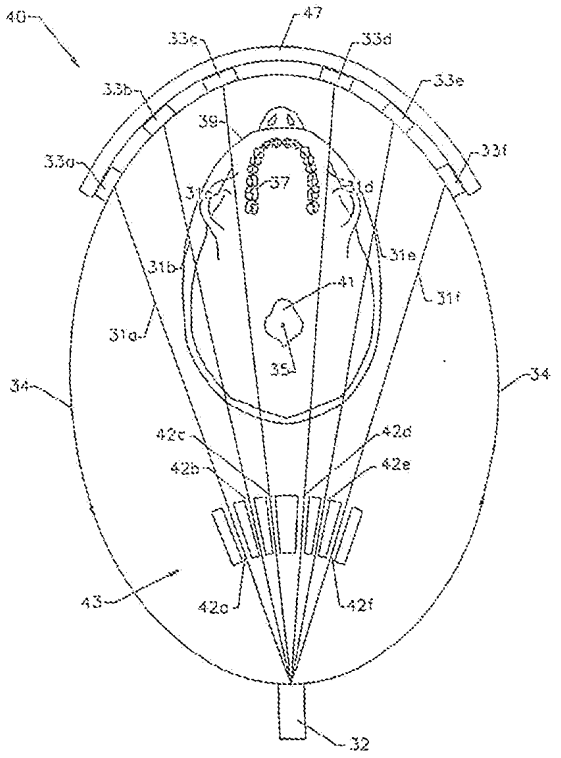
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(57) Abstract

A panoramic dental radiography system (40) projects multiple vertical fan-shaped radiation beams (31a-f) through a subject's teeth (37) and onto multiple detectors (33a-f) with each fan-shaped beam (31a-f) avoiding the subject's spine (41). The radiographic source (32) and radiographic detectors (33a-f) are rotated about a vertical axis (35), so that the detected radiation may be tomographically processed to produce a panoramic image of the teeth (37). The multiple vertical fan-shaped radiation beams (31a-f) are projected on either side of the spine (41), to reduce the radiographic dosage to the spine (41) and to prevent the spine (41) from blurring the panoramic radiograph. The resulting multiple projections can be tomosynthetically processed to produce a three-dimensional image of tissues of diagnostic interest, free of image artifacts produced by irradiation of the spine (41).



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THREE-DIMENSIONAL PANORAMIC DENTAL RADIOGRAPHY METHOD AND APPARATUS WHICH AVOIDS THE SUBJECT'S SPINE

Field of the Invention

This invention relates to radiographic imaging and more particularly to dental radiographic imaging.

Background of the Invention

Tomography is an analog imaging process which is widely used for radiographic imaging. In tomography, an x-ray beam source and an x-ray film are moved in predetermined directions relative to one another, such that the fulcrum of relative movement between the source and the film defines a region of interest. Since relative movement at the fulcrum is zero, this region is projected unchanged onto the film. The radiographic projections of all tissues lying outside this region move during exposure, so that they appear more or less blurred depending on their distance from the fulcrum. The amount of blur is directly proportional to their distance from the fulcrum. Accordingly, the region or fulcrum is often referred to as the "focal plane".

In summary, the tomographic process capitalizes on the angular disparity produced by relative motion between x-ray source and x-ray detector to selectively isolate a region, the location of which

can be varied by controlling motion relative to the tissues of interest. In tomographic imaging, linear motion of the source and detectors may be used ("linear tomography") or circular motion of the source and detector may be used ("circular tomography"). Depending upon the diagnostic task, other more complex motions may be used, such as hypercycloidal motion ("hypercycloidal tomography").

A related but computationally distinct imaging process for obtaining tomographic "slices" is computed tomography. In computed tomography, the projection geometry is characterized by a fan-shaped x-ray beam which lies in the same plane as a detector. This geometry renders details in one focal plane independent from those in another focal plane, but at the expense of having the plane of the source and detector motion coincident with the focal plane.

Linear tomography has been used in dental radiography to obtain images of individual teeth or groups of teeth. Computed tomography also has been used in dental radiography to obtain a slice through a subject's head, parallel to the plane of the subject's teeth.

In the above description, and in the description to follow, reference is made to the "plane of the teeth", which is defined as the plane formed by the intersection of a subject's upper and lower teeth. This plane, which is parallel to the plane of the jaw, is typically a horizontal plane when the subject is in a normal upright (standing or sitting) position. Accordingly, the term "horizontal" will be used to refer to a direction parallel to the plane of the teeth, which is typically a horizontal plane. The term "vertical" will be used to refer to a direction perpendicular to the plane of the teeth, which is generally parallel to a subject's spine, and is

vertical when the subject is in the typical upright position.

The process of tomography has been extended to digital tomosynthesis, which produces a series of discrete images taken from different positions as the x-ray source and detector move about a fixed fulcrum. Each discrete image corresponds to a different relative position of the source and film plane, rather than a single image produced continuously. In linear tomography and linear tomosynthesis the source and the detector move in a straight line about a fulcrum lying in the tissues which define the plane to be seen sharply in the reconstruction.

It has been shown that the tomosynthetic process is theoretically indistinguishable from the tomographic process, provided that the size of the smallest detail of interest can be specified and the number of discrete projections is sufficiently large. These processes are indistinguishable because they both operate by isolating a focal plane through a controlled blur as described above. However, tomosynthesis has an advantage over tomography, because simple manipulation of the radiographic intensity data obtained from the multiple images permits the position of the focal plane to be adjusted after the fact. Accordingly, a computer can be used to selectively search through the multiple images and to render the image of a particular structure of interest in proper focus, irrespective of its location.

The theoretical and practical designs of a tomosynthetic x-ray system are well known to those having skill in the art, and are described, for example, in an article entitled *Tomosynthesis: A Three-Dimensional Radiographic Imaging Technique* by D. G. Grant, published in the IEEE Transactions on Bio-Medical Engineering, Vol. BME-19, No. 1, January, 1972, pp. 20-28. The present inventor likewise has

coauthored a number of articles describing computer tomosynthesis. See the articles entitled *Computerized Tomosynthesis of Dental Tissues*, coauthored with Groenhuis and Ruttimann, published in Oral Surgery, Vol. 56, No. 2, pp. 206-214, August, 1983; *A Prototype Digital Tomographic X-Ray System For Dental Applications* coauthored with Groenhuis and Ruttimann, published in the IEEE International Symposium on Medical Images and Icons, July 24-27, 1984, pp. 218-221; *Restoration of Digital Multiplane Tomosynthesis By a Constrained Iteration Method*, coauthored with Ruttimann and Groenhuis, published in the IEEE Transactions on Medical Imaging, Vol. MI-3 September, 1984, pp. 141-148; and *Synthesis of Arbitrary X-ray Projections from a Finite Number of Existing Projections* coauthored with Ruttimann, Groenhuis and Edholm, published in Society of Photo-optical Instrumentation of Engineers, Application of Optical Instrumentation in Medicine XIII, Vol. 535, pp. 84-90, 1985.

Panoramic dental radiography is also widely used for dental imaging. In contrast with conventional single tooth exposures, panoramic dental radiography attempts to "unwrap" the curved jaw and teeth into a flat panoramic image. In other words, panoramic dental radiography is a unique imaging technique for showing all of the teeth and related dental tissues on a single exposed film in one "panoramic sweep". It results from a system that dynamically alters the swept projection using an exposure geometry that establishes foci that are different in the horizontal and vertical directions.

Panoramic radiography resembles linear tomography to the extent that it produces images characterized by a region of sharp focus that is controlled by the motion of the x-ray beam and the x-ray film relative to the irradiated tissues. However,

unlike tomography the image is produced from a fan-shaped x-ray beam which scans across a moving film as the source of radiation moves in a complicated path around the patient's head. The result is an image which shows relatively sharp images of the teeth unwrapped from the dental arch, but buried in blurred images of other tissues laying further away from the region of interest.

Panoramic radiography involves horizontal rotation of a single fan-shaped x-ray beam and an x-ray detector, such as a photographic plate, about an axis which is generally parallel to the subject's spine and orthogonal to the plane of the teeth. The single fan-shaped beam is a vertical beam, which extends orthogonal to the plane of the teeth. In contrast with tomography, the x-ray film is also moved relative to the x-ray beam, at a constant velocity which is synchronized to the rotation of the x-ray source and film. In the limit (i.e. when the fan-shaped beam is infinitely thin), this movement places the effective tomographic fulcrum at infinity, thus precluding all tomographic blur. On the other hand, by increasing the thickness of the fan-shaped beam, it is possible to introduce more and more tomographic blurring into the resulting panoramic radiograph, to render sharp only the image of structures lying a focal plane determined by the relative movement of the source and detector.

In summary, panoramic radiography sweeps an extended film with a modulated fan-shaped beam to produce an extended image with a lateral extent and projective attributes impossible to produce directly from a single exposure. The degree to which the unwanted out-of-plane structures are tomographically blurred is determined by the horizontal width of the fan beam as it is projected onto the moving film, and by the relative movement of the x-ray source and projected tissues relative to the plane of the fulcrum.

Taken together, these processes result in an imaging system that permits the teeth to be viewed tomographically in spite of the fact that they lie in an arched arrangement inside the head.

Panoramic radiography systems are described in U.S. Patents 4,589,122 to Nieminen entitled *Panoramic Tomography X-ray Apparatus*; 4,783,793 to Virta et al. entitled *X-ray Apparatus for Panoramic Tomography Including Control System*; 4,847,881 to Heubeck entitled *Dental X-ray Diagnostics Installation For Producing Panoramic Tomograms of the Jaw of a Patient*; and 4,878,234 to Pheiffer et al. entitled *Dental X-ray Diagnostics Installation for Producing Panorama Slice Exposures of the Jaw of a Patient*.

Although useful for producing panoramic images of a subject's teeth, known panoramic dental radiographic systems possess a number of shortcomings. For example, the usefulness of dental panoramic radiography depends greatly on the degree to which the structures of interest lie close to the focal plane. If the region of relative lack of blur is too wide, structures other than teeth and jaws also appear sharp, and obscure details of the structure of diagnostic interest. Hence, in order to prevent unwanted features from appearing clearly, tomographic blurring typically is adjusted to render only images quite near the focal plane in relative focus. Unfortunately, such a design makes the system highly sensitive to subject positioning. If the subject is not positioned properly, the dental structures of interest may not be present in the region of clear tomographic focus, so that the image of important diagnostic details becomes blurred.

A particular problem related to dental panoramic radiography stems from the fact that the images of unwanted structures outside the region of clear focus are only blurred, rather than being

eliminated completely. Accordingly, a large diffuse structure is less influenced by the blurring process than a small, sharply delineated tissue detail. This is a particular problem in dental panoramic radiography because the vertical fan-shaped x-ray beam passes through the spine. The midline position of the spine has heretofore precluded x-ray projections which avoid the spine.

The need to pass an x-ray beam through the spine in a dental radiographic applications, produces two deleterious effects. First, it requires a higher x-ray dose than would otherwise be required, in order to provide sufficient x-ray density at the teeth after passing through the spine. Moreover, it produces a large massive blur on the x-ray film which often obscures structures of interest.

Yet another problem with conventional panoramic radiographic systems is the overlap of the teeth in the panoramic radiograph. This overlap takes place because the x-rays are not always directed between the proximal surfaces of the teeth. Accordingly, the interproximal regions of a number of teeth typically overlap in the panoramic radiograph, thereby obscuring necessary details.

It is known that multiple beams can be produced from a single x-ray source, using a suitable x-ray collimator. See U.S. Patent 4,264,824 to Tosswill entitled *Far Field Imaging*, which describes a collimator for use in imaging far field sources, and U.S. Patent 4,304,999 to Richey et al. entitled *Eccentric Source Collimator Assembly for Rotating Source CT Scanner*. Multiple beams, which may be produced by collimating a single x-ray source, may be used in multiple beam computer tomography as described in U.S. Patent 4,315,157 to Barnes entitled *Multiple Beam Computed Tomography (CT) Scanner*. It is also known to use at least two fan-shaped beams having

different energy spectra which are obtained from a single x-ray source to produce several negatives or exposures of a single area or zone, and to superpose these exposures, as described in U.S. Patent 4,731,807 to Plessis et al. entitled *X-ray Examination Apparatus*.

Finally, it is also known to obtain panoramic dental x-ray images from multiple diverging fan-shaped beams, which extend orthogonal to the plane of the teeth, by synchronously rotating the fan-shaped beams, and corresponding detectors, about an axis orthogonal to the plane of the teeth. See U.S.Patent 4,481,650 to Kinanen. Five vertical fan-shaped beams are used, with one beam being a centrally located beam which passes radiation through the subject's spine. The remaining beams are symmetrically arranged about the central beam.

In summary, known panoramic dental radiography techniques, which use single or multiple fan-shaped x-ray beams are highly position sensitive, include excessive overlap of interproximal areas of the teeth, require higher doses, and produce interpretive artifacts due to the effects of the spine.

Summary of the Invention

It is therefore an object of the present invention to provide an improved panoramic dental radiography method and apparatus.

It is another object of the present invention to provide a panoramic dental radiography method and apparatus which reduces the effect of the spine on x-ray dose and image quality.

These and other objects are provided, according to the present invention, by simultaneously projecting a plurality of vertical (i.e. extending orthogonal to the plane of a subject's teeth) diverging, fan-shaped radiation beams through a subject's teeth, which each fan-shaped beam avoiding

the subject's spine. The attenuated radiation which emerges through the teeth is detected, with the detected attenuated radiation being free of attenuation produced by the spine. The radiographic source and radiographic detector are synchronously rotated about a vertical axis (i.e. orthogonal to the plane of the subject's teeth), with each of the fan-shaped beams avoiding the spine during rotation thereof. The detected attenuated radiation produces multiple panoramic images of the teeth which are free of image artifacts produced by irradiation of the spine.

According to the invention, the plurality of diverging vertical fan-shaped radiation beams pass through a subject's head, with each of the fan-shaped beams avoiding the subject's spine. The fan-shaped beams pass on either side of the spine but no beam passes through the spine. Accordingly, image artifacts caused by irradiation of the spine are eliminated. Moreover, a reduced dosage results, because the primary x-ray beams need not pass through the spine. Finally, exposure of the radiosensitive marrow producing spine is eliminated.

The plurality of diverging vertical fan-shaped x-ray beams may be produced by a collimated x-ray source. A linear radiation detector, such as a vertical, linear Charge Coupled Device (CCD) array, may be positioned to intercept a respective one of the fan-shaped beams which emerge from the subject's head, with each of the beams avoiding the subject's spine. The signals detected by the detectors may be processed as conventional panoramic data to produce a panoramic image of the teeth. The images so produced have decreased sensitivity to subject positioning and reduced interproximal overlap compared to conventional panoramic images.

The images produced according to the invention may be thought of as being equivalent to that produced from a hypothetical two-step process:

1) a highly nonlinear warping transformation that opens the head from the back and flattens it out such that the teeth are oriented in a relatively straight line rather than bent into the arch-shaped configuration that they normally occupy, and

2) application of linear tomosynthesis to the resulting grossly distorted tissue mass. The desired tomosynthetic slices are produced from focal planes parallel to the now flattened plane containing the "unwrapped" teeth.

The invention produces reduced blurring without extreme sensitivity to subject position. The distortion and dosage effects of the spine are eliminated, and reduced interproximal overlap is provided. The invention may be practiced by modifying conventional digital tomosynthesis systems to provide multiple vertical fan-shaped beams which avoid the spine, and multiple vertical linear detector arrays, to obtain simultaneous acquisition of multiple panoramic projections, each produced at a different angle. Tomosynthetic processing may then be used to obtain three-dimensional information.

Brief Description of the Drawings

Figure 1 schematically illustrates a conventional computed tomographic system.

Figure 2 schematically illustrates a conventional panoramic dental radiography system.

Figure 3 schematically illustrates a tomosynthetic panoramic dental radiography system according to the present invention.

Figure 4 schematically illustrates a cross sectional view of the tomosynthetic panoramic dental radiography system of Figure 3 taken through the plane of the teeth.

Figure 5 schematically illustrates the mechanical configuration of the system of Figure 3.

Figures 6A and 6B illustrate alternate configurations for the detector arrays of the system of Figure 3.

Figure 7 illustrates a general electrical schematic diagram of the system of Figure 3.

Figure 8 illustrates a more detailed electrical schematic diagram of the electronic controller of Figure 7.

Figures 9A-9C illustrate the theoretical morphological transformation of a subject's head during panoramic radiographic operations.

Figures 10A and 10B illustrate irradiation of the morphologically transformed head of Figure 9C during conventional panoramic radiography and during panoramic tomosynthesis underlying the present invention.

Figure 11 illustrates a general schematic diagram of an alternative embodiment of a panoramic dental radiography system of the present invention.

Description of a Preferred Embodiment

The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which a preferred embodiment of the invention is shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiment set forth herein; rather, this embodiment is provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those

skilled in the art. Like numbers refer to like elements throughout.

Prior to describing the panoramic radiography method and apparatus of the present invention, a description of a computed tomography system will be provided, followed by a description of a conventional panoramic radiographic system. Figure 1 schematically illustrates a computed tomography system, which is oriented to obtain a slice through the head, including the plane of the teeth. As shown, computed tomography system 10 projects a single, horizontal fan-shaped x-ray beam 11 from a source 12 to a linear detector array 13. The x-ray source 12 and virtual linear detector array 13 are rotated in a horizontal rotation path 14, without translational movement between the source 12 and the detector 13. Horizontal rotation typically takes place about a vertical axis 15 which is centered near the spine of the subject 19.

In circular tomography, the detector array 13 would be replaced by an x-ray film cassette, and the rotation is typically a continuous rotation. In computed tomography, multiple discrete line integrals are produced, each corresponding to a different relative position of the source and detector, rather than a continuous tomographic reproduction.

Tomography and tomosynthesis both rely on the blurring of unwanted details which are outside the region of sharp focus. However, tomosynthesis possesses a unique advantage over tomography because simple manipulation of data obtained from the multiple images permits the position of the focal plane to be adjusted after the fact. In particular, a computer can be used to selectively search through multiple images and render the image of a particular structure of interest in proper focus, regardless of its particular location. Moreover, the projection geometry responsible for the blurs, at any distance from the

focal plane, is known in advance. Accordingly, the exact nature of the blurring process produced by unwanted structures may be predicted with certainty. This means that deconvoluting algorithms may be used to further suppress blur resulting from structures lying outside the focal plane.

Referring now to Figure 2, a schematic illustration of a panoramic radiography system is shown. System 20 includes an x-ray source 22 which projects a single, vertical, fan-shaped x-ray beam 21 onto an x-ray film 23. A slit collimator 26 may be used to reduce the effects of unwanted radiation. The source 22 and film 23 are rotated about horizontal rotation path 24 centered about a moving vertical axis 25, typically located anterior to typically the spine of the subject 29. In contrast with the tomosynthetic system of Figure 1, there is relative motion between the source 22 and film 23. The relative motion is synchronized with the rotational movement of the source 22 and film 23 about axis 25. Accordingly, an extended film 23 is swept with a modulated fan-shaped beam to produce an extended image with a lateral extent and projective attributes impossible to produce directly from a single exposure.

Although the system of Figure 2 is widely used for panoramic dental radiography, it has been found that this system is highly sensitive to subject positioning. Also, the beam passes through the subject's spine, which contributes to the x-ray dose so that it is higher than would ordinarily be required for imaging the teeth and jaw. Moreover, the spine creates a blurred artifact on the panoramic image which often interferes with proper diagnosis.

In the description of Figures 1 and 2, and the description of the invention to follow, the terms "horizontal" and "vertical" are referenced to an upright (sitting or standing) subject 19, 29. In an

upright subject, the systems 10, 20 are rotated horizontally, with beam 11 being a horizontal fan-shaped beam and beam 21 being a vertical fan-shaped beam. However, it will be understood by those having skill in the art that the terms "horizontal" and "vertical" are generally defined relative to the plane of the teeth, which is formed by the intersection of the upper row of teeth 17, 27 and the lower row of teeth 18, 28, and which is parallel to the bottom of the jaw. A direction parallel to the plane of the teeth is referred to as "horizontal" and a direction which is orthogonal to the plane of the teeth will be referred to as "vertical" in this description.

Referring now to Figure 3, the panoramic dental radiography system of the present invention will now be described. As shown in Figure 3, panoramic radiography system 30 includes a plurality, here six, of vertical (orthogonal to the plane of the teeth) fan-shaped diverging beams 31a-31f, produced by a source 32. The beams 31 may be produced from a single source 32 using a six-way collimator, as is well known to those having skill in the art. As also shown in Figure 3, a vertical detector array having a plurality, here six, of linear detectors 33a-33f, is positioned so that a respective one of the beams 31 impinges on a respective one of the detectors 33 after passing through the subject 39. For reference purposes, upper and lower rows of teeth 37 and 38 are also shown. As also shown, source 32 and detector 33 are rotated in a horizontal rotation path 34, about a vertical axis 35 which may run through the subject's spine.

The system of Figure 3 may be viewed as having a very narrow fan beam, resulting in a relatively wide region of sharp focus, so as to preclude significant blurring of malpositioned structures of diagnostic interest. Multiple exposures are taken at carefully selected angles, so that all

areas of diagnostic interest are seen, and not obscured by superimposed images of irrelevant tissues in at least one projection. This results in a system that is characterized by multiple panoramic scans, each involving a different projection angle, to yield multiple, discrete, asymmetrical panoramic projections. By keeping track of the angles responsible for the resulting projections relative to the position of the subject, it is possible to tomosynthetically synthesize the resulting two-dimensional projections into a true three-dimensional representation of the tissues.

Referring now to Figure 4, a cross-sectional view of Figure 3 taken through the plane of the teeth is shown. Figure 4 illustrates that all of the beams 31a-31f are projected on either side of the spine 41, throughout the 360° rotation of the system around the subject. In particular, beams 31a-31c are on one side of the spine 41 and beams 31d-31f are on the opposite side of the spine 41. The spine is thereby minimally exposed to x-rays and the spine cannot act as a source for blurring the resulting image. As an example of the geometry of Figure 4, beams 31a-31f may be spaced about the centerline in increments of 6, 10 and 16 degrees respectively, with the length of each beam being approximately 40 inches, and the distance from source 32 to center axis 35 being approximately 20 inches. Axis 35 may coincide with the center of spine 41 or may be placed between spine 41 and teeth 37.

The signals produced by detector arrays 33a-33f may be processed tomosynthetically. However, in contrast with conventional tomosynthesis, the multiple discrete angular projections required for panoramic tomosynthetic reconstruction are generated simultaneously rather than serially. This is accomplished through the use of multiple fan-shaped x-ray beams, each exposing the tissues from a different direction as the single x-ray source and multiple

detector system rotates about a fixed or moveable center.

The present invention produces a number of advantages over known panoramic dental radiography systems. The x-rays can completely avoid the spine, so that no primary radiation reaches the radiosensitive marrow space in the spine. Moreover, projective artifacts of the spine do not find their way into the multiple panoramic images which are produced. Finally, the dose may be reduced because the x-rays are not directed through the spine.

The present invention also can differentially weight the dose distribution in the head so that it is concentrated in the tissues of diagnostic interest. For example, referring again to Figure 4, the disk shaped region defined by the sector between beams 31c and 31d, as they rotate over 360°, is not exposed to any radiation dosage. The annular region between beams 31b and 31c (and 31d and 31e) is exposed to two beams as these beams rotate. The annular region between beams 31a and 31b (and beams 31e and 31f) is exposed to four beams. The remaining annular region is exposed to a total of six beams. Accordingly, the system tends to reduce and equalize the maximum intensity distribution of the x-rays.

The present invention produces multiple projections, at least one of which is likely to open most of the points of interproximal contact between the teeth. As is well known to those having skill in the art, it is desirable for a radiography system to allow points of interproximal contact between the teeth to be accurately viewed.

The panoramic image may be obtained by the present invention without the precise subject placement heretofore required. Finally, since theory and existing software have demonstrated that tomosynthetic data can be processed into any desired two-dimensional

projection, tissue changes can be quantitatively obtained from careful comparison of existing panoramic radiographs and those produced according to the present invention.

The present invention can utilize well known commercially available components to achieve improved results. In particular, a conventional source 32 such as contained on a model Panex-E1 machine, marketed by Morita Corporation, and a customized multi-slit collimator may be used to produce the multiple vertical fan-shaped beams. A plurality of detectors, such as six model THX 1089 linear x-ray detectors, marketed by Thompson CSF, may be used to detect the radiation. This device is a 4½ inch linear array of 1000 CCD elements.

In contrast with conventional radiography of Figure 2, relative movement between detectors 33 and source 32 is not necessary, so that mechanical synchronization is not required. The signals from the detectors 33 may be processed using conventional tomographic processing steps, so that new processing algorithms need not be developed, and known tomosynthetic enhancement techniques may be used. For example, Computer correction of artifacts such as variations in contrast and differential magnifications, and computer pattern recognition techniques may be used. The electronic images produced may be transmitted from one computer to another, facilitating communications for diagnostic and forensic purposes.

Referring now to Figure 5, a simplified schematic illustration of the mechanical configuration of the system 30 of the present invention will now be described. As shown, x-ray source 32 and collimator 43 are carried at one end of support arm 44, with the detectors 33a-33f being mounted at the other end thereof. The detectors 33 may be mounted on a detector support 47. As shown, arm 44 is mounted for horizontal

movement about axis 35 using a motor 45 which is mounted on support member 46.

Apparatus 30 also includes subject positioning means, for positioning the subject relative to the source 32 and detector array 33 to obtain the geometric relationship described in connection with Figures 3 and 4. The subject support may include a jaw support 48 mounted on a base 49, and may also include an optional skull support 51. The supports 48 and 51 are preferably adjustable, to permit precise positioning of a subject's head 39 relative to the apparatus 30. The detailed mechanical design may be based upon known panoramic dental x-ray systems, and need not be described herein further. For example, a Panex-E machine, marketed by J. Morita Corp., Tustin, CA, may be modified.

Referring now to Figures 6A and 6B, alternate embodiments for the detectors of Figure 5 are shown. Figure 6A illustrates four detector arrays 33a'-33d', each of which include a plurality (such as three) of rows of CCDs. The two-dimensional detector arrays 33' may encompass the full extent of a widened but still collimated fan-shaped beam. Accordingly, the number of independent projection angles for tomosynthetic reconstruction may be multiplied by the number of rows of CCDs. The array of Figure 6A increases the flexibility of the system, which may permit tailoring the projection geometry to a specific imaging task. For example, a hybrid system may be generated which anisotropically samples both at low and at high angular resolutions depending on the importance of the structures passing through the fan-shaped beams at specific rotational angles. Figure 6B illustrates a single large two-dimensional matrix of detector elements 53, which provides the ultimate in flexibility.

Referring now to Figure 7, a general hardware block diagram of the apparatus 30 of the present invention will now be described. As shown, an electronic controller such as a stored program microcomputer may be electrically connected to x-ray source 32, motor 45 and detector array 33, for electronically controlling x-ray generation by x-ray source 32, and the rotation of motor 45. The signals from the detector array 33 may be stored in controller 50 and may be processed therein as described below in connection with Figure 8. The processed signals may be transferred to a remote computer 52 for remote analysis or viewing. The image may also be projected onto a visual display 54 such as a cathode ray tube (CRT) screen. The manner of connecting the elements of Figure 7 are well known to those having skill in the art and need not be described in further detail herein.

Referring now to Figure 8, a detailed description of controller 50 will now be described. As shown, a plurality of signal lines 55 may connect detector array 33 to a buffer 56 in controller 50, to allow high speed parallel transmission of data. Alternatively, serial transmission over fewer lines may be provided. It will also be understood by those having skill in the art that less than all of the linear arrays may be activated during a given scan, so that the depth of field around the focal plane may be altered during the process of data acquisition. This decreases the required frame buffer size, and the required data transfer rates.

After appropriate storage of the signals in the buffer 56, a nonlinear transformation may be applied by transforming means 57 in order to convert the curved detector geometry of Figure 3 into the equivalent of the flat detector geometry of Figure 1. Alternatively, this transformation need not be performed, and the data produced by the geometry of

Figure 3 may be directly processed tomosynthetically, as described below. Conventional tomosynthetic processing means 58 may be used to synthesize tomosynthetic slices. A conventional display converter may be used to convert the tomosynthetic signals into a format for display on display 54. The design of these elements are well known to those having skill in the art and need not be described herein further.

The data produced by the geometry of Figure 3 may be directly processed tomosynthetically because the projection process responsible for conventional panoramic imaging is the conceptual equivalent of applying a morphological transformation to the actual head of the subject and then irradiating the resulting grossly distorted tissue mass with parallel collimated x-rays as might be produced from a conventional x-ray machine Figures 9A-9C illustrate schematically how the head 39 might be cut along line 62, and stretched to achieve this result. The arrows 63 indicate the direction of the warping displacements and they also approximate the altered direction of the x-radiation as it passes through the tissues. In the limit, the arrows 63 become parallel, suggesting that a conventional fixed transmission radiograph of the distorted tissue mass would produce the equivalent of a conventional panoramic radiograph.

Referring to Figure 10, instead of irradiating the distorted tissue mass with a single beam of collimated x-rays coming from a single source as shown in Figure 10A, the distorted tissue mass is irradiated with multiple beams directed from multiple angles in such a way that each projection is produced independently from the others, as shown for three arbitrary angles in Figure 10B. The resulting projections on x-ray films labeled 64a, 64b and 64c may be considered to be the equivalent of three (or any reasonable number) tomosynthetic component projections

so produced that need only be shifted laterally and added together to yield tomosynthetic slices which would parallel the film planes in this conceptual simulation, and which would pass through any desired depth in the distorted tissue mass. The multiple fan beams of the present invention, achieve this effect simultaneously while the panoramic sweep is performed. The result is hybrid tomosynthetic component projections that may be shifted and added to yield slices which when related to the undistorted head are of nonuniform thickness and are curved in a pattern which parallels the dental arch in the region of the teeth.

Referring now to Figure 11, an additional aspect of the present invention is illustrated. Figure 9 illustrates the same geometrical projection as Figure 4, except that the apparatus has rotated 90° clockwise. In this position, half the beams 31d, 31e, and 31f pass through an area of no dental interest. Accordingly, to minimize the subject's radiographic dosage, at least one of the beams are suppressed during a portion of the rotation thereof. In particular, a shield 61a is provided to block beams 31d, 31e and 31f in synchronism with the rotation of the apparatus. Similarly, a shield 61b may be provided to block beams 31a, 31b and 31c at the appropriate times during the rotation. Shields 61a-61b may be moved in the direction shown by arrows 62a, 62b, to block one or more of the fan-shaped beams 31 when they are not imaging an area of interest. Dosage is thereby reduced further without reducing the quality or resolution of the radiographic image. It will be understood by those having skill in the art that the beams may also be individually turned off at various rotational positions, rather than blocked, to suppress the beams and achieve lower subject dosage.

In the drawings and specification, there have been disclosed typical preferred embodiments of the invention and, although specific terms are employed, they are used in a generic and descriptive sense only and not for purposes of limitation, the scope of the invention being set forth in the following claims.

CLAIMS:

1. A dental radiography system comprising:

radiographic source means, for simultaneously projecting a plurality of diverging, fan-shaped radiation beams through a subject's teeth, each fan-shaped beam lying in a plane which is orthogonal to the plane of the teeth, with each fan-shaped beam avoiding the subject's spine;

radiographic detecting means, for detecting attenuated radiation which emerges through the teeth, the detected attenuated radiation being free of attenuation produced by the subject's spine; and

means for synchronously rotating said radiographic source means and said radiographic detecting means about an axis which is orthogonal to the plane of the teeth, each of said fan-shaped beams avoiding the subject's spine during rotation thereof, such that the detected attenuated radiation produces a panoramic image of the teeth, which is free of image artifacts produced by irradiation of the spine.

2. The dental radiography system of Claim 1 wherein said plurality of diverging, fan-shaped beams are symmetrically projected about the subject's spine, and wherein each of said fan-shaped beams avoids the subject's spine.

3. The dental radiography system of Claim 1 further comprising means for positioning a subject's head such that said plurality of diverging fan-shaped beams pass through the subject's teeth, lie in a plane which is orthogonal to the plane of the subject's teeth, and avoid the subject's spine, and said radiographic source means and said radiographic detecting means synchronously rotate on opposite sides of the subject's head, about an axis which is orthogonal to the plane of the subject's teeth, with

each of said fan-shaped beams avoiding the subject's spine during rotation thereof, such that the detected radiation produces a panoramic image of the subject's teeth which is free of image artifacts produced by irradiation of the spine.

4. The dental radiography system of Claim 1 wherein said radiographic detecting means comprises a like plurality of linear radiation detectors, orthogonal to the plane of the teeth, a respective one of which is positioned to intercept a respective one of the fan-shaped beams which emerge through the teeth, free of attenuation produced by the subject's spine.

5. The dental radiography system of Claim 4 wherein each linear radiation detector comprises a linear array of solid state detectors, arranged in a single row orthogonal to the plane of the teeth.

6. The dental radiography system of Claim 4 wherein each linear radiation detector comprises a linear array of solid state detectors, arranged in a plurality of rows orthogonal to the plane of the teeth.

7. The dental radiography system of Claim 1 wherein said radiographic detecting means comprises a two-dimensional array of solid state detectors, for intercepting all of said fan-shaped beams which emerge through the teeth, free of attenuation produced by the subject's spine.

8. The dental radiography system of Claim 1 wherein said synchronous rotating means comprises means for synchronously rotating said radiographic source means and said radiographic detecting means about an axis which is orthogonal to the plane of the teeth and passes through the subject's spine.

9. The dental radiography system of Claim 1 further comprising electronic controlling means, electrically connected to said radiographic detecting means, for producing a representation of a panoramic dental image from the detected attenuated radiation which emerges through the teeth.

10. The dental radiography system of Claim 1 wherein at least one of said fan-shaped beams fails to pass through the teeth during a portion of its rotation about said axis, said dental radiography system further comprising means for selectively suppressing said at least one of said radiation beams during said portion of rotation thereof, to reduce the subject's radiation dosage.

11. The dental radiography system of Claim 10 wherein said selective suppressing means comprises a moveable radiation shield, for selectively blocking said at least one of said radiation beams during said portion of rotation thereof.

12. A dental radiography method comprising the steps of:

simultaneously projecting a plurality of diverging, fan-shaped radiation beams through a subject's teeth, each fan-shaped beam lying in a plane which is orthogonal to the plane of the teeth and avoiding the subject's spine;

rotating said plurality of diverging, fan-shaped radiation beams about an axis which is orthogonal to the plane of the teeth, each of said fan-shaped beams avoiding the subject's spine during rotation thereof; and

detecting attenuated radiation which emerges through the teeth, the detected attenuated radiation being free of attenuation produced by the subject's spine, to produce a panoramic image of the teeth which is free of image artifacts produced by irradiation of the spine.

13. The dental radiography method of Claim 12 wherein said simultaneously projecting step comprises the step of symmetrically projecting the plurality of diverging, fan-shaped beams about the subject's spine, with each of said fan-shaped beams avoiding the subject's spine.

14. The dental radiography method of Claim 12 wherein said detecting step comprises the step of individually detecting each of said plurality of fan-shaped radiation beams at an individual radiation detector.

15. The dental radiography method of Claim 12 wherein said rotating step comprises the step of rotating said radiographic beams about an axis which is orthogonal to the plane of the teeth and passes through the subject's spine.

16. The dental radiography method of Claim 12 further comprising the step of producing a representation of a panoramic dental image from the detected attenuated radiation which emerges through the teeth, free of attenuation produced by the subject's spine.

17. The dental radiography method of Claim 12 wherein at least one of said fan-shaped beams fails to pass through the teeth during a portion of its rotation about said axis, said method further comprising the step of selectively suppressing said at least one of said radiation beams during said portion of rotation thereof, to reduce the subject's radiation dosage.

18. The dental radiography method of Claim 17 wherein said selective suppressing step comprises the step of selectively blocking said at least one of said radiation beams during said portion of rotation thereof.

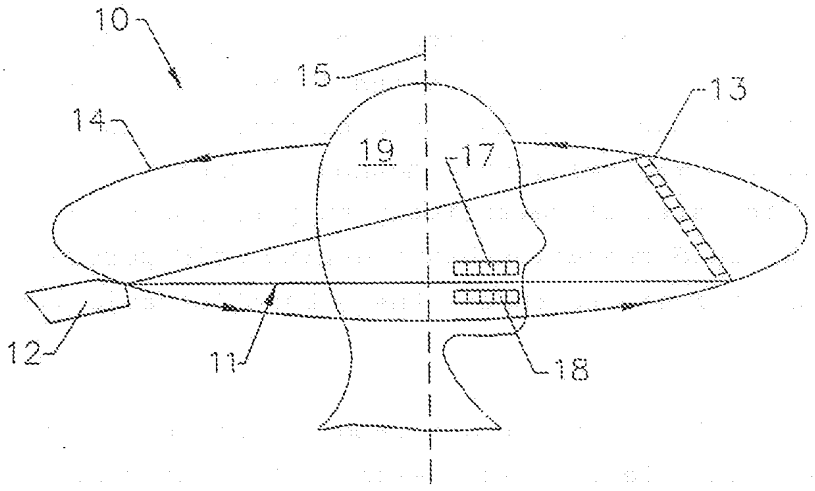


FIG. 1.
(PRIOR ART)

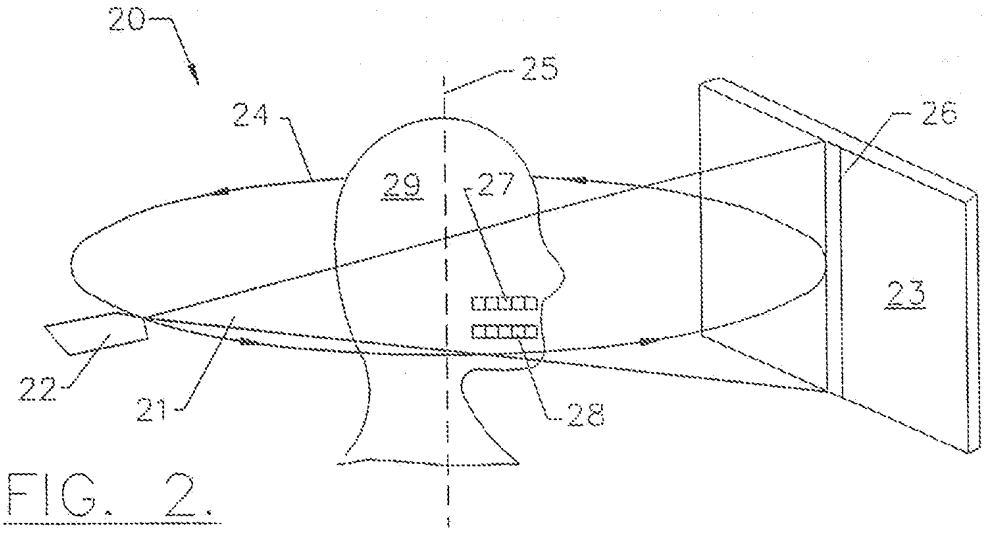


FIG. 2.
(PRIOR ART)

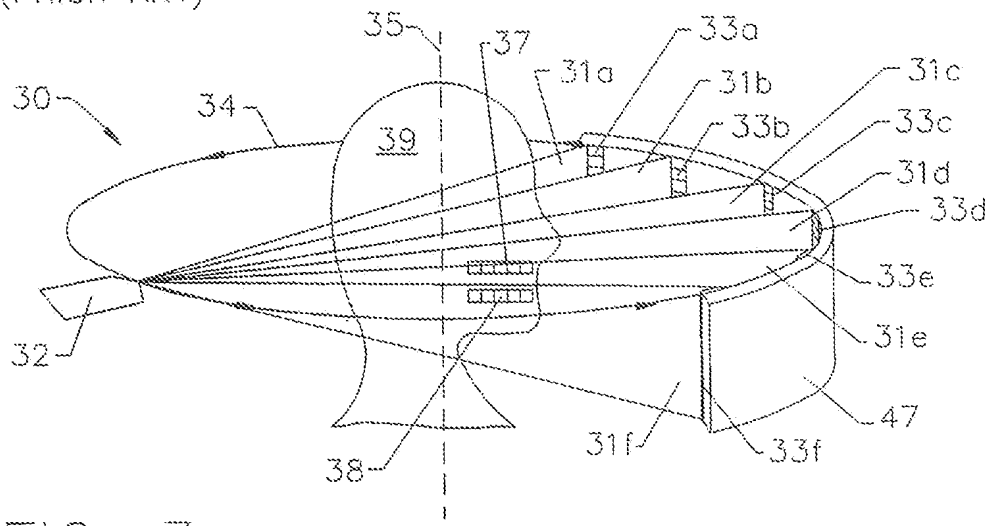


FIG. 3.

