

01/24/03



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Approved for use through 10/31/2002. OMB 0651-0032

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No. 3097

First Inventor Ronald E. Massie

Title DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Express Mail Label No. EL 946030935 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 26]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 11]
5. ☒ Oath or Declaration [Total Pages 2]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63 (d))
(for continuation/divisional with Box 18 completed)
 - i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☒ Application Data Sheet. See 37 CFR 1.76

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Form (CRF)
 - b. Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
 - c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement of Attorney (when there is an assignee) ☒ Power of Attorney
11. ☐ English Translation Document (if applicable)
12. ☒ Information Disclosure Statement (IDS)/PTO-1449 ☒ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☒ Other: Additional Return Receipt Postcard

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP)

of prior application No. 10/134,153

Prior application information:

Examiner

Group Art Unit: 3732

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

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or ☒ Correspondence address below

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Signature	<i>Mark Brown</i>	Date	January 24, 2003

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FEE TRANSMITTAL

for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	(\$) 375.00
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Complete if Known

Application Number	
Filing Date	1/24/03
First Named Inventor	Ronald E. Massie
Examiner Name	
Art Unit	
Attorney Docket No.	3097

METHOD OF PAYMENT *(check all that apply)*☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:

Deposit Account	03-1425
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Account Number	00 1720
Deposit Account Name	Chase & Yakimo

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☐ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	750	2001	375	Utility filing fee	375.00
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1)	(\$) 375.00
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2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims	Fee from below	Fee Paid
Total Claims	14	-20** = 0	X	
Independent Claims	3	-3** = 0	X	
Multiple Dependent				

Large Entity		Small Entity		<u>Fee Description</u>
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2)	(\$) 0.00
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FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3)	(\$)
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APPLICATION DATA SHEET

Application Information

Application Type:	Regular
Application No.:	
Subject Matter:	Utility
Suggested Classification:	
Suggested Group Art Unit:	3732
CD-ROM or CD-R?	None
Title:	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
Attorney Docket Number	3097
Request for Early Publication:	No
Request for Non-Publication:	No
Suggested Drawing Figure:	
Total Drawing Sheets:	
Small Entity:	Yes
Petition included?	No
Secrecy Order in Parent Appl.?	No

Applicant Information

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Associate	42,720	James J. Kernell
Associate	46,572	Sean T. Bradley

Domestic Priority Information

<u>Application</u>	<u>Continuity Type</u>	<u>Parent Application</u>	<u>Parent Filing Date</u>
10/134,153	C.I.P.	09/452,348	12/01/1999

Assignee Information

Assignee Name:

Assignee mailing address

City of mailing address:

State or Province of mailing address:

Country of mailing address:

Postal or Zip code of mailing address:

**DENTAL AND ORTHOPEDIC DENSITOMETRY
MODELING SYSTEM AND METHOD**

Cross-reference to Related Applications

[0001] This application is a continuation-in-part of Serial No.10/134,153, filed April 27, 2002, which is a continuation of Serial No. 09/452,348, filed December 1, 1999, now U.S. patent No. 6,381,301 B1, in which priority is claimed and which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates generally to dental and orthopedic diagnosis, forensics, identification, biometrics 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 within the enamel surface, often go undetected with conventional equipment. When such caries are finally found, considerable

(Docket 3121)

damage to tooth structure may have already occurred. Subsurface, incipient caries are located entirely within the enamel layer of the teeth. They 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. The dental structure that has been weakened by various causes, such as decalcification, is particularly susceptible to fractures. Fractures can assume various configurations, including "craze", vertical, oblique and horizontal 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 as well as the osseous tissue around the apex of the root. Early detection of apical abscesses can lead to appropriate, early-stage treatment, thus avoiding advanced disease processes with resultant pain, swelling, and other serious health consequences and complications.

[0008] 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 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. Pat. No. 5,533,080; U.S. Pat. No. 5,838,765; and U.S. Pat. No. Re. 36,162, which are incorporated herein by reference. Medical applications of densitometry include the diagnosis and treatment of such bone diseases as osteoporosis.

[0010] 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 a and in a different 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. Applications of the system and methodology include diagnosis, treatment, identification, forensics and biometrics.

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 and other equipment as described; 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; providing such a system and method which have applications in dental and medical diagnosis, treatment, identification, forensics and biometrics; and providing such a system and method which are 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.

[0018] Fig. 3 is a block diagram of a dental or orthopedic densitometry modeling system comprising a first modified embodiment of the present invention.

[0019] Fig. 4a is diagram of an application with an external electron beam source and an external sensor/receptor.

[0020] Fig. 4b is a diagram of an application with an external electron beam source and an internal sensor/receptor.

[0021] Fig. 4c is a diagram of an application with an internal electron beam source and an external sensor/receptor.

[0022] Fig. 4d is a diagram of an application with an internal electron beam source and an internal sensor/receptor.

[0023] Fig. 5 is a diagram of a tooth structure, showing the locations of particular areas that are suited for densitometry monitoring with the system and method of the present invention.

[0024] Figs. 6a,b show a flowchart of a patient-specific densitometry modeling method according to the present invention.

[0025] Fig. 7 is a flowchart of a general population baseline database densitometry modeling method according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. Introduction and Environment

[0026] 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

[0027] 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 programmable 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.

[0028] 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.

[0029] 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. Pat. No. 5,533,080; U.S. Pat. No. 5,838,765; and U.S. Pat. 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.

[0030] 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

[0031] 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.

[0032] 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.

[0033] 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. Pat. U.S. Pat. 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.

[0034] 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.

IV. Modified Embodiment Densitometry Modeling Systems 102

[0035] A densitometry modeling system 102 comprising a first modified embodiment of present invention is shown in Fig. 3 and generally includes a computer 104 with an input 104a and an output 104b. Input and output devices 106 and 108 are connected to the computer input and output 104a,b respectively.

[0036] The computer 102 includes a memory 110, such as a hard drive, a tape drive, an integrated circuit (e.g., RAM) or some other suitable digital memory component, which can be either internal or external to the computer 102. Imaging software 112 is provided for converting the digital data into images, which are adapted for visual inspection by displaying same on a monitor 114 or by printing same on a printer 116 of the output device 108. Such images can also be transmitted by a suitable transmission device 117, such as a fax or modem. The computer 104 also includes comparison software 118, which is adapted for digitally comparing baseline and patient-specific dental and orthopedic densitometry models.

[0037] The input device 106 includes an electron beam source 120 and a sensor/receptor 122, which are adapted for positioning with at least a portion of the patient 124 therebetween. A wide variety of source and sensor/receptor combinations are included in the scope of the present invention. Preferably the electron beam source 120 emits a collimated electron beam adapted for scanning the patient's dental/orthopedic structure. Such devices can be located internal or external to the patient and include "wands" and "pens". Micro devices are also available that are adapted for mounting on the end of a stylus apparatus. Both hard-wired and wireless (RF) types of source devices can be employed. External devices include electron beam heads mounted on articulated arm assemblies, which are commonly found in dental operatories and other medical workstations. Various hand-held, fixed-position and enclosure-type devices can also provide the electron beam emissions. Control of electron beam source 120 can be automated with the computer 104, or manual in the case of hand-held devices.

[0038] The sensor/receptor 122 can likewise be positioned internal or external to the patient. For example, various types of intraoral sensors are available. Phosphorus film sensors are used like X-ray film and are converted and "read" by the computer to transfer the digital data recorded thereon. Other types include charge coupled devices (CCD) and charged metal oxide semiconductor (CMOS) devices, which output digital data from respective circuits associated therewith. Micro printed circuits can be installed on such sensors and provide digital sensor output to the computer input 104a.