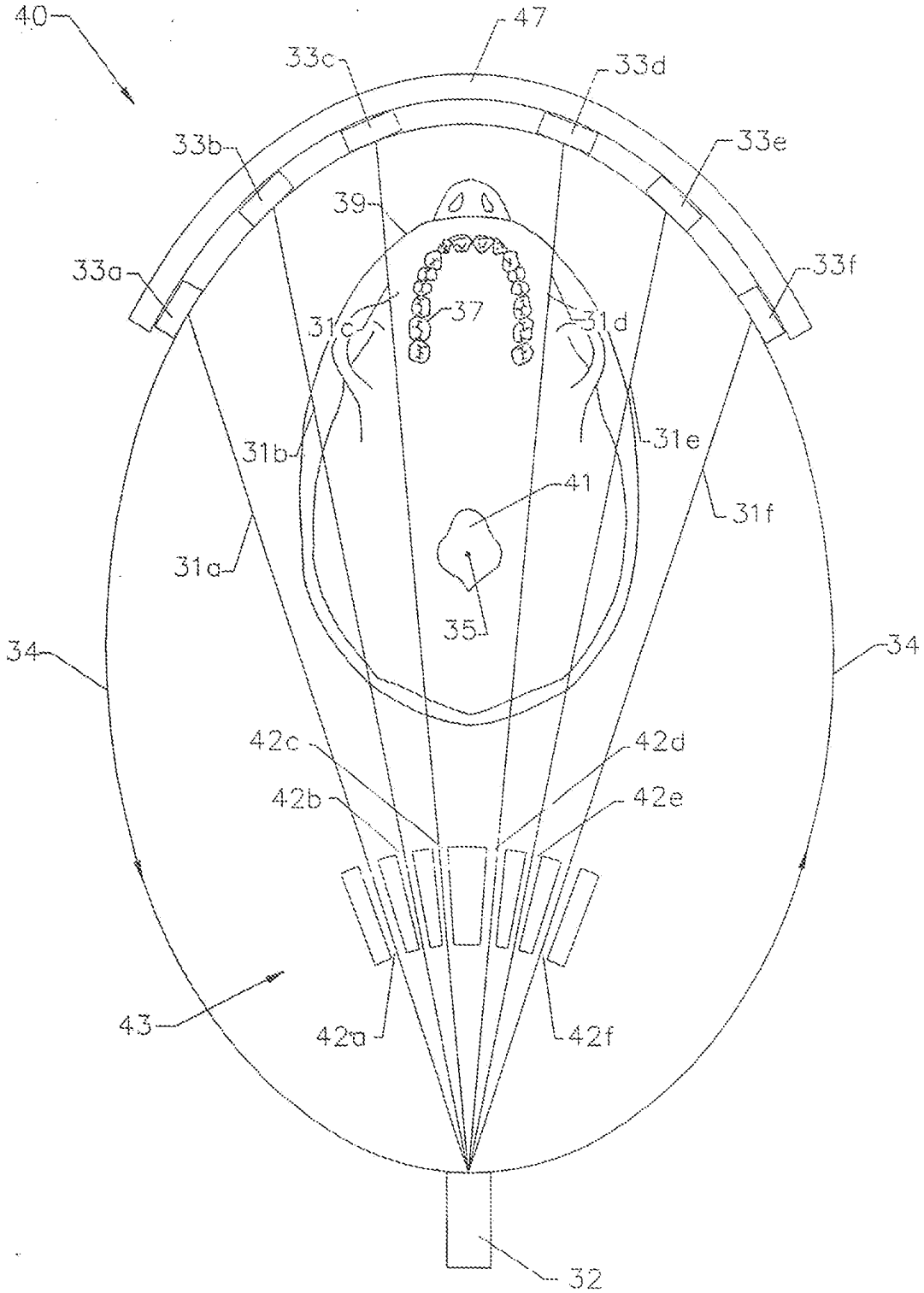

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33c
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33f
37
31c
31d
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41
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42c
42d
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43
42a
42f
32

FIG. 4.

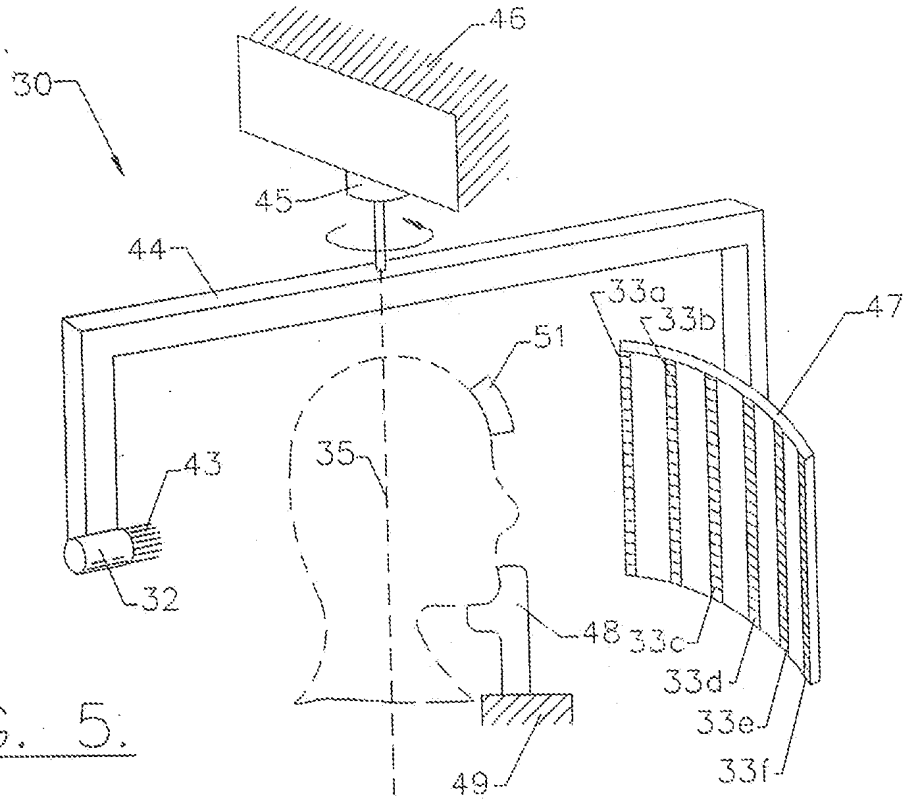


FIG. 5.

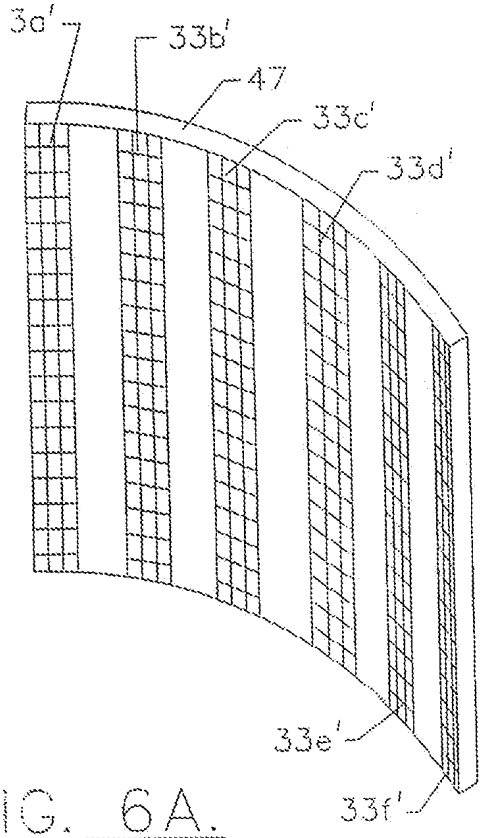


FIG. 6A.

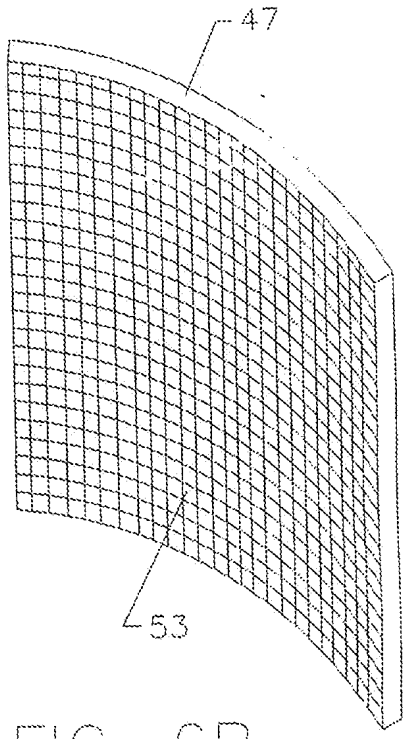


FIG. 6B.

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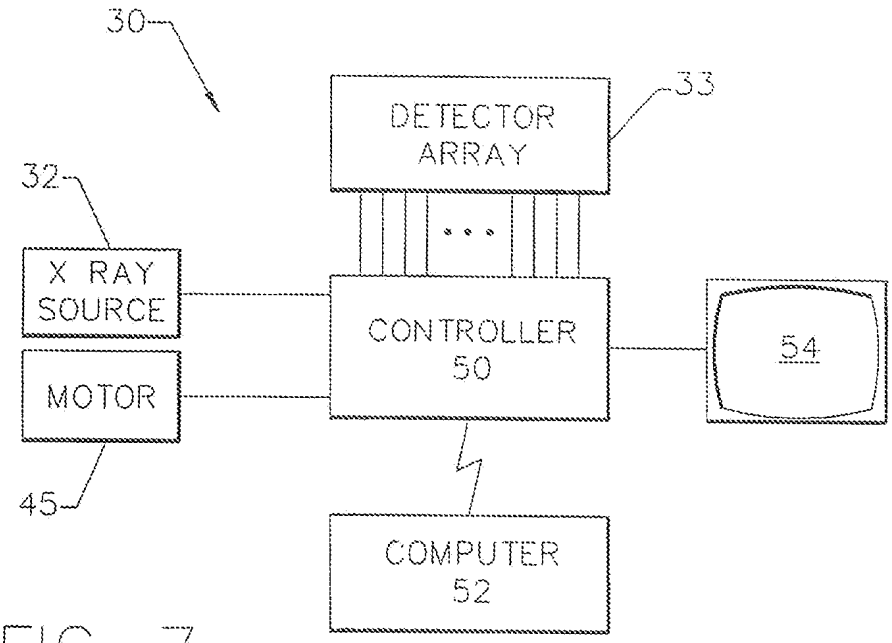

30
DETECTOR ARRAY
33
32
X RAY SOURCE
CONTROLLER 50
54
MOTOR
45
COMPUTER 52

FIG. 7.

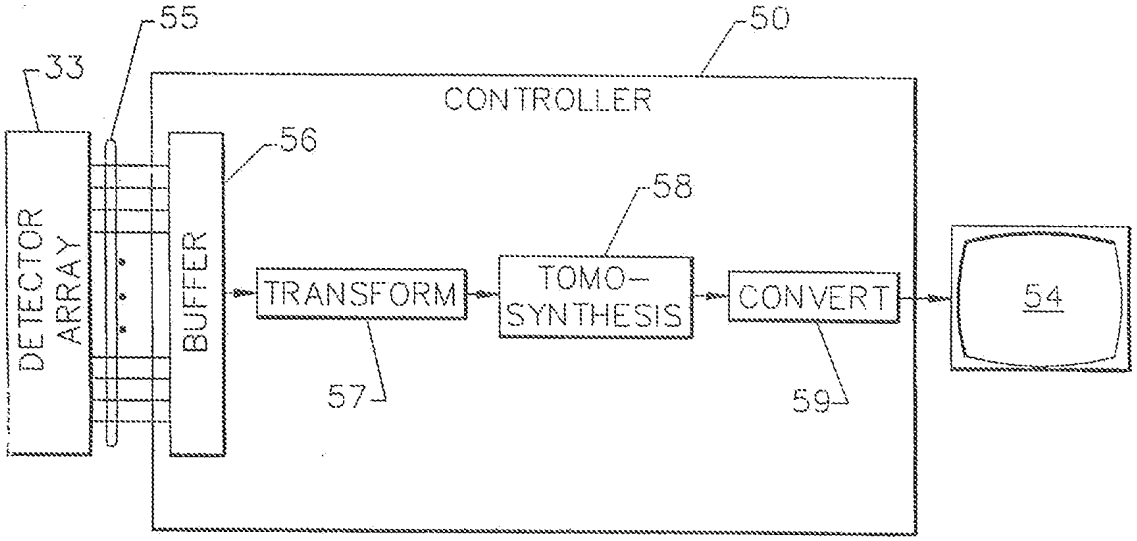

55
50
33
CONTROLLER
56
58
DETECTOR ARRAY
BUFFER
TRANSFORM
TOMO-SYNTHESIS
CONVERT
54
57
59

FIG. 8.

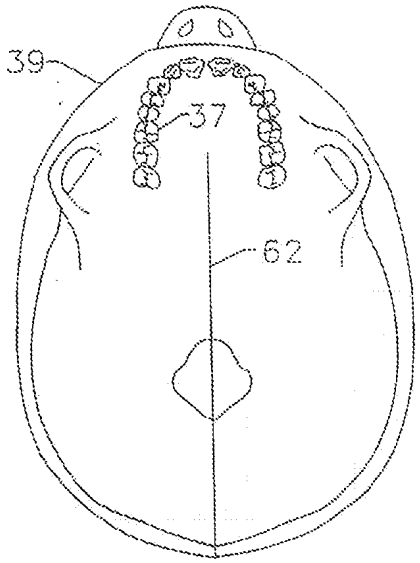


FIG. 9A.

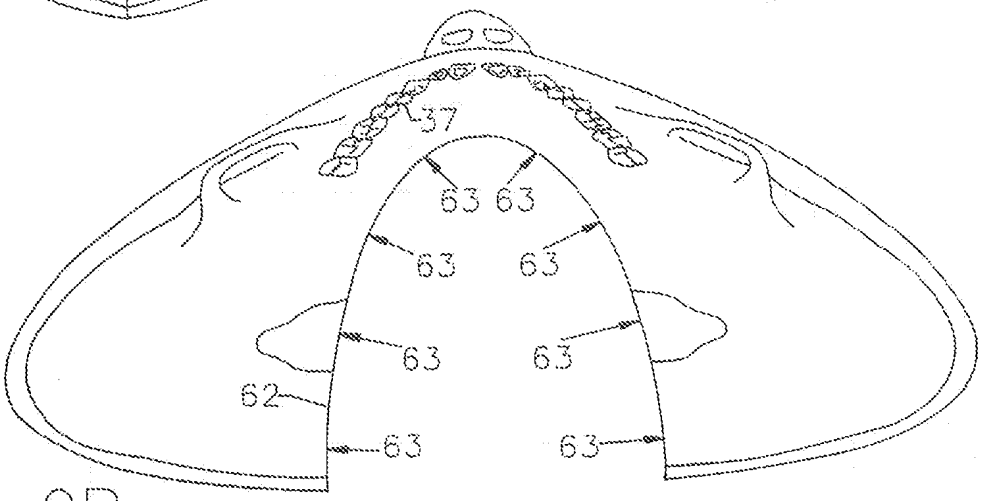


FIG. 9B.

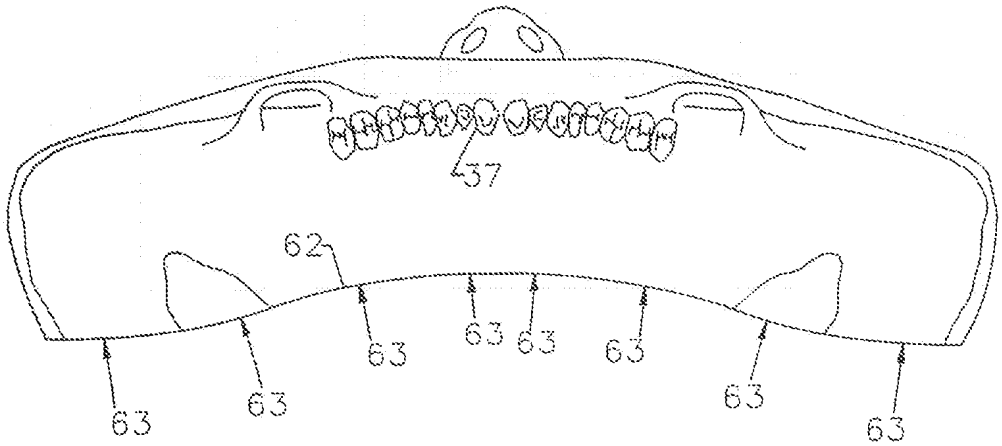


FIG. 9C.

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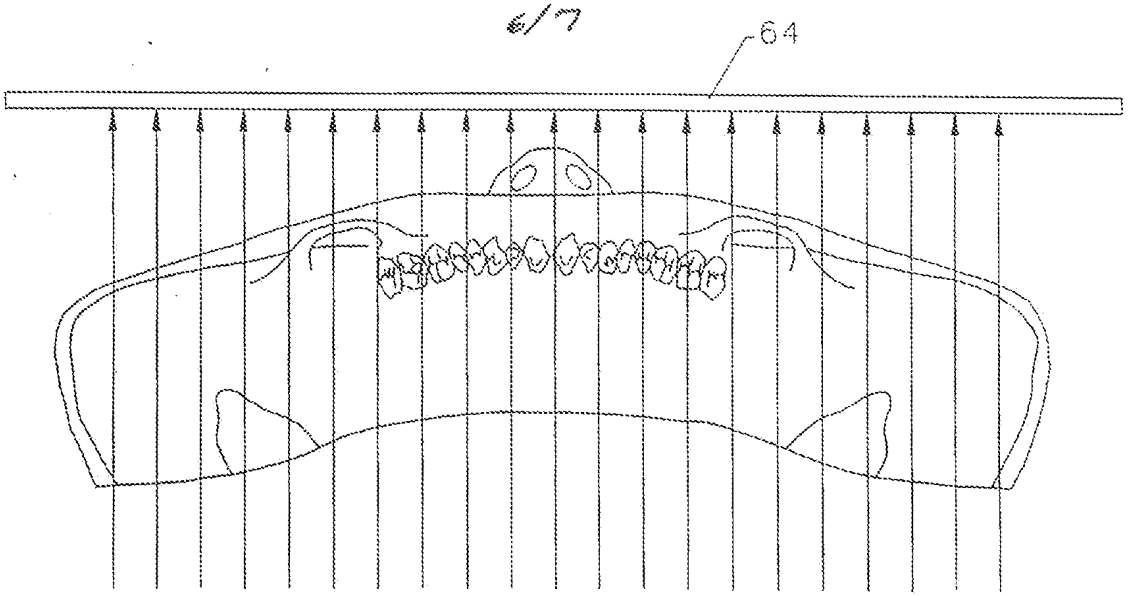


FIG. 10A.

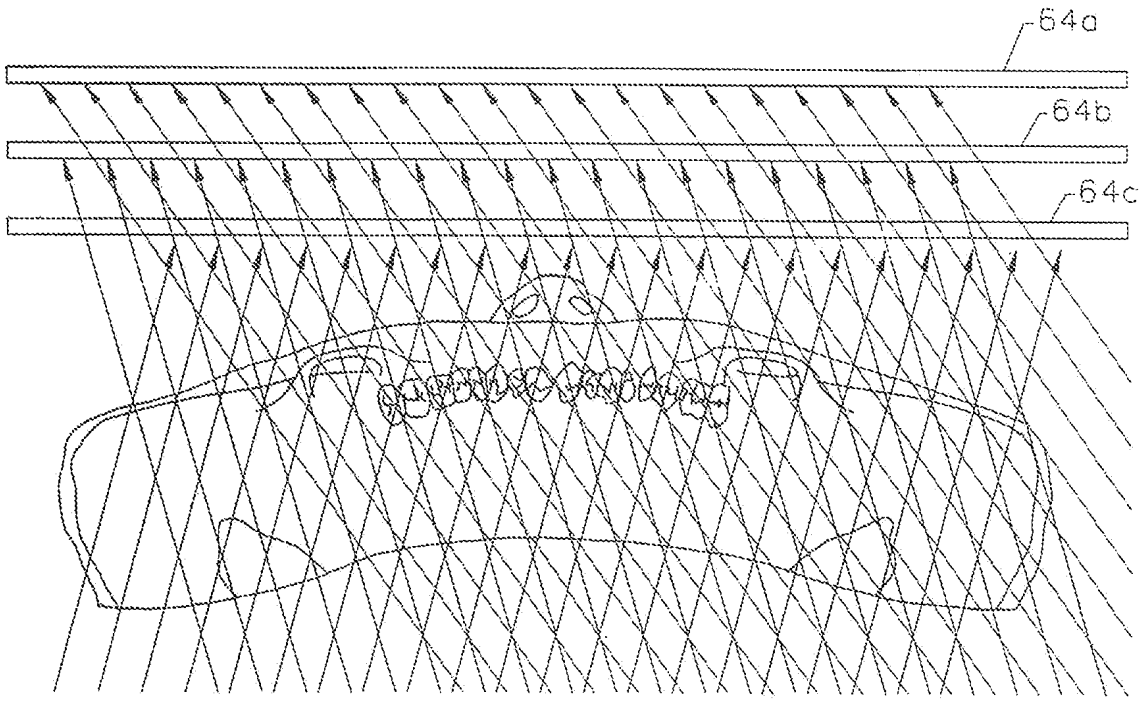


FIG. 10B.

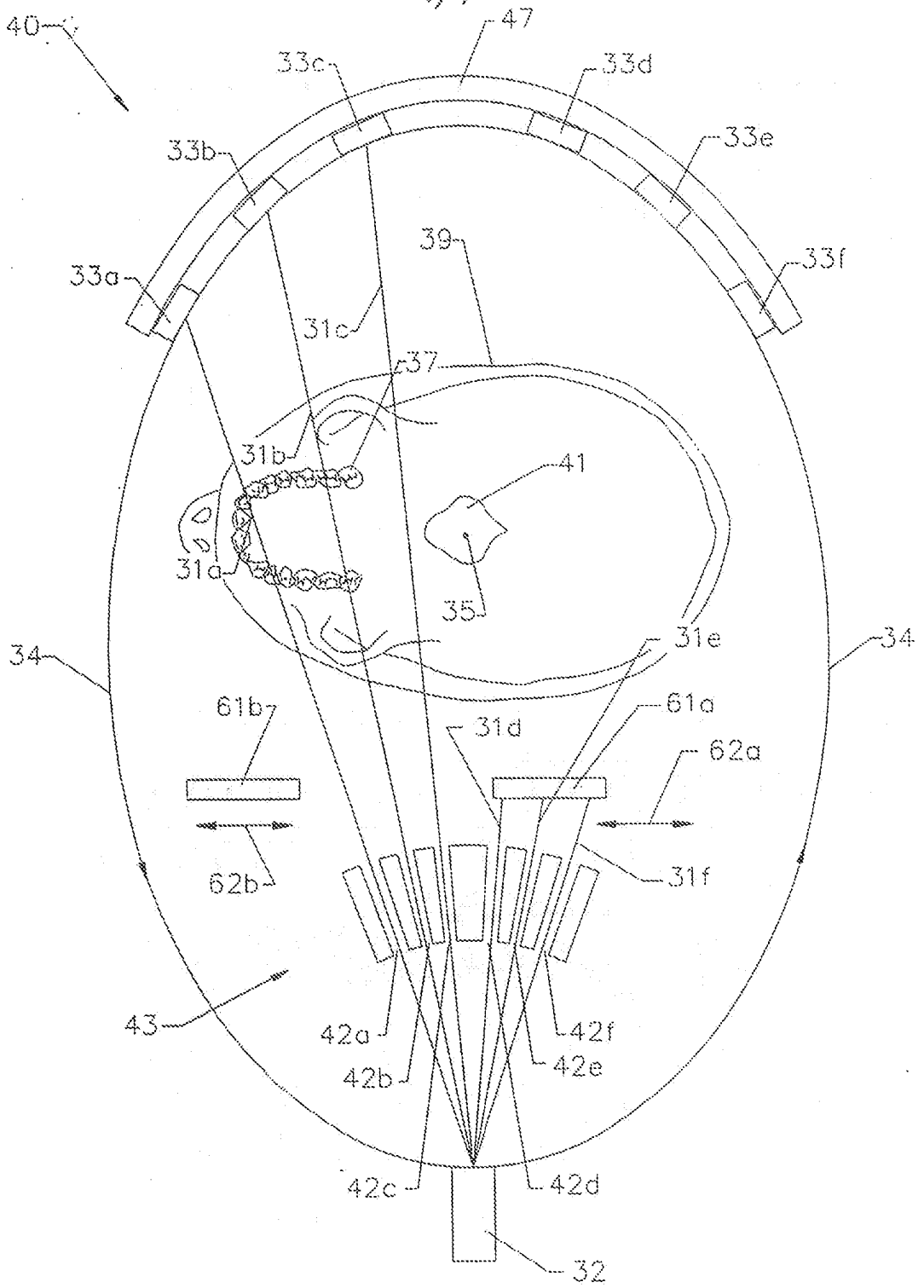

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31e
34
61b
61a
31d
62a
62b
31f
43
42a
42f
42b
42e
42c
42d
32

FIG. 11.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 92/10615

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B6/14

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[9]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	US,A,4 481 650 (KINANEN) 6 November 1984 cited in the application see column 3, line 36 - column 6, line 27 see figures	1,8-12, 14-18
A	US,A,4 878 234 (PFEIFFER ET AL.) 31 October 1989 cited in the application see column 2, line 48 - column 5, line 54 see figures 1-3	1,4-9, 12,14-16
A	US,A,4 304 999 (RICHEY ET AL.) 8 December 1981 cited in the application see column 3, line 54 - column 6, line 62	10,11, 17,18

-/--

[9] Special categories of cited documents :[10]

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

"E" earlier document 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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
07 APRIL 1993	07.05.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	CHEN A.H.

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,3 045 118 (HOLLMAN ET AL.) 17 July 1962 see column 2, line 18 - line 49 see column 4, line 38 - column 5, line 40 see figures 1,8,9	1,3,8, 12,15,16

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 9210615
SA 68217

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4481650	06-11-84	DE-A- 3215280	23-12-82
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(54) Computed tomography scanner.

(57) A computed tomography scanner for obtaining a tomographic image of a subject to be examined including a radiation emitting device for emitting radiation in a shape of a fan beam to the subject, a radiation detecting device for detecting the radiation that has passed through the subject to obtain detection data with respect to a tomographic plane of the subject. The radiation emitting device and the radiation detecting device determines a scanning area constituting a data collection region in a radiation plane of the fan beam. The subject has external dimensions exceeding the scanning area. The computed tomography scanner further includes a scanning device for relatively moving the subject, the radiation emitting device and the radiation detecting device in a condition that the radiation plane and the tomographic plane are on a same plane and a device for obtaining the tomographic image of a part of the subject corresponding to the scanning area from the detection data obtained by the radiation detecting device.

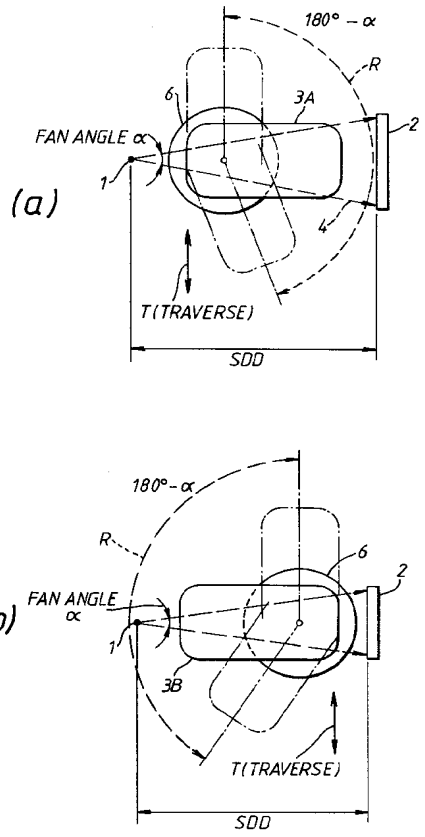


Fig. 2

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BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a computed tomography scanner that is adapted, for example, to non-destructive examination devices.

Description of the Related Art

Computed tomography scanners of this kind (hereinbelow abbreviated to CTs) include second-generation CTs of, for example, the traverse/rotation (hereinbelow abbreviated to T/R) system shown in Fig. 9 and third-generation CTs of the rotate/rotate system (hereinbelow abbreviated to R/R) shown in Fig. 10.

In a second-generation CT of the T/R system shown in Fig. 9, an X-ray fan beam 4 of fan angle α that is output from an X-ray source 1 is directed on to a subject to be examined not shown, placed on a T/R table 3 corresponding to the scanning area. Meanwhile, T/R table 3, on which the subject is placed, is rotated as shown by an arrow R and is traversed as shown by an arrow T, thereby effecting scanning. The X-rays that have passed through the subject are detected by a detector 2. This X-ray transmission data of the subject that is thus detected is collected, and this collected X-ray transmission data of the subject is subjected to processing by a reconstruction device, not shown, to obtain a tomographic image of the subject. With T/R table 3, the necessary scanning area is guaranteed by the space between X-ray source 1 and detector 2. From the point of view of efficiency of utilization of the X-rays, a distance SDD between X-ray source 1 and detector 2 should be very small.

Hereinafter scanning will be described in more detail. A prescribed distance traverse operation as shown by arrow T in Fig. 9 is performed such that T/R table 3 is made to traverse through the fan angle α of the X-ray beam. Indexing of the angle of rotation of T/R table 3 is performed with fan angle α, and data collection is performed by effecting rotation through an angle α for each traverse.

The prior art second-generation CT of the T/R system described above is disclosed in detail in U.S. Patent No. 5,027,378 issued on June 25, 1991.

However, when a subject is placed on T/R table 3, if some parts of the subject stick out from T/R table 3, they interfere with, for example, the X-ray shutter, the collimator and the frame etc, not shown, on X-ray source 1 side, or interfere with structural objects, not shown, on detector 2 side, with the result that scanning cannot be achieved. In general, T/R table 3 would be capable of 360° rotation.

In the case of the third-generation CT of the R/R system shown in Fig. 10, the arrangement of X-ray source 1 and detector 2 is the same as in Fig. 9. In this system, instead of both traverse and rotation only rotation can be performed, and the scanning action is achieved solely by rotation of a R table 5, by rotating R table 5 as shown by arrow R.

Also, when a subject is placed on R table 5, just as in the case of the T/R system described above, if the subject is placed on R table 5 with some parts sticking out, such parts of the subject interfere with structural items, not shown around the periphery of X-ray source 1 or detector 2, preventing scanning. Also, in general, R table 5 can be rotated through 360°.

As described above, in the case of the prior art CTs as shown in Fig. 9 and Fig. 10, if the subject has external dimensions larger than the scanning area, there is the problem that scanning cannot be achieved.

SUMMARY OF THE INVENTION

Accordingly, one object of this invention is to provide a computed tomography scanner which can achieve CT scanning and can obtain a tomographic image of a subject to be examined even when parts of the subject project beyond the scanning area.

Another object of this invention is to provide a computed tomography scanner in which the distance between the radiation emitting device and the radiation detecting device can be made smaller, and which can raise the radiation utilization efficiency and can be reduced in size and weight.

Still another object of this invention is to provide a computed tomography scanner which can scan only a specified part of a subject to be examined and can thereby obtain a tomographic image of increased spatial resolution and SN ratio.

These and other objects of this invention can be achieved by providing a computed tomography scanner for obtaining a tomographic image of a subject to be examined including a radiation emitting device for emitting radiation in a shape of a fan beam to the subject, a radiation detecting device for detecting the radiation that has passed through the subject to obtain detection data with respect to a tomographic plane of the subject.

The radiation emitting device and the radiation detecting device determines a scanning area constituting a data collection region in a radiation plane of the fan beam. The subject has external dimensions exceeding the scanning area. The computed tomography scanner further includes a scanning device for relatively moving the subject, the radiation emitting device and the radiation detecting device in a condition that the radiation plane and the tomographic plane are on a same plane and a device for obtaining the tomographic image of a part of the subject corresponding to the scanning area from the detection data obtained by the radiation detecting device.

With a computed tomography scanner of this invention, a subject that projects outside the scanning area can be arranged on one side only towards the radiation detection device side or radiation emitting device side. For data collection, scanning is carried out such that the rotation is (180° - fan angle α) in the case of the traverse/rotation system or (180° + fan angle α) in the case of the rotate/rotate system, and a reciprocating rotary action can be performed that is symmetric with respect to the line joining the centers of the radiation emitting device and radiation detecting device.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete appreciation of the invention and many of the attendant advantages thereof will be readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

Fig. 1 is a block diagram illustrating the layout of a computed tomography scanner according to an embodiment of this invention;

Fig. 2 is an explanatory diagram of the X-ray geometry of a second-generation CT of the T-R system according to an embodiment of this invention;

Fig. 3 is an explanatory diagram of the X-ray geometry of a second-generation CT of the T-R system;

Fig. 4 is an explanatory diagram of the X-ray geometry of a second-generation CT of the T-R system according to an embodiment of this invention;

Fig. 5 is an explanatory diagram of the X-ray geometry of a third-generation CT of the R-R system according to an embodiment of this invention;

Fig. 6 is a view showing the X-ray geometry of the embodiment with the mechanical unit illustrated in Fig. 7;

Fig. 7 is a view showing the detailed layout of the mechanical unit of the embodiment illustrated in Fig. 1;

Fig. 8 is a diagram illustrating a method of varying the scanning area in a T/R system according to another embodiment of this invention;

Fig. 9 is a view illustrating a prior art example of a second-generation CT of the T/R system; and

Fig. 10 is a view illustrating a prior art example of a third-generation CT of the R/R system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views, the embodiments of this invention will be described below.

Fig. 1 is a block diagram illustrating the layout of a computed tomography scanner 100 according to an embodiment of this invention. In this Figure, a scanner 10 is composed of X-ray source 1 consisting of an X-ray tube that continuously emits X-rays, a collimator 7A that shapes the X-rays emitted from this X-ray source 1 to a fixed fan beam shape, a collimator 7B that prevents incidence of the X-rays outside the prescribed directions, detector 2 that detects X-rays that have passed through the subject, and a data collection unit 11 that executes processing such as A/D conversion on the detection data output from detector 2 and outputs as projection data. Furthermore, scanner 10 includes a mechanical unit 13 which is provided with, in the case of the T/R system, a traverse mechanism and rotation mechanism, or, in the case of the R/R system, a rotation mechanism etc, and an operating panel 15 for inputting the settings of various measurement conditions etc.

Also, detector 2 is composed of, for example, a combination of 22 detection blocks each constituted by 8 photodiodes and 8 scintillators respectively, thereby providing 176 channels (8 channels per block). In the case of the R/R system, there would be at least 512 channels in detector 2.

A CPU 17 is connected to scanner 10, a console 19 and a control panel 21. CPU 17 controls the operation of computed tomography scanner 100 as a whole, and reconstructs a tomographic image of the subject whilst applying various kinds of correction, using the projection data that are input from data collection unit 11.

Console 19 is used to control the execution of various operations, and is connected to an image pickup unit 23, display 25 and X-ray controller 27.

Display 25 displays the setting conditions etc that are input from operating panel 15 and also displays a

tomographic image of the subject that is reconstructed by CPU 17.

Image pick-up unit 23 picks up and records the tomographic image that is displayed on display 25 under the control of CPU 17 through console 19.

Control panel 21 is connected to mechanical unit 13, operating panel 15, CPU 17, console 19, and X-ray controller 27. Control panel 21 controls mechanical unit 13 and X-ray controller 27 in accordance with control instruction from CPU 17 or operating instructions from operating panel 15 and console 19. X-ray controller 27 controls the voltage and current of X-ray tube.

A high voltage transformer 29 together with a high voltage generator 31 generates high voltage drive power, which is supplied to X-ray source 1. An oil cooler 33 cools X-ray source 1 and high voltage transformer 29.

Fig. 2 is a diagram illustrating the X-ray geometric system and scanning system of the second generation CT of the T/R system. In Fig. 2 (a), scanning area 6 is formed on the side near X-ray source 1 with respect to X-ray fan beam 4 determined by X-ray source 1 and detector 2, and T/R table 3A is provided, being of a shape which projects from scanning area 6 towards detector 2. In Fig. 2 (b), scanning area 6 is formed on the side near detector 2, and T/R table 3B is arranged so as to project towards X-ray source 1 from scanning area 6. Also, in these case, traversing is performed in the direction as shown by arrow T, and rotation is performed through (180° - α), as shown by arrow R.

T/R systems shown in Figs 2 (a) and (b) can be employed in the embodiment of this invention shown in Fig. 1.

Fig. 3 shows the X-ray geometry and scanning system of a second-generation CT which is also of the T/R system, like Fig. 2 (a). Scanning area 6 is likewise arranged on the side near X-ray source 1 with respect to X-ray fan beam 4 determined by X-ray source 1 and detector 2, and T/R table 32 is arranged within scanning area 6. In this case also, just as in the case of Fig. 2 (a), traversing as shown by arrow T and rotation are performed, and rotation is likewise through (180° - α). Next, the cases are considered in which T/R table 32 projects towards detector 2, as shown by the dotted line 32a. In a first case in which rotation is performed within the range (180° - α), as shown in Fig. 3, projecting portion 32a of T/R table 32 does not collide with X-ray source 1, so that distance SDD between X-ray source 1 and detector 2 is comparatively shorter, as shown. But in a second case in which T/R table 32 rotates through 360° as shown by the double-dashed lines, the required distance between X-ray source 1 and detector 2 becomes SDD' as shown in the drawings. Consequently, when T/R table 32 projects towards detector 2 as shown by 32a, distance SDD in the first case becomes smaller than distance SDD' in the second case of 360 degree rotation by the difference between distances SCD and SCD' of X-ray sources 1 and center C of scanning area 6, through a distance CDD between center C of scanning area 6 and detector 2 is not changed in the two cases.

As described in Fig. 3, in the case of Fig. 2 (a) or (b), the distance SDD between X-ray source 1 and detector 2 can be reduced, enabling the overall equipment size to be reduced, by having T/R table 3A or 3B offset towards X-ray source 1 or detector 2 and having it projected on the opposite side, and performing rotation through (180° - α). It should be noted that data collection can still be performed without violating the requirements of CT projection data by performing rotation with an Angle of (180° - α) during scanning.

Fig. 4 is a view showing the X-ray geometry of a second generation CT of the T/R system. In this Figure, a T/R table 33 is provided that projects towards detector 2 from scanning area 6 with respect to X-ray fan beam 4 determined by X-ray source 1 and detector 2. The arc portion near X-ray source 1 of T/R table 33 coincides with scanning area 6 and its radius is r. The radius from the center C of scanning area 6 of the part of T/R table 33 projecting towards detector 2 is R.

T/R table 33 shown in Fig. 4 can be used in mechanical unit 13 of the embodiment shown in Fig. 1.

Fig. 5 shows the X-ray geometry of a third generation CT of the R/R system. In this Figure, scanning area 6 is positioned near to detector 2 within X-ray fan beam 4 determined by X-ray source 1 and detector 2. Table 41 is arranged having a portion that projects with fan angle α, the same as fan beam 4, towards X-ray source 1 from scanning area 6.

In the case of a CT of the R/R system, as shown in Fig. 5, fan angle α must provide an angle sufficient to cover scanning area 6. In general, because of restriction on the X-ray emission angle of the X-ray source 1, distance SCD between X-ray source 1 and center C of scanning area 6 is large. On account of this, as shown in Fig. 5, the case of projection of table 41 towards X-ray source 1 enables distance SDD between X-ray source 1 and detector 2 to be made smaller than in the case of projection towards detector 2.

The tomographic plane can be reconstructed by picking up the projection data within the angular range (180° + α). Of course, in the case of an X-ray source 1 whose fan angle α can be taken larger, an arrangement can be adopted in which projection is allowed towards detector 2.

In Fig. 5, the radius of the portion of scanning area 6 constituted by table 41 is r, and the radius of the portion projecting towards X-ray source 1 from this portion is R, as shown.

Table 41 shown in Fig. 5 can also be used in mechanical unit 13 of the embodiment shown in Fig. 1.

Fig. 4 and Fig. 5 show the boundaries of the table shape determined from the X-ray geometry. The various restricting conditions may be summarized as follows in table 1.

[Table 1]

Scanning system	r	R	Extension of table
T/R (Fig. 4)	Scanning area	Distance from Scanning center to structural item	Wider area in which scanning area is enclosed by α
R/R (Fig. 5)	As above	As above	Narrower area in which scanning area is enclosed by α

The difference between the extents of the tables in the T/R system and R/R system is determined by the angle ($180° \pm \alpha$) through which the table can rotate in the scanning system in question. Also reciprocatory operation is performed within the range of rotation through angle ($180° \pm \alpha$).

Hereinbelow mechanical unit 13 of the embodiment shown in Fig. 1 will be described in detail. Fig. 7 is a view showing the detailed layout of mechanical unit 13 of the embodiment illustrated in Fig. 1. Fig. 6 is a view showing the X-ray geometry of the embodiment with mechanical unit 13 shown in Fig. 7. Mechanical unit 13 shown in Fig. 6 and Fig. 7 is adapted to a CT for tyres which images a tomographic plane of one side of a tyre, as an example. The tomographic plane on one side of the tyre is arranged to be imaged by an arrangement with the same geometry as Fig. 2 (a). Fig. 7 (b) is a view seen from the direction of arrow A in Fig. 7 (a). Fig. 6 shows the X-ray geometry at a tomographic plane 117 shown in Fig. 7 (b).

In Fig. 6 and Fig. 7, a tyre 101 is supported by a wheel 102 and the load is applied to tyre 101 by a loading plate 112. Fig. 7 (a) and (b) show how the load is applied to tyre 101. A support base 104 is fixed on a T/R table 3A that constitutes the scanning means capable of traverse/rotation. T/R table 3A is provided with traverse function provided by a rail and traverse mechanism etc. and rotation function. Support base 104 is provided with a holder 107 which is rotatable and constitutes tyre support means, through a rotary support unit 106 constituted by a bearing. A rotary drive unit 109 is provided between the bottom end of holder 107 and T/R table 3A. Holder 107 is arranged to be rotated by extension and contraction of rotary drive unit 109 by a control signal from control panel 21. The subject, constituted by tyre 101, is mounted on ordinary commercial wheel 102 and is maintained in holder 107 by means of screws 111 at the hub portion of this wheel 102.

Above and below holder 107 there are provided drive means for pressing a pressure plate or load plate 112 constituting load means against tyre 101. Drive means is composed of a drive unit 113, a drive screw rod 115, a support shaft 116 and a drive motor 114. By means of this mechanism, load plate 112 can be moved in the left or right direction of Fig. 7 (b). Also, as described above, X-ray source 1 and detector 2 are arranged opposite each other in positions on either side of tyre 101 supported on holder 107.

The tomographic plane 117 that is scanned by the X-rays on the fan beam that is emitted from X-ray source 1 is usually formed as shown in Fig. 7 (b) on a plane passing through the wheel center, which is also the center of tyre 101. A pressure measurement device, not shown, is provided on the pressurizing mechanism including load plate 112 so that the load force or pressurizing force can be suitably regulated.

In the CT for tyres constructed as above, in non-destructive inspection of tyre 101, tyre 101 is first mounted on holder 107 by the hub portion of wheel 102. Then, tyre 101 is rotated and held by rotary drive unti 109 such that the tomographic plane 117 of the desired tomographic image coincides with the plane of the X-ray fan beam that is emitted by X-ray source 1. In this condition, load plate 112 is driven by drive unit 113 so that a suitable load is applied to tyre 101. After this, a prescribed distance traverse operation as shown by arrow T in Fig. 6 is performed such that T/R table 3A is made to traverse through the fan angle α of the X-ray beam. Indexing of the angle of rotation of T/R table 3A is performed with fan angle α, and data collection is performed by effecting rotation through an angle α for each traverse.

As described above, with this embodiment, a tomographic image can be obtained in a condition in which load is applied to tyre 101. X-ray source 1 does not need to be inserted into the hollow space of tyre 101 as it would with a conventional CT for tyres. An ordinary commercial wheel 102 can therefore be used without modification. Tyre 101 can be mounted from A direction in Fig. 7 (a) by using holder 107, so convenient operation can be achieved. since there are provided rotary holding unti 106 of tyre 101 and rotary drive unit 109 of tyre 101, the scanning position i.e. the position of the tomographic plane can easily be altered. Consequently, a tomographic image can be obtained with respect to the portions of tire 101 from the road-contacting region of tyre 101 to the raised portions of the tyre tread.

Combination with mechanical tests of the tyre enables various load tests of tyre braking, steering, side

walls and bead in addition to the test described above. Also, CT scanning can be performed under other experimental conditions, not just under a condition with load applied to tyre 101 by a load plate as described above.

As described above, with this embodiment, scanning can be performed of a part of a subject to be examined that projects beyond the scanning area. Also, compared with a CT that scans the entire subject to be scanned, distance SDD between X-ray source 1 and detector 2 can be made smaller, and the X-ray utilization efficiency can be raised. Also, the computed tomography scanner as a whole can be reduced in size and in weight.

Since distance SDD between X-ray source 1 and detector 2 can be made small, the number of channels of detector 2 can be reduced, enabling detector 2 to be made of smaller size. As shown in Figs. 2 (a) and 3, the distance between X-ray source 1 and scanning area 6 can be made small, so, if the dimensions of the X-ray focal spot are small, the spatial resolution can be raised. Also, the traverse distance can be shortened, enabling the computed tomography scanner as a whole to be reduced in size and weight. As scanning of a part of a subject is possible, spatial resolution and/or image SN ratio can be improved.

In the embodiment shown in Fig. 6 and Fig. 7, CT scanning can be performed in a condition in which air pressure is applied to the tyre and in a condition with load applied to the tyre. Also, scanning can be performed whilst conducting other mechanical tests. Furthermore, in a CT for tyres, scanning can be reduced to the portion of the tyre under test. So, the traverse distance can be shortened and scanning area 6 will be nearer to the X-ray focal spot, thereby enabling a tomographic image of increased spatial resolution and SN ratio.

It should be noted that, although, in the above embodiments, second generation and third generation CTs were described, the same benefits can be obtained with CTs using other scanning systems by taking into consideration fan angel a and data collection range. Also, the same benefits can be obtained with other types of radiation source and detector, not just X-rays.

The scanning area can be altered, in the case of the T/R system, by altering the traverse distance and data sampling pitch etc, or, in the case of the R/R system, by shifting the center of rotation between the X-ray source and the detector.

Fig. 8 is a diagram given in explanation of a method of varying the scanning area of the T/R system. X-ray source 1 and detector 2 are shifted to positions 1', 2' as shown by the dotted lines, whilst maintaining distance SDD between X-ray source 1 and detector 2 constant. By this shifting scanning area 6 is made much wider as shown by 61, since the space wherein there is no interference with the subject of scanning can be widened.

Also, the same effect can be obtained by fixing X-ray source 1 and detector 2 and shifting the traverse position of the T/R table in the left or right direction.

In the alteration of the scanning area described above, the scanning area was varied with the geometry between X-ray source 1 and detector 2 kept fixed. However it is also possible to move X-ray source 1 and detector 2 with respect to the center of scanning so as to vary the geometry by changing the distance SDD between X-ray source 1 and detector 2. If this is done, the path (angle) of incidence of X-rays onto detector 2 from the X-ray source will change, so separators between the channels of detector 2 or countermeasures to prevent cross-talk must be fully considered.

As described above, with this invention, the subject to be examined can be arranged sticking out from the scanning area towards one only of the radiation detecting device or radiation emitting device, so a partial tomographic image can be obtained even from a subject whose external dimensions are larger than the scanning area. Also, the distance between the radiation emitting device and radiation detecting device can be made smaller, so the radiation utilization efficiency can be raised and the computed tomography scanner as a whole can be reduced in size and weight.

Furthermore, as scanning of a specified part of a subject is possible, spatial resolution and/or image SN ratio can be improved.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Claims

1. A computed tomography scanner for obtaining a tomographic image of a subject to be examined, comprising:

   radiation emitting means for emitting radiation in a shape of a fan beam to said subject;

   radiation detecting means for detecting said radiation that has passed through said subject to obtain detection data with respect to a tomographic plane of said subject;

said radiation emitting means and said radiation detecting means determining a scanning area constituting a data collection region in a radiation plane of said fan beam; characterised by

scanning means for relatively moving said subject, said radiation emitting means and said radiation detecting means in such a way that said radiation plane and said tomographic plane are in the same plane; and

means for obtaining said tomographic image of a part of said subject corresponding to said scanning area from said detection data obtained by said radiation detecting means;

whereby a relatively large subject may be scanned with a scanning beam of smaller area.

2. The computed tomography scanner according to claim 1, wherein:

said scanning means includes a traverse/rotation system for executing relative traverse/rotation movement to said subject, said radiation emitting means and said radiation detecting means; and

said scanning means performs scanning operation with rotation by an angle of (180° - α), where an angle of said fan beam is a fan angle (α).

3. The computed tomography scanner according to Claim 2, further comprising:

movement means for relatively moving said subject, said radiation emitting means and said radiation detecting means in a direction of a line joining centers of said radiation emitting means and said radiation detecting means such that a distance (SCD) between said radiation emitting means and a center of traverse of said scanning area is changed, when a distance (SDD) between said radiation emitting means and said radiation detecting means is fixed;

whereby said scanning area is variable.

4. The computed tomography scanner according to Claim 2, wherein:

said scanning means is provided with a base to which said subject is supported;

said scanning area is formed on a side near said radiation emitting means;

said base has a shape provided with a portion corresponding to said scanning area and a portion projecting from said scanning area toward said radiation detecting means; and

rotation in the scanning operation is performed symmetrically with respect to a line joining centers of said radiation emitting means and said radiation detecting means.

5. The computed tomography scanner according to Claim 2, wherein:

said scanning means is provided with a base to which said subject is supported;

said scanning area is formed on a side near said radiation detecting means;

said base has a shape provided with a portion corresponding to said scanning area and a portion projecting from said scanning area toward said radiation emitting means; and

rotation in the scanning operation is performed symmetrically with respect to a line joining centers of said radiation emitting means and said radiation detecting means.

6. The computed tomography scanner according to Claim 2, wherein:

said scanning means is provided with a base to which said subject is supported;

said base has a shape extending with a fan angle (α) of said fan beam in one direction, and defined by having dimensions in which a radius on a first side for said radiation emitting means is a first value (r) and a radius on a second side for said radiation detecting means is a second value (R) larger than said first value (r); and

rotation in the scanning operation is performed symmetrically with respect to a line joining centers of said radiation emitting means and said radiation detecting means.

7. The computed tomography scanner according to Claim 1, wherein:

said scanning means includes a rotate/rotate system for executing relative rotation movement to said subject, said radiation emitting means and said radiation detecting means; and

said scanning means performs scanning operation with rotation by an angle of (180° + α), where an angle of said fan beam is a fan angel (α).

8. The computed tomography scanner according to Claim 7, further comprising:

movement means for relatively moving said subject, said radiation emitting means and said radiation detecting means in a direction of a line joining centers of said radiation emitting means and said radiation detecting means such that a distance (SCD) between said radiation emitting means and a center of rotation of said scanning area is changed, when a distance (SDD) between said radiation emitting

means and said radiation detecting means is fixed;

whereby said scanning is variable.

9. The computed tomography scanner according to Claim 7, wherein:

said scanning means is provided with a base to which said subject is supported;

said scanning area is formed on a side near said radiation detecting means;

said base has a shape provided with a portion corresponding to said scanning area and a portion projecting from said scanning area and narrowing with a fan angle (α) of said fan beam toward said radiation emitting means; and

rotation in the scanning operation is performed symmetrically with respect to a line joining centers of said radiation emitting means and said radiation detecting means.

10. The computed tomography scanner according to Claim 7, wherein:

said scanning means is provided with a base to which said subject is supported;

said base has a shape narrowing with a fan angle (α) of said fan beam in one direction, and respectively restricted by spaces on the side of said radiation emitting means and on the side of said radiation detecting means; and

rotation in the scanning operation is performed symmetrically with respect to a line joining centers of said radiation emitting means and said radiation detecting means.

11. The computed tomography scanner according to Claim 1, wherein:

said subject includes a tyre having said external dimensions exceeding said scanning area;

said radiation emitting means includes an X-ray source for emitting X-ray in said shape of said fan beam to said tyre;

said radiation detecting means includes an X-ray detector for detecting said X-rays that have passed through said tyre to obtain said detection data with respect to said tomographic plane of said tyre;

said scanning means includes a table to which said tire is supported for moving said subject between said X-ray source and said X-ray detector in said condition that said radiation plane and said tomographic plane are on said same plane; and

said means includes a reconstruction device for obtaining said tomographic image of said part of said tyre corresponding to said scanning area from said detection data obtained by said X-ray detector.

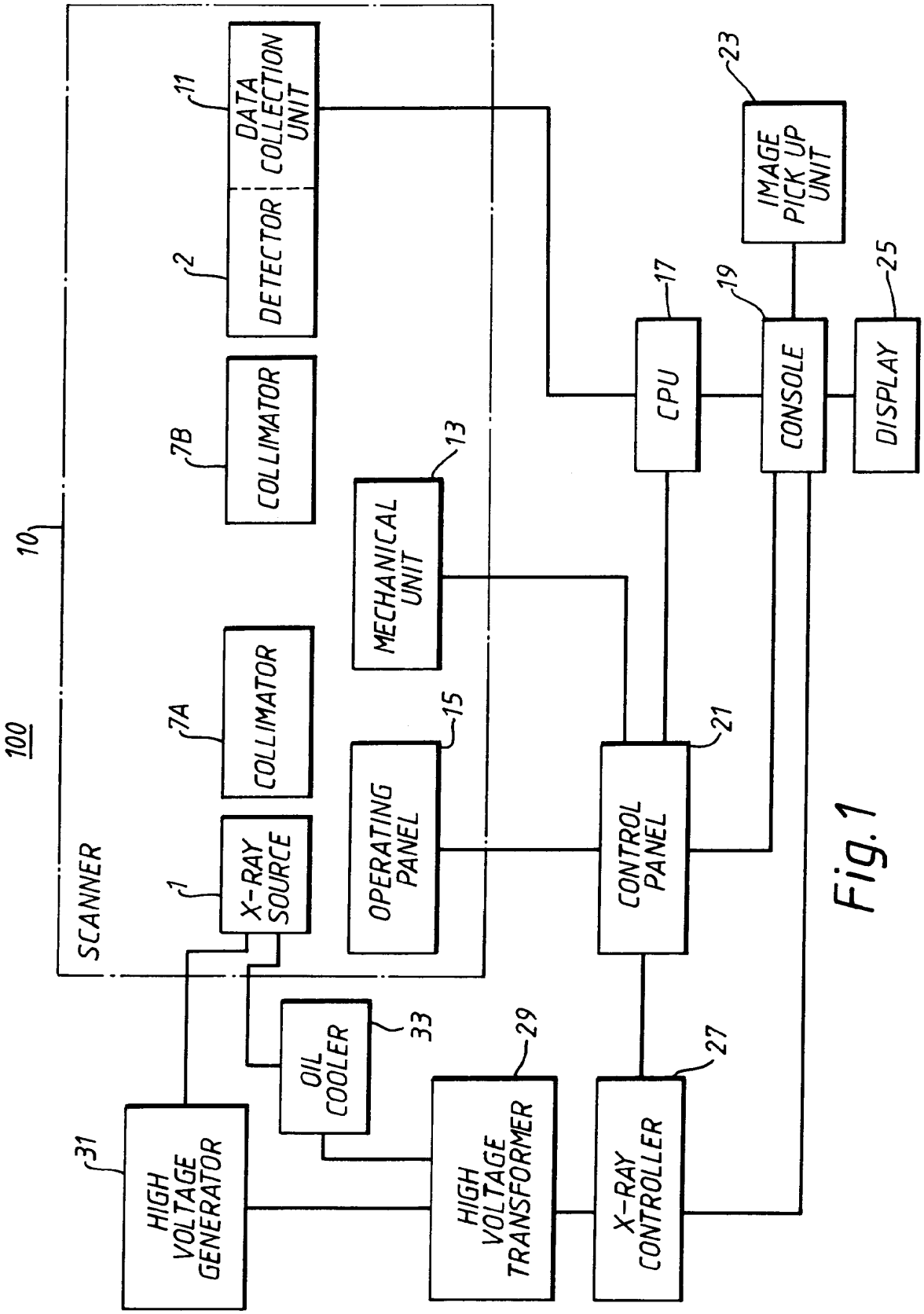

100
SCANNER
10
X-RAY SOURCE
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COLLIMATOR
7A
COLLIMATOR
7B
DETECTOR
2
DATA COLLECTION UNIT
11
MECHANICAL UNIT
13
OPERATING PANEL
15
CPU
17
CONSOLE
19
CONTROL PANEL
21
IMAGE PICK UP UNIT
23
DISPLAY
25
X-RAY CONTROLLER
27
HIGH VOLTAGE TRANSFORMER
29
HIGH VOLTAGE GENERATOR
31
OIL COOLER
33

Fig. 1

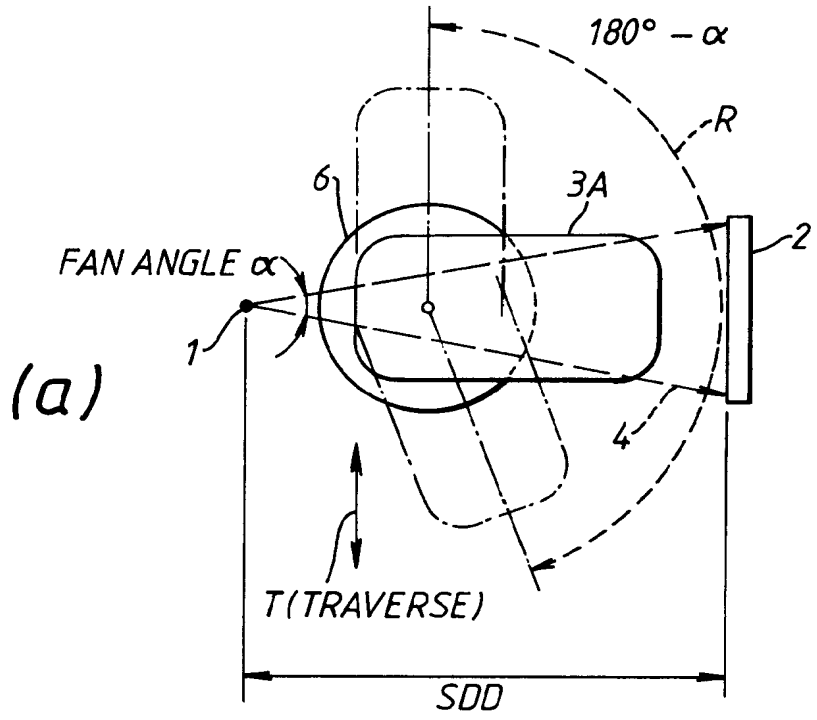
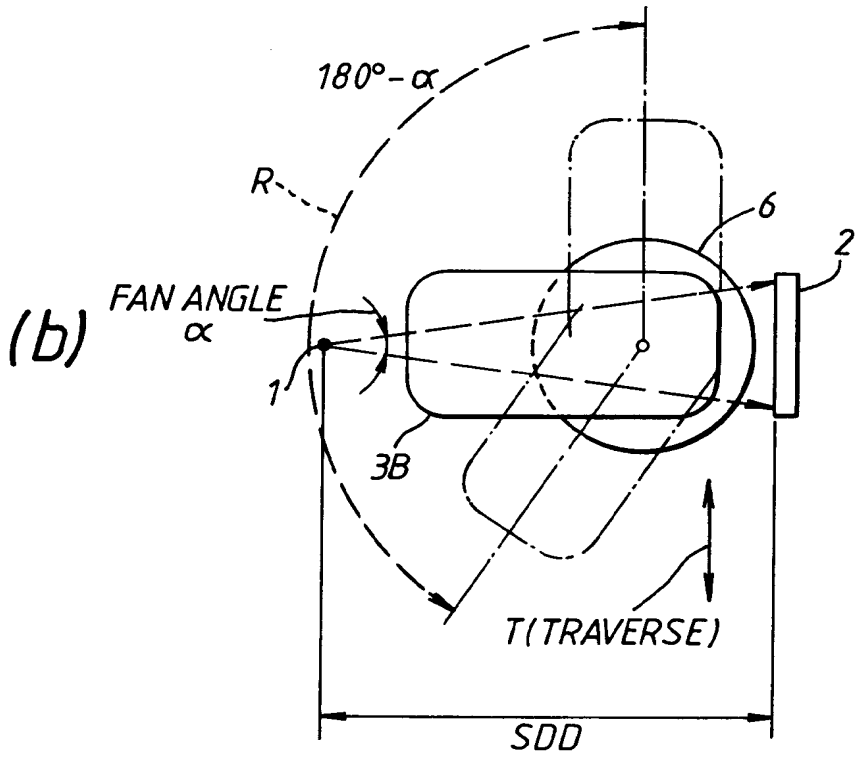

180° – α
R
6
3A
2
FAN ANGLE α
1
(a)
4
T(TRAVERSE)
SDD

Fig. 2


180°–α
R
6
2
(b)
FAN ANGLE
α
1
3B
T(TRAVERSE)
SDD

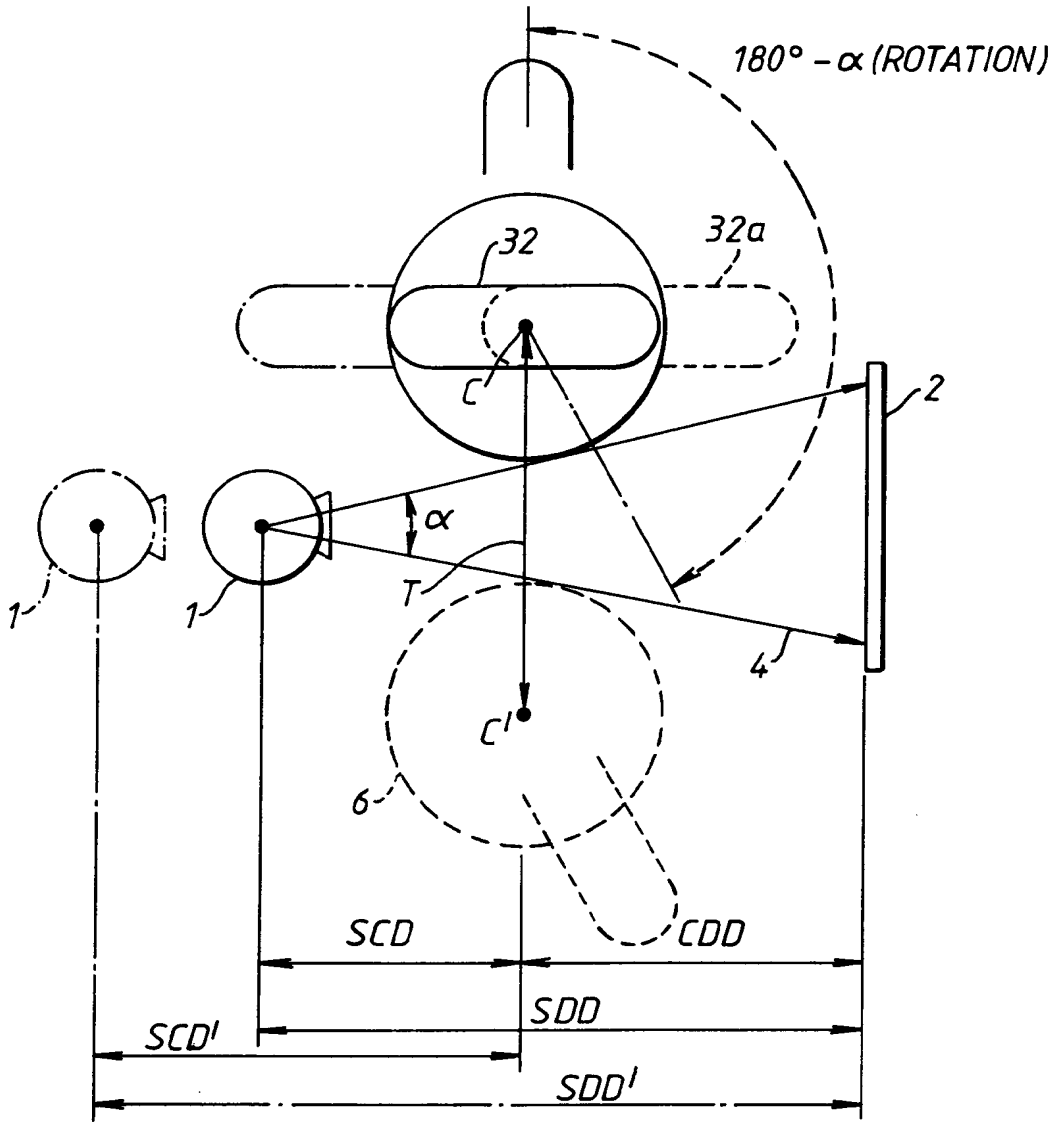


Fig. 3

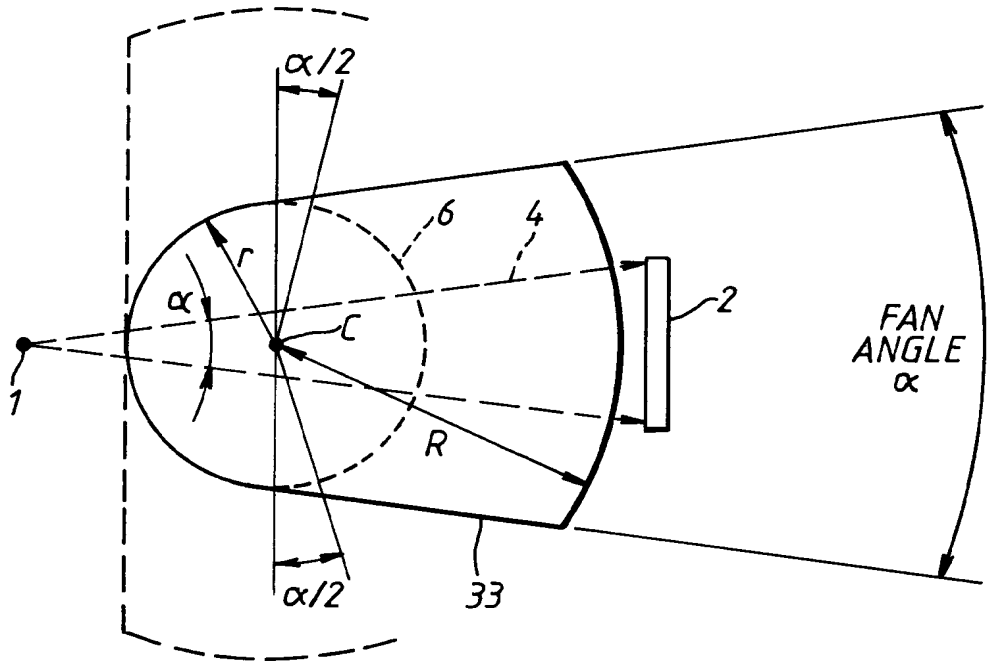

α/2
6
4
r
α
C
2
FAN
ANGLE
α
1
R
α/2
33

Fig. 4

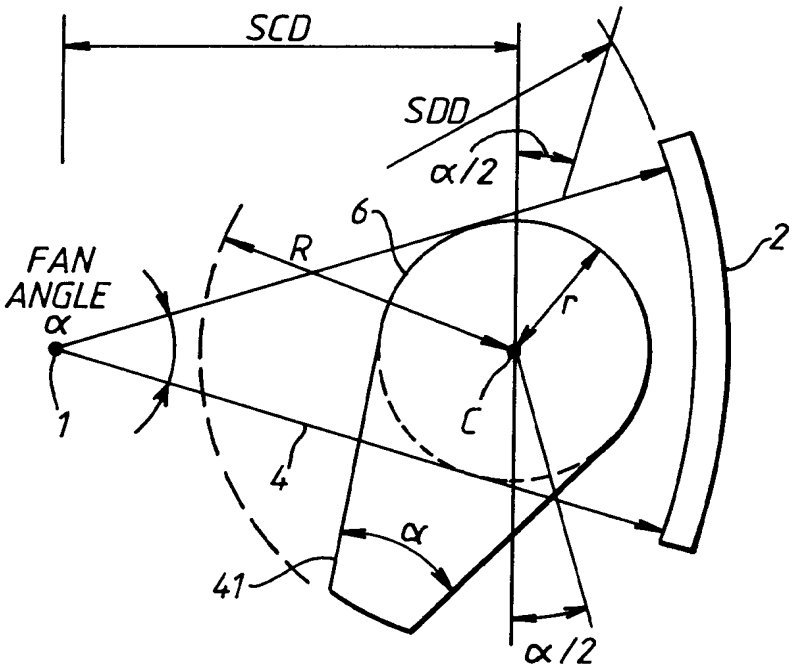

SCD
SDD
α/2
6
R
2
FAN
ANGLE
α
r
1
C
4
α
41
α/2

Fig. 5

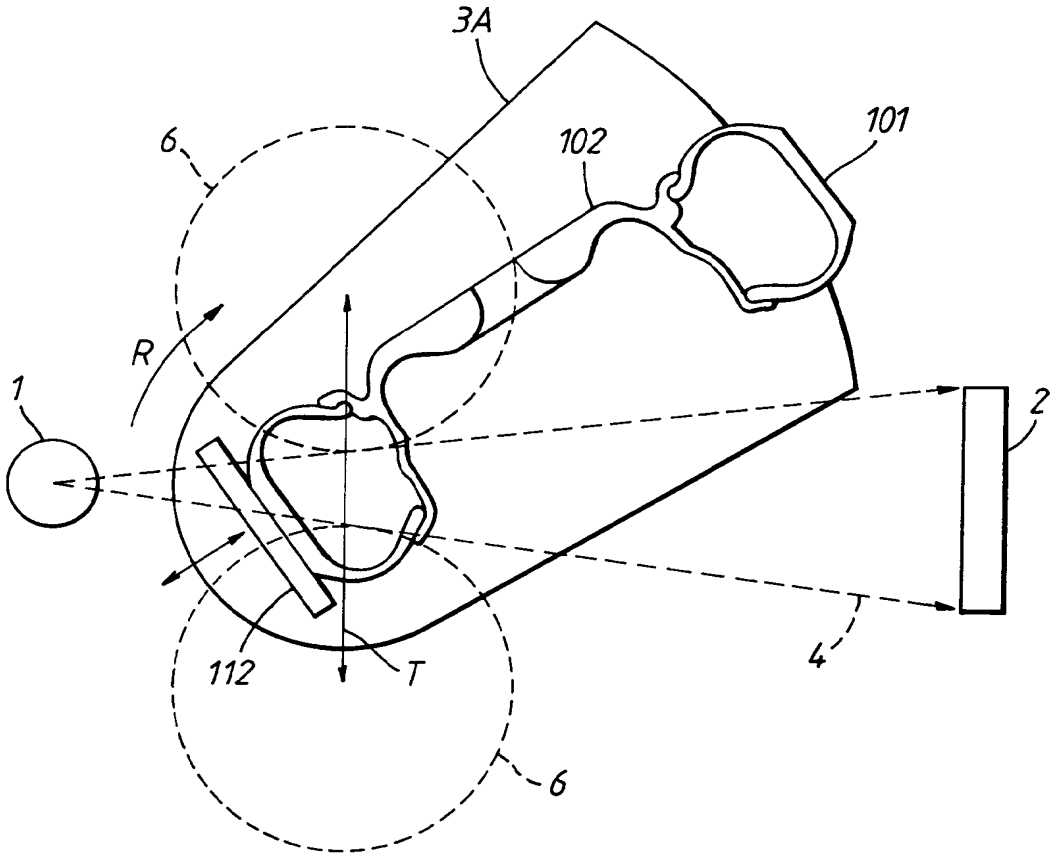


Fig.6

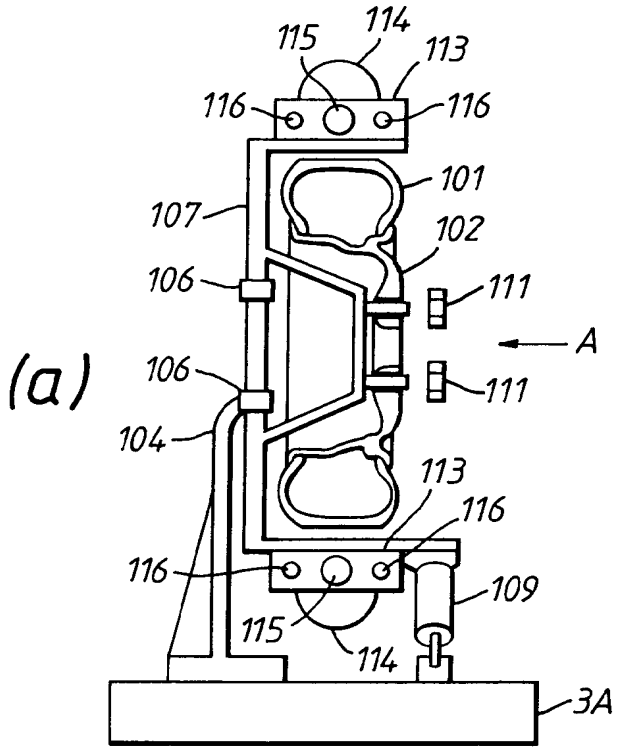
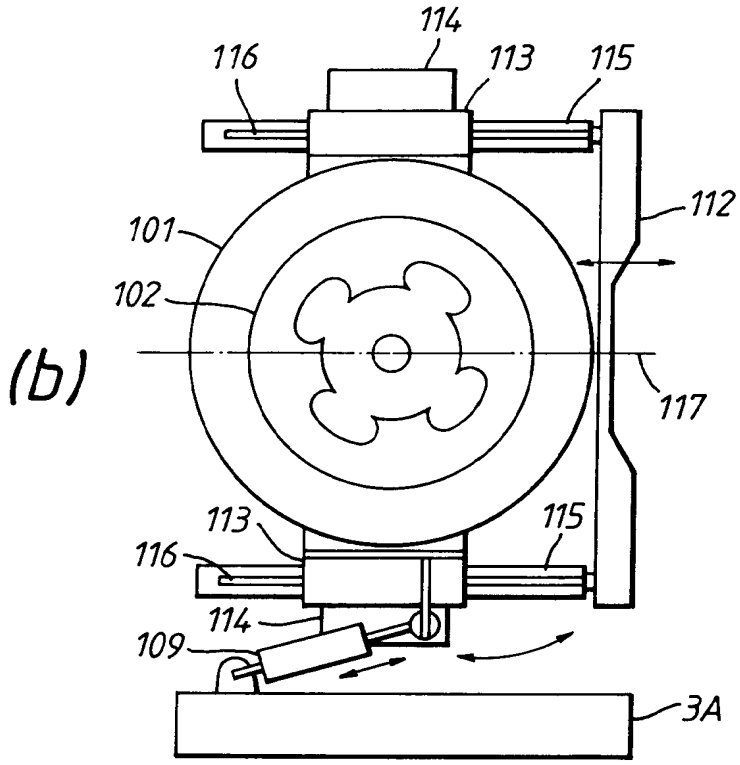