[0039] Still further, either or both of the beam source 120 and the sensor/receptor 122 can be preprogrammed for computer-controlled movement with respect to the patient 124. Thus, panoramic or tomographic images can be obtained with the patient immobilized. Such equipment is commercial available and typically moves through an arc of

approximately 120 degrees for dental applications. The specific electron beam source 120 and sensor/receptor 122 components can be chosen as necessary for the type of model desired. For example, periapical, bite wing, full mouth, panoramic and cephalometric imaging are all widely used in dentistry, oral surgery and related fields. Still further, the system contemplates removable use on and inspection of individual tooth anatomy by use of a wand, pen or similar device adapted for placement intraorally by the dentist. Thus, the densitometry changes with respect to particular "watch" areas can be closely monitored.

[0040] Yet another type of electron beam source 120 comprises a miniaturized, hand-held CRT adapted for localized applications. For example, areas deemed susceptible to incipient caries and decay can be diagnosed and identified as "watch" areas, which the dental practitioner would specifically examine with such a miniaturized CRT source device during the course of follow-up office visits and procedures. Thus, patients would be exposed to only minimal levels of radiation in connection with such highly localized and tooth-specific densitometry models. An advantage of the system 102 is that models can be processed and compared nearly instantaneously. Thus, in a single appointment the dentist can obtain, compare and analyze multiple, limited-scope densitometry models specifically directed to areas of concern.

[0041] Figs. 4a-d show alternative configurations and placements of the electron beam sources 120 and the sensor/receptors 122 with respect to the mandible 126 and teeth 128 of the patient 124. Fig. 4a shows a beam source 120a and a sensor/receptor 122a both placed externally whereby the electron beam passes through the patient 124. Such configurations can be preprogrammed to travel through predetermined arcs or orbits around the patient 124 in order to compile a panoramic, whole mouth or cephalometric image. Fig. 4b shows an external beam source 120b and an internal sensor/receptor 122b. Fig. 4c shows

an internal beam source 120c and an external sensor/receptor 122c. Fig. 4d shows both the beam source 120d and the sensor/receptor 122d positioned intraorally.

V. Modified Densitometry Modeling Methods and Applications

[0042] Without limitation on the generality of useful dental and orthopedic applications of the modeling methods and applications for the present invention, several dental applications are described in detail. Fig. 5 shows a tooth 128 with a crown 128a and a root 128b. The crown 128a includes enamel 128c covering dentin 128d. The root 128b is embedded within a periodontal membrane 128e and includes a root canal 128f through which a neurovascular bundle 128g comprising a nerve, artery and vein passes. The root canal 128f is filled with pulp 128h and surrounded by cementum 128k. The root 128b is embedded in the bone structure of the mandible or the maxilla 126, over which the gingiva and the gingival fibers 128i are located. The cemento-enamel junction (CEJ) is located where the crown 128a meets the root 128b and is the common reference point for periodontal disease. Locations on the crown 128a between the adjacent teeth 130 are common locations for caries because bacteria tend to congregate in such locations unless dislodged by brushing and flossing. Another common problem area is located at the root apex 128j, where abscesses form.

[0043] Figs. 6a-b show a flowchart of the densitometry modeling method with respect to an individual patient. The steps of the flowchart generally correspond to routines, which can be performed either manually or with the computer 104. After starting and initializing the software, a population database/baseline is loaded. The population database/baseline can include densitometry data pertaining to the general population, or population subsets grouped by such variables as age, gender, geographic area, etc. A

predictive patient model is created from both population database information and patient-specific information, as discussed in more detail below. Examples of typical information used for creating dental models are shown, and include periapical, bite wing, whole mouth, panoramic and cephalometric densitometry data captures. Other types of data would be captured and used for creating patient models for other applications, such as orthopedic. Internal/external source/receptor selections (see Figs.4a-d) are made at the appropriate decision steps.

[0044] An initial patient model is created, and can be compared to a corresponding baseline model for "normal" dental/orthopedic densitometries in individuals of corresponding age, gender and other variables. The initial model can be designated A.1. If indicated, treatment can be performed.

[0045] In a follow-up session, a second model A.X can be built. The variable "X" can correspond to, for example, the version number or a time period, such as the number of days since the first model A.1 was created. The software can perform a comparison between the two patient-specific models A.1 and A.X. Densitometry changes can be noted and brought to the attention of the dentist or physician. For example, areas showing significant decreases in densitometry would alert the dentist to the possibility of incipient caries. Depending on the extent of change and compromised density, preemptive treatment might be indicated, or the area can be designated for careful future monitoring for further deterioration or change. Because certain changes are normal, the baseline, plus the patient's dental/medical history, can be utilized in distinguishing conditions requiring treatment from normal decalcification/calcification.

[0046] Implant osseointegration can also be monitored with the system and methodology of the present invention. For example, the densitometry techniques described

herein can monitor the progress of a bone-implant interface, indicating successful osseointegration, whereas the continued or increased presence of soft tissue granulation would indicate a failed implant.

[0047] Other conditions that are particularly well-suited for monitoring with the system and method of the present invention include fractures, decay, abscesses, plaque and periodontal disease. Still further, 3D imaging can be provided with the system and method whereby fractures and other lesions, which are difficult to detect in 2D imaging, can be made apparent.

[0048] Fig. 7 shows a flowchart for creating a baseline database, utilizing same in a dental or medical practice, and building individual patient densitometry models. As shown, the process is interactive with individual patient data being utilized in building the practice database, which in turn can be contributed to the general population baseline database. Thus, greater accuracy can be achieved in the baseline database over a period of time with contributed data from individual patients and practices. Still further, the individual patient model can be updated with each visit, and monitored against projected patient densities, as derived from the baseline.

[0049] Environmental factors, such as fluoridated, municipal or well water and geographic regional considerations can be applied as shown. Likewise, patient factors can influence the densitometry models. These include general dental health, dental hygiene (such as frequent and thorough brushing and flossing), systemic influences, oncology, xerostomia (dry mouth), transplant patients on anti-rejection medication, susceptibility to infection and decay, etc.

[0050] Additional embodiments and aspects of the method of the present invention include a number of additional applications of densitometry modeling, such as

forensics, biometrics and individual identification. For example, individual identification from dental and medical records can be expedited by the digital data capture, processing, comparison and display techniques and procedures disclosed herein and adapted for use with densitometry models. In addition to the medical and dental applications, such procedures and the resulting models have applications in such fields as forensics, security (e.g., biometric identification techniques) and law enforcement.

[0051] Is to be understood that while certain aspects and embodiments of the invention are described and shown, the invention is not limited thereto and can assume a wide range of other, alternative aspects and embodiments.

CLAIMS

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

1. A digital modeling system for creating dental or orthopedic models of patients, which system comprises:
 - a computer including a digital memory adapted for storing patient densitometry information, an input and an output;
 - a dental or orthopedic input device including an energy source and an energy sensor;
 - said source and said sensor being adapted for placement with at least a portion of the patient's dental or orthopedic structure therebetween;
 - said sensor being adapted for transferring signals to the computer input;
 - said signals representing densitometry of the patient's dental or orthopedic structure;
 - said computer being adapted for creating, storing and comparing digital densitometry models of patient dental or orthopedic structure; and
 - an output device connected to said computer output and adapted for communicating densitometry model comparison information.