(a)
115
114
113
116
116
101
107
102
106
111
A
106
111
104
113
116
116
109
115
114
3A

Fig.7


(b)
114
116
113
115
112
101
102
117
113
115
116
114
109
3A

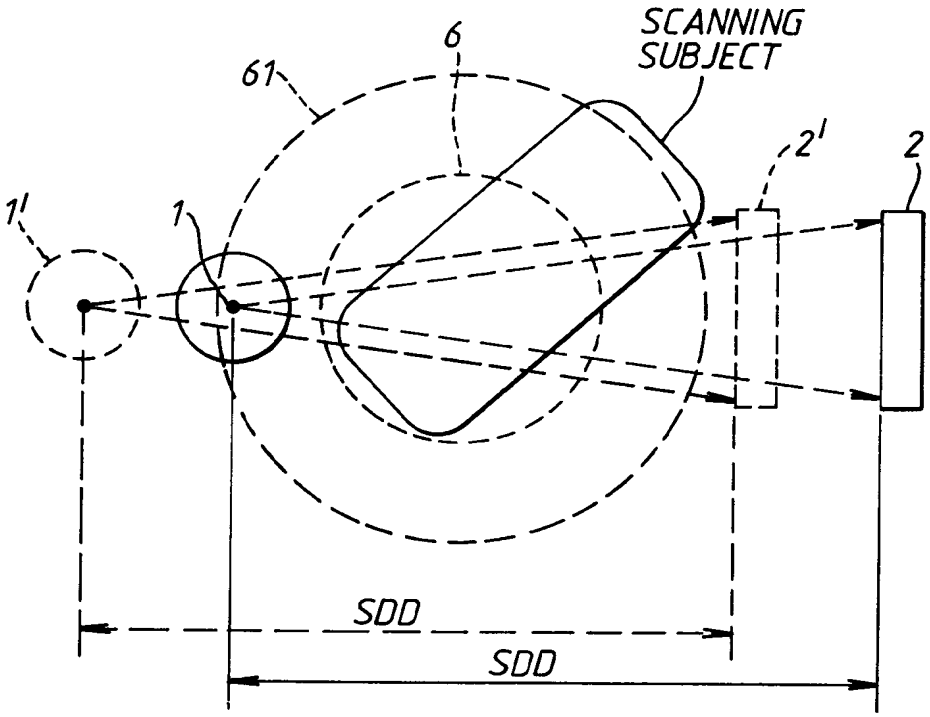


Fig. 8

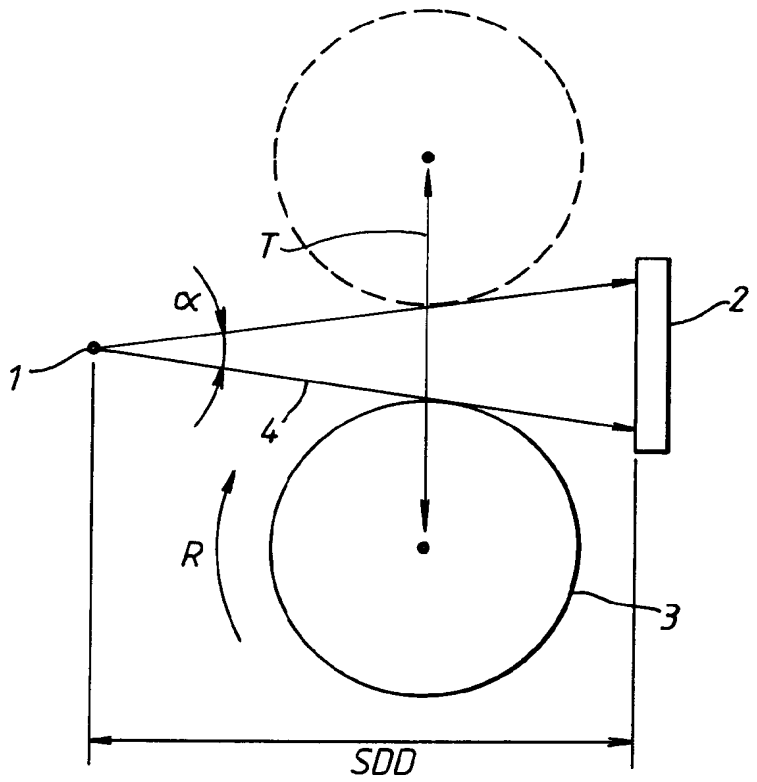


Fig.9
(PRIOR ART)

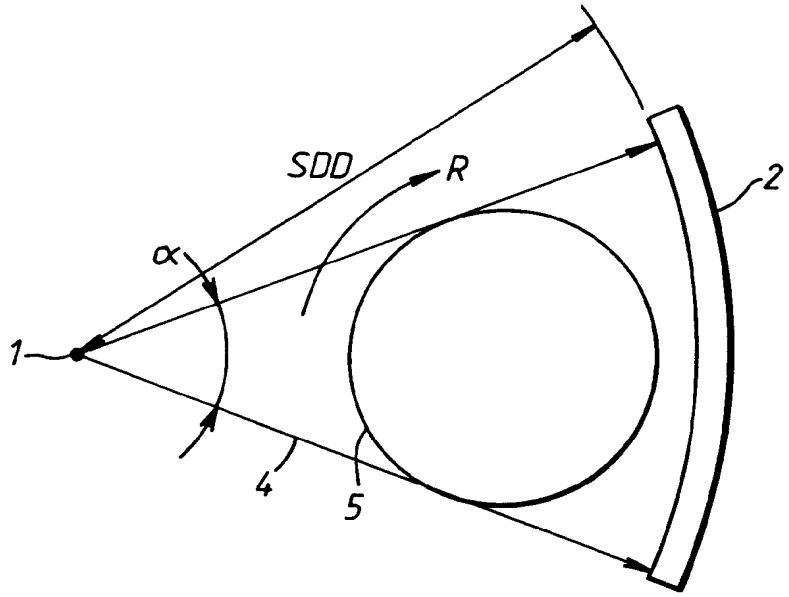


Fig.10 (PRIOR ART)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 94 30 8155

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
D,X D,Y	US-A-5 027 378 (FUJII) 25 June 1991 * abstract * * column 4, line 10 - column 6, line 9; figures 5,8 *	1-3,5,6 7,8,10, 11	G01N23/04 G01M17/02
Y	US-A-5 119 408 (LITTLE) 2 June 1992 * abstract * * column 3, line 47 - column 4, line 30; figure 2 *	7,8,10, 11	
A	GB-A-2 232 332 (GEN ELECTRIC) 5 December 1990 * abstract * * page 1, line 20 - page 3, line 18; figure 1 *	1	
A	PATENT ABSTRACTS OF JAPAN vol. 010 no. 111 (P-451) ,25 April 1986 & JP-A-60 242348 (TOSHIBA) 2 December 1985, * abstract *	1	TECHNICAL FIELDS SEARCHED (Int.Cl.6) G01N G01M
A	PATENT ABSTRACTS OF JAPAN vol. 9 no. 210 (P-383) [1933] ,28 August 1985 & JP-A-60 073441 (TOSHIBA) 24 April 1985, * abstract *	1	

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	3 February 1995	Thomas, R.M.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 94 30 8155

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	TOSHIBA REVIEW (INTERNATIONAL EDITION), SUMMER 1987, JAPAN, no.160, ISSN 0303-416X, pages 13-17, TANIMOTO Y ET AL 'X-ray CT scanner for heavy and valuable components' * page 13, right column, line 11 - line 31 * * page 17, left column, line 1 - line 17; figures 1,11 * -----	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

The present search report has been drawn up for all claims

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THE HAGUE	3 February 1995	Thomas, R.M.

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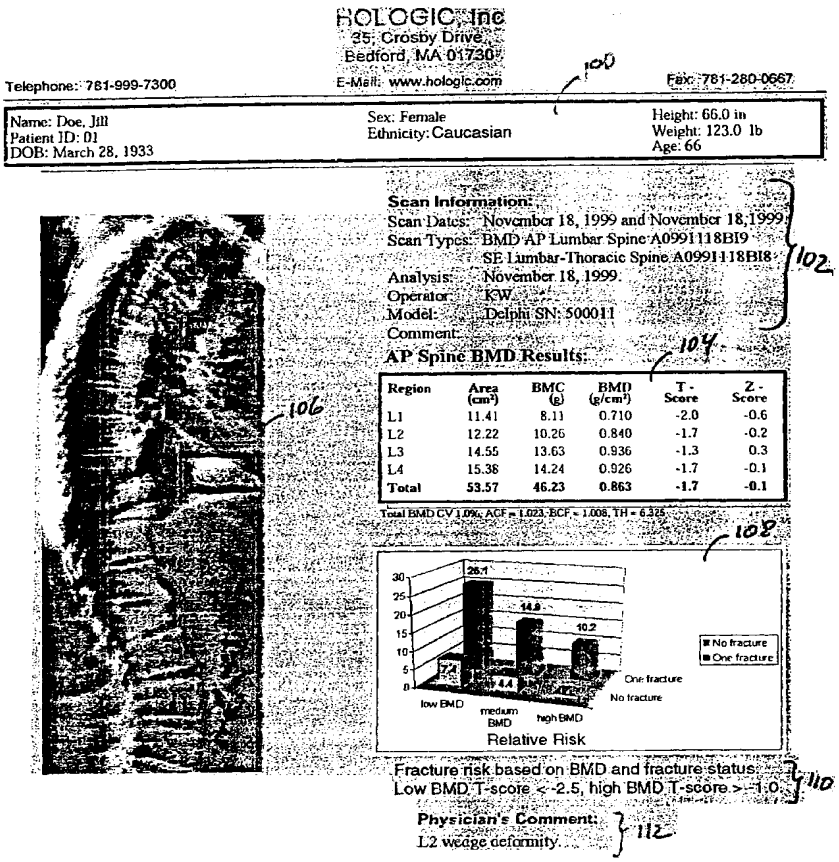
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(54) Title: DEVICE AND METHOD FOR DETERMINING FUTURE FRACTURE RISK



(57) Abstract: A DEXA bone densitometer produces estimates of future fracture risk from a current fracture data derived from a lateral image of a patient's thoracic and lumbar spine taken in a single scan, typically with the patient on her or his side, and from numerical bone mineral density measurements. The bone densitometer produces a lateral image of the patient's thoracic and lumbar spine (106) and develops numerical bone characteristics data (104), and future bone fracture risk data and produces a 3D graph (108). Single to dual energy scanning is utilized, with different proportions of two x-ray energy ranges available for different parts of the image.

WO 01/38824 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE AND METHOD FOR DETERMINING FUTURE FRACTURE RISK

Field

This patent specification relates to the general field of osteoporosis diagnosis, bone density, and vertebral imaging, and in particular to using a single device to predict future fracture risk by combining several measurements made on a single device along with biographical and/or other information about a patient to produce an estimate of the patient's future risk of bone fracture.

Background

Dual-energy bone densitometers such as the QDR machines manufactured by the assignee hereof, Hologic Corporation of Bedford, MA, and similar devices manufactured by LUNAR Corporation and Norland Corporation are used to measure Bone Mineral Density (BMD) and Bone Mineral Content (BMC) of the spine, hip, and peripheral sites. See, e.g., U.S. Patents 5,771,272, 5,778,045, 5,835,555, and 5,838,765, which are hereby incorporated by reference. These devices use the information from a particular BMD measurement at a particular site to classify patients with respect to their risk for future fractures. Further, some of the bone densitometer machines, namely the QDR4500A by Hologic and the Expert by LUNAR are capable of imaging the spine in the supine lateral position. The image of the spine thus obtained is used for quantitative morphometric analysis by the placing of points on the image and measuring morphometric parameters as discussed, for example, in U.S. Patents 5,850,836, 5,673,298, and 5,483,960, which are hereby incorporated by reference. These quantitative

morphometric measurements may be combined with values related to the bone mass to indicate the likelihood of future vertebral fractures in the vertebra. However, in spite of attempts at automating the calculation of morphometric indicia and the placement of points on the digital image provided by the bone densitometers, the procedure of quantitative morphometry to determine vertebral deformity (or fracture) can be labor intensive and tedious. Further, some of the bone densitometry machines use both a single energy and dual energy scan of the lumbar-thoracic spine. The single energy scan is faster and has a lower dose, but in the thoracic part of the spine soft tissue can sometimes obscure the vertebral endplates. The dual-energy scan subtracts out the soft tissue artifacts seen in the thoracic region and displays only the bone image. But dual-energy imaging, because it is effectively a difference of two images, has difficulty obtaining a high enough signal-to-noise ratio in the lumbar region of thicker patients using the low dose x-ray sources typically employed in densitometry. Besides morphometric imaging in the supine lateral position (patient lying on her or his back), some bone densitometers (e.g. QDR4500C by Hologic) have an imaging mode that allows imaging of the vertebral column while the patient is in a decubitus position, lying on her or his side. This positioning of the patient allows the physician to look for fractures in much the same way as when a supine lateral view is taken. There are services available on the Internet or through software licenses that combine information obtained from BMD measurements, information about significant prevalent fractures, ethnicity and age of a patient to calculate Remaining Lifetime Fracture Probability (RLFP). In the service located at www.medsurf.com, the physician types in information about the patient and the software generates a report, which includes an estimate of the likelihood of future fractures. In

particular, this software emphasizes the probability that a patient, typically a woman, will have a fracture during her remaining lifetime. Many other methods of reporting fracture have been discussed in the literature and include the probability of a fracture within a specified time frame (e.g., 1 year), the relative risk of fracture compared to other patients of the same sex, ethnicity, and age, or simply qualitative measures such as not increased, increased, and high risk compared to a reference population (which may or may not have the same sex, age, and/or ethnicity). Factual bases for determining a patient's future risk of fracture are discussed in many studies of a relationship between future fracture risk and such factors as age, sex, ethnicity, BMD, prevalent vertebral fracture, maternal history of fracture, corticoid use, etc. Other information can also be used for fracture risk estimates, including information from ultrasound bone units such as the Sahara unit manufactured by Hologic and from biochemical test strips. See, e.g., U.S. Patent 5,785,041, incorporated herein by reference. Fracture risk can also be divided by fracture site, with hip fractures often being a separate category because of the significant cost and morbidity associated with this type of osteoporotic fracture.

The following documents may be of interest to the device and method disclosed herein, and are hereby incorporated by reference: (1) J.A. Rea et. al. – Bone Vol. 23, Number 5, Supplement pg. S160; (2) S.R. Cummings et. al. The New England Journal of Medicine, March 23, 1995 Vol. 332 No. 12 "Risk Factors for Hip Fracture in White Women;" (3) C.C. Gluer et. al. – Radiology 1996;199:725-732 "Osteoporosis: Association of Recent Fractures with Quantitative US Findings;" (4) D.C. Bauer et. al., Archives of Internal Medicine March 2, 1997, Vol. 157 Pg. 629 "Broadband Ultrasound Attenuation Predicts Fractures Strongly and

independently of densitometry in Older Women;" (5) H. Genant et al.– Journal of Bone and Mineral Research Vol. 8, Number 9, 1993, pg. 1137 and J. Bone and Mineral Research Vol. 11 Number 7, 1996; (6) J.A. Kanis – Osteoporsis Int. (1997) 7:390-406 "Guidelines for diagnosis and management of Osteoporosis;" (7) J.A. Kanis Osteoporosis International (1997) 7 (Suppl. 3):S108-S116 "Diagnosis of Osteoporosis;" (8) National Osteoporosis Foundation Guidelines 1998 (see, e.g., Fig. 4); (9) Merrill's Atlas of Radiographic Positions and Radiologic Procedures 9th ed. Vol. 1 pg. 420-421; (10) M.C. Nevitt et. al. Bone Vol. 25 No. 5, November 1999:613-619; (11) P.D. Ross et. al. Osteoporosis Int. (1993) 3:120-126 "Predicting Vertebral Fracture Incidence from Prevalent Fractures and Bone Density among Non-Black, Osteoporotic Women;" (12) S.J. Jacobsen et. al. Epidemiology 1992 3(6):515-8 "Hospitalization with vertebral fracture among the aged: a national population-based study;" (13) M.A. Kotowicz et. al., Journal of Bone Mineral Research "Risk of hip fracture in women with vertebral fracture;" (14) P.D. Ross et.al. Osteoporosis International 1993; 3(3):120-126 "Predicting vertebral fracture incidence from prevalent fractures and bone density among non-black, osteoporotic women;" (15) L.J. Melton 3rd, et. al. Osteoporosis International 1999 10(3):214-221 "Vertebral Fractures Predict Subsequent Fractures;" (16) The Merck Manual of Geriatrics – Section 82 "Disorders of Mineral Metabolism" www.merck.com/pubs/mm_geriatrics/toc.htm; (17) FDA 510k –FDA pre-market notification k9972775 clearance date Oct. 1 1999. MXA-II software option; (18) QDR 4500 Image Works – View User Guide Hologic Doc. No. 080-0570 Rev. C Copyright 1996.

Summary

This patent specification discloses a device and a method in which an integrated device that not only measures bone mineral density (BMD) and provides an image that is useful for determining prevalent vertebral fractures, but also combines the BMD and the prevalent vertebral fracture information with biographical information and/or other risk factors to provide an indicator of a patient's future fracture risk to the physician (or other health services provider). This saves the physician time, prevents transcription errors, and provides a single report that the physician can provide to and discuss with the patient or the patient's referring physician. It also can help increase the accuracy of the diagnosis, since usually risk factors are not completely independent of each other, and could be combined based on relationships found in clinical studies. To combine such risk factors otherwise can be tedious and time consuming, and can require an extensive literature search. Moreover, by summarizing this information along with the scan reports and making this quickly available, the device and method disclosed herein can allow the physician to immediately discuss these results with the patient and can eliminate the need for the patient to have a return visit. Further, this arrangement can provide a single-energy X-ray scan of the entire lumbar-thoracic region, with the operator selecting a part of this region for repeat scanning using a dual-energy X-ray scan mode. This is useful because the single-energy scan is of a much lower dose and is much quicker, and only sometimes will it be necessary to repeat a certain part of the scan with a dual-energy scan. Thus, dose to the patient and time are conserved, especially since scan time for the dual-energy scan is approximately linearly proportional to the length of spine under examination. A typical single-energy high resolution scan requires

12 seconds for 18 inches, compared with 6 minutes for 18 inches for dual-energy on a QDR4500A. Also allowed, is for a scan window to be set on a dual-energy image, and another scan with different technique factors (collimators, dose, dual- or single-energy) performed based on the window set. The arrangement disclosed herein also allows different images to be displayed side by side and compared, for example, a single and dual energy lateral image, or two images taken on different dates.

Brief Description of the Drawing

Fig. 1 illustrates a prior art DEXA (dual energy x-ray absorptiometry) system.

Fig. 2 illustrates a report in accordance with one embodiment of the disclosed device and method.

Fig. 3 illustrates another example of a report.

Fig. 4 illustrates main steps in practicing an embodiment of a disclosed method.

Description of Preferred Embodiment

A preferred embodiment uses an x-ray bone densitometer to be offered under the name Delphi by Hologic, which can determine the bone density of a patient and produce a lateral image of a patient's spine with the patient in a decubitus position, lying on her or his side, and the X-rays in a vertically oriented fan-shaped beam using both a single-energy and/or dual-energy X-ray mode. The lateral image can be viewed by the physician to determine prevalent vertebral fractures and thus current fracture data. The study typically consists of, at least, a BMD measurement and a lateral image of the spine. The BMD measurement can be done

following the user guide for the QDR 4500 bone densitometer manufactured by Hologic, as described in Hologic Document No. 080-0451 Rev. G and incorporated by reference herein. The lateral image can be obtained by following the QDR 4500 Image Works –View User's Guide Document No. 080-0570 Rev. C and incorporated by reference herein. In performing the scan, the operator can fill in the patient's name, sex, age, ethnicity, height, weight, and other biographical or other data that may be relevant to the physician and this information is displayed on the report and stored with the measurement results in a database. The report can be displayed on a computer monitor and/or printed with a suitable printer or other output device, and can be archived in digital form, such as DICOM format.

The lateral image can be viewed by the physician, either on the computer monitor, or by other high-quality output devices for the presence of vertebral fractures. This can be preferable to the placement of points and quantitative analysis of the morphometry of the image because it is more convenient, expeditious and intuitive. Further, the combination of age, sex, BMD and prevalent vertebral fracture are strong predictors of future fracture risk.

In one embodiment, the device gives the physician the opportunity to input into the database the number of prevalent vertebral fractures seen by the physician in the single or dual-energy image(s). The software combines this information with other information in the database, such as age, sex, ethnicity, BMD of the spine and/or BMD of the hip to produce a report with prediction of future bone fracture risk. The prediction of fracture risk may be relative fracture risk compared to an age, sex and ethnicity matched population, or an absolute fracture risk based on a specific time frame, such as one year or projected remaining lifetime. Alternatively, along with the lateral image of the spine, the device includes in the displayed

report fracture risk data such as an indication based on no vertebral fractures, one vertebral fracture, or two or more vertebral fractures. The physician can then view the image for fractures, and determine which future fracture risk applies to this patient. The physician can then write his report based on his findings, incorporating the appropriate future fracture risk.

In another embodiment, the risk of future fractures is expressed as the risk of future hip fractures and the risk of other fractures.

In a further embodiment, other clinical risk factors are input into the database, such as corticoid use, maternal history of osteoporotic fracture, ultrasound measurements of bone quality such as made by the Sahara bone sonometer manufactured by Hologic, results of biochemical markers, serum calcium and albumin levels, estrogen use, alendonate use, lifestyle factors, family history, etc. These additional risk factors are incorporated into the future fracture risk prediction, thus integrating all of the clinical risk factors into a single number (or two if the risk of hip fractures is reported separately). Usually, risk factors are not completely independent of each other, so it is may not be easily apparent to the physician, without a tedious literature search, how each additional risk factor increases or decreases a patient's future fracture risk. For example, the additional relative risk factor of a low ultrasound bone measurement when a patient has a BMD measurement is only about 1.5, while if nothing is known about the patients BMD, the relative risk of a low ultrasound bone measurement is about 2.0 (Bauer 1997 reference). In another embodiment, the value of treatment is incorporated into the risk model. In this embodiment, the doctor is given the patient's future risk of fracture under the assumption of no treatment, or various treatment options which could include life-style modifications, estrogen replacement therapy, or BMD-

increasing medications. How much a given treatment option decreases a patient's future fracture risk may be dependent on that patient's specific risk factors. For example, calcium supplementation may significantly reduce the risk factor of a patient who is calcium deficient as evidenced by serum calcium and albumin levels, but have very little effect on a patient who is not calcium deficient.

Another embodiment allows the operator, after finishing the single-energy X-ray scan, to select a part of the spine to scan with a user selected technique factor, for example, in dual-energy mode or in a higher resolution single energy mode. While it may not always be necessary, a different technique scan can be useful in cases of soft tissue artifacts or where there is a motion artifact. By limiting the portion of the spine over which the additional scan is acquired, the dose to the patient and the time of examination can be kept low. This additional scan can be part of the same study as the single-energy scan, and the physician can refer to either image to determine vertebral fractures. In the preferred embodiment, there are two indicators or lines that can be moved on the single energy image with a mouse or other pointing device. These two lines delimit the area of the scan that will be done with a different scan mode. QDR 4500 devices manufactured by Hologic have the ability to use the information, along with the encoders of the instrument, to accurately reposition over the area to be rescanned. After the second image is acquired, the software allows both images to be viewed simultaneously, or for several images to be viewed, even images which were obtained at an earlier date. By comparing images, the physician can diagnose incident fractures on repeated visits, and this can be a method of monitoring treatment efficacy.

Referring to Fig. 1, which illustrates a prior art QDR 4500 x-ray bone densitometer, a scanning system 30 includes a patient table unit 32 comprising a patient table 50 and a C-arm 56 serving as a source-detector support. A workstation 34 controls patient table unit 32 and C-arm 56 and processes scan data into numerical bone density data such as BMD and images. Workstation 34 includes a power supply module 36, a host computer 38 with a mass data storage device 40, an operator console keyboard 42, a display monitor 44 and a printer 46. Table 50 can move up and down and along its long dimension. C-arm 56 also moves along the length of table 50 to scan a patient thereon with a fan beam of x-rays from source 52 so that a detector array 54 and associated electronics can produce dual energy or single energy scan data. The C-arm can also move across the table to correctly position the source and detector over the desired body part.

The Delphi bone densitometer to be offered by Hologic and incorporating an embodiment described in this patent specification is generally similar to the QDR 4500 illustrated in Fig. 1 and described in the patents incorporated by reference, and has two models, one with whole body (Delphi – W) and one without whole body (Delphi – C). The designation Delphi refers to both models. The Delphi C and W correspond approximately to the existing QDR4500 C and QDR4500W, with certain enhancements, some similar to features of QDR4500 SL. For example, the detectors in the Delphi models are approximately half the size as the detectors in the 4500 C and W, providing 2x better image resolution perpendicular to the scan direction, as is the case with the existing 4500 SL model. The Delphi has two collimators (slits), a 1 mm and a 0.5 mm collimator, while the QDR4500C/W

have only the 1 mm collimator. The additional 0.5 mm collimator is used to provide better resolution in the direction of scanning., as in the QDR4500 SL model.

The Delphi models provide an Instant Vertebral Assessment feature of the Delphi using the process of future risk estimation discussed above. The Delphi models need not have a rotating C-arm, in which case a lateral view image can be obtained with the patient in the decubitus position, lying on her side instead of her back, which is a well know X-ray technique that can be done well with proper training. An advantage of this position is that certain patients tend to be thinner in the direction of the x-rays than if supine (body mass can hang forward instead of around the sides), and this can reduce image noise and enhance contrast between bone and soft tissue. Another advantage is that the source can be closer to the patient, increasing the magnification and improving the effective image resolution. Another improvement in the Delphi system is an Auto Analysis feature, that can use a region of interest locator of the type described in U.S. Provisional Patent Application Ser. No. 60/148,027, hereby incorporated by reference. This includes improved placement of the femoral neck box. Another improvement is a Dual Hip feature.

Fig. 2 illustrates an example of a patient report produced in accordance with an embodiment described in this patent specification. Box 100 contains patient-specific information that can be entered by the operator or can come from a database. At 102, the report shows scan information (which in this illustration is representative rather than specific to a patient or to a scan). Box 104 shows representative numeric bone characteristics data such as BMD estimates for the lumbar vertebrae. A lateral image of the patient's thoracic and lumbar spine is shown at 106, obtained in a single and unidirectional scan at single energy.

This image demonstrates a vertebral fracture or deformation, i.e., current fracture data to the effect that this patient has a vertebral fracture or deformation. Box 108 illustrates future bone fracture risk estimates that take into account both numerical bone characteristics data (BMD) and current fracture data. A 3D graph at 108 shows relative future fracture risk (relative to risk of unity for a patient with no current fracture of deformation and high BMD). For this patient, with one fracture, the three columns in the back of the graph are pertinent (relative risk of 10.2, 14.9 and 25.1), and the particular column pertinent to this patient is determined by the patient's numerical BMD data, classified as illustrated at 110, for example. This patient has a medium BMD T-score, so a relative future bone fracture risk of 14.9. The physician can enter comments at 112, for example through keyboard 42, identifying the current fracture or deformity data observed in the image at 106 — in this case a wedge deformity at lumbar vertebral body L2.

Fig. 3 illustrates another report format that is otherwise similar to Fig. 2 but contains comments that can be automatically generated as a result of the scan data analysis by the densitometer and the entry by the physician of current fracture or deformity data observed in image 106. The densitometer in this case reports the physician's entry of "one vertebral fracture" and automatically generates a report based in that entry and on the BMD estimates, stating in narrative form that the patient's relative risk of future fracture is 14.9 (without treatment). Moreover, the densitometer includes in the report estimates of future fracture risk with different treatment scenarios — with hormone replacement therapy, the relative risk is 10.3 and with alendronate, the relative risk is reduced to 7.9. Still further, the densitometer calculates and prints out in the report at 116, estimates of absolute risk of fracture during the

year after the scan in three different scenarios — 2.4% without treatment, 1.7% with hormone replacement therapy, and 1.3% with alendronate.

Fig. 4 illustrates main steps in a process carried out in a suitably programmed computer, such as computer 36 in Fig. 1, to generate reports such as those illustrated in Figs. 2 and 3. A patient is scanned with a densitometer such as the Delphi from Hologic at 118, and produces x-ray scan data at 120 that can be dual energy and/or single energy. The scan data includes dual energy data for numerical estimates of bone characteristics as well as single and/or dual energy data for a lateral image of at least a majority of the patient's thoracic and lumbar vertebrae. At 122 the scan data is processed as in known in the art to produce an image displayed at 124 as well as numerical estimates of bone characteristics data such as BMD. Processing step 126 receives such numeric bone characteristics data, as well as current fracture or deformation data provided on the basis of observing the image displayed at 124, or otherwise, and also can receive other data from 128 that can be used in estimating future fracture risk, such as data from biochemical analysis of bone resorption, data from previous patient examinations, etc. Processing step 126 then produces estimates of future bone fracture risk, such as those illustrated in Figs. 2 and 3, for example by accessing a database relating combinations of inputs to estimates of future fracture risk. At 130, reports such as those illustrated in Figs. 2 and 3 are displayed and/or printed.

The scan data produced at 120 for the lateral view can be for a single energy image of some or all of the patient's spine, or can include a dual energy image for a part of the spine, for example some or all of the thoracic vertebrae. The dual energy image can be produced by rescanning a part of the spine designated by the operator by markers placed on the single

energy image. Alternatively, a part of the spine can be scanned for a single energy image and the remainder scanned for a dual energy image, with the change taking place during the scan, at a point indicated by the operator or detected by the densitometer, for example on the basis of the exposure received at the detector.

While in the preferred embodiments described above the current fracture data is derived from a visual observation of the lateral image, an alternative is to use a known automated or partly automated processes to computer-analyze the scan data for the purpose of detecting vertebral fractures or deformities. Each approach can provide the requisite current fracture data. The reports can be displayed in a number of ways, for example on a monitor or by printing them or by storing them for later viewing or printing or otherwise displaying them, and can be a single page or screen or multi-page reports. While in preferred embodiments the lateral image is taken with the patient recumbent on her or his side on the patient table and the central ray of the x-ray beam generally vertical, it is possible to derive a useful lateral image in other patient positions and x-ray beam orientations, such as with the patient supine and the central x-ray beam generally horizontal.

While various embodiments have been described above, it should be clear that they are merely illustrative of the inventions set forth in the following claims that encompass other variations that are not specifically described above.

Claims:

1. A method of using an x-ray bone densitometer to derive and display each of numerical bone mineral density (BMD) data for the patient, a lateral image of at least a majority of both the lumbar and thoracic vertebrae of the patient, and future bone fracture risk data for the patient, comprising:

using the same x-ray densitometer to scan a patient with x-rays and generate both numerical bone mineral density (BMD) data for the patient and a lateral image of at least a majority of both the lumbar and thoracic vertebrae of the patient;

providing current fracture data relating to the presence or absence of vertebral fractures or deformities in the image;

computer-processing the BMD data and the current fracture data to produce future bone fracture data taking into account both the BMD data and the image-based data; and

displaying a report showing the numeric BMD data, the image, and the future bone fracture risk data.

2. A method as in claim 1 in which the lateral image is taken with the patient recumbent on her or his side.

3. A method as in claim 2 in which the image is a single energy image.

4. A method as in claim 2 in which a selected portion of the image is a single energy image while another portion is a dual energy image.

5. A method as in claim 1 in which the step of scanning the patient to derive said image comprises scanning the patient in a single, unidirectional scan and changing technique factors during the scan.

6. A method as in claim 4 in which the change of technique factors during the scan includes changing from single energy scanning to dual energy scanning during the scan.

7. A method as in claim 4 in which the change of technique factors during the scan includes changing the scanning speed during the scan.

8. A method as in claim 4 in which the change of technique factors during the scan includes changing relative contributions to the image of x-ray measurements in different x-ray energy ranges.

9. A method as in claim 1 in which the report comprises a lateral image of the patient's spine, numerical BMD data of the patients lumbar vertebrae, and a graphical display of the future bone fracture risk data.

10. A method as in claim 1 in which the report comprises a lateral image of the patient's spine, numerical BMD data of the patients lumbar vertebrae, and a narrative display of the future bone fracture risk data.

11. A method as in claim 1 further comprising producing future bone fracture risk data based on selected treatments and displaying in said report the future bone fracture risk in the absence of treatment and in the presence of the respective treatments.

12. A method as in claim 1 in which the lateral image is taken with the patient in a supine position.

13. A method as in claim 1 in which the lateral image is taken with a central ray of the x-rays in a generally vertical orientation.

14. A method as in claim 1 in which the lateral image is taken with a central ray of the x-rays in a generally horizontal orientation.

15. A method as in claim 1 in which the step of using the densitometer to scan comprises using a dual energy densitometer.

16. A method as in claim 1 in which the step of providing current fracture data comprises providing data based on a visual assessment of the lateral image.

17. A method comprising:

scanning a patient with an x-ray bone densitometer to produce x-ray scan data;

using the x-ray scan data to produce both numerical bone characteristic data and a lateral image of both lumbar and thoracic spine of the patient;

using the image to produce current fracture data regarding the presence or absence of vertebral fractures or deformations;

using both the numerical bone characteristic data and the current bone fracture data to produce and display a report indicative both of numeric data regarding current bone characteristics and regarding future bone fracture risk for the patient.

18. A method as in claim 17 in which said scanning comprises scanning both with single energy x-rays and with dual energy x-rays.

19. A method as in claim 18 in which said scanning includes scanning the patient in a recumbent position on the patient's side.

20. A method as in claim 19 in which the scanning comprises scanning a part of the patient's spine with single energy x-rays and a part with dual energy x-rays.

21. A method as in claim 17 in which the scanning comprises changing x-ray technique factors during a single, unidirectional scan of the patient with x-rays.

22. A method as in claim 21 in which the changing of x-ray technique factors during a scan comprises changing from one to the other of single to dual energy scanning.

23. A method as in claim 17 in which the step of using the scan data to produce a lateral image comprises using dual energy x-ray data and different proportions of two x-ray energy ranges for different parts of the image.

24. A system comprising:

a bone densitometer scanner selectively producing x-ray scan data for a lateral image of at least a major portion of the thoracic and lumbar spine of a patient in a single scan and scan data for numerical bone characteristics estimates;

a processor receiving x-ray scan data from the scanner and processing the received data to produce numerical estimates of bone characteristics and a lateral image of at least a major portion of the patient's thoracic and lumbar spine, and responsive both to data regarding said numerical estimates and to data regarding current fractures or deformities in the patient's spine derived from said lateral image to produce estimates of future fracture risk; and

a display showing the lateral image as well as said numerical data and said estimates of future fracture.

25. A system as in claim 24 in which the x-ray scan data comprises dual energy data.

26. A system as in claim 24 in which the numerical estimates comprise BMD data.

27. A system as in claim 24 in which the bone densitometer comprises an x-ray source scanning the patient with a generally vertically oriented beam of x-rays to produce the scan data for said lateral image.

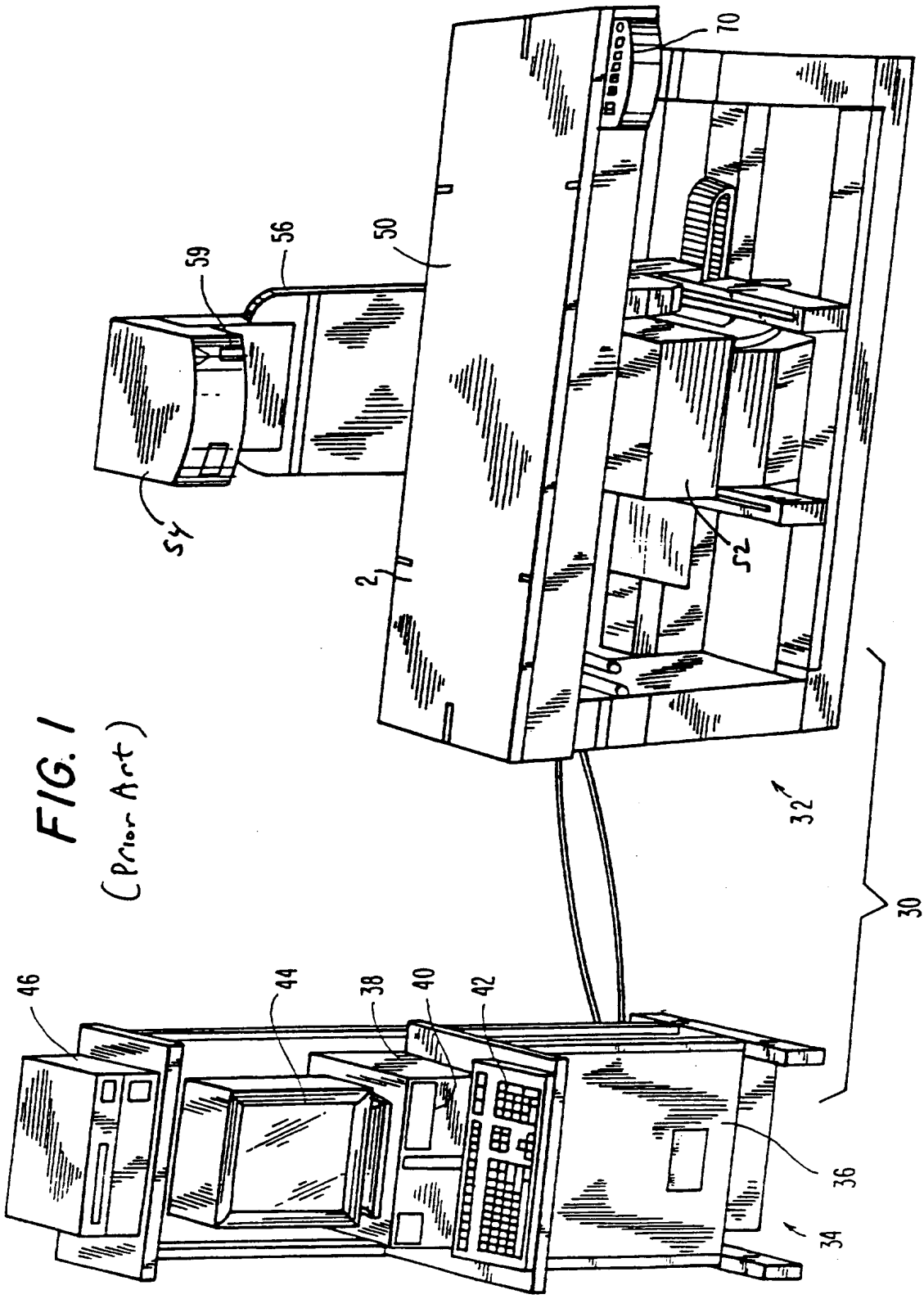


FIG. 1
(Prior Art)

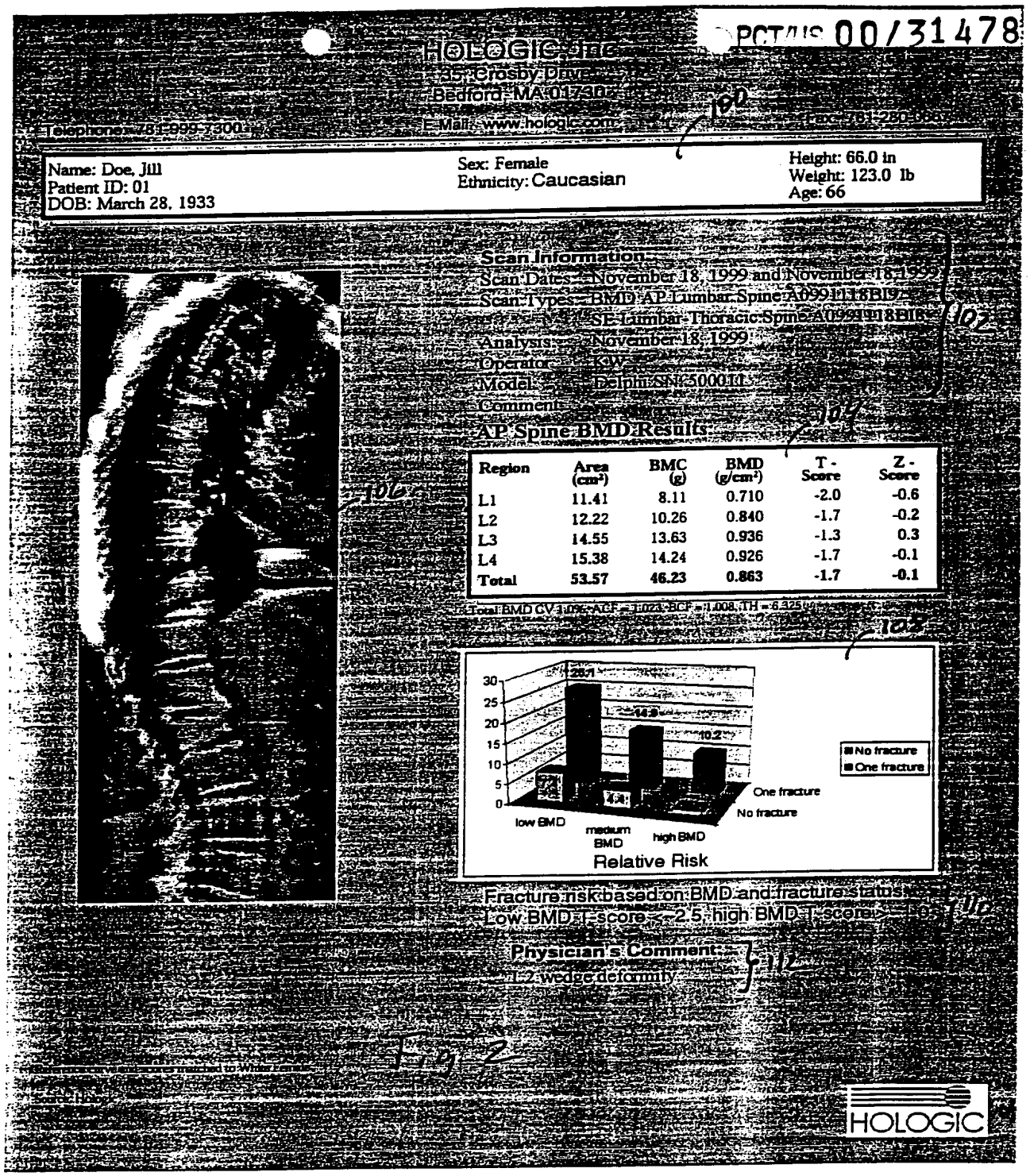
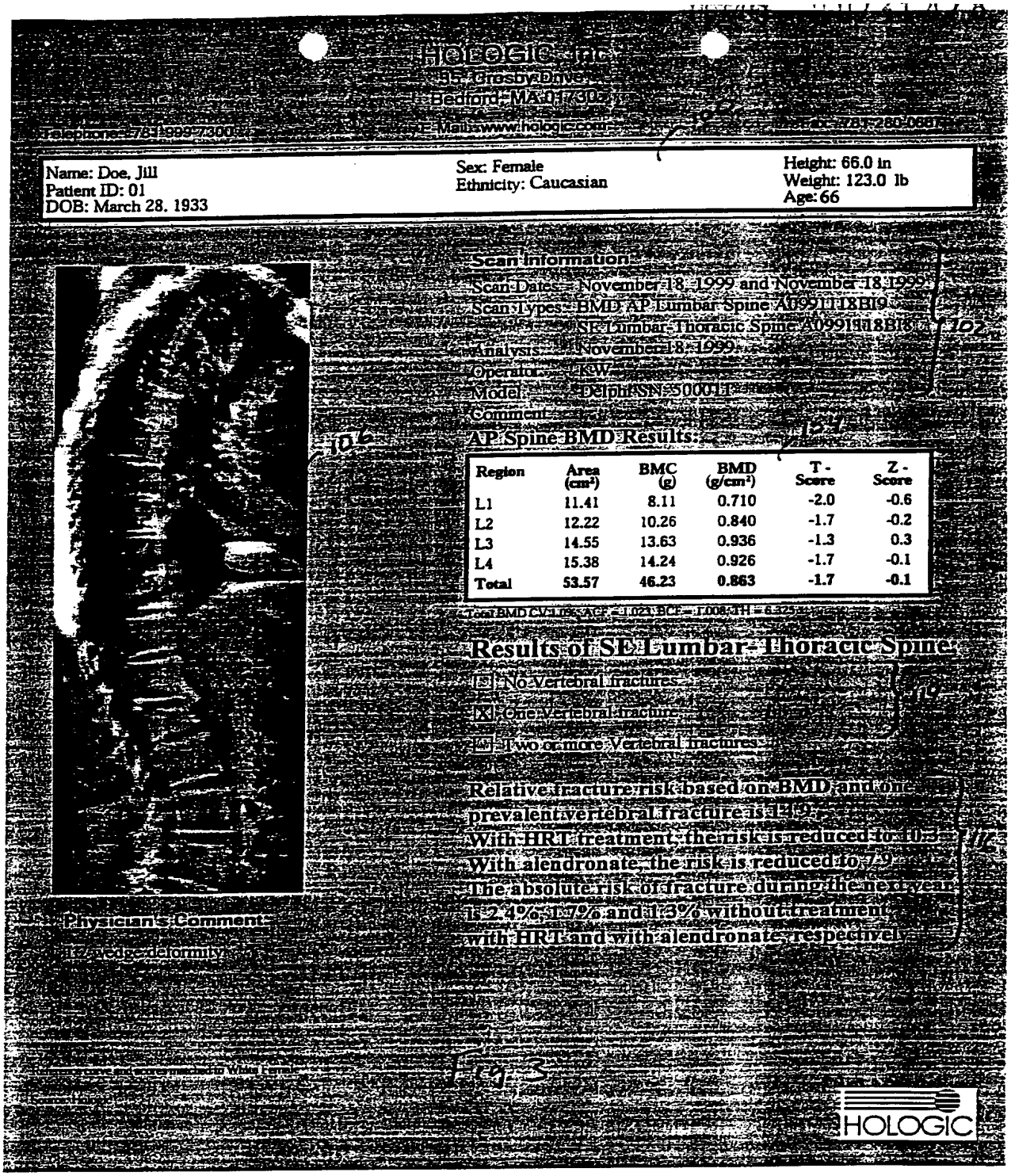

PCT/US 00/31478
HOLOGIC, Inc.
35 Crosby Drive
Bedford, MA 01730
Telephone: 781-999-7300
E-Mail: www.hologic.com
Fax: 781-280-0668
Name: Doe, Jill
Patient ID: 01
DOB: March 28, 1933
Sex: Female
Ethnicity: Caucasian
Height: 66.0 in
Weight: 123.0 lb
Age: 66
Scan Information
Scan Dates: November 18, 1999 and November 18, 1999
Scan Types: BMD AP Lumbar Spine A099111 8BI9
SE Lumbar-Thoracic Spine A099111 8BI9
Analysis: November 18, 1999
Operator: KW
Model: Delphi SN: 50001
Comment:
AP Spine BMD Results
Region | Area (cm²) | BMC (g) | BMD (g/cm²) | T-Score | Z-Score
L1 | 11.41 | 8.11 | 0.710 | -2.0 | -0.6
L2 | 12.22 | 10.26 | 0.840 | -1.7 | -0.2
L3 | 14.55 | 13.63 | 0.936 | -1.3 | 0.3
L4 | 15.38 | 14.24 | 0.926 | -1.7 | -0.1
Total | 53.57 | 46.23 | 0.863 | -1.7 | -0.1
Total BMD CV 1.0% ACF = 1.023 BCF = 1.008 TH = 6.325
30
25
20
15
10
5
0
28.1
14.9
10.2
4.9
One fracture
No fracture
low BMD
medium BMD
high BMD
Relative Risk
Fracture risk based on BMD and fracture status:
Low BMD: T-score <= -2.5 high BMD: T-score >= -2.5
Physician's Comment:
L1-2 wedge deformity
HOLOGIC

Fig 2



HOLOGIC, Inc.
35 Crosby Drive
Bedford, MA 01730
Telephone: 781 999 7300
E-Mail: www@hologic.com
781 280 0881

Name: Doe, Jill
Patient ID: 01
DOB: March 28, 1933

Sex: Female
Ethnicity: Caucasian

Height: 66.0 in
Weight: 123.0 lb
Age: 66

Scan Information:
Scan Dates: November 18, 1999 and November 18 1999
Scan Types: BMD AP Lumbar Spine A099111 8B19, SE Lumbar-Thoracic Spine A099111 8B18
Analysis: November 18, 1999
Operator: KW
Model: Delphi SN 50001
Comment:

AP Spine BMD Results:

Region	Area (cm^2)	BMC (g)	BMD (g/cm^2)	T-Score	Z-Score
L1	11.41	8.11	0.710	-2.0	-0.6
L2	12.22	10.26	0.840	-1.7	-0.2
L3	14.55	13.63	0.936	-1.3	0.3
L4	15.38	14.24	0.926	-1.7	-0.1
Total	53.57	46.23	0.863	-1.7	-0.1

Total BMD CV 1.0% ACF = 1.021 BCF = 1.008 TH = 6.925

Results of SE Lumbar-Thoracic Spine:

[ ] No Vertebral fractures
[X] One Vertebral fracture
[ ] Two or more Vertebral fractures

Relative fracture risk based on BMD and one prevalent vertebral fracture is 1.9.
With HRT treatment, the risk is reduced to 1.0.
With alendronate, the risk is reduced to .9.
The absolute risk of fracture during the next year is 2.4%, 1.7% and 1.3% without treatment, with HRT and with alendronate, respectively.

Physician's Comment:
Wedge deformity

HOLOGIC

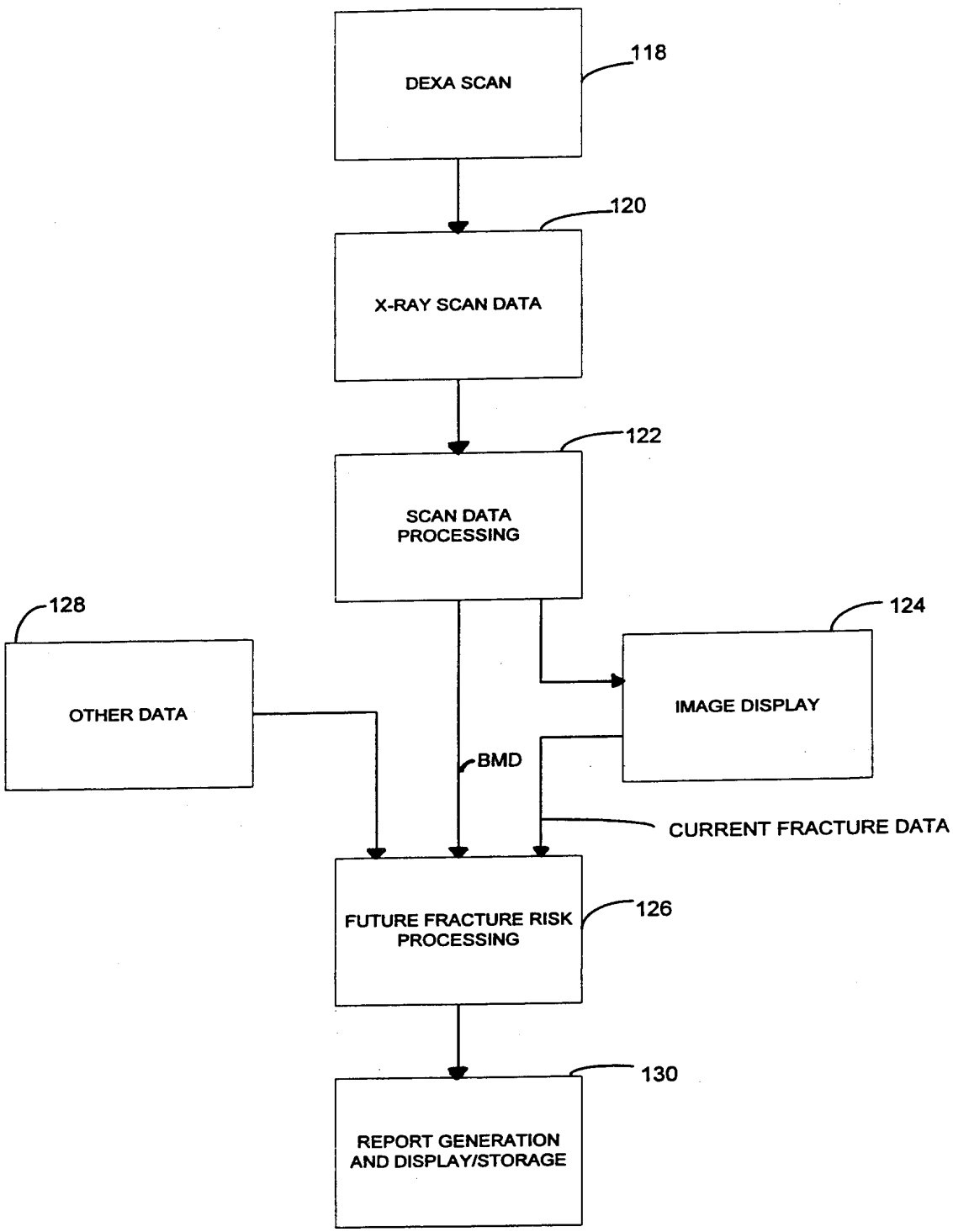

DEXA SCAN
118
X-RAY SCAN DATA
120
SCAN DATA PROCESSING
122
128
OTHER DATA
124
IMAGE DISPLAY
BMD
CURRENT FRACTURE DATA
FUTURE FRACTURE RISK PROCESSING
126
REPORT GENERATION AND DISPLAY/STORAGE
130

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/31478

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G01B 15/02
US CL : 378/54

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)
U.S. : 378/54, 56, 51, 89, 207, 174

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,673,298 A (MAZESS) 30 September 1997 (30.09.1997), Column 13 line 38-Column 15 line 12; Examples 8, 9,and 10; Figures 1,10, and 11.	1-8,11-18,20-22,24-27
---		---
Y		9,10,19,23
Y	US 4,829,549 A (VOGEL et al.) 09 May 1989 (09.05.1989), figures 11 and 13.	9,10,19
Y	US 4,811,373 A (STEIN) 07 March 1989 (07.03.1989), figure 5.	23

☐ 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 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
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Continuation of B. FIELDS SEARCHED Item 3: EAST
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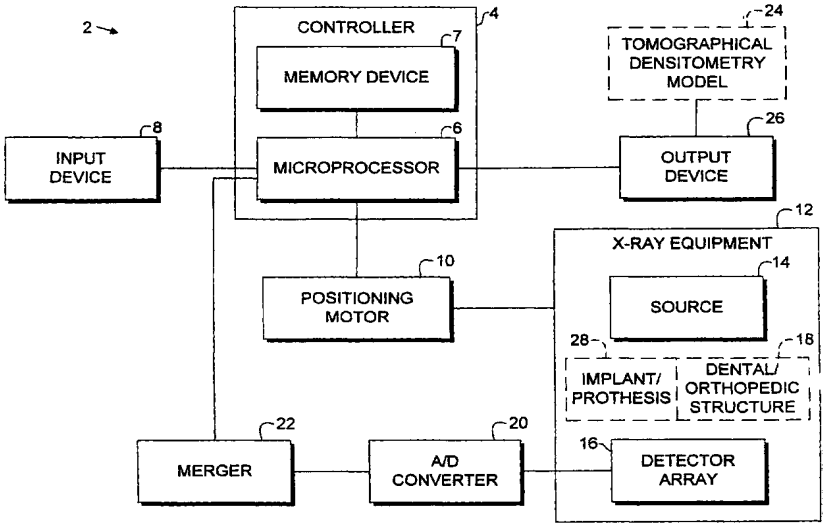
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(54) Title: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD



(57) Abstract: A dental and orthopedic densitometry modeling system includes a controller (4) with a microprocessor (6) and a memory device (7) connected to the microprocessor (6). An input device (8) is also connected to the microprocessor (6) for inputting diagnostic procedure parameters and patient information. X-ray equipment including an X-ray source (14) and an X-ray detector array (16) are connected to a positioning motor (10) for movement relative to a patient's dental or orthopedic structure (18) in response to signals from the microprocessor (6). The output consists of a tomographical densitometry model. A dental/orthopedic densitometry modeling method involves moving the X-ray equipment across a predetermined scan path, emitting dual-energy X-ray beams, and outputting an image color-coded to correspond to a patient's dental or orthopedic density.

WO 01/39667 A1

DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Background of the Invention

1. Field of the Invention

The present invention relates generally to dental and orthopedic diagnosis and treatment, and in particular to a densitometry modeling system and method.

2. Description of the Related Art

The field of dental diagnostics is generally concerned with locating pathologies in the dental structure, i.e. the teeth and surrounding tissue and bone. Three of the most common pathologies are: 1) caries associated with decay; 2) fractures; and 3) apical abscesses. The system and method of the present invention are primarily, but not exclusively, concerned with detecting these pathologies and with orthopedics.

Early detection of dental pathologies is very important in minimizing damage. Conventional diagnosis procedures are generally performed using dental X-rays (both fixed beam and scanning beam), explorers, and other conventional equipment.

Incipient caries, particularly those located beneath the enamel surface, often go undetected with conventional equipment. When such caries are finally found, considerable damage to tooth structure may have already occurred. Subsurface, incipient caries are located almost entirely within the enamel layer of the teeth. They are

sometimes referred to as "smooth surface" caries and are particularly difficult to locate using conventional diagnostic equipment and procedures. By the time such incipient caries are located, the extent of the damage is often 17% to 23% greater than it would appear to be on a conventional X-ray negative.

Dental fractures can result from bruxism (teeth grinding), trauma, etc. Dental structure which is weakened by various causes, such as decalcification, is particularly susceptible to fractures. Fractures can assume various configurations, including craize line patterns. Fracture patterns and configurations can be particularly difficult to locate using conventional X-ray equipment and procedures. For example, fractures which are generally parallel to the X-ray beam are often undetectable on an X-ray negative. Undetected, and hence untreated, fractures can provide direct paths through the enamel layer of the teeth whereby bacteria can invade the dentin and pulp layers. Pathologies in the dentin and pulp layers are often associated with considerable pain and tooth loss.

Apical abscesses comprise yet another dental condition which can be difficult to diagnose with conventional equipment, particularly in the early stages. Advanced apical abscesses can cause considerable pain because they involve the neurovascular bundles located in the root canals. Early detection of apical abscesses can lead to appropriate, early-stage treatment, thus avoiding advanced disease processes with resultant pain, swelling, and/or space involvement which left untreated could ultimately result in death.

Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications. For example, U.S. Patents No.

4,188,537; No. 4,259,583; No. 4,823,369; No. 4,856,038; and No. 5,214,686 all relate to dental X-ray diagnosis utilizing scanning techniques and are incorporated herein by reference.

In the medical field, densitometry procedures are used for measuring bone morphology density (BMD) by utilizing scanning X-ray beam techniques. Examples are shown in U.S. Patents No. 5,533,080; No. 5,838,765; and Re. 36,162, which are incorporated herein by reference. Medical applications of densitometry include the diagnosis and treatment of such bone diseases as osteoporosis.

The availability of relatively fast computers with large memories at reasonable costs has led to the digitalization of X-ray images for mapping BMD models in various formats. For example, BMD images use color to identify varying densities. Digital BMD patient models are also used for comparison purposes with standard models and with patients' own prior BMD histories. Age correction factors can be applied to patients' models for diagnosing and monitoring the onset and progress of such medical conditions as osteoporosis and the like. The present invention utilizes such densitometry modeling and mapping techniques for dental applications.

In addition to pathology detection and diagnosis, the present invention has applications in monitoring osseointegration. Osseointegration occurs at the interface between bone structures and prostheses, such as implants and replacement joints. For example, dental implants osseointegrate with patients' dental structure. The application of tomographical densitometry techniques to osseointegration monitoring can provide the

dental or medical practitioner with important information in evaluating the effectiveness of implant procedures.

Heretofore there has not been available a system or method for applying the technology of densitometry to dental and medical applications such as the detection of caries and decalcification and the monitoring of osseointegration in connection with dental and medical prostheses.

Summary of the Invention

In the practice of the present invention, a dental and orthopedic densitometry modeling system utilizes a controller with a microprocessor and memory. An input device inputs data to the microprocessor for controlling the operation of the modeling system and for providing a database including densitometry parameters for comparison with a patient's densitometry model. The controller controls the operation of X-ray equipment, which is adapted for scanning patients' dental and orthopedic structures along preprogrammed scan paths. The X-ray output is processed by the microprocessor for creating a densitometry model, which can be output in various formats. In the practice of the method of the present invention, a patient and the X-ray equipment are positioned relative to each other. A controller is preprogrammed with a scan path and with data corresponding to the patient. The X-ray equipment emits and detects X-ray beams at first and second energy levels to provide densitometry output. The densitometry output is digitized and merged to provide a tomographic model, which can be compared to

predetermined parameters unique to the patient. The model can be output in various formats, including a visual image color-coded to depict varying dental and orthopedic structure densities.

Principle Objects and Advantages of the Invention

The principle objects and advantages of the present invention include: providing a dental and orthopedic diagnostic application for densitometry; providing such an application which includes a method for modeling dental and orthopedic structure using densitometry; providing such a method which includes dual-energy, X-ray emission and detection; providing such a method which includes providing a color-coded output model showing dental density; providing such a method which detects incipient caries; providing such a method which is adapted for detecting decalcification beneath the surface of the dental enamel layer; providing such a method which employs scanning X-ray techniques; providing such a method which utilizes commercially available tomography equipment; providing such a method which detects dental fractures; providing such a method which detects dental apical abscesses; providing such a method which detects dental pathologies at the micron level; providing such a method which facilitates the monitoring of decalcification in dental structures for determining appropriate treatment; providing such a method which is adaptable for monitoring osseointegration; providing such a method which can be practiced with relatively minor

changes to existing densitometry equipment; and providing such a method which is economical in operation and particularly well adapted for the proposed usage thereof.

Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

Brief Description of the Drawings

Fig. 1 is a schematic, block diagram of a dental and orthopedic densitometry modeling system embodying the present invention.

Fig. 2 is a flowchart of a dental and orthopedic densitometry modeling method embodying the present invention.

Detailed Description of the Preferred Embodiments

I. Introduction and Environment

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as

a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

II. Dental Densitometry Modeling System 2

Referring to the drawings in more detail, the reference numeral 2 generally designates a dental and orthopedic densitometry modeling system embodying the present invention. The system 2 includes a controller 4 with a microprocessor 6 connected to a digital memory device 7. The hardware components of the controller 4, i.e. the microprocessor 6 and the memory device 7, can comprise any of a number of suitable hardware devices which are commercially available and are suitable for this application. In addition to various programable logic devices (PLDs) and special-purpose microprocessors, general purpose, commercially available personal computers can be utilized in the controller 4. The controller 4 can be programmed in any suitable manner utilizing any of a variety of commercially available programming languages and software development systems.

The microprocessor 6 is adapted to receive input from one or more input devices 8, such as a keyboard, a pointing device (e.g., a mouse), a communications link, or another computer. Without limitation on the generality of useful data which can be input via the input device(s) 8, such data can include: 1) a patient's dental and orthopedic records, including previous tomographical densitometry models; 2) baseline tomographical densitometry models, which can be adjusted to accommodate for such

factors as age, gender, size, weight, etc.; and 3) a preprogrammed scan path for the X-ray equipment.

The microprocessor 6 controls a positioning motor 10 which is operably connected to X-ray equipment 12 and is adapted for moving same through three axes of movement. Examples of X-ray equipment adaptable for use with the present invention are disclosed in U.S. Patents No. 5,533,080; No. 5,838,765; and No. Re. 36,162, which are incorporated herein by reference. The X-ray equipment 12 includes an X-ray beam source 14 and a detector array 16. The X-ray beam can suitably collimated to assume any suitable configuration, such as fan, pencil, cone, etc. With the scanning technique disclosed, a restricted (i.e. collimated) beam is preferred. The source and the detector array 14, 16 are adapted for positioning on either side of a patient's dental/orthopedic structure 18.

Analog signals from the detector array 16 are output to an analog-to-digital (A/D) convertor 20, from which digitized signals are transmitted to a merger device 22 for merging into formats suitable for processing and analyzing by the microprocessor 6. The microprocessor 6, using data from the merger device 22, creates a tomographical densitometry model 24 which is transmitted to an output device or devices 26. Without limitation on the generality of useful output devices 26, it can comprise a monitor, a display, a printer, a communications link, and/or another computer. For example, a color printer can be utilized to provide a color-coded graphical representation of the tomographical densitometry model 24. The color coding can correspond to densities,

thus identifying potential problem areas where decalcification has occurred and resulted in lower density. The tomographical densitometry model 24 can also be useful for monitoring osseointegration, since the density of the dental/orthopedic structure 18 (tissue and bone) in the vicinity of an implant 28 or other prostheses can provide an important diagnostic tool for the use of the dental or medical practitioner in assessing the effectiveness of an implant or prosthetic procedure. The tomographical densitometry model 24 is also entered into the computer's memory device 7.

III. Dental and Orthopedic Densitometry Modeling Method

Fig. 2 is a flow chart of a dental and orthopedic densitometry method embodying the present invention. The method steps include positioning a patient and positioning the X-ray equipment relative to the patient, i.e. with the patient's dental/orthopedic structure to be examined located between the X-ray source 14 and the detector array 16.

Diagnostic parameters are input to the system and can comprise, for example, the patient's prior tomographical densitometry models and standardized models. The tomographical densitometry models can be corrected and/or adjusted to account for patients' age, gender, physical characteristics, etc. The input diagnostic parameters can be stored in the computer's memory device. A scan path for the X-ray equipment is preprogrammed in the computer.

The scanning procedure is commenced by collimating a first energy band beam, detecting emissions from same with a detector array, and converting the analog output of the detector array to a digital signal. The digital signal is output for storage in the

computer. The steps of collimating the energy band beam and detecting, digitizing and storing same are repeated for a second energy band beam. The Bisek et al. U.S. Patent No. Re. 36,362 discloses the use of dual-energy X-ray beams in medical densitometry applications. As discussed therein, dual-energy densitometry can result in a more accurate patient model.

The X-ray equipment then traverses the preprogrammed scan path and the first/second energy band steps are repeated until the scanning procedure is complete. The digitized detector array output is merged and compared to the diagnostic parameters which are stored in the computer's memory. The dental/orthopedic densitometry is tomographically modeled and output, for example to a monitor or printer for converting the model to a visual image. The visual image is output in a visible form for use by dental and medical practitioners.

CLAIMS

What is claimed and desired to be secured by Letters Patent is as follows:

1. A system for tomographically modeling dental and orthopedic structure densitometry, which includes:

   a) a controller with a microprocessor and a memory device connected to the microprocessor;

   b) an input device connected to the microprocessor;

   c) a positioning motor connected to the microprocessor and movable in response to signals from said microprocessor;

   d) X-ray equipment including an X-ray source and a detector array;

   e) conversion means for converting a signal from said detector array, said conversion means being connected to said detector array and to said microprocessor; and

   f) an output device connected to said microprocessor and adapted for receiving a tomographical densitometry model from said microprocessor.

2. The system according to Claim 1 wherein said positioning motor is adapted for positioning said X-ray equipment with respect to three axes of movement.

3. The system according to Claim 1 wherein said conversion means comprises an analog-to-digital convertor connected to said detector array.

4. The system according to Claim 3 wherein said conversion means includes a merger device connected to said analog-to-digital converter and to said microprocessor.

5. The system according to Claim 1 wherein said X-ray equipment comprises a dual energy level, restricted beam device.

6. The system according to Claim 1 which includes:

a) a preprogrammed scan path for said X-ray equipment, said scan path being programmed into said microprocessor.

7. The system according to Claim 1 wherein said output device includes a color monitor adapted to receive said tomographical densitometry model output color-coded to represent densitometry.

8. The system according to Claim 1 wherein said output device includes a color printer adapted to print images color-coded to correspond to the densitometry of said model.

9. The system according to Claim 1 wherein said controller includes:

a) means for storing a pre-existing tomographical dental/orthopedic densitometry model; and

b) means for comparing pre-existing and current tomographical densitometry models.

10. A method of tomographically modeling dental and orthopedic densitometry, which includes the steps of:

a) providing a controller with a microprocessor and a memory device connected to said microprocessor;

b) providing an input device connected to said microprocessor;

c) inputting patient diagnostic parameters with said input device;

d) storing said diagnostic parameters in memory;

e) providing X-ray equipment with an X-ray source and an X-ray detector array;

f) positioning said X-ray equipment and a patient's dental/orthopedic structure relative to each other with said patient's dental/orthopedic structure between said source and said detector array;

g) emitting an X-ray beam from said source through said dental structure and to said detector array;

h) outputting a signal from said detector array to said microprocessor;

i) forming with said microprocessor a tomographical densitometry model of said dental/orthopedic structure;

j) providing an output device connected to said microprocessor; and

k) outputting said densitometry model to said output device.

11. The method according to Claim 10 which includes the additional steps of emitting, detecting, digitizing, and storing signals corresponding to first and second energy levels from said X-ray source.

12. The method according to Claim 10 which includes the additional steps of:

a) inputting to said controller a predetermined scan path for said X-ray equipment; and

b) traversing said X-ray equipment along said scan path.

13. The method according to Claim 12 which includes the additional steps of:

a) providing a positioning motor connected to said microprocessor and to said X-ray equipment for moving same through three axes of movement along said scan path.

14. The method according to Claim 10 which includes the additional step of detecting incipient caries with said tomographical densitometry model.

15. The method according to Claim 10 which includes the additional step of detecting dental fractures with said tomographical densitometry model.

16. The method according to Claim 10 which includes the additional step of detecting apical abscesses with said tomographical densitometry model.

17. The method according to Claim 10 which includes the additional step of analyzing the extent of osseointegration of a dental or orthopedic prostheses with respect to a patient's dental or orthopedic structure with said tomographical densitometry model.

18. The method according to Claim 10 which includes the additional steps of:

a) inputting to said microprocessor a pre-existing tomographical densitometry model; and

b) comparing said patient's current densitometry model to said pre-existing densitometry model.

19. The method according to Claim 10 which includes the additional steps of:

a) providing a color output device connected to said microprocessor; and

b) color coding said densitometry model in colors corresponding to the patient's dental or orthopedic structure density and outputting said densitometry model to said output device.

20. A method of tomographically modeling dental and orthopedic densitometry, which includes the steps of:

a) providing a controller with a microprocessor and a memory device connected to said microprocessor;

b) providing an input device connected to said microprocessor;

c) inputting with said input device dental or orthopedic patient diagnostic parameters, including a pre-existing densitometry model;

d) storing said diagnostic parameters in said memory device;

e) providing X-ray equipment connected to said microprocessor, said equipment including an X-ray source and an X-ray detector array;

f) positioning said X-ray equipment and a patient's dental or orthopedic structure relative to each other with said patient's dental or orthopedic structure located between said X-ray source and said detector array;

g) emitting an X-ray beam from said source at a first X-ray beam energy level, passing same through said dental or orthopedic structure, and detecting same with said detector array;

h) outputting a signal corresponding to said detected X-ray beam from said detector array;

i) digitizing said detector array output signal;

j) storing said digitized output signal in said memory device,

k) repeating steps f) - j) at a second X-ray beam energy level;

l) merging said stored output signals to form a present tomographical densitometry model of said dental or orthopedic structure;

m) comparing said present densitometry model with said pre-existing densitometry model;

n) adjusting said present densitometry model to account for patient parameters including age and gender;

o) providing an output device connected to said microprocessor;

p) color coding said present tomographical densitometry model with colors corresponding to dental or orthopedic structure density; and

q) outputting said color-coded model to said output device.