2. The system according to claim 1 wherein said source is external.

3. The system according to claim 1 wherein said source is intraoral.

4. The system according to claim 1 wherein said sensor is external.

5. The system according to claim 1 wherein said sensor is intraoral.

6. The system according to claim 1, which includes:

said energy being collimated;

imaging software associated with said computer; and

a display associated with said output device and adapted for displaying densitometry
model information.

7. A dental or orthopedic diagnostic system, which includes:
a patient-specific database of dental or orthopedic densitometry data corresponding to
respective patients; and
time-lapse, automated digital comparisons of said patient-specific database, said
comparisons identifying dental or orthopedic densitometry changes in the dental
or orthopedic structures of individual patients.
8. The system according to claim 7, which includes:
a baseline database of patient dental or orthopedic densitometry data including
variables for age and gender; and
automated digital comparisons of said patient-specific data with said baseline data.
9. The system according to claim 7 wherein 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.
10. The system according to claim 7, which includes a predictive patient
model.
11. The system according claim 7, which includes localized, tooth-specific
densitometry model information.

12. The system according to claim 7, which includes:
a baseline database of patient dental or orthopedic densitometry data including
variables for age and gender; and
automated digital comparisons of said patient-specific data with said baseline data.

13. A dental or orthopedic densitometry modeling method, which comprises the steps of:

building an initial patient-specific densitometry model;

obtaining current densitometry data on said patient; and

updating said patient-specific densitometry model.

14. The method according to claim 13, which includes 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.

15. The method according to claim 13, which includes the additional step of:

updating said database with information obtained from a patient-specific densitometry model.

16. The method according to claim 13, which includes 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:
periapical, bite wing, whole mouth, panoramic or cephalometric.

17. The method according to claim 13, which includes the additional steps
of:

providing a hand-held energy or field 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.

18. The method according to claim 17 wherein said source is a hand-held
CRT.

19. The method according to claim 18, which includes the additional step of:

identifying a localized dental or orthopedic structure area as a watch area based on densitometry model changes 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.

20. The method according to claim 13, which includes 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.

ABSTRACT OF THE DISCLOSURE

A dental or orthopedic densitometry modeling system includes a computer with a digital memory adapted for storing patient densitometry information, an input and an output. A dental or orthopedic input device includes energy source and an energy sensor, both of which can be either external or intraoral to the patient. The sensor transfers densitometry signals to the computer, which creates, stores and compares digital densitometry models. A densitometry modeling method includes the steps of creating a densitometry database consisting of dental or orthopedic information and obtaining current dental or orthopedic densitometry information from a patient. The current information is compared to the database, which can include the patient's previous densitometry models, and an updated patient densitometry model is created.