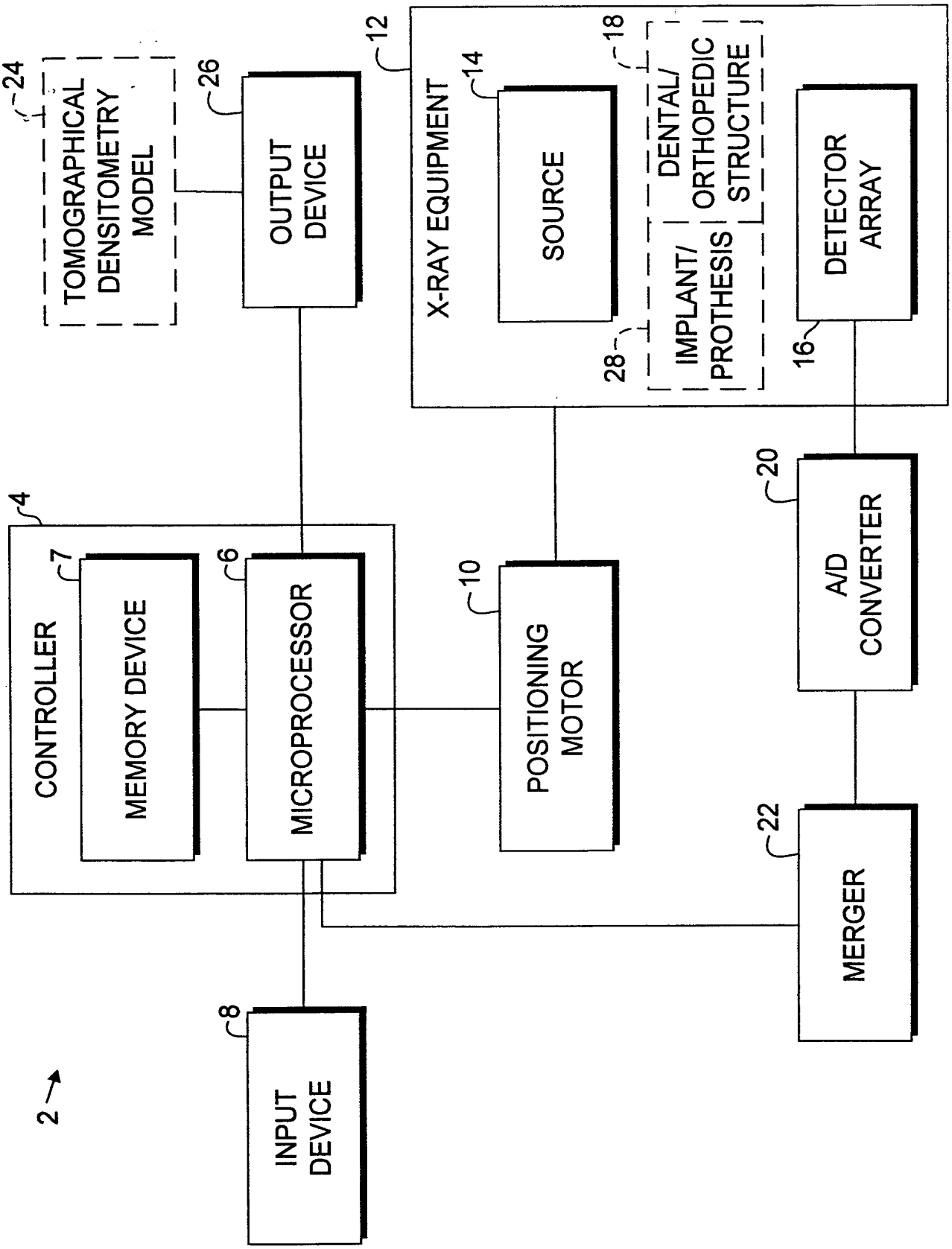

2
CONTROLLER
4
MEMORY DEVICE
7
MICROPROCESSOR
6
INPUT DEVICE
8
POSITIONING MOTOR
10
X-RAY EQUIPMENT
12
SOURCE
14
DETECTOR ARRAY
16
IMPLANT/ PROTHESIS
28
DENTAL/ ORTHOPEDIC STRUCTURE
18
A/D CONVERTER
20
MERGER
22
OUTPUT DEVICE
26
TOMOGRAPHICAL DENSITOMETRY MODEL
24

Fig. 1

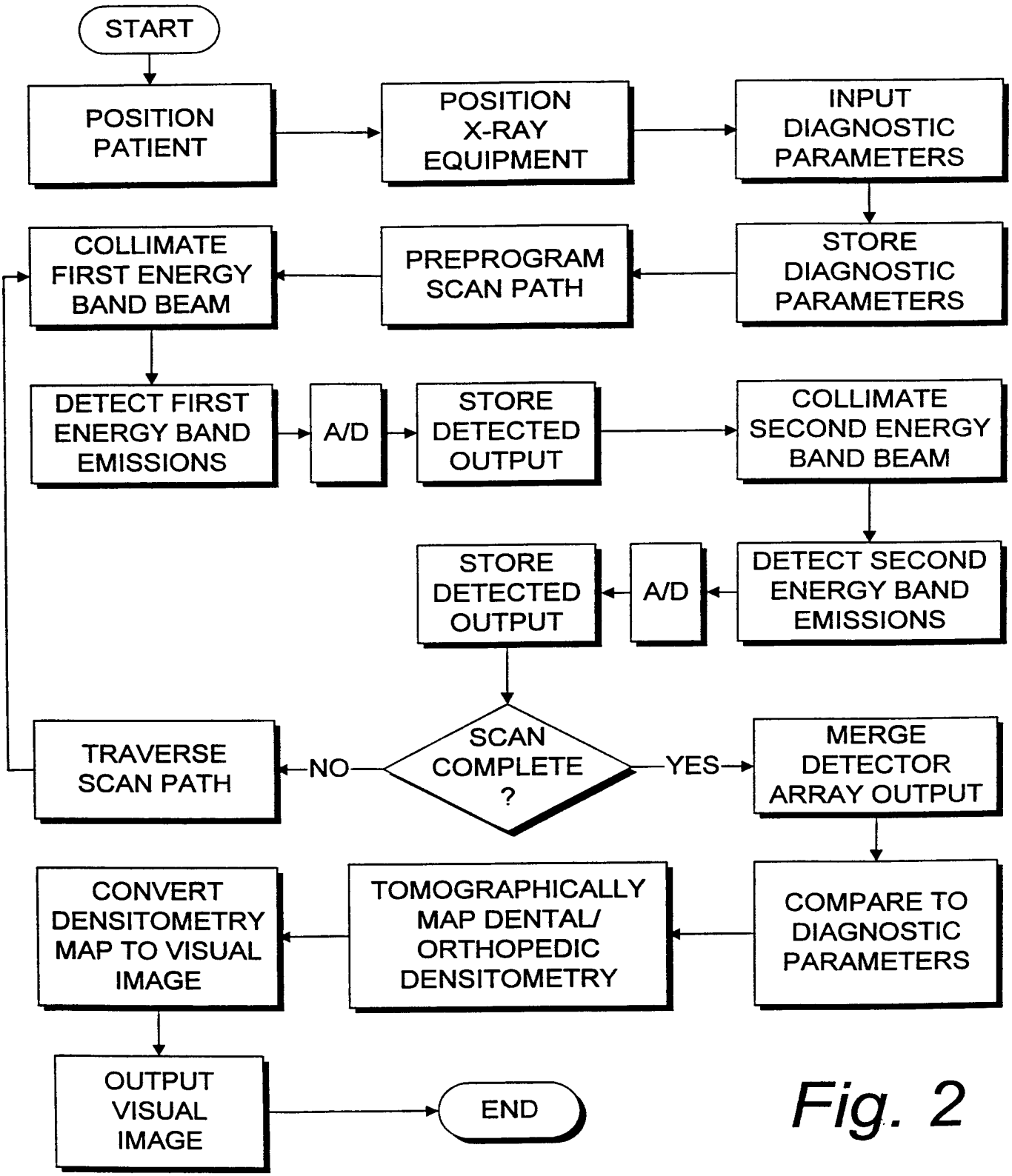

START
POSITION PATIENT
POSITION X-RAY EQUIPMENT
INPUT DIAGNOSTIC PARAMETERS
STORE DIAGNOSTIC PARAMETERS
PREPROGRAM SCAN PATH
COLLIMATE FIRST ENERGY BAND BEAM
DETECT FIRST ENERGY BAND EMISSIONS
A/D
STORE DETECTED OUTPUT
COLLIMATE SECOND ENERGY BAND BEAM
DETECT SECOND ENERGY BAND EMISSIONS
A/D
STORE DETECTED OUTPUT
SCAN COMPLETE ?
NO
TRAVERSE SCAN PATH
YES
MERGE DETECTOR ARRAY OUTPUT
COMPARE TO DIAGNOSTIC PARAMETERS
TOMOGRAPHICALLY MAP DENTAL/ ORTHOPEDIC DENSITOMETRY
CONVERT DENSITOMETRY MAP TO VISUAL IMAGE
OUTPUT VISUAL IMAGE
END

Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/32905

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 6/14; H05G 1/64

US CL : 378/205, 168, 170, 38, 39, 98.8

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)

U.S. : 378/205, 168, 170, 38, 39, 98.8

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

NONE

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

EAST: Dental, Density, Densitomet$6, Position, Energy, Source, Detector

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,813,060 A (HEUBECK et al.) 14 March 1989 (14.03.1989), all.	1-20
Y	US 5,214,686 A (WEBBER) 25 May 1993 (25.05.1993), all.	1-20
Y	US 5,528,645 A (KOIVISTO) 18 June 1996 (18.06.1996), all.	1-20
Y	US 5,995,583 A (SCHICK et al.) 20 November 1999 (20.11.1999), all.	1-20

☐ 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 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

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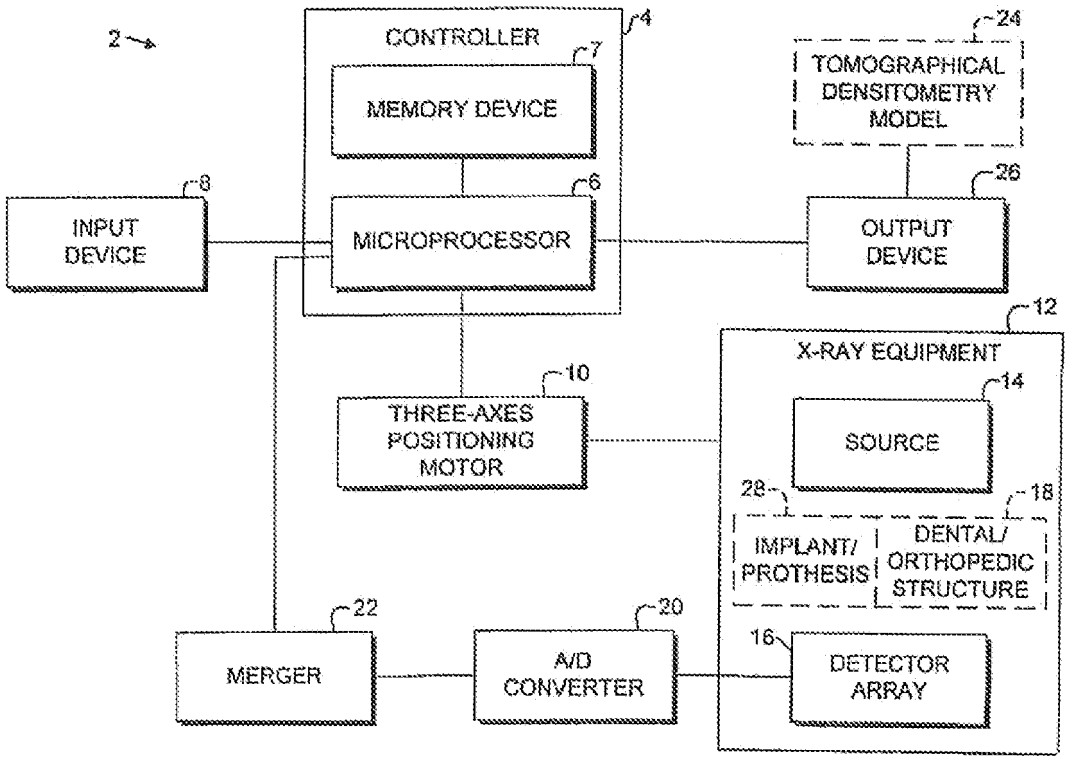
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(54) Titre : SYSTEME ET METHODE DE MODELISATION EN DENSITOMETRIE DENTAIRE ET ORTHOPEDIQUE
(54) Title: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD



(57) Abrégé/Abstract:
A dental and orthopedic densitometry modeling system includes a controller (4) with a microprocessor (6) and a memory device (7) connected to the microprocessor (6). An input device (8) is also connected to the microprocessor (6) for inputting diagnostic procedure parameters and patient information. X-ray equipment including an X-ray source (14) and an X-ray detector array (16) are connected to a positioning motor (10) for movement relative to a patient's dental or orthopedic structure (18) in response to signals from the microprocessor (6). The output consists of a tomographical densitometry model. A dental/orthopedic densitometry modeling method involves moving the X-ray equipment across a predetermined scan path, emitting dual-energy X-ray beams, and outputting an image color-coded to correspond to a patient's dental or orthopedic density.

ABSTRACT

A dental and orthopedic densitometry modeling system includes a controller (4) with a microprocessor (6) and a memory device (7) connected to the microprocessor (6). An input device (8) is also connected to the microprocessor (6) for inputting diagnostic procedure parameters and patient information. X-ray equipment including an X-ray source (14) and an X-ray detector array (16) are connected to a positioning motor (10) for movement relative to a patient's dental or orthopedic structure (18) in response to signals from the microprocessor (6). The output consists of a tomographical densitometry model. A dental/orthopedic densitometry modeling method involves moving the X-ray equipment across a predetermined scan path, emitting dual-energy X-ray beams, and outputting an image color-coded to correspond to a patient's dental or orthopedic density.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A system for tomographically modelling dental and orthopaedic structure densitometry, including: a controller (4) with a microprocessor (6) and a memory device (7) connected to the microprocessor (6); an input device connected to the microprocessor (6); X-ray equipment (12) including an X-ray source (14) and a detector array (16); conversion means (20) comprising an analog-to-digital (A-D) converter (20) connected to said detector array (16) and to said microprocessor (6) and being arranged to convert a signal from said detector array (16); an output device (26) connected to said microprocessor (6) and adapted for receiving a tomographical densitometry model from said microprocessor (6); and a merger device (22) connected to said converter (20) and to said microprocessor (6); said tomographical modeling system including:

a positioning motor (10) adapted for positioning said X-ray equipment (12) with respect to three axes of movement;

said X-ray equipment (12) comprising a dual energy level, restricted beam device (14);

means (7) for storing pre-existing, graphical dental or orthopaedic densitometry models comprising a patient's previous graphical densitometry models and baseline standardized graphical densitometry models;

a preprogrammed scan path for said X-ray equipment (12), said scan path being programmed into said microprocessor (6) and said scan path including movement of said X-ray equipment in three axes;

said microprocessor (6) receiving digital data corresponding to a graphical densitometry dental or orthopedic model and converting said densitometry model to a visual image

computer means (6) for digitally comparing pre-existing and current tomographical densitometry models, said output device (26) displaying a visual representation of said comparison of said pre-existing and current graphical densitometry models.

2. The system according to claim 1 wherein said output device includes a colour monitor (26) adapted to receive said tomographical densitometry model output colour-coded to represent densitometry.

3. The system according to claim 1 wherein said output device includes a colour printer (26) adapted to print images colour-coded to correspond to the densitometry of said model.

4. A method for topographically modelling dental and orthopaedic structure densitometry including the steps of providing: a controller (7) with a microprocessor (6) and a memory device (7) connected to the microprocessor (6); an input device (8) connected to the microprocessor (6); X-ray equipment (12) including an X-ray source (14) and a detector array (16); an analog-to-digital (A-D) converter (20) connected to said detector array (16) and to said microprocessor (6) for converting a signal from said detector array (16); an output device (26) connected to said microprocessor (6) and adapted for receiving a tomographical densitometry model from said microprocessor (6); which method further includes the steps of:

inputting patient diagnostic parameters with said input device (8);

inputting baseline diagnostic parameters with said input device (8);

storing said diagnostic parameters in said memory device (7);

positioning said X-ray equipment (12) and a patient's dental or orthopaedic structure (18) relative to each other with said patient's dental or orthopaedic structure (18) between said source (14) and said detector array (16);

emitting an X-ray beam from said source (14) through said dental or orthopaedic structure (18) and to said detector array (16);

outputting a signal from said detector array (16) to said microprocessor (6) and storing said signal from said detector array (16) in said microprocessor;

forming with said microprocessor (6) a current tomographical densitometry model of said dental or orthopaedic structure (18);

converting said current tomographical densitometry model to a visual image;

outputting said current tomographical densitometry model to said output device (26);

emitting, detecting, digitizing and storing signals corresponding to first and second energy levels from said X-ray source (14);

inputting to said controller (4) a predetermined scan path including movement with respect to three axes for said X-ray equipment (12);

traversing said X-ray equipment (12) along said scan path;

providing a positioning motor (10) connected to said microprocessor (6) and to said X-ray equipment (12) for moving same through three axes of movement along said scan path;

inputting to said microprocessor (6) a patient's pre-existing tomographical densitometry model;

digitally comparing said patient's current densitometry model to said pre-existing tomographical densitometry model ; and

visually displaying with said output device (26) a visual representation of said comparison of said patient's pre-existing and current densitometry models.

5. The method according to claim 4, which includes the additional step of detecting incipient caries with said tomographical densitometry model.

6. The method according to claim 4, which includes the additional step of detecting dental fractures with said tomographical densitometry model.

7. The method according to claim 4, which includes the additional step of detecting apical abscesses with said tomographical densitometry model.

8. The method according to claim 4, which includes the additional step of analysing the extent of osseointegration of a dental or orthopaedic prosthesis with respect

to said patient's dental or orthopaedic structure with said tomographical densitometry model.

9. The method according to claim 4, which includes the additional steps of:

a) providing a colour output device (26) connected to said microprocessor (6); and

b) colour coding said densitometry model in colours corresponding to the patient's dental or orthopaedic structure density and outputting said densitometry model to said output device (26).

10. The method according to claim 4, which includes the additional steps of:

repeating said microprocessor input, detector array output, x-ray equipment positioning and detector array output signal storing steps;

merging said stored detector array output signals to form a present tomographical densitometry model of said dental or orthopaedic structure (18);

comparing said present densitometry model with said pre-existing densitometry model;

adjusting said present densitometry model to account for patient parameters including age and gender;

colour coding said present tomographical densitometry model with colours corresponding to dental or orthopaedic structure (18) density; and

outputting said colour-coded model to said output device (26).

PCT/US 00/32905
IPEA/US 30 JUN 2001

DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Background of the Invention

1. Field of the Invention

The present invention relates generally to dental and orthopedic diagnosis and treatment, and in particular to a densitometry modeling system and method.

2. Description of the Related Art

The field of dental diagnostics is generally concerned with locating pathologies in the dental structure, i.e. the teeth and surrounding tissue and bone. Three of the most common pathologies are: 1) caries associated with decay; 2) fractures; and 3) apical abscesses. The system and method of the present invention are primarily, but not exclusively, concerned with detecting these pathologies and with orthopedics.

Early detection of dental pathologies is very important in minimizing damage. Conventional diagnosis procedures are generally performed using dental X-rays (both fixed beam and scanning beam), explorers, and other conventional equipment.

Incipient caries, particularly those located beneath the enamel surface, often go undetected with conventional equipment. When such caries are finally found,

incipient caries are located almost entirely within the enamel layer of the teeth. They are sometimes referred to as "smooth surface" caries and are particularly difficult to locate using conventional diagnostic equipment and procedures. By the time such incipient caries are located, the extent of the damage is often 17% to 23% greater than it would appear to be on a conventional X-ray negative.

Dental fractures can result from bruxism (teeth grinding), trauma, etc. Dental structure which is weakened by various causes, such as decalcification, is particularly susceptible to fractures. Fractures can assume various configurations, including craize line patterns. Fracture patterns and configurations can be particularly difficult to locate using conventional X-ray equipment and procedures. For example, fractures which are generally parallel to the X-ray beam are often undetectable on an X-ray negative. Undetected, and hence untreated, fractures can provide direct paths through the enamel layer of the teeth whereby bacteria can invade the dentin and pulp layers. Pathologies in the dentin and pulp layers are often associated with considerable pain and tooth loss.

Apical abscesses comprise yet another dental condition which can be difficult to diagnose with conventional equipment, particularly in the early stages. Advanced apical abscesses can cause considerable pain because they involve the neurovascular bundles located in the root canals. Early detection of apical abscesses can lead to appropriate, early-stage treatment, thus avoiding advanced disease processes with resultant pain, swelling, and/or space involvement which left untreated could ultimately result in death.

Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications. For example, U.S. Pat. No. 4,188,537; U.S. Pat. No. 4,259,583; U.S. Pat. No. 4,823,369; U.S. Pat. No. 4,856,038; and U.S. Pat. No. 5,214,686 all relate to dental X-ray diagnosis utilizing scanning techniques.

In the medical field, densitometry procedures are used for measuring bone morphology density (BMD) by utilizing scanning X-ray beam techniques. Examples are shown in U.S. Pat. No. 5,533,080; U.S. Pat. No. 5,838,765; and U.S. Pat. No. Re. 36,162. Medical applications of densitometry include the diagnosis and treatment of such bone diseases as osteoporosis.

The availability of relatively fast computers with large memories at reasonable costs has led to the digitalization of X-ray images for mapping BMD models in various formats. For example, BMD images use color to identify varying densities. Digital BMD patient models are also used for comparison purposes with standard models and with patients' own prior BMD histories. Age correction factors can be applied to patients' models for diagnosing and monitoring the onset and progress of such medical conditions as osteoporosis and the like. The present invention utilizes such densitometry modeling and mapping techniques for dental applications.

In addition to pathology detection and diagnosis, the present invention has applications in monitoring osseointegration. Osseointegration occurs at the interface between bone structures and prostheses, such as implants and replacement joints. For example, dental implants osseointegrate with patients' dental structure. The

application of tomographical densitometry techniques to osseointegration monitoring can provide the dental or medical practitioner with important information in evaluating the effectiveness of implant procedures.

Heretofore there has not been available a system or method for applying the technology of densitometry to dental and medical applications such as the detection of caries and decalcification and the monitoring of osseointegration in connection with dental and medical prostheses.

Summary of the Invention

In the practice of the present invention, a dental and orthopedic densitometry modeling system utilizes a controller with a microprocessor and memory. An input device inputs data to the microprocessor for controlling the operation of the modeling system and for providing a database including densitometry parameters for comparison with a patient's densitometry model. The controller controls the operation of X-ray equipment, which is adapted for scanning patients' dental and orthopedic structures along preprogrammed scan paths. The X-ray output is processed by the microprocessor for creating a densitometry model, which can be output in various formats. In the practice of the method of the present invention, a patient and the X-ray equipment are positioned relative to each other. A controller is preprogrammed with a scan path and with data corresponding to the patient. The X-ray equipment emits and detects X-ray beams at first and second energy levels to provide densitometry output. The densitometry output is digitized and merged to provide a tomographic model,

which can be compared to predetermined parameters unique to the patient. The model can be output in various formats, including a visual image color-coded to depict varying dental and orthopaedic structure densities.

In a broad aspect, the present invention relates a system for tomographically modelling dental and orthopaedic structure densitometry, including: a controller with a microprocessor and a memory device connected to the microprocessor; an input device connected to the microprocessor; X-ray equipment including an X-ray source and a detector array; conversion means comprising an analog-to-digital converter connected to said detector array and to said microprocessor and being arranged to convert a signal from said detector array; an output device connected to said microprocessor and adapted for receiving a tomographical densitometry model from said microprocessor; and a merger device connected to said converter and to said microprocessor; said tomographical modeling system including: a positioning motor adapted for positioning said X-ray equipment with respect to three axes of movement; said X-ray equipment comprising a dual energy level, restricted beam device; means for storing pre-existing, graphical dental or orthopaedic densitometry models comprising a patient's previous graphical densitometry models and baseline standardized graphical densitometry models; a preprogrammed scan path for said X-ray equipment, said scan path being programmed into said microprocessor and said scan path including movement of said X-ray equipment in three axes; said microprocessor receiving digital data corresponding to a graphical densitometry dental or orthopedic model and converting said densitometry model to a visual image computer means for digitally comparing pre-existing and current tomographical densitometry models, said output device displaying a visual representation of said comparison of said pre-existing and current graphical densitometry models.

In another broad aspect, the present invention relates to a method for topographically modelling dental and orthopaedic structure densitometry including the steps of providing: a controller with a microprocessor and a memory device connected to the microprocessor; an input device connected to the microprocessor; X-ray equipment including an X-ray source and a detector array; an analog-to-digital converter connected to said detector array and to said microprocessor for converting a signal from said detector array; an output device connected to said microprocessor and adapted for receiving a tomographical densitometry model from said microprocessor; which method further includes the steps of: inputting patient diagnostic parameters with said input device; inputting baseline diagnostic parameters with said input device; storing said diagnostic parameters in said memory device; positioning said X-ray equipment and a patient's dental or orthopaedic structure relative to each other with said patient's dental or orthopaedic structure between said source and said detector array; emitting an X-ray beam from said source through said dental or orthopaedic structure and to said detector array; outputting a signal from said detector array to said microprocessor and storing said signal from said detector array in said microprocessor; forming with said microprocessor a current tomographical densitometry model of said dental or orthopaedic structure; converting said current tomographical densitometry model to a visual image; outputting said current tomographical densitometry model to said output device; emitting, detecting, digitizing and storing signals corresponding to first and second energy levels from said X-ray source; inputting to said controller a predetermined scan path including movement with respect to three axes for said X-ray equipment; traversing said X-ray equipment along said scan path; providing a positioning motor connected to said microprocessor and to said X-ray equipment for moving same through three axes of movement along said scan path;

inputting to said microprocessor a patient's pre-existing tomographical densitometry model; digitally comparing said patient's current densitometry model to said pre-existing tomographical densitometry model ; and visually displaying with said output device a visual representation of said comparison of said patient's pre-existing and current densitometry models.

Principle Objects and Advantages of the Invention

The principle objects and advantages of the present invention include: providing a dental and orthopaedic diagnostic application for densitometry; providing such an application which includes a method for modelling dental and orthopaedic structure using densitometry; providing such a method which includes dual-energy, X-ray emission and detection; providing such a method which includes providing a color-coded output model showing dental density; providing such a method which detects incipient caries; providing such a method which is adapted for detecting decalcification beneath the surface of the dental enamel layer; providing such a method which employs scanning X-ray techniques; providing such a method which utilizes commercially available tomography equipment; providing such a method which detects dental fractures; providing such a method which detect dental apical abscesses; providing such a method which detects dental pathologies at the micron level; providing such a method which facilitates the monitoring of decalcification in dental structures for determining appropriate treatment; providing such a method which is adaptable for monitoring osseointegration; providing such a method which can be practiced with relatively minor changes to existing densitometry equipment; and providing such a

method which is economical in operation and particularly well adapted for the proposed usage thereof.

Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

Brief Description of the Drawings

Fig. 1 is a schematic, block diagram of a dental and orthopedic densitometry modeling system embodying the present invention.

Fig. 2 is a flowchart of a dental and orthopedic densitometry modeling method embodying the present invention.

Detailed Description of the Preferred Embodiments

I. Introduction and Environment

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching

one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

II. Dental Densitometry Modeling System 2

Referring to the drawings in more detail, the reference numeral 2 generally designates a dental and orthopedic densitometry modeling system embodying the present invention. The system 2 includes a controller 4 with a microprocessor 6 connected to a digital memory device 7. The hardware components of the controller 4, i.e. the microprocessor 6 and the memory device 7, can comprise any of a number of suitable hardware devices which are commercially available and are suitable for this application. In addition to various programable logic devices (PLDs) and special-purpose microprocessors, general purpose, commercially available personal computers can be utilized in the controller 4. The controller 4 can be programmed in any suitable manner utilizing any of a variety of commercially available programming languages and software development systems.

The microprocessor 6 is adapted to receive input from one or more input devices 8, such as a keyboard, a pointing device (e.g., a mouse), a communications link, or another computer. Without limitation on the generality of useful data which can be input via the input device(s) 8, such data can include: 1) a patient's dental and orthopedic records, including previous tomographical densitometry models; 2) baseline tomographical densitometry models, which can be adjusted to accommodate for such factors as age, gender, size, weight, etc.; and 3) a preprogrammed scan path for the X-ray equipment.

The microprocessor 6 controls a positioning motor 10 which is operably connected to X-ray equipment 12 and is adapted for moving same through three axes of movement. Examples of X-ray equipment adaptable for use with the present invention are disclosed in U.S. Patents No. 5,533,080; No. 5,838,765; and No. Re. 36,162. The X-ray equipment 12 includes an X-ray beam source 14 and a detector array 16. The X-ray beam can suitably collimated to assume any suitable configuration, such as fan, pencil, cone, etc. With the scanning technique disclosed, a restricted (i.e. collimated) beam is preferred. The source and the detector array 14, 16 are adapted for positioning on either side of a patient's dental/orthopaedic structure 18.

Analog signals from the detector array 16 are output to an analog-to-digital (A/D) convertor 20, from which digitized signals are transmitted to a merger device 22 for merging into formats suitable for processing and analyzing by the microprocessor 6. The microprocessor 6, using data from the merger device 22, creates a tomographical densitometry model 24 which is transmitted to an output device or devices 26. Without limitation on the generality of useful output devices 26, it can comprise a monitor, a display, a printer, a communications link, and/or another computer. For example, a color printer can be utilized to provide a color-coded graphical representation of the tomographical densitometry model 24. The color coding can correspond to densities, thus identifying potential problem areas where decalcification has occurred and resulted in lower density. The tomographical densitometry model 24 can also be useful for monitoring osseointegration, since the

density of the dental/orthopedic structure 18 (tissue and bone) in the vicinity of an implant 28 or other prostheses can provide an important diagnostic tool for the use of the dental or medical practitioner in assessing the effectiveness of an implant or prosthetic procedure. The tomographical densitometry model 24 is also entered into the computer's memory device 7.

III. **Dental and Orthopedic Densitometry Modeling Method**

Fig. 2 is a flow chart of a dental and orthopedic densitometry method embodying the present invention. The method steps include positioning a patient and positioning the X-ray equipment relative to the patient, i.e. with the patient's dental/orthopedic structure to be examined located between the X-ray source 14 and the detector array 16.

Diagnostic parameters are input to the system and can comprise, for example, the patient's prior tomographical densitometry models and standardized models. The tomographical densitometry models can be corrected and/or adjusted to account for patients' age, gender, physical characteristics, etc. The input diagnostic parameters can be stored in the computer's memory device. A scan path for the X-ray equipment is preprogrammed in the computer.

The scanning procedure is commenced by collimating a first energy band beam, detecting emissions from same with a detector array, and converting the analog output of the detector array to a digital signal. The digital signal is output for storage in the computer. The steps of collimating the energy band beam and detecting, digitizing and

storing same are repeated for a second energy band beam. The Bisek et al. U.S. Patent No. Re. 36,362 discloses the use of dual-energy X-ray beams in medical densitometry applications. As discussed therein, dual-energy densitometry can result in a more accurate patient model.

The X-ray equipment then traverses the preprogrammed scan path and the first/second energy band steps are repeated until the scanning procedure is complete. The digitized detector array output is merged and compared to the diagnostic parameters which are stored in the computer's memory. The dental/orthopedic densitometry is tomographically modeled and output, for example to a monitor or printer for converting the model to a visual image. The visual image is output in a visible form for use by dental and medical practitioners.

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IPEA/US 29 OCT 2001

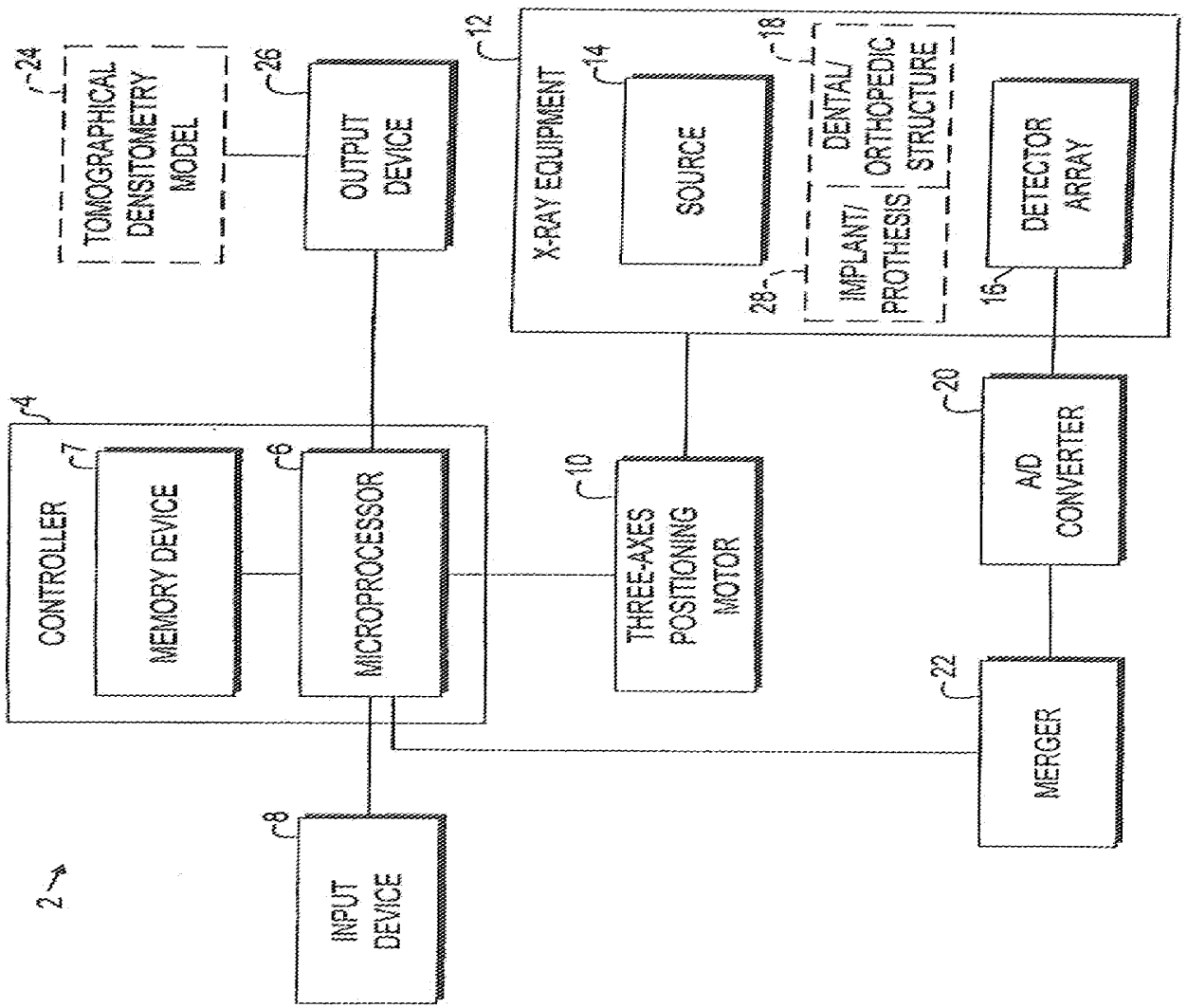


Fig. 1

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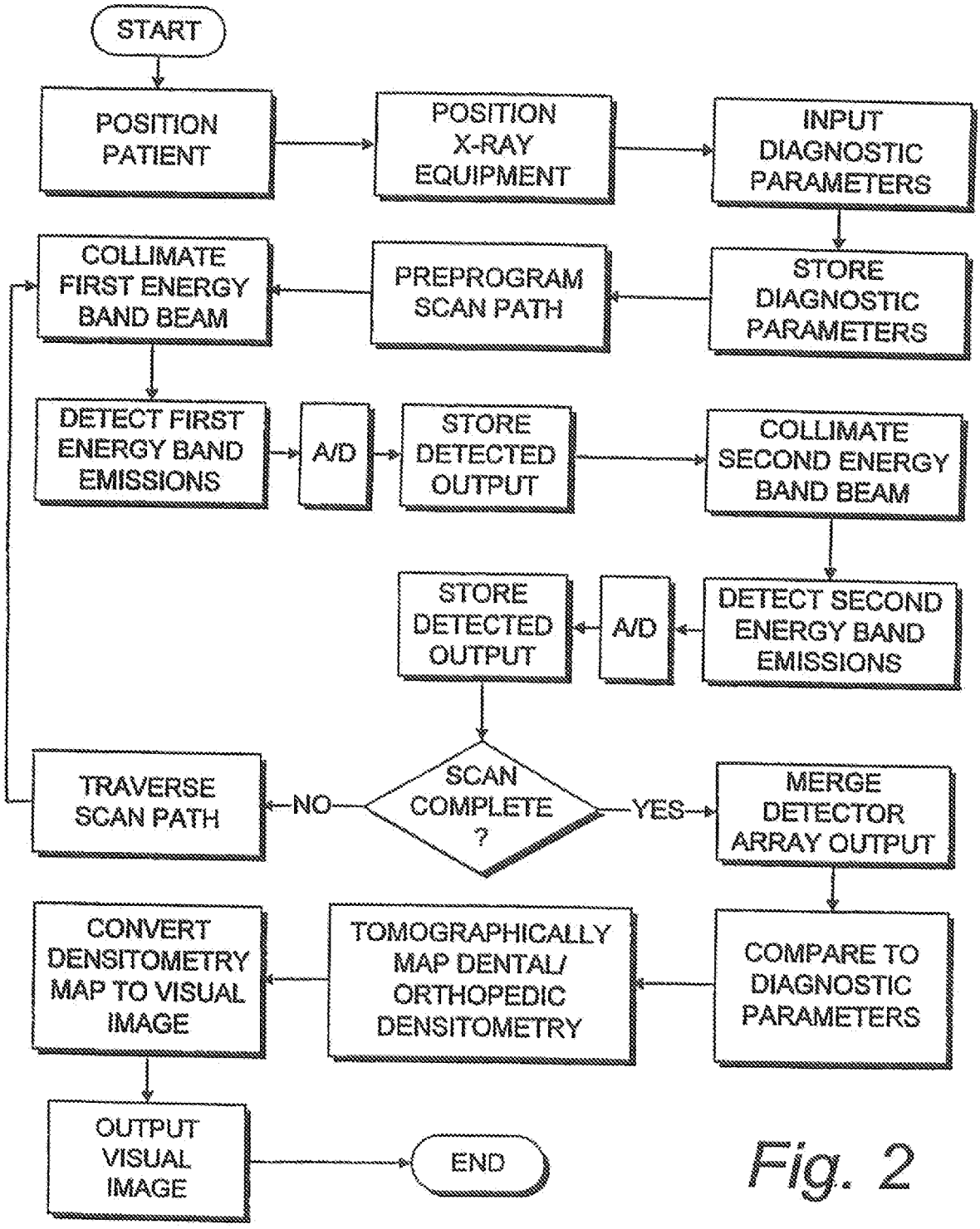
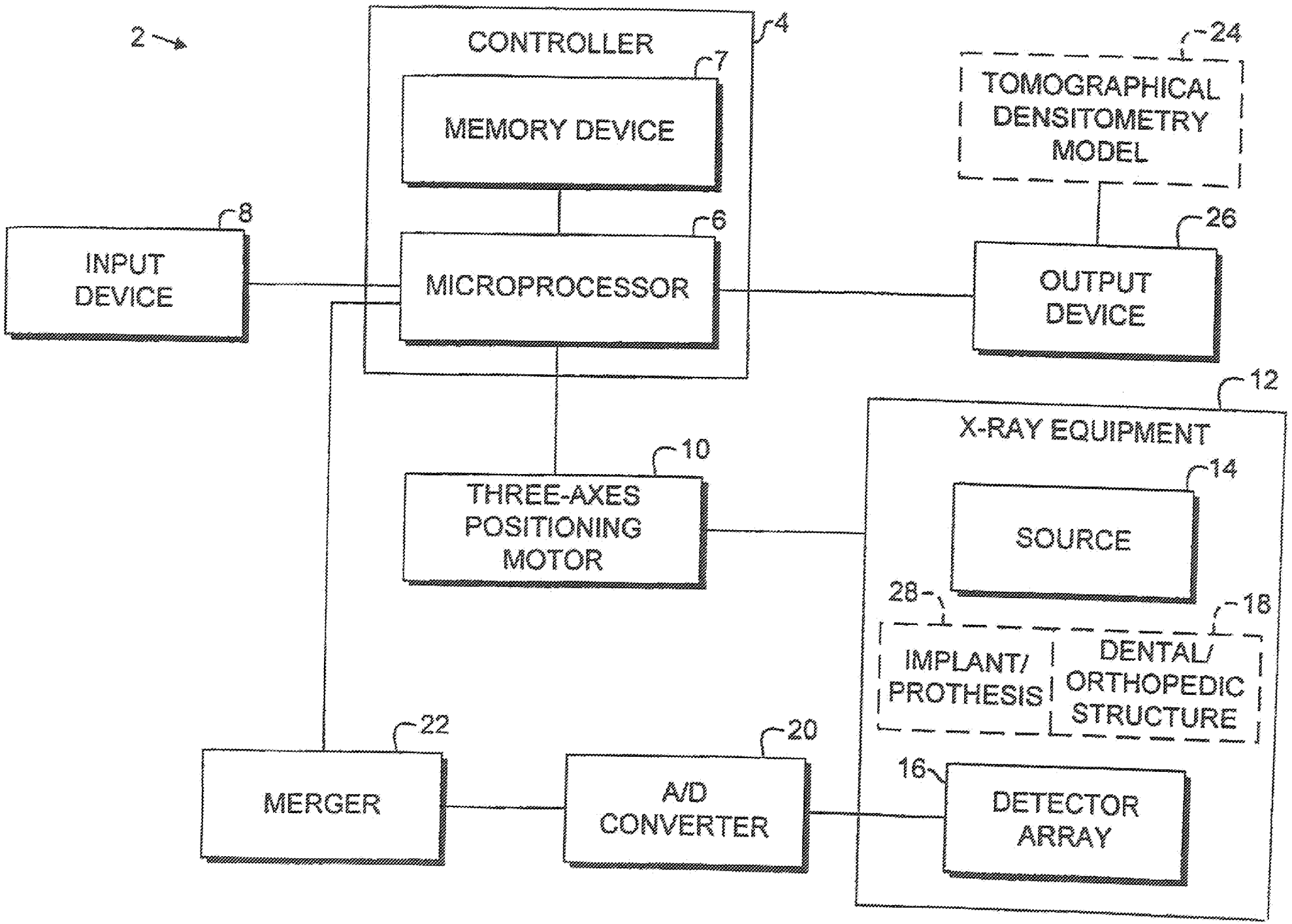


Fig. 2


2
CONTROLLER
4
7
MEMORY DEVICE
24
TOMOGRAPHICAL DENSITOMETRY MODEL
8
INPUT DEVICE
6
MICROPROCESSOR
26
OUTPUT DEVICE
12
X-RAY EQUIPMENT
10
THREE-AXES POSITIONING MOTOR
14
SOURCE
28
18
IMPLANT/ PROTHESIS
DENTAL/ ORTHOPEDIC STRUCTURE
22
20
16
MERGER
A/D CONVERTER
DETECTOR ARRAY

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(54) DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM

DENTALES UND ORTHOPÄDISCHES DENSITOMETRIEMODELLSYSTEM

SYSTEME DE MODELISATION EN DENSITOMETRIE DENTAIRE ET ORTHOPEDIQUE

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US-E- R E36 162

- **BOYDE A. ET AL: 'The Mineralization Density of Iliac Crest Bone from Children with Osteogenesis Imperfecta' CALCIFIED TISSUE INTERNATIONAL vol. 64, no. 3, 1999, pages 185 - 190**

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Description

[0001] The present invention relates generally to dental and orthopedic diagnosis and treatment, and in particular to a densitometry modeling system.

[0002] The field of dental diagnostics is generally concerned with locating pathologies in the dental structure, i.e. the teeth and surrounding tissue and bone. Three of the most common pathologies are: 1) caries associated with decay; 2) fractures; and 3) apical abscesses. The system and method of the present invention are primarily, but not exclusively, concerned with detecting these pathologies and with orthopedics.

[0003] Early detection of dental pathologies is very important in minimizing damage. Conventional diagnosis procedures are generally performed using dental X-rays (both fixed beam and scanning beam), explorers, and other conventional equipment.

[0004] Incipient caries, particularly those located beneath the enamel surface, often go undetected with conventional equipment. When such caries are finally found, considerable damage to tooth structure may have already occured. Subsurface, incipient caries are located almost entirely within the enamel layer of the teeth. They are sometimes referred to as "smooth surface" caries and are particularly difficult to locate using conventional diagnostic equipment and procedures. By the time such incipient caries are located, the extent of the damage is often 17% to 23% greater than it would appear to be on a conventional X-ray negative.

[0005] Dental fractures can result from bruxism (teeth grinding), trauma, etc. Dental structure which is weakened by various causes, such as decalcification, is particularly susceptible to fractures. Fractures can assume various configurations, including craize line patterns. Fracture patterns and configurations can be particularly difficult to locate using conventional X-ray equipment and procedures. For example, fractures which are generally parallel to the X-ray beam are often undetectable on an X-ray negative. Undetected, and hence untreated, fractures can provide direct paths through the enamel layer of the teeth whereby bacteria can invade the dentin and pulp layers. Pathologies in the dentin and pulp layers are often associated with considerable pain and tooth loss.

[0006] Apical abscesses comprise yet another dental condition which can be difficult to diagnose with conventional equipment, particularly in the early stages. Advanced apical abscesses can cause considerable pain because they involve the neurovascular bundles located in the root canals. Early detection of apical abscesses can lead to appropriate, early-stage treatment, thus avoiding advanced disease processes with resultant pain, swelling, and/or space involvement which left untreated could ultimately result in death.

[0007] Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications. For example, U.S. Patents No. 4,188,537; No. 4,259,583; No. 4,823,369; No. 4,856,038; and No. 5,214,686 all relate to dental X-ray diagnosis utilizing scanning techniques.

[0008] In the medical field, densitometry procedures are used for measuring bone morphology density (BMD) by utilizing scanning X-ray beam techniques. Examples are shown in U.S. Patents No. 5,533,080; No. 5,838,765; and Re. 36, 162, Medical applications of densitometry include the diagnosis and treatment of such bone diseases as osteoporosis.

[0009] The availability of relatively fast computers with large memories at reasonable costs has led to the digitalization of X-ray images for mapping BMD models in various formats. For example, BMD images use color to identify varying densities. Digital BMD patient models are also used for comparison purposes with standard models and with patients' own prior BMD histories. Age correction factors can be applied to patients' models for diagnosing and monitoring the onset and progress of such medical conditions as osteoporosis and the like. The present invention utilizes such densitometry modeling and mapping techniques for dental applications.

[0010] In addition to pathology detection and diagnosis, the present invention has applications in monitoring osseointegration. Osseointegration occurs at the interface between bone structures and prostheses, such as implants and replacement joints. For example, dental implants osseointegrate with patients' dental structure. The application of tomographical densitometry techniques to osseointegration monitoring can provide the dental or medical practitioner with important information in evaluating the effectiveness of implant procedures.

[0011] Heretofore there has not been available a system or method for applying the technology of densitometry to dental and medical applications such as the detection of caries and decalcification and the monitoring of osseointegration in connection with dental and medical prostheses.

[0012] The invention is defined in claim 1.

[0013] In the practice of the present invention, a dental and orthopedic densitometry modeling system utilizes a controller with a microprocessor and memory. An input device inputs data to the microprocessor for controlling the operation of the modeling system and for providing a database including densitometry parameters for comparison with a patient's densitometry model. The controller controls the operation of X-ray equipment, which is adapted for scanning patients' dental and orthopedic structures along preprogrammed scan paths. The X-ray output is processed by the microprocessor for creating a densitometry model, which can be output in various formats. In the practice of the method of the present invention, a patient and the X-ray equipment are positioned relative to each other. A controller is preprogrammed with a scan path and with data corresponding to the patient. The X-ray equipment emits and detects X-ray beams at first and second energy levels to provide densitometry output. The densitometry output is digitized and merged to provide a tomographic model, which can be compared

to predetermined parameters unique to the patient. The model can be output in various formats, including a visual image color-coded to depict varying dental and orthopedic structure densities.

[0014] The principle objects and advantages of the present invention include: providing a dental and orthopedic diagnostic application for densitometry; providing such an application which includes a method for modeling dental and orthopedic structure using densitometry; providing such a method which includes dual-energy, X-ray emission and detection; providing such a method which includes providing a color-coded output model showing dental density; providing such a method which detects incipient caries; providing such a method which is adapted for detecting decalcification beneath the surface of the dental enamel layer; providing such a method which employs scanning X-ray techniques; providing such a method which utilizes commercially available tomography equipment; providing such a method which detects dental fractures; providing such a method which detects dental apical abscesses; providing such a method which detects dental pathologies at the micron level; providing such a method which facilitates the monitoring of decalcification in dental structures for determining appropriate treatment; providing such a method which is adaptable for monitoring osseointegration; providing such a method which can be practiced with relatively minor changes to existing densitometry equipment; and providing such a method which is economical in operation and particularly well adapted for the proposed usage thereof.

[0015] Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

[0016] The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof

Fig. 1 is a schematic, block diagram of a dental and orthopedic densitometry modeling system embodying the present invention.

Fig. 2 is a flowchart of a dental and orthopedic densitometry modeling method embodying the present invention.

[0017] As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

[0018] Referring to the drawings in more detail, the reference numeral 2 generally designates a dental and orthopedic densitometry modeling system embodying the present invention. The system 2 includes a controller 4 with a microprocessor 6 connected to a digital memory device 7. The hardware components of the controller 4, i.e. the microprocessor 6 and the memory device 7, can comprise any of a number of suitable hardware devices which are commercially available and are suitable for this application. In addition to various programable logic devices (PLDs) and special-purpose microprocessors, general purpose, commercially available personal computers can be utilized in the controller 4: The controller 4 can be programmed in any suitable manner utilizing any of a variety of commercially available programming languages and software development systems.

[0019] The microprocessor 6 is adapted to receive input from one or more input devices 8, such as a keyboard, a pointing device (e.g., a mouse), a communications link, or another computer. Without limitation on the generality of useful data which can be input via the input device(s) 8, such data can include: 1) a patient's dental and orthopedic records, including previous tomographical densitometry models; 2) baseline tomographical densitometry models, which can be adjusted to accommodate for such factors as age, gender, size, weight, etc.; and 3) a preprogrammed scan path for the X-ray equipment.

[0020] The microprocessor 6 controls a positioning motor 10 which is operably connected to X-ray equipment 12 and is adapted for moving same through three axes of movement. Examples of X-ray equipment adaptable for use with the present invention are disclosed in U.S. Patents No. 5,533,080; No. 5,838,765; and No. Re. 36,162. The X-ray equipment 12 includes an X-ray beam source 14 and a detector array 16. The X-ray beam can suitably collimated to assume any suitable configuration, such as fan, pencil, cone, etc. With the scanning technique disclosed, a restricted (i.e. collimated) beam is preferred. The source and the detector array 14, 16 are adapted for positioning on either side of a patient's dental/orthopedic structure 18.

[0021] Analog signals from the detector array 16 are output to an analog-to-digital (A/D) convertor 20, from which digitized signals are transmitted to a merger device 22 for merging into formats suitable for processing and analyzing by the microprocessor 6. The microprocessor 6, using data from the merger device 22, creates a tomographical densitometry model 24 which is transmitted to an output device or devices 26. Without limitation on the generality of useful output devices 26, it can comprise a monitor, a display, a printer, a communications link, and/or another computer. For example, a color printer can be utilized to provide a color-coded graphical representation of the tomographical densitometry model 24. The color coding can correspond to densities, thus identifying potential problem areas where decalcification has occurred and resulted in lower density. The tomographical densitometry model 24 can also be useful for moni-

toring osseointegration, since the density of the dental/orthopedic structure 18 (tissue and bone) in the vicinity of an implant 28 or other prostheses can provide an important diagnostic tool for the use of the dental or medical practitioner in assessing the effectiveness of an implant or prosthetic procedure. The tomographical densitometry model 24 is also entered into the computer's memory device 7.

[0022] Fig. 2 is a flow chart of a dental and orthopedic densitometry method embodying the present invention. The method steps include positioning a patient and positioning the X-ray equipment relative to the patient, i.e. with the patient's dental/orthopedic structure to be examined located between the X-ray source 14 and the detector array 16.

[0023] Diagnostic parameters are input to the system and can comprise, for example, the patient's prior tomographical densitometry models and standardized models. The tomographical densitometry models can be corrected and/or adjusted to account for patients' age, gender, physical characteristics, etc. The input diagnostic parameters can be stored in the computer's memory device. A scan path for the X-ray equipment is preprogrammed in the computer.

[0024] The scanning procedure is commenced by collimating a first energy band beam, detecting emissions from same with a detector array, and converting the analog output of the detector array to a digital signal. The digital signal is output for storage in the computer. The steps of collimating the energy band beam and detecting, digitizing and storing same are repeated for a second energy band beam. The Bisek et al. U.S. Patent No. Re. 36,162 discloses the use of dual-energy X-ray beams in medical densitometry applications. As discussed therein, dual-energy densitometry can result in a more accurate patient model.

[0025] The X-ray equipment then traverses the preprogrammed scan path and the first/second energy band steps are repeated until the scanning procedure is complete. The digitized detector array output is merged and compared to the diagnostic parameters which are stored in the computer's memory. The dental/orthopedic densitometry is tomographically modeled and output, for example to a monitor or printer for converting the model to a visual image. The visual image is output in a visible form for use by dental and medical practitioners.

Claims

1. A system for tomographically modeling dental and orthopedic structure densitometry, said system including:

   a controller (4) comprising a microprocessor (6) and a memory device (7) connected to the microprocessor (6);
   an input device connected to the microprocessor (6);
   X-ray equipment (12) including an X-ray source (14) and a detector array (16);
   a positioning motor (10) adapted for positioning said X-ray equipment (12) with respect to three axes of movement;
   said X-ray equipment (12) comprising a dual energy level, restricted beam device (14);
   conversion means (20) comprising an analog-to-digital (A-D) converter (20) connected to said detector array (16) and said microprocessor (6) for converting a signal from said detector array (16); comprising

   a merger device (22) connected to said converter (20) and to said microprocessor (6);
   said memory device (7) storing a pre-existing graphical dental/orthopedic densitometry model for comparison with a patient's densitometry model;
   said microprocessor being programmed with a preprogrammed scan path for said X-Ray equipment (12) and being arranged to adjust the patient's densitometry model to account for patient parameters including age and gender and to compare said pre-existing and current tomographical densitometry models;
   a colour output device (26) connected to said microprocessor (6) and adapted to receive and output a tomographical densitometry model from said microprocessor (6) colour coded in colours corresponding to the patient's dental or orthopedic structure density.

2. The system according to claim 1, wherein said output device includes a colour monitor (26) adapted to receive said tomographical densitometry model output colour-coded to represent densitometry.

3. The system according to claim 1, wherein said output device includes a colour printer (26) adapted to print images colour-coded to correspond to the densitometry of said model.

4. A method for tomographically modeling dental and orthopedic structure densitometry, said method including the steps of providing:

   a controller (7) with a microprocessor (6) and a memory device (7) connected to the microprocessor (6);
   an input device (8) connected to the microprocessor (6);
   X-ray equipment (12) including an X-ray source (14) and a detector array (16);
   an analog-to-digital (A-D) converter (20) con-

nected to said detector array (16) and to said microprocessor (6) for converting a signal from said detector array (16);
a colour output device (26) connected to said microprocessor (6) and adapted to receive and output a tomographical densitometry model from said microprocessor (6) colour coded in colours corresponding to the patient's dental or orthopedic structure density;
a positioning motor (10) connected to said microprocessor (6) and to said X-ray equipment (12) for moving same through three axes of movement along said scan path; which method further includes the steps of:

inputting patient diagnostic parameters with said input device (8);
storing said diagnostic parameters in said memory device (7);
positioning said X-ray equipment (12) and a patient's dental/orthopedic structure (18) relative to each other with said patient's dental/orthopedic structure 18 between said source (14) and said detector array (16);
inputting to said controller (6) a pre-existing tomographical densitometry model;
inputting to said controller (4) a predetermined scan path for said X-ray equipment (12);
emitting an X-ray beam corresponding to first and second energy levels from said source (14) through said dental/orthopedic structure (18) and to said detector array (16);
outputting a signal from said detector array (16) to said microprocessor (6);
traversing said X-ray equipment (12) along said scan path;
forming with said microprocessor (6) a present tomographical densitometry model of said dental/orthopedic structure (18);
adjusting said present densitometry model to account for patient parameters including age and gender;
comparing said patient's current densitometry model to said pre-existing densitometry model;
colour coding said densitometry model (18) in colours corresponding to the patient's dental or orthopedic structure density;
outputting said colour-coded densitometry model to said output device (26).

5. The method according to claim 4, which includes the additional steps of:

repeating said input, output, positioning and storing steps; and
merging said stored output signals to form a present tomographical densitometry model of said dental or orthopedic structure (18).

Patentansprüche

1. System zum tomographischen Modellieren dentaler und orthopädischer Strukturdensitometrie, wobei das System aufweist:

eine Steuerung (4) mit einem Mikroprozessor (6) und einem mit dem Mikroprozessor (6) verbundenen Speicherbauelement (7);
eine mit dem Mikroprozessor (6) verbundene Eingabevorrichtung;
eine Röntgenanlage (12) mit einer Röntgenquelle (14) und einem Detektorarray (16);
einen Positioniermotor (10), der zum Positionieren der Röntgenanlage (12) im Hinblick auf drei Bewegungsachsen geeignet ist;

wobei die Röntgenanlage (12) eine Vorrichtung (14) mit zwei Energieniveaus und begrenztem Strahl aufweist;
eine Umwandlungseinrichtung (20) mit einem Analog-Digital- (A-D) Wandler (20), der mit dem Detektorarray (16) und dem Mikroprozessor (6) verbunden ist, zum Umwandeln eines Signals vom Detektorarray (16); mit
einer Zusammenführungsvorrichtung (22), die mit dem Wandler (20) und mit dem Mikroprozessor (6) verbunden ist;
wobei das Speicherbauelement (7) ein schon vorhandenes graphisches dentales/orthopädisches Densitometriemodell zum Vergleich mit einem Patienten-Densitometriemodell speichert;
wobei der Mikroprozessor mit einem vorprogrammierten Abtastweg für die Röntgenanlage (12) programmiert und so angeordnet ist, daß er das Patienten-Densitometriemodell einstellt, um Patientenparametern, darunter Alter und Geschlecht, Rechnung zu tragen, und das schon vorhandene sowie das aktuelle tomographische Densitometriemodell vergleicht;
eine Farbausgabevorrichtung (26), die mit dem Mikroprozessor (6) verbunden und geeignet ist, ein tomographisches Densitometriemodell vom Mikroprozessor (6) zu empfangen und auszugeben, das in Farben farbcodiert ist, die der dentalen oder orthopädischen Patientenstrukturdichte entsprechen.

2. System nach Anspruch 1, wobei die Ausgabevorrichtung einen Farbmonitor (26) aufweist, der geeignet ist, das tomographische Densitometriemodell zu empfangen, das so farbcodiert ausgegeben ist, daß es Densitometrie darstellt.

3. System nach Anspruch 1, wobei die Ausgabevorrichtung einen Farbdrucker (26) aufweist, der geeignet ist, Bilder auszudrucken, die so farbcodiert sind, daß sie der Densitometrie des Modells entsprechen.

4. Verfahren zum tomographischen Modellieren dentaler und orthopädischer Strukturdensitometrie, wobei das Verfahren die Schritte des Bereitstellens von folgendem aufweist:

einer Steuerung (4) mit einem Mikroprozessor (6) und einem mit dem Mikroprozessor (6) verbundenen Speicherbauelement (7);
einer mit dem Mikroprozessor (6) verbundenen Eingabevorrichtung;
einer Röntgenanlage (12) mit einer Röntgenquelle (14) und einem Detektorarray (16);
einem Analog-Digital- (A-D) Wandler (20), der mit dem Detektorarray (16) und dem Mikroprozessor (6) verbunden ist, zum Umwandeln eines Signals vom Detektorarray (16); einer Farbausgabevorrichtung (26), die mit dem Mikroprozessor (6) verbunden und geeignet ist, ein tomographisches Densitometriemodell vom Mikroprozessor (6) zu empfangen und auszugeben, das in Farben farbcodiert ist, die der dentalen oder orthopädischen Patientenstrukturdichte entsprechen;
einem Positioniermotor (10), der mit dem Mikroprozessor (6) und mit der Röntgenanlage (12) verbunden ist, zum Bewegen derselben über drei Bewegungsachsen entlang dem Abtastweg;

wobei das Verfahren ferner die Schritte aufweist:

Eingeben diagnostischer Patientenparameter mit der Eingabevorrichtung (8);
Speichern der diagnostischen Parameter im Speicherbauelement (7);
Positionieren der Röntgenanlage (12) und einer dentalen/orthopädischen Patientenstruktur (18) relativ zueinander, wobei sich die dentale/orthopädische Patientenstruktur (18) zwischen der Quelle (14) und dem Detektorarray (16) befindet;
Eingeben eines schon vorhandenen tomographischen Densitometriemodells in die Steuerung (4);
Eingeben eines vorbestimmten Abtastwegs für die Röntgenanlage (12) in die Steuerung (4);
Abstrahlen eines Röntgenstrahls, der einem ersten und einem zweiten Energieniveau entspricht, von der Quelle (14) durch die dentale/orthopädische Struktur (18) und zum Detektorarray (16);
Ausgeben eines Signals vom Detektorarray (16) zum Mikroprozessor (6);
Verfahren der Röntgenanlage (12) entlang dem Abtastweg;
Bilden eines aktuellen tomographischen Densitometriemodells der dentalen/orthopädischen Struktur (18) mit dem Mikroprozessor (6);
Einstellen des aktuellen Densitometriemodells, um Patientenparametern, darunter Alter und Geschlecht, Rechnung zu tragen;
Vergleichen des aktuellen Patienten-Densitometriemodells mit dem schon vorhandenen Densitometriemodell;
Farbcodieren des Densitometriemodells (18) in Farben, die der dentalen oder orthopädischen Patientenstrukturdichte entsprechen;
Ausgeben des farbcodierten Densitometriemodells zur Ausgabevorrichtung (26).

5. Verfahren nach Anspruch 4, das die zusätzlichen Schritte aufweist:

Wiederholen des Eingabe-, Ausgabe-, Positionier- und Speicherschritts; und
Zusammenführen der gespeicherten Ausgabesignale, um ein aktuelles tomographisches Densitometriemodell der dentalen oder orthopädischen Struktur (18) zu bilden.

Revendications

1. Système pour la modélisation tomographique de densitométrie de structure dentaire et orthopédique, ledit système comprenant :

un contrôleur (4) comprenant un microprocesseur (6) et un dispositif de mémoire (7) connecté au microprocesseur (6) ;
un dispositif d'entrée connecté au microprocesseur (6) ;
un équipement de radiologie (12) comprenant une source de rayons X (14) et un réseau de détecteurs (16) ;
un moteur de positionnement (10) adapté pour positionner ledit équipement de radiologie (12) par rapport à trois axes de mouvement ;
ledit équipement de radiologie (12) comprenant un dispositif à faisceau limité à deux niveaux d'énergie (14) ;
des moyens de conversion (20) comprenant un convertisseur analogique-numérique (A-N) (20) connecté audit réseau de détecteurs (16) et audit microprocesseur (6) pour convertir un signal provenant dudit réseau de détecteurs (16) ; comprenant :

un dispositif de fusion (22) connecté audit convertisseur (20) et audit microprocesseur (6) ;

ledit dispositif de mémoire (7) mémorisant un modèle de densitométrie dentaire/orthopédique graphique préexistant pour une comparaison avec un modèle de densitométrie d'un patient ;
ledit microprocesseur étant programmé avec un trajet de balayage préprogrammé pour ledit équipement de radiologie (12) et étant agencé pour ajuster le modèle de densitométrie du patient pour prendre en compte des paramètres de patient comprenant l'âge et le sexe et pour comparer lesdits modèles de tomodensitométrie préexistant et actuel ;
un dispositif de sortie couleur (26) connecté audit microprocesseur (6) et adapté pour recevoir et délivrer un modèle de tomodensitométrie dudit microprocesseur (6) codé par couleurs en couleurs correspondant à la densité de la structure dentaire ou orthopédique du patient.

2. Système selon la revendication 1, dans lequel ledit dispositif de sortie comprend un écran couleur (26) adapté pour recevoir ladite sortie de modèle de tomodensitométrie codé par couleurs pour représenter la densitométrie.

3. Système selon la revendication 1, dans lequel ledit dispositif de sortie comprend une imprimante couleur (26) adaptée pour imprimer des images codées par couleurs pour correspondre à la densitométrie dudit modèle.

4. Procédé pour la modélisation tomographique de densitométrie de structure dentaire et orthopédique, ledit procédé comprenant les étapes consistant à prévoir :

un contrôleur (4) comprenant un microprocesseur (6) et un dispositif de mémoire (7) connecté au microprocesseur (6) ;
un dispositif d'entrée (8) connecté au microprocesseur (6) ;
un équipement de radiologie (12) comprenant une source de rayons X (14) et un réseau de détecteurs (16) ;
un convertisseur analogique-numérique (A-N) (20) connecté audit réseau de détecteurs (16) et audit microprocesseur (6) pour convertir un signal provenant dudit réseau de détecteurs (16) ;
un dispositif de sortie couleur (26) connecté audit microprocesseur (6) et adapté pour recevoir et délivrer un modèle de tomodensitométrie dudit microprocesseur (6) codé par couleurs en couleurs correspondant à la densité de la structure dentaire ou orthopédique du patient ;
un moteur de positionnement (10) connecté audit microprocesseur (6) et audit équipement de radiologie (12) pour déplacer le susdit selon trois axes de mouvement le long dudit trajet de balayage ; lequel procédé comprend les étapes consistant à :

entrer des paramètres de diagnostic de patient au moyen dudit dispositif d'entrée (8) ;
mémoriser lesdits paramètres de diagnostic dans ledit dispositif de mémoire (7) ;
positionner ledit équipement de radiologie (12) et une structure dentaire/orthopédique (18) d'un patient l'un par rapport à l'autre avec ladite structure dentaire/orthopédique (18) du patient entre ladite source (14) et ledit réseau de détecteurs (16) ;
entrer dans ledit contrôleur (6) un modèle de tomodensitométrie préexistant ;
entrer dans ledit contrôleur (4) un trajet de balayage prédéterminé pour ledit équipement de radiologie (12) ;
émettre un faisceau de rayons X correspondant à des premier et deuxième niveaux d'énergie à partir de ladite source (14) à travers ladite structure dentaire/orthopédique (18) et vers ledit réseau de détecteurs (16) ;
fournir un signal dudit réseau de détecteurs (16) audit microprocesseur (6) ;
déplacer ledit équipement de radiologie (12) le long dudit trajet de balayage ;
former, avec ledit microprocesseur (6), un modèle de tomodensitométrie actuel de ladite structure dentaire/orthopédique (18) ;
ajuster ledit modèle de densitométrie actuel pour prendre en compte des paramètres de patient comprenant l'âge et le sexe ;
comparer ledit modèle de densitométrie actuel dudit patient audit modèle de densitométrie préexistant ;
coder par couleurs ledit modèle de densitométrie (18) en couleurs correspondant à la densité de structure dentaire ou orthopédique du patient ;
fournir ledit modèle de densitométrie codé par couleurs audit dispositif de sortie (26).

5. Procédé selon la revendication 4, qui comprend les étapes supplémentaires consistant à :

répéter lesdites étapes d'entrée, de fourniture, de positionnement et de mémorisation ; et
fusionner lesdits signaux de sortie mémorisés pour former un modèle de tomodensitométrie actuel de ladite structure dentaire ou orthopédique (18).

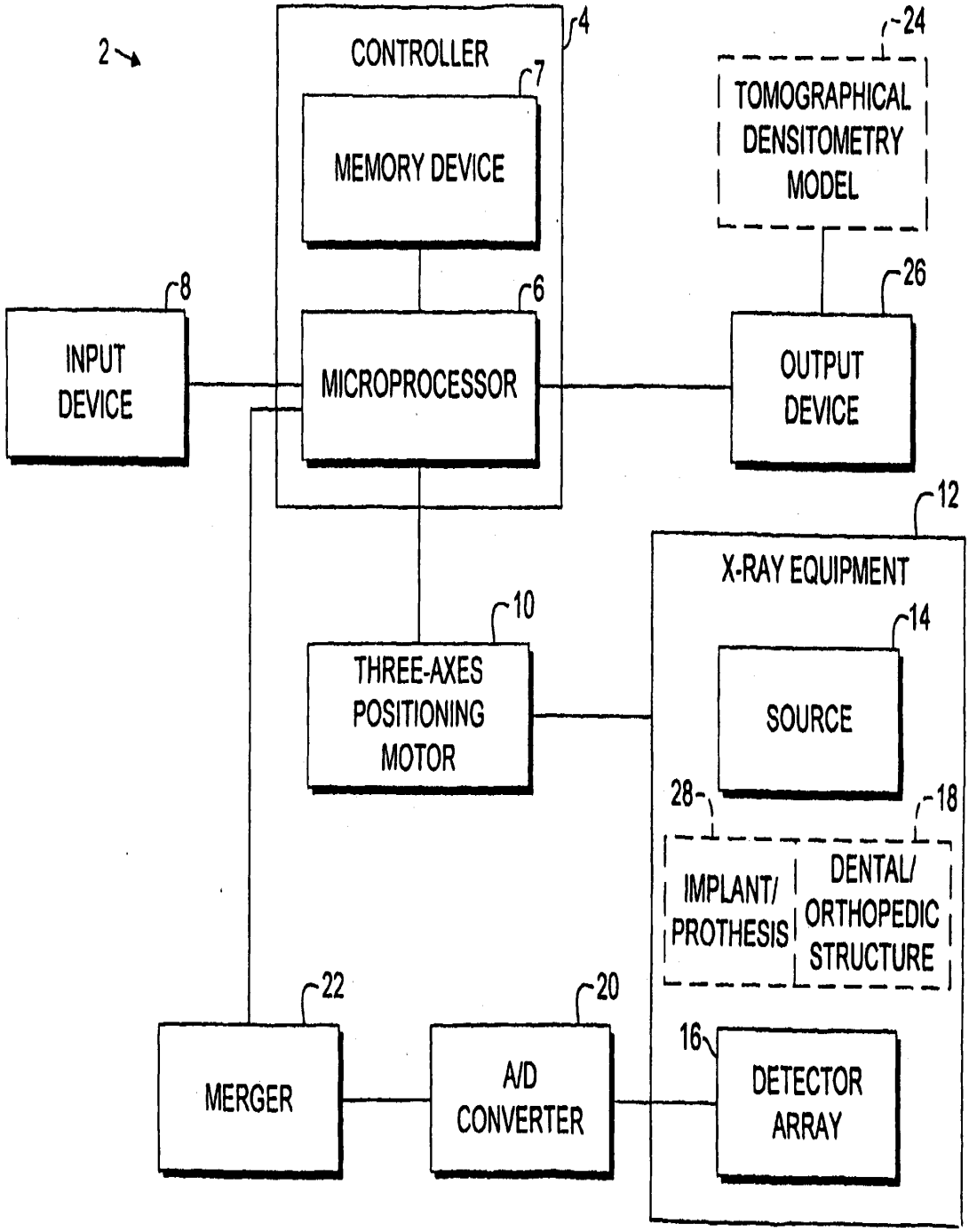


Fig. 1

EP 1 237 483 B1

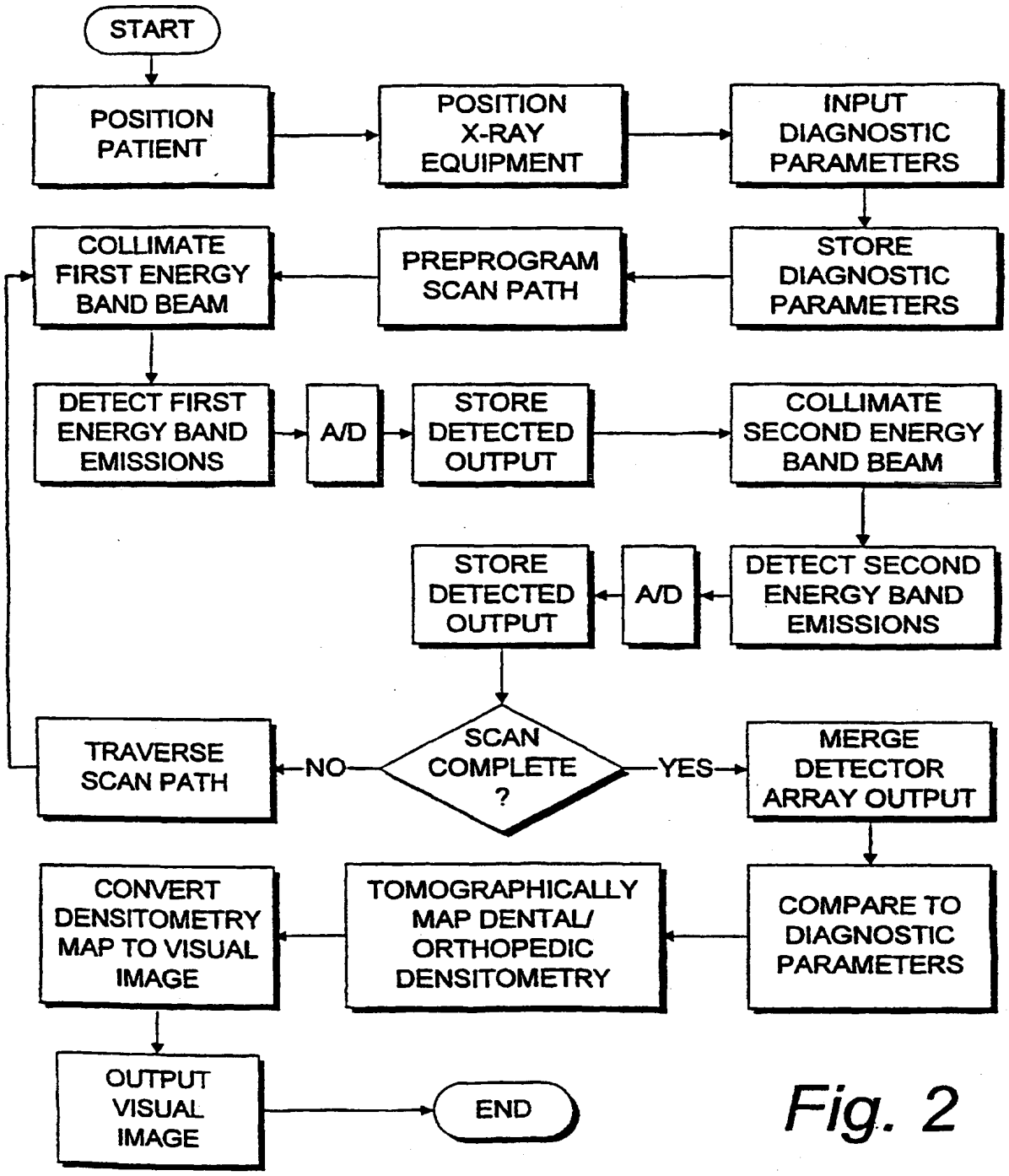

START
POSITION PATIENT
POSITION X-RAY EQUIPMENT
INPUT DIAGNOSTIC PARAMETERS
STORE DIAGNOSTIC PARAMETERS
PREPROGRAM SCAN PATH
COLLIMATE FIRST ENERGY BAND BEAM
DETECT FIRST ENERGY BAND EMISSIONS
A/D
STORE DETECTED OUTPUT
COLLIMATE SECOND ENERGY BAND BEAM
DETECT SECOND ENERGY BAND EMISSIONS
A/D
STORE DETECTED OUTPUT
SCAN COMPLETE ?
NO
YES
TRAVERSE SCAN PATH
MERGE DETECTOR ARRAY OUTPUT
COMPARE TO DIAGNOSTIC PARAMETERS
TOMOGRAPHICALLY MAP DENTAL/ ORTHOPEDIC DENSITOMETRY
CONVERT DENSITOMETRY MAP TO VISUAL IMAGE
OUTPUT VISUAL IMAGE
END

Fig. 2

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 4188537 A **[0007]**
- US 4259583 A **[0007]**
- US 4823369 A **[0007]**
- US 4856038 A **[0007]**
- US 5214686 A **[0007]**
- US 5533080 A **[0008] [0020]**
- US 5838765 A **[0008] [0020]**
- US RE36162 E **[0008] [0020] [0024]**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/32905

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 6/14; H05G 1/64
US CL : 378/205, 168, 170, 38, 39, 98.8

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)
U.S. : 378/205, 168, 170, 38, 39, 98.8

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST: Dental, Density, Densitomet$6, Position, Energy, Source, Detector

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,813,060 A (HEUBECK et al.) 14 March 1989 (14.03.1989), all.	1-20
Y	US 5,214,686 A (WEBBER) 25 May 1993 (25.05.1993), all.	1-20
Y	US 5,528,645 A (KOIVISTO) 18 June 1996 (18.06.1996), all.	1-20
Y	US 5,995,583 A (SCHICK et al.) 20 November 1999 (20.11.1999), all.	1-20

☐ 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 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
16 January 2001 (16.01.2001)	26 JAN 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Drew A. Dunn Telephone No. 703-308-0956

Form PCT/ISA/210 (second sheet) (July 1998)

PATENT COOPERATION TREATY

REC'D 28 FEB 2005
WIPO PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MARK E. BROWN
CHASE LAW FIRM, L.C.
4400 COLLEGE BOULEVARD, SUITE 130
OVERLAND PARK, KS 66217

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	25 FEB 2005
Applicant's or agent's file reference 3396	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US04/01825	23 January 2004 (23.01.2004)	24 January 2003 (24.01.2003)

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

IPC(7): A61B 6/14 and US Cl.: 378/38-40, 191, 168-170, 56-56

Applicant

MASSIE, RONALD E.

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Hoon Song FOR Telephone No. 571-272-2494

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/01825

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/01825

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3-4, 8, 12	YES
	Claims 1-2, 5-7, 9-11 and 13-20	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-20	NO
Industrial applicability (IA)	Claims 1-20	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

Form PCT/ISA/237 (Box No. V) (January 2004)

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-2, 5-7, 9-11 and 13-20 lacks novelty under PCT Article 33(2) as being anticipated by Schuller et al. (US 4941164).

Regarding claim 1, Schuller teaches a digital modeling system for creating dental or orthopedic models of patients, which system comprises:

a computer (column 4 line 41) including a digital memory adapted for storing patient densitometry information, an input and an output (column 6 line 12);

a dental or orthopedic input device including an energy source (x-ray source, figure 4) and an energy sensor (17a or digital sensor, column 5 line 2-3);

said source (x-ray source) and said sensor (17a) being adapted for placement with at least a portion of the patient's dental or orthopedic structure therebetween (figure 4);

said sensor (17a with film scanner as shown by 1a, or digital sensor column 5 line 2-3) being adapted for transferring signals to the computer input (processor);

said signals representing densitometry of the patient's dental or orthopedic structure (figure 5);

said computer being adapted for creating, storing and comparing digital densitometry models of patient dental or orthopedic structure (column 9 line 56); and

an output device (display) connected to said computer output and adapted for communicating densitometry model comparison information (column 9 line 68-column 10 line 1).

Regarding claim 2, Schuller teaches that said source is external (figure 4).

Regarding claim 5, Schuller teaches that said sensor is intra-oral (figure 4).

Regarding claim 6, Schuller teaches that said energy being collimated (see x-ray source in figure 4); imaging software (column 7 line 48) associated with said computer; and a display (column 9 line 68) associated with said output device and adapted for displaying densitometry model information.

Regarding claim 7, Schuller teaches a patient-specific database (digitalized dental image) of dental or orthopedic densitometry data corresponding to respective patients (column 6 line 11+); and

time-lapse, automated digital comparisons of said patient-specific database (column 1 line 25), said

comparisons identifying dental or orthopedic densitometry changes in the dental or orthopedic structures of individual patients (column 10 line 25+).