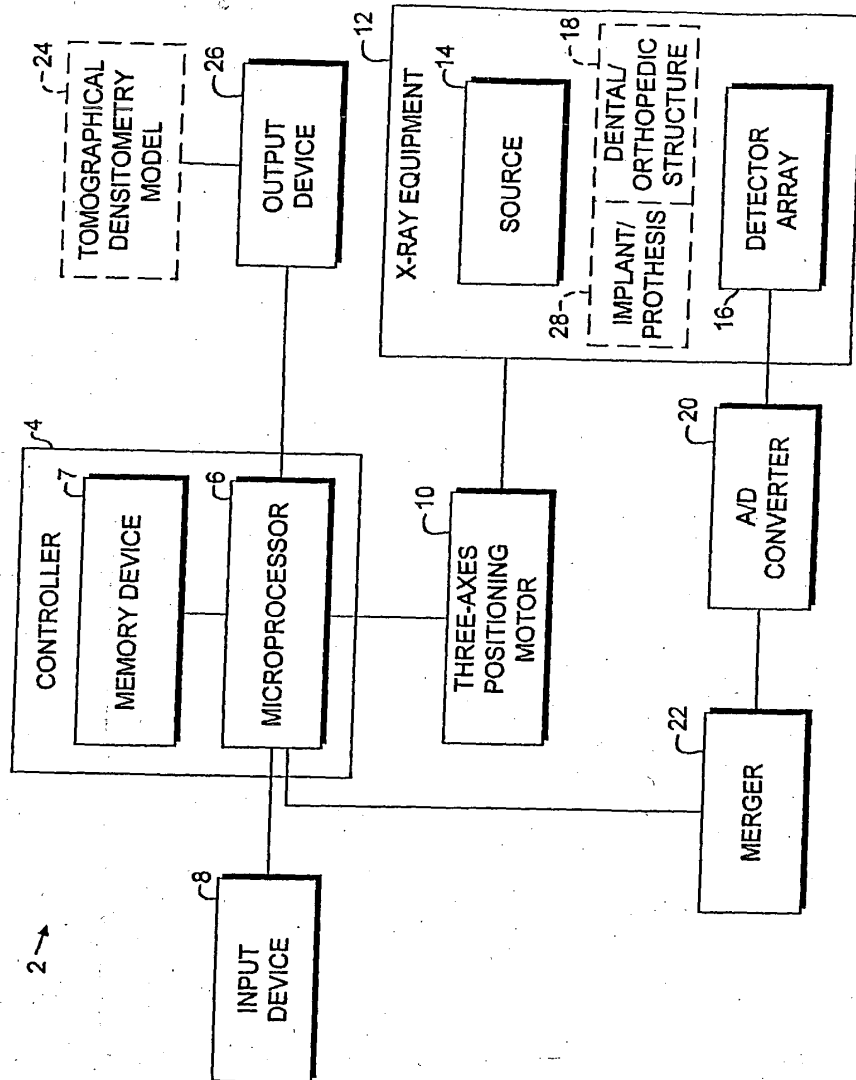


Fig. 1

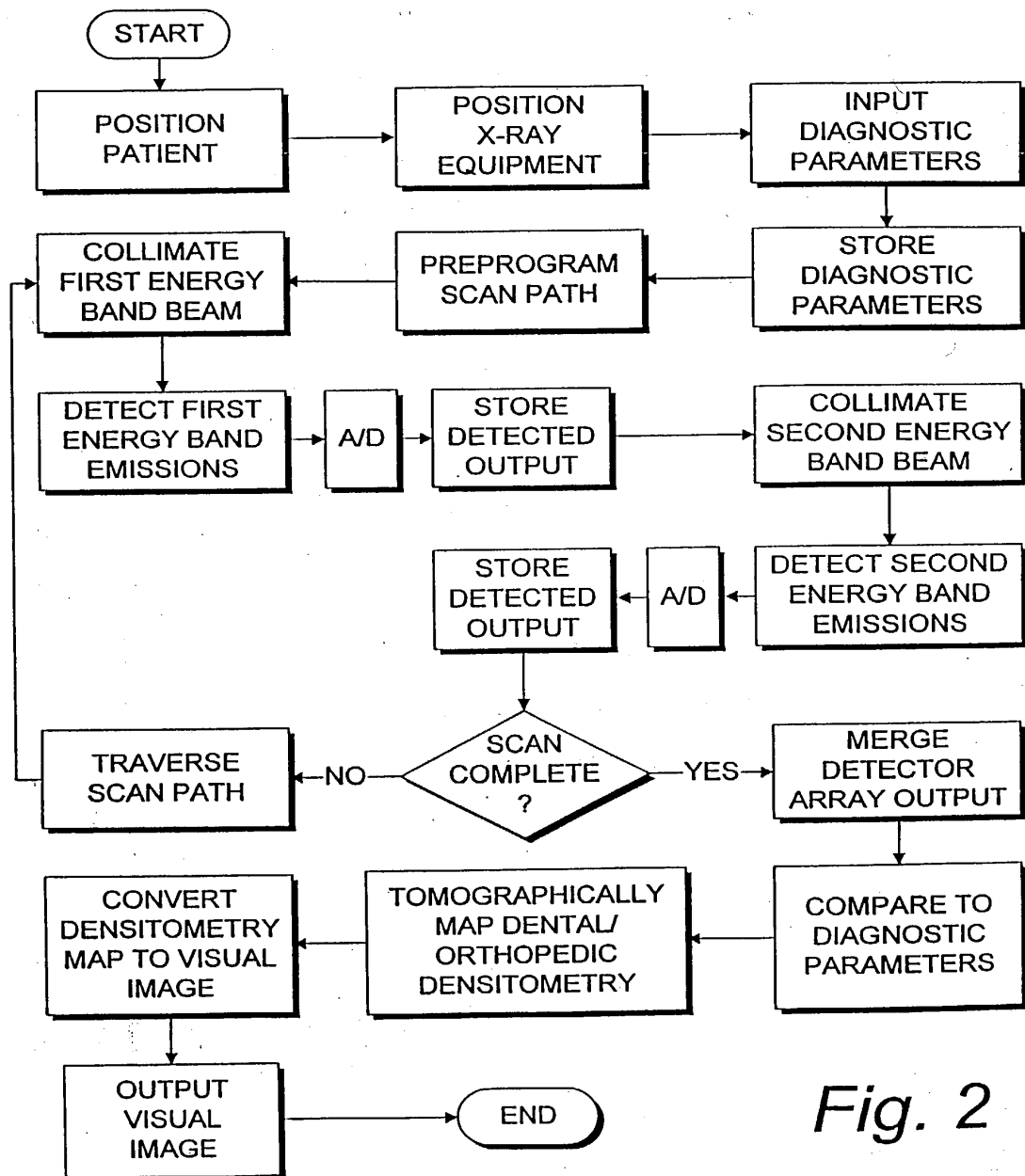


Fig. 2

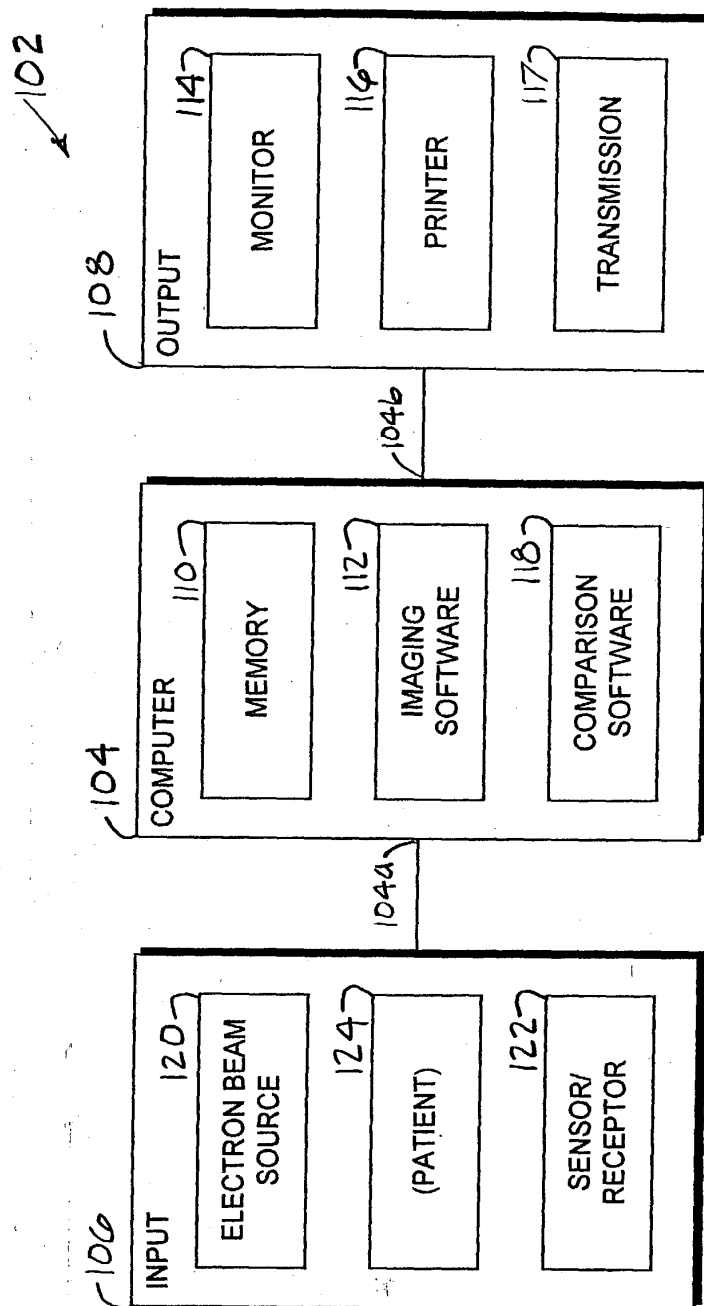


FIG. 3

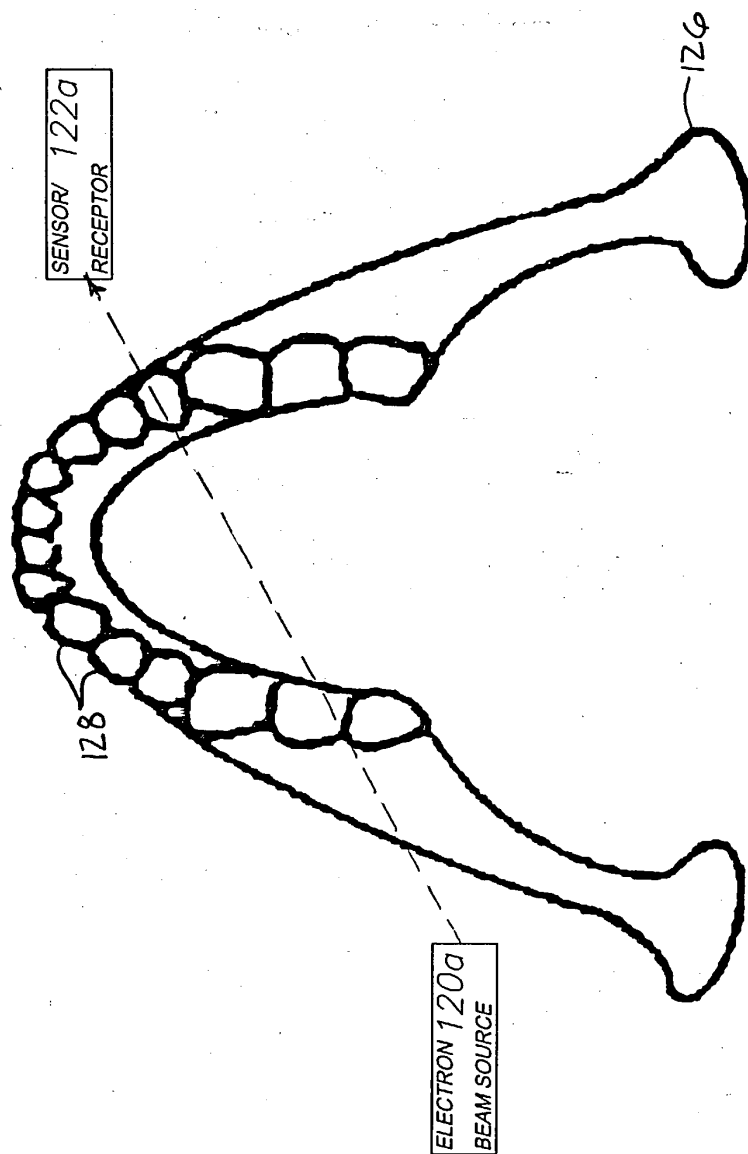


FIG. 4a

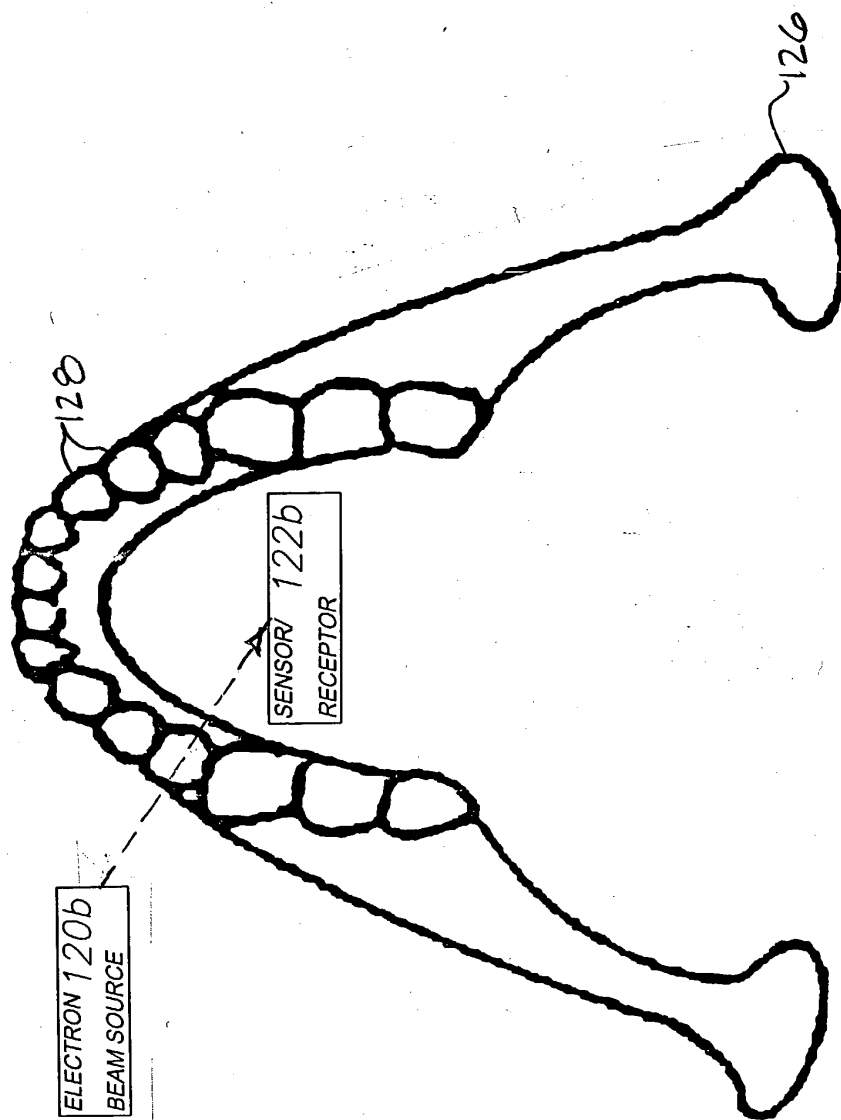


FIG. 4b

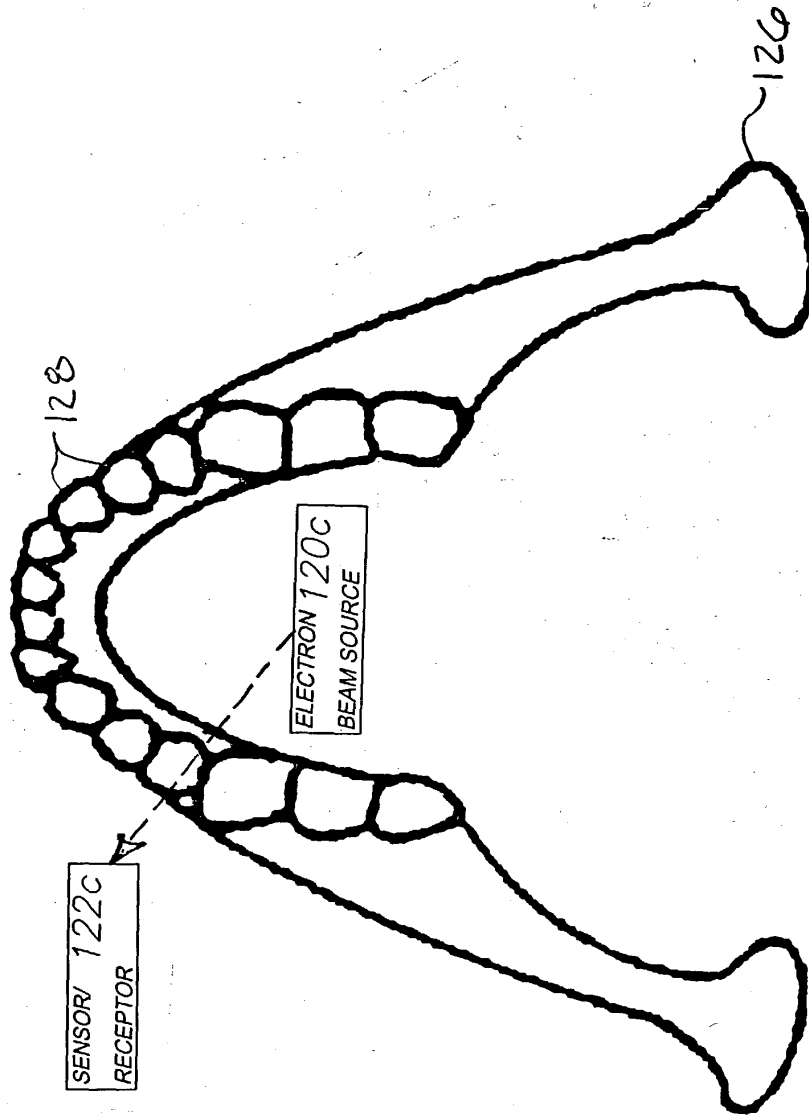


FIG. 4c

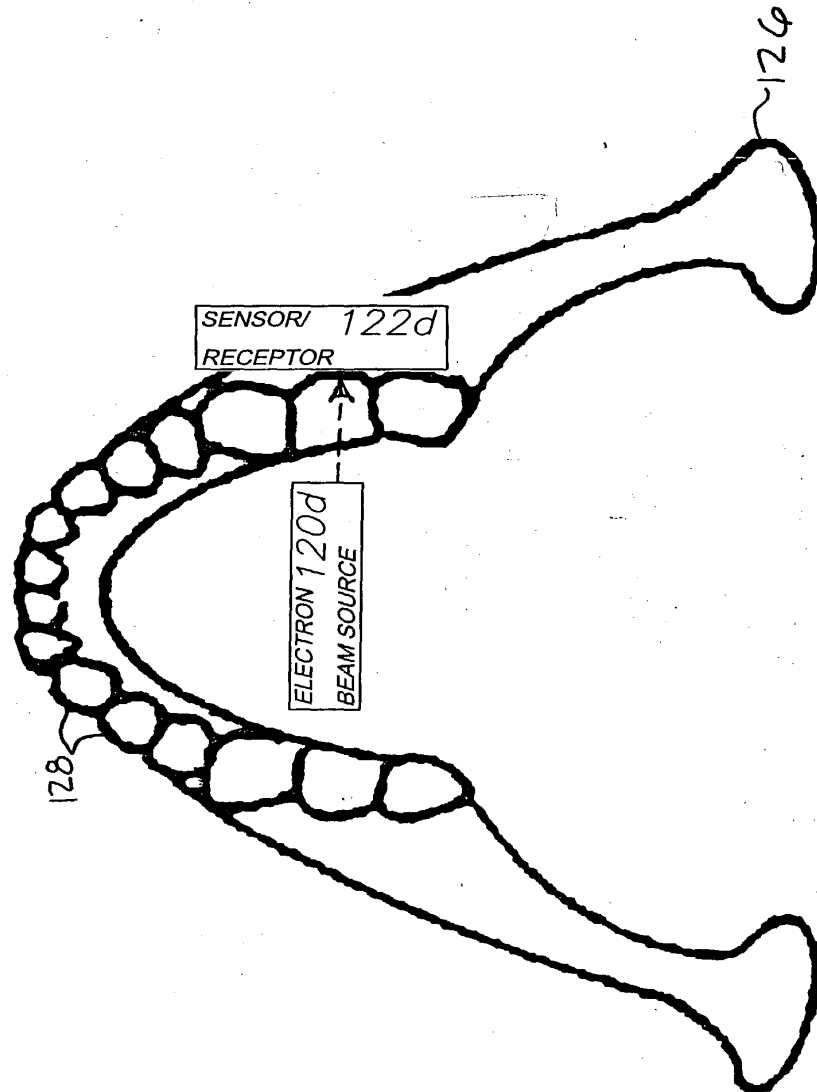


Fig. 4d

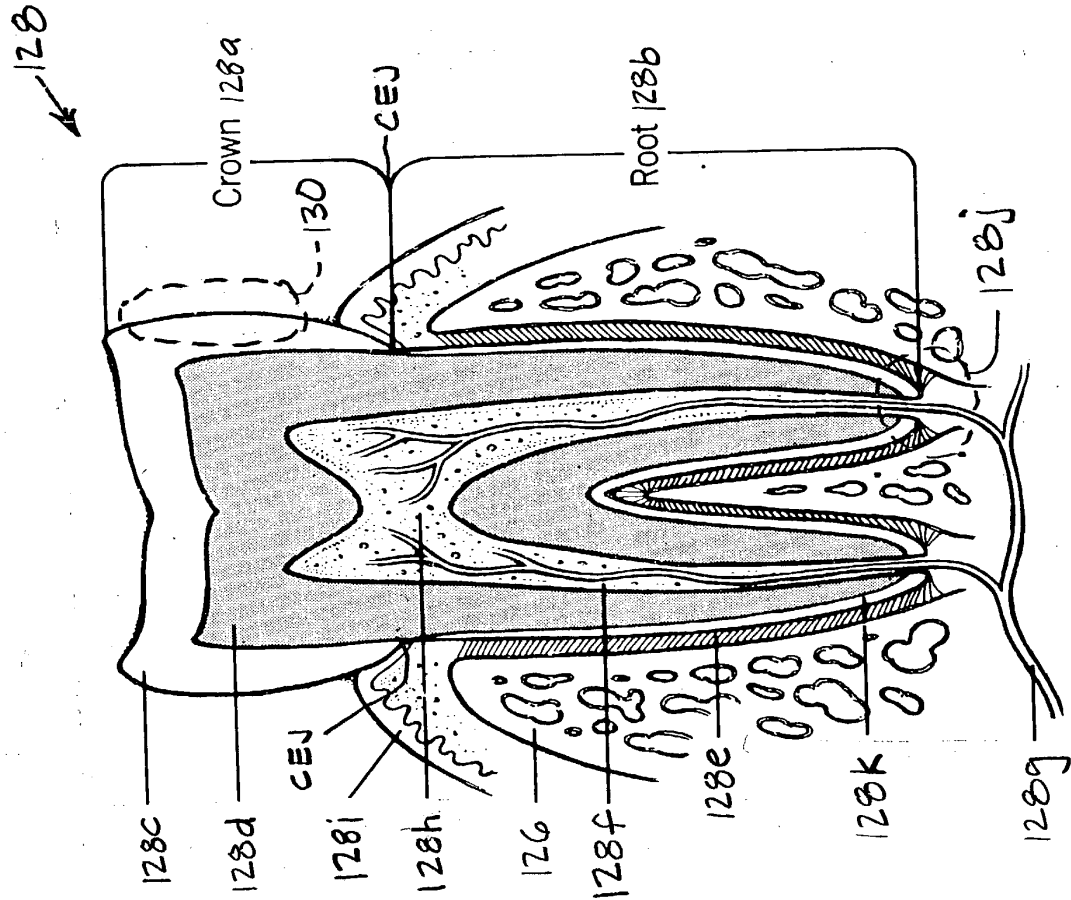


FIG. 5

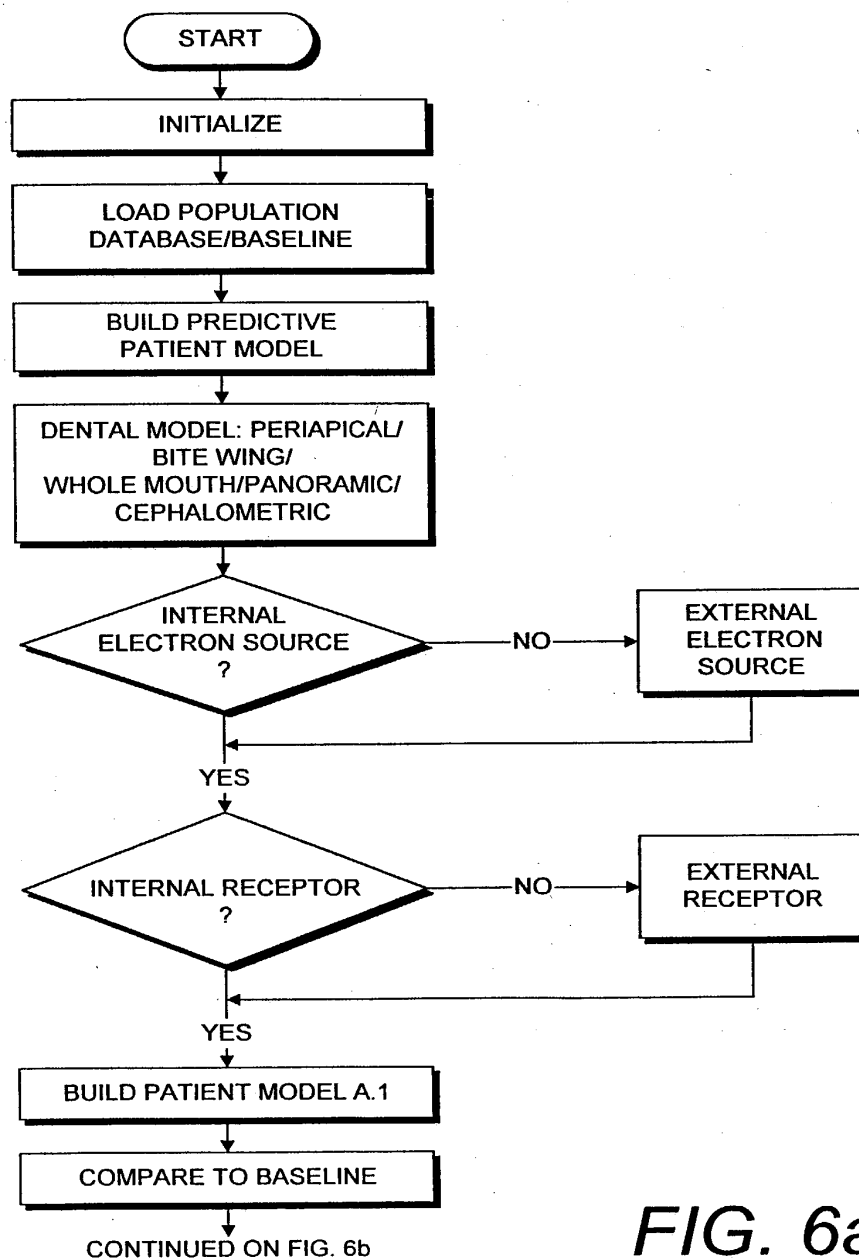
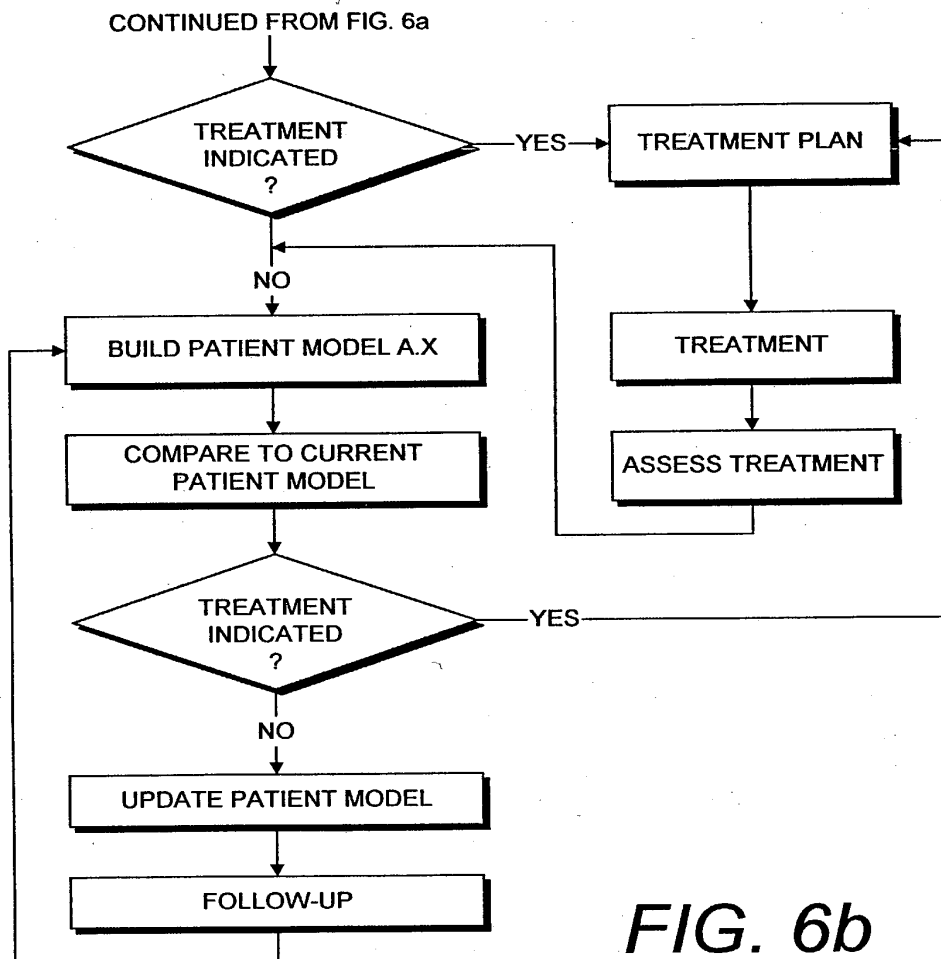