Regarding claim 9, Schuller teaches said patient-specific database includes information pertaining to one or more the following: general dental health, dental hygiene, systemic influences, oncology, zerostomia, medications, susceptibility to infection and susceptibility to tooth decay (column 9 line 67+).

Regarding claim 10, Schuller teaches a predictive patient model (later taken image).

Regarding claim 11, Schuller teaches localized, tooth-specific densitometry model information (column 9 line 10+).

Regarding claim 13, Schuller teaches a dental or orthopedic densitometry modeling method, which comprises the steps of:

building an initial patient-specific densitometry model (dental x-ray film);

obtaining current densitometry data on said patient (digitalized dental data, column 6 line 13+); and

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

updating said patient-specific densitometry model (comparison, column 10 line 26+).
Regarding claim 14, Schuller teaches the additional steps of :
building a database of dental or orthopedic densitometry data; and
building a predictive densitometry model for a patient based on information from said database (later taken image).
Regarding claim 15, Schuller teaches the additional step of : updating said database with information obtained from a patient-specific densitometry model (later taken image).
Regarding claim 16, Schuller teaches the additional steps of:
including in said patient-specific densitometry model dental densitometry information obtained from a dental examination of one or more the following areas: periodical, bite wing, whole mouth, panoramic or cephalometric (figure 3).
Regarding claim 17, Schuller teaches the additional steps providing a hand-held energy or field source (x-ray source);
providing a sensor for energy or a field emitted by said source;
placing said source and sensor on opposite sides of a patient's dental or orthopedic structure to be modeled; and
emitting energy or a field from said source, passing same through said patient's structure; and
sensing said energy or field with said sensor (column 4 line 38+).
Regarding claim 18, Schuller teaches said source is a hand-held CRT.
Regarding claim 19, Schuller teaches the additional step of:
identifying a localized dental or orthopedic structure area as a watch area based on densitometry model change! with respect to a patient;
directing said CRT towards the localized dental or orthopedic structure watch area; and
obtaining specific, localized densitometry information concerning the densitometry model of said area (column 7 line 10+).
Regarding claim 20, Schuller teaches the additional step of: converting a former procedure using subjective or analog information in a dental or medical office to the use of digital densitometry data (column 6 line 13+).
Claims 8 and 12 lacks an inventive step under PCT Article 33(3) as being obvious over Schuller.
Regarding claims 8 and 12, Schuller fails to teach that the densitometry data includes variables for age and gender.
Dental patient information system having data categorized by age and gender is known in the art.
It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the system of Schuller with known variables for age and gender, since the variable would provide more accurate patient management.
Claims 3-4 lacks an inventive step under PCT Article 33(3) as being obvious over Schuller in view of Weiss (US 4104532).
Regarding claims 3-4, Schuller fails to teach said source is intra-oral or said sensor is external (figure 4).
Weiss teaches an intra-oral x-ray source (23) and external sensor (34).
It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the system of Schuller with the intra-oral x-ray source as taught by Weiss, since the source of Weiss would provide high resolution, panoramic radiograph (column 1 line 21-22).

Electronic Acknowledgement Receipt

EFS ID:	14176110
Application Number:	13619356
International Application Number:	
Confirmation Number:	4681
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Customer Number:	63151
Filer:	Mark E. Brown/Autumn Winegar
Filer Authorized By:	Mark E. Brown
Attorney Docket Number:	2932.2
Receipt Date:	07-NOV-2012
Filing Date:	14-SEP-2012
Time Stamp:	19:54:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS110712.pdf	137012 f48d3da837d82a5771a5006b58a8a4f3cf28e42f	no	3

Warnings:	
Information:	

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2	Foreign Reference	EP0180482.pdf	966465 029959f63e8336bafdb63cc1f71363599af3efdc	no	28
Warnings:					
Information:					
3	Foreign Reference	EP0314506.pdf	1013572 804e7dfb70e6cc96d60d6021b72eb61c7dd9f45a	no	18
Warnings:					
Information:					
4	Foreign Reference	WO9311707.pdf	19349327 324964b0e098d4fd0cf44ee6e0da2a56e9666b39	no	39
Warnings:					
Information:					
5	Foreign Reference	EP0652433.pdf	196112 353f8717ba3ceb6f701b93968fcc79c83ca3ab99	no	18
Warnings:					
Information:					
6	Foreign Reference	WO01038824.pdf	1382778 5b3de005b0b75cb65cb9f880aa0cd8d9504eb233	no	28
Warnings:					
Information:					
7	Foreign Reference	WO01039667.pdf	670591 f3bc7acd6d76637ce802a223687b227935fe4aa4	no	21
Warnings:					
Information:					
8	Foreign Reference	CA2390334.pdf	5181088 dd881ce87cbd301d9550172b958c9bb3a73fad83	no	21
Warnings:					
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9	Foreign Reference	EP1237483.pdf	2526150 1c35ff6096ad27327762687781c511f76f2d58be	no	10
Warnings:					
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10	Non Patent Literature	JPA2006-502953FinalRejection033010.pdf	1438376 b3fe033e8932879069c902f50fa7b5ab37314cf6	no	3
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Information:					
11	Non Patent Literature	IntlSrchRptPCTUS0032905.pdf	47348 6bf67b0148727e29fd6f9f0e1ec70b36545e18e2	no	1
Warnings:					
Information:					
12	Non Patent Literature	JPA2001-541403ReasonForRejection031910.pdf	13469566 07605409117cd79dede237eab47325a29d953ea2	no	9
Warnings:					
Information:					
13	Non Patent Literature	JPA2006-502953ReasonForRejection080309.pdf	523372 89b211fd730eccbe13ab94537ef0bf955709bca9	no	4
Warnings:					
Information:					
14	Non Patent Literature	JPA2001-541403ReasonForRejection112409.pdf	1053915 dd7070e91ccb17a9cc790b22d210ad055a7dfd39	no	4
Warnings:					
Information:					
15	Non Patent Literature	SuppSrchRptEPO04704878-0.pdf	170095 928953f562a55ab975f5e30736c5b115454f92c4	no	4
Warnings:					
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16	Non Patent Literature	WrittenOpinPCTUS0401825.pdf	216539 ab28556776d00938c419436d6a2714780af769f0	no	5
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Information:					
17	Non Patent Literature	BoydeMineralizationDensity.pdf	480995 56591c33d36b4222b6186048f62d4b9056a288a6	no	6
Warnings:					
Information:					
18	Non Patent Literature	BranemarkIntroOsseointegration.pdf	5172949 85a6a5e290921b02cbf21b14fcc1fe04d501926f	no	60
Warnings:					
Information:					

19	Non Patent Literature	ElsasserBoneDensityMeasurement.pdf	3435398 17462b1b67773ae823bfdaf58d75a5671430d08a	no	6
Warnings:					
Information:					
20	Non Patent Literature	ExnerBoneDensitometryUsingComputedTomography.pdf	3702119 1e756bddf2a4733197aae8c147650a75499e1e64	no	10
Warnings:					
Information:					
21	Non Patent Literature	KrennmairMaxillarySinusAspergillosis.pdf	2822550 451d0450777ee9772c9d09454cddc24c00a8f7be	no	8
Warnings:					
Information:					
			Total Files Size (in bytes):	63956317	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/619,356	09/14/2012	Ronald E. Massie	2932.2	4681

63151 7590 12/17/2012

LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

EXAMINER	
KIKNADZE, IRAKLI	
ART UNIT	PAPER NUMBER
2882	
MAIL DATE	DELIVERY MODE
12/17/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	13/619,356	MASSIE, RONALD E.	
	Examiner	Art Unit	
	IRAKLI KIKNADZE	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-24* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-24* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *14 September 2012* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/07/2012*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) or 120 as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 09/452,348 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 4, -7, 9, 10 and 45-59 of U.S. Patent No. 13/367,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because of following reasons:

4. The application 13/367,150 claims a tomographic modeling system comprising: a controller with a microprocessor and a memory device connected to the microprocessor, the controller being adapted for storing a computed tomographic model of an object; an input device connected to the microprocessor; a positioning motor connected to the microprocessor and responsive to commands from the microprocessor; X-ray equipment including an X-ray source, a detector array, and a restricted beam device; a convertor for converting a signal from the detector array, the convertor being connected to the detector array and to the microprocessor; and an output device connected to the microprocessor and adapted for receiving a tomographic model from the microprocessor (see claims 1, 2, 4-7, 9 and 10) that clearly anticipate the currently pending applications claims 1-4 and 7-10.

5. The application 13/367,150 claims a tomographic modeling system comprising a tomographic modeling system comprising: a controller with a microprocessor and a memory device connected to the microprocessor, the controller being adapted for creating, storing, and comparing 3D digital tomographic models of an object without the use of fiducial markers of the object; an input device connected to the microprocessor; a positioning motor connected to the microprocessor and responsive to commands from the microprocessor; X-ray equipment including an X-ray source, a detector array, and a restricted beam device; a convertor for converting a signal from the detector array, the convertor being connected to the detector array and to the microprocessor; and an output device connected to the microprocessor and adapted for

receiving a tomographic model from the microprocessor (see claims 45-59) that clearly anticipate the currently pending applications claims 13-24.

6. The application 13/367,150 claims a tomographic modeling system claims a controller that is adapted for storing a first tomographic model and a second tomographic model; the first tomographic model is a preexisting, commercially available standard model; the second tomographic model is a current patient model; and the controller is further adapted to compare the first tomographic model with the second tomographic model and/or wherein: the controller is adapted for storing a first tomographic model and a second tomographic model; the first tomographic model is a preexisting patient model;
the second tomographic model is a current patient model; and the controller is further adapted to compare the first tomographic model with the second tomographic model (see claims 14-20) that clearly anticipate the currently pending applications claims 5, 6, 11 and 12.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to IRAKLI KIKNADZE whose telephone number is (571)272-2493. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Toan Ton can be reached on 571-272-2303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Irakli Kiknadze

/Irakli Kiknadze/

Primary Examiner, Art Unit 2882

/I. K./ December 13, 2012

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	0	"13619356"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/10 11:10
L2	20	"6381301"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/10 11:10
L3	0	2002/012420	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/10 11:12
L4	4	2002/0012420	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/10 11:12
L5	2	"20020012420"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/12/10 11:12

12/10/2012 11:15:46 AM
C:\Users\ikiknadze\Documents\EAST\Workspaces\121.wsp

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BIB DATA SHEET

CONFIRMATION NO. 4681

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/619,356	09/14/2012 RULE	378	2882	2932.2

APPLICANTS

Ronald E. Massie, Lake Ozark, MO;

**** CONTINUING DATA ***************************

This application is a CON of 13/367,150 02/06/2012
which is a CON of 09/452,348 12/01/1999 PAT 6,381,301
and is a CON of 12/250,423 10/13/2008 PAT 8,126,112 *
which is a CIP of 11/932,809 10/31/2007 PAT 8,073,101
which is a CIP of 11/224,472 09/12/2005 PAT 7,839,970
which is a CON of 10/351,567 01/24/2003 PAT 6,944,262
which is a CIP of 10/134,153 04/27/2002 ABN
which is a CON of 09/452,348 12/01/1999 PAT 6,381,301
(*)Data provided by applicant is not consistent with PTO records.

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
09/28/2012

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/IRAKLI KIKNADZE/ Examiner's Signature	MO	2	24	3
	☐ Met after Allowance	Initials				

ADDRESS

LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112
UNITED STATES

TITLE

DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

FILING FEE RECEIVED		
950	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13619356	MASSIE, RONALD E.
	Examiner	**Art Unit**
	IRAKLI KIKNADZE	2882

SEARCHED

Class	Subclass	Date	Examiner
378	5,16,15,21,19,38,39 and 62	12/13/2012	IK

SEARCH NOTES

Search Notes	Date	Examiner
EAST search	12/13/2012	IK

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

	/IRAKLI KIKNADZE/ Primary Examiner.Art Unit 2882

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13619356	MASSIE, RONALD E.
	Examiner	Art Unit
	IRAKLI KIKNADZE	2882

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/13/2012								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
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	24	✓								

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	13/619,356
Filing Date	September 14, 2012
First Named Inventor	Massie, Ronald E.
Art Unit	2882
Examiner Name	~~Ho, Allen C.~~ /Irakli Kiknadze/

Sheet	1	of	3

Attorney Docket No: 2932.2

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		US-3949229	04/06/1976	Albert	
		US-4188537	02/12/1980	Franke	
		US-4239971	12/16/1980	Cushman	
		US-4259583	03/31/1981	Albert	
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		US-5836876	11/17/1998	Dimarogonas, Andrew D.	
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		US-RE36162	03/23/1999	Bisek et al.	
		US-5917882	06/29/1999	Khutoryansky et al.	

EXAMINER /Irakli Kiknadze/ **DATE CONSIDERED** 12/04/2012

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH /IK/

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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Application Number	13/619,356
Filing Date	September 14, 2012
First Named Inventor	Massie, Ronald E.
Art Unit	2882
Examiner Name	~~Ho, Allen C.~~ /Irakli Kiknadze/

Sheet	2	of	3

Attorney Docket No: 2932.2

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
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		US-5930327	07/27/1999	Lin	
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		EP-0314506	05/03/1989	Schuller, Paul D.	
		WO-9311707	06/24/1993	Webber, Richard L.	
		EP-0652433	05/10/1995	Fujii, Masashi	
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		WO-01/39667	06/07/2001	Massie, Ronald E.	
		CA-2390334	11/18/2008	Massie, Ronald E.	
		EP-1237483	11/26/2008	Massie, Ronald E.	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

EXAMINER /Irakli Kiknadze/ **DATE CONSIDERED** 12/04/2012

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH /IK/

PTO/SB/08a(04-07)
Approved for use through 7/31/2006. OMB 0651-0031
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	13/619,356
Filing Date	September 14, 2012
First Named Inventor	Massie, Ronald E.
Art Unit	2882
Examiner Name	~~He, Allen C.~~ /Irakli Kiknadze/

Sheet	3	of	3

Attorney Docket No: 2932.2

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"Final Decision for Rejection", Japan Patent Application No. 2006-502953 based on PCT/US2001/001825, (03/30/2010),	
		"International Search Report", PCT/US00/32905, (01/26/2001),	
		"Notice of Reason for Rejection", Japan Appl. No. 2001-541403 based on PCT/US00/32905, (03/19/2010),	
		"NOTICE OF REASON FOR REJECTION", Japan Patent Application No. 2006-502953 based on PCT/US2004/001825, (08/03/2009),	
		"Notice of Reason for Rejection", Japan Patent Application No. 2001-541403 based on PCT/US00/32905, (11/24/2009),	
		"Supplemental European Search Report", Massie Application No. 04704878.0, PCT/US2004001825, June 10, 2008,	
		"Written Opinion of the ISA", PCT/US/04/01825, 25 Feb. 2005,	
		BOYDE, A. et al., "The Mineralization Density of Iliac Crest Bone From Children with Osteogenesis Imperfecta", A. Boyde, R. Travers, F.H. Glorieux, S. J. Jones, The Mineralization Density of Iliac Crest Bone From Children with Osteogenesis Imperfecta, Calcified Tissue International, Vaolume 64 Issue 3, Mar 1999, pg 185-190, (Mar 1999),185-90	
		BRANEMARK, M.D., PH.D., INGVAR et al., "Tissue-Integrated Prosthese, Osseointegration in clinical denistry", Quintessence Publishing Co., Inc., 1985, 11-70	
		ELSASSER, URS, P., et al., "Bone Density Measurement with Computed Tomography", British Medical Bulletin Vol. 36, No. 3, (1980),293-296	
		EXNER, G., M., et al., "Bone Densitometry Using Computed Tomography", British Journal of Radiology, Vol. 52, (1979),14-23	
		KRENNMAIR, GERALD, MD et al., "Maxillary Sinus Aspergillosis: Diagnosis and Differentiation of the Pathogenesis Based on Computed Tomography Densitometry of Sinus Concretions", American Association of Oral and Maxillofacial Surgeons,(1995),657-663	

EXAMINER /Irakli Kiknadze/ **DATE CONSIDERED** 12/04/2012

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH /IK/

PTO/SB/08a(04-07)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1

Complete if Known

Application Number	13/619,356
Filing Date	September 14, 2012
First Named Inventor	Massie, Ronald E.
Art Unit	2882
Examiner Name	Kiknadze, Irakli

Attorney Docket No: 2932.2

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		US-4741007	04/26/1988	Virta, Arto et al.	
		US-5224140	06/29/1993	Virta, Arto et al.	
		US-5267293	11/30/1993	Virta, Arto	
		US-5900883	05/04/1999	Crucs, Kevin	
		US-6233305	05/15/2001	Muller, Timo	
		US-6332891	12/25/2001	Himes, David M.	
		US-6398549	06/04/2002	Koivisto et al.	
		US-6452997	09/17/2002	Muller, Timo et al.	
		US-6466641	10/15/2002	Virta, Arto et al.	
		US-6470069	10/22/2002	Muller, Timo	
		US-6516216	02/04/2003	Fontenot, Mark G., et al.	
		US-6530688	03/11/2003	Muller, Timo	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	T[2]

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"Apteryx, Inc. 501(k) Summary for Xray Vision – K983111", http://www.accessdata.fda.gov/cdrh_docs/pdf/K983111.pdf, (11/16/1998)	
		"Sirona Dental Systems GmbH Special 501(k) Summary for SIDEXIS Digital Radiography Imaging System – K992644", http://www.accessdata.fda.gov/cdrh_docs/pdf/K992644.pdf, (08/23/1999)	
		LINDH, et al., "Quantitative Computed Tomography of Trabecular Bone in the Mandible", Dentomaxillofac. Radiol., Vol. 25, No. 3, pp. 146-150, (06/1996)	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)
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Electronic Patent Application Fee Transmittal

Application Number:	13619356
Filing Date:	14-Sep-2012
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Filer:	Mark E. Brown/Autumn Winegar
Attorney Docket Number:	2932.2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	14682797
Application Number:	13619356
International Application Number:	
Confirmation Number:	4681
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Customer Number:	63151
Filer:	Mark E. Brown/Autumn Winegar
Filer Authorized By:	Mark E. Brown
Attorney Docket Number:	2932.2
Receipt Date:	11-JAN-2013
Filing Date:	14-SEP-2012
Time Stamp:	18:06:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	5847
Deposit Account	503424
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

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Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	2932-2SuppIDS011113.pdf	123901 6f7d995a0ecc006a2de30b3158d75330d3cb6c67	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	K983111.pdf	361952 5423161abd15db7086413b678ce5f1fdad4c0420	no	5
Warnings:					
Information:					
3	Non Patent Literature	K992644.pdf	172787 d109d73ce06c5fc07212c88e04bb63cdf690ee07	no	4
Warnings:					
Information:					
4	Non Patent Literature	Lindh.pdf	1881130 0708ab8b99095363fc214f2ada51f4bcb1c8580d	no	7
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30674 815f67829c3dd6f0450b2cb1f960baa15284f328	no	2
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		Total Files Size (in bytes):	2570444		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/619,356	09/14/2012	Ronald E. Massie	2932.2

CONFIRMATION NO. 4681

63151
LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

PUBLICATION NOTICE

OC000000058843313

Title:DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Publication No.US-2013-0022164-A1
Publication Date:01/24/2013

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed	PTO/SB/25 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION**
Application Number	13619356
Filing Date	14-Sep-2012
First Named Inventor	Ronald Massie
Attorney Docket Number	2932.2
Title of Invention	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Osseo iMaging, LLC	100%

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

13367150 filed on 02/06/2012

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

◉ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

○ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.
○ Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ○ Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). ◉ Applicant(s) status remains as SMALL ENTITY. ○ Applicant(s) status remains as other than SMALL ENTITY. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number 30361 ○ A sole inventor ○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors ○ A joint inventor; all of whom are signing this request ○ The assignee of record of the entire interest that has properly made itself of record pursuant to 37 CFR 3.71

Signature	/Mark Brown/
Name	Mark Brown

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	13619356
Filing Date:	14-Sep-2012
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Filer:	Mark E. Brown/Autumn Winegar
Attorney Docket Number:	2932.2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Statutory or terminal disclaimer	2814	1	80	80
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**80**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 13619356

Filing Date: 14-Sep-2012

Applicant/Patent under Reexamination: Massie et al.

Electronic Terminal Disclaimer filed on February 8, 2013

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	14913484
Application Number:	13619356
International Application Number:	
Confirmation Number:	4681
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Customer Number:	63151
Filer:	Mark E. Brown/Autumn Winegar
Filer Authorized By:	Mark E. Brown
Attorney Docket Number:	2932.2
Receipt Date:	08-FEB-2013
Filing Date:	14-SEP-2012
Time Stamp:	13:56:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$80
RAM confirmation Number	160
Deposit Account	503424
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	34133 0d21db6a732718dfa74be5f1c9f96fb999d26828	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30509 18345bcaead776b58e7c44508060d5ba4543ed95	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	64642		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	13/619,356	Confirmation No. 4681
Applicant	:	Ronald E. Massie	
Filed	:	09/14/2012	
TC/AU.	:	2882	
Examiner	:	Irakli Kiknadze	
Title	:	DENTAL AND ORTHOPEDIC DENISTOMETRY MODELING SYSTEM AND METHOD	
Docket No.	:	2932.2	
Dated:	:	02/08/2013	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT WITH TERMINAL DISCLAIMER

Commissioner:

In response to the Office action of December 17, 2012 please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

An **Electronic Terminal Disclaimer** is being filed herewith.

Amendments to the Specification

The following paragraph of the specification should be amended as indicated:

[0001] This application is a continuation of and claims priority in Serial No. 13/367,150, filed February 6, 2012, which is a continuation of ~~Serial No. 09/452,348, filed December 1, 1999, now U.S. Pat. No. 6,381,301,~~ and claims priority in Serial No. 12/250,423, filed October 13, 2008, now U.S. Pat. No. ~~9,126,112~~ 8,126,112, which is a continuation-in-part of Serial No. 11/932,809, filed October 31, 2007, now U.S. Pat. No. 8,073,101, which is a continuation-in-part of Serial No. 11/224,472, filed September 12, 2005, now U.S. Pat. No. 7,839,970, which is a continuation of Serial No. 10/351,567, filed January 24, 2003, now U.S. Pat. No. 6,944,262, which is a continuation-in-part of Serial No. 10/134,153, filed April 27, 2002, now abandoned, which is a continuation of Serial No. 09/452,348, filed December 1, 1999, now U.S. Pat. No. 6,381,301, which are all incorporated herein by reference.

Remarks

Applicants sincerely appreciate the Examiner's review of the present application. Responsive to the priority claim objection, paragraph [0001] of the specification has been amended to identify the sequence of co-pending applications.

Responsive to the double-patenting rejection, an Electronic Terminal Disclaimer is submitted herewith.

Based on the foregoing, all of the claims are in condition for allowance and a Notice of Allowance is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if prosecution of this application can be expedited thereby.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required by this paper to Deposit Account No. 503424.

Respectfully Submitted,

February 8, 2013

/Mark Brown/
MARK E. BROWN
Patent Office Reg. No. 30,361

LAW OFFICE OF MARK BROWN, LLC
4700 Belleview, Suite 210
Kansas City, MO 64112
Telephone: (816) 268-8950

Attorneys for Applicant

Electronic Acknowledgement Receipt

EFS ID:	14913683
Application Number:	13619356
International Application Number:	
Confirmation Number:	4681
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Customer Number:	63151
Filer:	Mark E. Brown/Autumn Winegar
Filer Authorized By:	Mark E. Brown
Attorney Docket Number:	2932.2
Receipt Date:	08-FEB-2013
Filing Date:	14-SEP-2012
Time Stamp:	14:03:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		AmdtWithTerminalDisclaimer020813.pdf	89158 6ace0cc8bf0f88e7c062ef309342c6eac5bd05c0	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
Warnings:			
Information:			
	Total Files Size (in bytes):	89158	

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New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

63151 7590 03/18/2013

LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

EXAMINER
KIKNADZE, IRAKLI

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 03/18/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/619,356	09/14/2012	INV001Ronald E. Massie	2932.2	4681

TITLE OF INVENTION: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$885	$0	$0	$885	06/18/2013

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

63151 7590 03/18/2013
LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/619,356	09/14/2012	INV001Ronald E. Massie	2932.2	4681

TITLE OF INVENTION: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$885	$0	$0	$885	06/18/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
KIKNADZE, IRAKLI	2882	378-005000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29	NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
❑ Applicant asserting small entity status. See 37 CFR 1.27	NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
❑ Applicant changing to regular undiscounted fee status.	NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/619,356	09/14/2012	INV001Ronald E. Massie	2932.2	4681

63151 7590 03/18/2013

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KANSAS CITY, MO 64112

EXAMINER	
KIKNADZE, IRAKLI	

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 03/18/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	13/619,356	MASSIE, RONALD E.	
	Examiner	Art Unit	
	IRAKLI KIKNADZE	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed on 2/8/2013*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *1-24*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 1/11/2013
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Irakli Kiknadze/
Primary Examiner, Art Unit 2882

DETAILED ACTION

1. In response to the Office action mailed on December 17, 2012 the Amendment has been received on February 8, 2013.

Claims 1-24 are currently pending in this application.

Terminal Disclaimer

2. The terminal disclaimer filed on February 8, 2013 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application number 13/367,150 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

3. Claims 1-24 are allowed.

4. The following is an examiner's statement of reasons for allowance:

Claim 1 is allowed because prior art fails to teach or make obvious a system for tomographically modeling a dental structure, the system comprising: a controller with a microprocessor and a memory device connected to the microprocessor, the controller being adapted for storing computed tomographic models of a dental structure; and a convertor for converting a signal from a detector array, the convertor being connected to

the detector array and to the microprocessor as claimed in combination with all of the remaining limitations of the claim.

Claim 13 is allowed because prior art fails to teach or make obvious a tomographic modeling system comprising: a controller with a microprocessor and a memory device connected to the microprocessor, the controller being adapted for creating, storing, and comparing 3D digital tomographic models of an object without the use of fiducial markers of the object; and a convertor for converting a signal from a detector array, the convertor being connected to the detector array and to the microprocessor as claimed in combination with all of the remaining limitations of the claim.

Claim 21 is allowed because prior art fails to teach or make obvious a system for tomographically modeling a dental structure, which system comprises: a controller with a microprocessor and a memory device connected to the microprocessor, the controller being adapted for creating, storing, and comparing 3D digital tomographic models of a dental structure without the use of fiducial markers of a dental structure; and a convertor for converting a signal from a detector array, the convertor being connected to the detector array and to the microprocessor as claimed in combination with all of the remaining limitations of the claim.

Claims 2-12, 14-20 and 22-24 are allowed by virtue of their dependence.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

5. Applicant's arguments, see page 3, filed on February 8, 2013, with respect to claims 1-24 have been fully considered and are persuasive. The rejection of claims 1-24 has been withdrawn.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to IRAKLI KIKNADZE whose telephone number is (571)272-2493. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Toan Ton can be reached on 571-272-2303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Irakli Kiknadze

/Irakli Kiknadze/

Primary Examiner, Art Unit 2882

/I. K./ March 10, 2013

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13619356	MASSIE, RONALD E.
	Examiner	Art Unit
	IRAKLI KIKNADZE	2882

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
378	5,16,15,21,19,38,39 and 62	12/13/2012	IK
updated search		3/10/2013	IK

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search	12/13/2012	IK
EAST search	3/10/2013	IK
PGPUB text search	3/10/2013	IK

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
378	5,19	3/10/2013	IK

	/IRAKLI KIKNADZE/ Primary Examiner.Art Unit 2882

PTO/SB/08a(04-07)
Approved for use through 7/31/2006. OMB 0651-0031
US Patent & Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1

Complete if Known

Application Number	13/619,356
Filing Date	September 14, 2012
First Named Inventor	Massie, Ronald E.
Art Unit	2882
Examiner Name	Kiknadze, Irakli

Attorney Docket No: 2932.2

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		US-4741007	04/26/1988	Virta, Arto et al.	
		US-5224140	06/29/1993	Virta, Arto et al.	
		US-5267293	11/30/1993	Virta, Arto	
		US-5900883	05/04/1999	Crucs, Kevin	
		US-6233305	05/15/2001	Muller, Timo	
		US-6332891	12/25/2001	Himes, David M.	
		US-6398549	06/04/2002	Koivisto et al.	
		US-6452997	09/17/2002	Muller, Timo et al.	
		US-6466641	10/15/2002	Virta, Arto et al.	
		US-6470069	10/22/2002	Muller, Timo	
		US-6516216	02/04/2003	Fontenot, Mark G., et al.	
		US-6530688	03/11/2003	Muller, Timo	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	T[2]

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"Apteryx, Inc. 501(k) Summary for Xray Vision – K983111", http://www.accessdata.fda.gov/cdrh_docs/pdf/K983111.pdf, (11/16/1998)	
		"Sirona Dental Systems GmbH Special 501(k) Summary for SIDEXIS Digital Radiography Imaging System – K992644", http://www.accessdata.fda.gov/cdrh_docs/pdf/K992644.pdf, (08/23/1999)	
		LINDH, et al., "Quantitative Computed Tomography of Trabecular Bone in the Mandible", Dentomaxillofac. Radiol., Vol. 25, No. 3, pp. 146-150, (06/1996)	

EXAMINER /Irakli Kiknadze/ **DATE CONSIDERED** 02/20/2013

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH /IK/

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13619356	MASSIE, RONALD E.
	Examiner	**Art Unit**
	IRAKLI KIKNADZE	2882

CPC

Symbol				Type	Version
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CPC Combination Sets

Symbol				Type	Set	Ranking	Version
			/				
			/				

US ORIGINAL CLASSIFICATION

CLASS	SUBCLASS
378	5

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
378	19				

INTERNATIONAL CLASSIFICATION

CLAIMED					NON-CLAIMED				
A	6	1	B	6 / 03 (2006.01.01)					
H	0	5	G	1 / 60 (2006.01.01)					
A	6	1	B	6 / 14 (2006.01.01)					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 24
/IRAKLI KIKNADZE/ Primary Examiner.Art Unit 2882 (Primary Examiner)	03/10/2013 (Date)	O.G. Print Claim(s): 1 / O.G. Print Figure: 1

U.S. Patent and Trademark Office

Part of Paper No. 20130310

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13619356	MASSIE, RONALD E.
	Examiner	**Art Unit**
	IRAKLI KIKNADZE	2882

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	24	
/IRAKLI KIKNADZE/ Primary Examiner.Art Unit 2882	03/10/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13619356	MASSIE, RONALD E.
	Examiner	**Art Unit**
	IRAKLI KIKNADZE	2882

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17												
2	2	18	18												
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15	15														
16	16														

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 24	
/IRAKLI KIKNADZE/ Primary Examiner.Art Unit 2882 (Primary Examiner)	03/10/2013 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

U.S. Patent and Trademark Office

Part of Paper No. 20130310

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L11	4	(x-ray and dental and tomographic$4 and memory and signal and convert$4 and detector).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2013/03/10 13:52
L12	3	378/5 and (x-ray and dental and tomographic$4 and memory and signal and convert$4 and detector)	US-PGPUB; USPAT; UPAD	OR	ON	2013/03/10 13:52
L13	16	378/19 and (x-ray and dental and tomographic$4 and memory and signal and convert$4 and detector)	US-PGPUB; USPAT; UPAD	OR	ON	2013/03/10 13:52
L14	29	378/38 and (x-ray and dental and tomographic$4 and memory and signal and convert$4 and detector)	US-PGPUB; USPAT; UPAD	OR	ON	2013/03/10 13:52

3/ 10/ 2013 1:52:45 PM
C:\ Users\ ikiknadze\ Documents\ EAST\ Workspaces\ 121.wsp

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"13619356"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:42
L2	2	378/5.ccls. and dental same tomographic$4 same memory and signal same convert$4 same detector	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:47
L3	0	378/16.ccls. and dental same tomographic$4 same memory and signal same convert$4 same detector	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:48
L4	3	378/19.ccls. and dental same tomographic$4 same memory and signal same convert$4 same detector	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:48
L5	0	378/21.ccls. and dental same tomographic$4 same memory and signal same convert$4 same detector	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:48
L6	6	378/38.ccls. and dental same tomographic$4 same memory and signal same convert$4 same detector	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:48
L7	3	378/39.ccls. and dental same tomographic$4 same memory and signal same convert$4 same detector	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:48
L8	0	378/62.ccls. and dental same tomographic$4 same memory and signal same convert$4 same detector	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:49
L9	4	(x-ray and dental and tomographic$4 and memory and signal and convert$4 and detector).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/03/10 13:49
L10	3	(x-ray and dental and tomographic$4 and memory and signal and convert$4 and detector).clm.	US-PGPUB	OR	ON	2013/03/10 13:51

3/ 10/ 2013 1:51:55 PM
C:\ Users\ ikiknadze\ Documents\ EAST\ Workspaces\ 121.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13619356	MASSIE, RONALD E.
	Examiner	**Art Unit**
	IRAKLI KIKNADZE	2882

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/13/2012	03/10/2013							
1	1	✓	=							
2	2	✓	=							
3	3	✓	=							
4	4	✓	=							
5	5	✓	=							
6	6	✓	=							
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16	16	✓	=							
17	17	✓	=							
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19	19	✓	=							
20	20	✓	=							
21	21	✓	=							
22	22	✓	=							
23	23	✓	=							
24	24	✓	=							

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

63151 7590 03/18/2013
LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/619,356	09/14/2012	INV001Ronald E. Massie	2932.2	4681

TITLE OF INVENTION: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$885	$0	$0	$885	06/18/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
KIKNADZE, IRAKLI	2882	378-005000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Law Office of Mark Brown,LLC
2 Mark E. Brown
3 Christopher M. DeBacker

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Osseo Imaging, LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Topeka, KS

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 503424 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

☐ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

☐ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature Mark Brown Date 4/16/13

Typed or printed name Mark Brown Registration No. 30361

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Electronic Patent Application Fee Transmittal

Application Number:	13619356
Filing Date:	14-Sep-2012
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Filer:	Mark E. Brown/Laura Brown
Attorney Docket Number:	2932.2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	890	890
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**890**

Electronic Acknowledgement Receipt

EFS ID:	15531788
Application Number:	13619356
International Application Number:	
Confirmation Number:	4681
Title of Invention:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Ronald E. Massie
Customer Number:	63151
Filer:	Mark E. Brown/Laura Brown
Filer Authorized By:	Mark E. Brown
Attorney Docket Number:	2932.2
Receipt Date:	16-APR-2013
Filing Date:	14-SEP-2012
Time Stamp:	15:54:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$890
RAM confirmation Number	2498
Deposit Account	503424
Authorized User	BROWN, LAURA

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2013_04_16_14_31_55.pdf	219535 4492851015 36fdfef3f92e027ab3fbf7ce6713cc	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30368 30ecd3d510c88009316e878b3edd45de2ddad437	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	249903		

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/619,356	09/14/2012	2882	950	2932.2	24	3

CONFIRMATION NO. 4681

63151
LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

CORRECTED FILING RECEIPT

OC000000061874133

Date Mailed: 06/11/2013

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Ronald E. Massie, Lake Ozark, MO;

Applicant(s)

Ronald E. Massie, Lake Ozark, MO;

Power of Attorney: The patent practitioners associated with Customer Number 63151

Domestic Priority data as claimed by applicant

This application is a CON of 13/367,150 02/06/2012
which is a CON of 12/250,423 10/13/2008 PAT 8126112 *
which is a CIP of 11/932,809 10/31/2007 PAT 8073101
which is a CIP of 11/224,472 09/12/2005 PAT 7839970
which is a CON of 10/351,567 01/24/2003 PAT 6944262
which is a CIP of 10/134,153 04/27/2002 ABN
which is a CON of 09/452,348 12/01/1999 PAT 6381301
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

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If Required, Foreign Filing License Granted: 09/28/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/619,356**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Preliminary Class

378

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	13/619,356
Filing Date	September 14, 2012
First Named Inventor	Massie, Ronald E.
Art Unit	2882
Examiner Name	~~Ho, Allen C.~~ /Irakli Kiknadze/

Sheet	2	of	3

Attorney Docket No: 2932.2

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		US-5917883	06/29/1999	Khutoryansky et al.	
		US-5930327	07/27/1999	Lin	
		US-5995583	11/30/1999	Schick et al.	
		US-6038287	03/14/2000	Miles, Dale A.	
		US-6069935	05/30/2000	Schick et al.	
		US-6320931	11/20/2001	Arnold	
		US-6381301	04/30/2002	Massie, Ronald E.	
		US-6385283	05/07/2002	Stein et al.	
		US-6424694	07/23/2002	Molteni	
		US-20020114425	08/22/2002	Lang et al.	
		US-20020178032	11/28/2002	Benn et al.	
		US-6496558	12/17/2002	Graumann	
		US-6664986	02/16/2003	Kopelman et al.	
		US-6690761	02/10/2004	~~Kopelman et al.~~ Lang, et al.	
		US-6821116	11/23/2004	Severance	
		US-6405071	~~09/23/2005~~	Analoui June 11, 2002	
		US-7099428	08/29/2006	Clinthorne, Neal H., et al.	
		US-7203273	04/10/2007	Linnosaari, Matti	

Change(s) applied to document, /L.K.H./ 6/19/2013

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	T[2]
		EP-0180482	05/07/1986	Hirano, Yoshio	
		EP-0314506	05/03/1989	Schuller, Paul D.	
		WO-9311707	06/24/1993	Webber, Richard L.	
		EP-0652433	05/10/1995	Fujii, Masashi	
		WO-0138824	05/31/2001	Stein, Jay A., et al.	
		WO-01/39667	06/07/2001	Massie, Ronald E.	
		CA-2390334	11/18/2008	Massie, Ronald E.	
		EP-1237483	11/26/2008	Massie, Ronald E.	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

EXAMINER /Irakli Kiknadze/ **DATE CONSIDERED** 12/04/2012

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH /IK/

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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/619,356	07/30/2013	8498374	2932.2	4681

63151 7590 07/10/2013

LAW OFFICE OF MARK BROWN, LLC
4700 BELLEVIEW SUITE 210
KANSAS CITY, MO 64112

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Ronald E. Massie, Lake Ozark, MO;

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AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	10/3/2017	for the District of Delaware

PLAINTIFF	DEFENDANT
OSSEO IMAGING, LLC	PLANMECA USA INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	6,381,301	4/30/2002	OSSEO IMAGING, LLC
2	6,944,262	9/13/2005	OSSEO IMAGING, LLC
3	8,498,374	7/30/2013	OSSEO IMAGING, LLC
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**