FIG. 6a



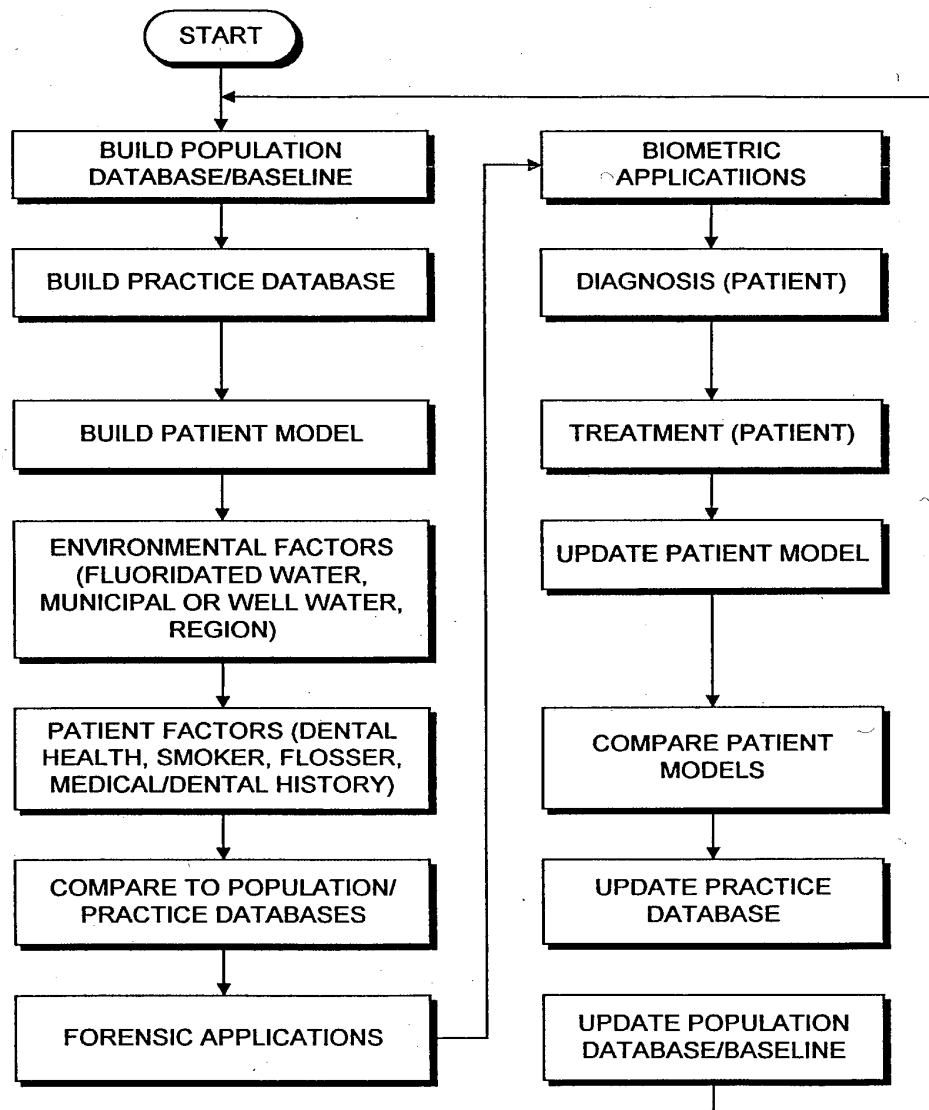


FIG. 7

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**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD
---------------------------	---

As the below named inventor(s), I/we declare that:

This declaration is directed to:

- ☒ The attached application, or
☐ Application No. _____, filed on _____,
☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be 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.

All statements made herein of my/own knowledge are true, all statements made herein 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 are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR(S)

Inventor one: Ronald E. Massie

Signature: Ronald E. Massie Citizen of: USA

Inventor two: _____

Signature: _____ Citizen of: _____

Inventor three: _____

Signature: _____ Citizen of: _____

Inventor four: _____

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☐ Additional inventors are being named on _____ additional form(s) attached hereto.

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Application Number

Filing Date

First Named Inventor

Ronald E Massie

Title

DENTAL & ORTHOPEDIC DENSITOMETRY
MODELING SYSTEM & METHOD

Group Art Unit

Examiner Name

Attorney Docket Number 3097

I hereby appoint:

☐ Practitioners at Customer Number

OR

☒ Practitioner(s) named below:

Name	Registration Number
D.A.N. Chase	20,682
Michael Yakimo, Jr.	28,549
Ginnie C. Derusseau	35,855
James J. Kernell	42,720
Sean T. Bradley	46,572
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I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name

Ronald E. Massie

Signature

Ronald E. Massie

Date

1/24/03

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.

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PATENT APPLICATION FEE DETERMINATION RECORD

Effective January 1, 2003

Application or Docket Number

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	20	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	20 minus 20 =	* 0
INDEPENDENT CLAIMS	1 minus 3 =	* 0
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE		RATE	FEE
BASIC FEE	\$375	OR	BASIC FEE	\$750
X\$ 9=		OR	X\$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL	375	OR	TOTAL	

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐		

SMALL ENTITY OR OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 9=		OR	X\$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
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	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐		

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X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐		

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X\$ 9=		OR	X\$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. 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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FEE RECORD SHEET

PTO-1556
(5/87)

*U.S. Government Printing Office: 2001 — 481-697/59173

CLAIMS ONLY							SERIAL NO.	FILING DATE			
							APPLICANT(S)				
CLAIMS											
	AS FILED		AFTER 1ST AMENDMENT		AFTER 2ND AMENDMENT						
	IND	DEP	IND	DEP	IND	DEP		IND	DEP	IND	DEP
1							51				
2							52				
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TOTAL IND							TOTAL IND				
TOTAL DEP							TOTAL DEP				
TOTAL CLAIMS							TOTAL CLAIMS				

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Complete if Known

Application Number	
Filing Date	
First Named Inventor	Ronald E. Massie
Group Art Unit	
Examiner Name	
Attorney Docket Number	3097

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		3,949,229		Albert	04/06/1976	
		4,188,537		Franke	02/12/1980	
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		5,793,837		Mezhinsky et al.	08/11/1998	
		5,828,720		Syrjanen	10/27/1998	
		5,828,721		Schulze-Ganzlin et al.	10/27/1998	

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Date
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				First Named Inventor	Ronald E. Massie
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	3097
Sheet	2	of	2		

[illegible][illegible]

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PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031
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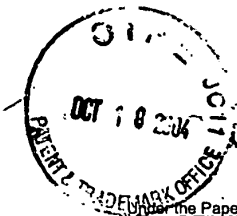
TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/351,567
	Filing Date	01/24/2003
	First Named Inventor	Ronald E. Massie
	Art Unit	2882
	Examiner Name	
Total Number of Pages in This Submission	Attorney Docket Number	3097

ENCLOSURES (Check all that apply)		
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		Application Number	10/351,567
		Filing Date	01/24/2003
		First Named Inventor	Ronald E. Massie
		Art Unit	2882
		Examiner Name	
Sheet 1 of 1	Attorney Docket Number	3097	

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 4,813,060	03-14-1989	Heubeck et al.	
		US- 5,306,306	04-26-1994	Bisek et al.	
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		US- 6,381,301	04-30-2002	Massie	
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		EP88310182.6	05-01-1989	Governors of Univ of Alberta		
		EP1237483	09-11-2002	Massie		

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DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

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Inventor: MASSIE RONALD E (US)

Applicant: MASSIE RONALD E (US)

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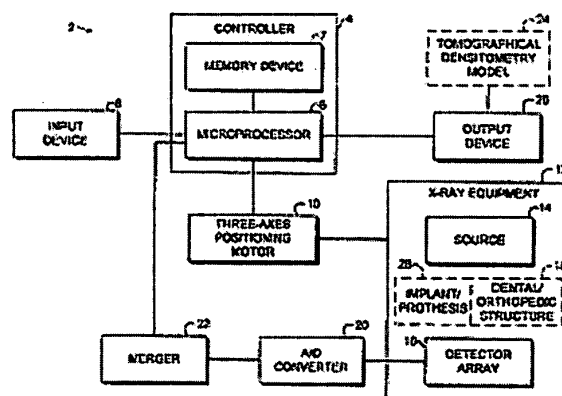
Cited documents:

EP0314506
US5335260

Abstract not available for EP1237483

Abstract of correspondent: **US6381301**

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, which may include a pre-existing densitometry model. 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.



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DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Description of correspondent: **US6381301**

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to dental and orthopedic diagnosis and treatment, and in particular to a densitometry modeling system and method.

[0004] 2. Description of the Related Art

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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 craze 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.

[0009] 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.

[0010] 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 and are incorporated herein by reference.

[0011] 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, which are incorporated herein by reference. Medical applications of densitometry include the diagnosis and treatment of such bone diseases as osteoporosis.

[0012] 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.

[0013] 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.

[0014] 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

[0015] 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

[0016] 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.

[0017] 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.

[0018] 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

[0019] FIG. 1 is a schematic, block diagram of a dental and orthopedic densitometry modeling system embodying the present invention.

[0020] 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

[0021] 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

[0022] 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 programmable 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.

[0023] 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.

[0024] 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. Pat. No. 5,533,080; U.S. Pat. No. 5,838,765; and U.S. Pat. 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.

[0025] 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

[0026] 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.

[0027] 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.

[0028] 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. Pat. U.S. Pat. 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.

[0029] 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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DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

Claims of correspondent: **US6381301**

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

[0030] 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, said controller including means for storing a pre-existing tomographical dental/orthopedic densitometry model; b) an input device connected to the microprocessor; c) a positioning motor connected to the microprocessor and movable in response to 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.

[0031] 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.

[0032] 3. The system according to claim 1 wherein said conversion means comprises an analog-to-digital convertor connected to said detector array.

[0033] 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.

[0034] 5. The system according to claim 1 wherein said X-ray equipment comprises a dual energy level, restricted beam device.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] 9. The system according to claim 1 wherein said controller includes means for comparing said pre-existing tomographical densitometry model to a current tomographical densitometry model.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] 14. The method according to claim 10 which includes the additional step of detecting incipient caries with said tomographical densitometry model.

[0044] 15. The method according to claim 10 which includes the additional step of detecting dental fractures with said tomographical densitometry model.

[0045] 16. The method according to claim 10 which includes the additional step of detecting apical abscesses with said tomographical densitometry model.

[0046] 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.

[0047] 18. The method according to claim 10 which includes the additional step of comparing said patient's current densitometry model to pre-existing densitometry model.

[0048] 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.

[0049] 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.

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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.

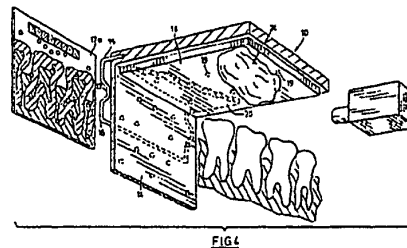


FIG. 1

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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

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 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 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 repeatedly 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 flow-charts 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

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 meat 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

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 hardware 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, or 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

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

5 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".

45 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

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 constrained 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 $N \times N$ 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

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.

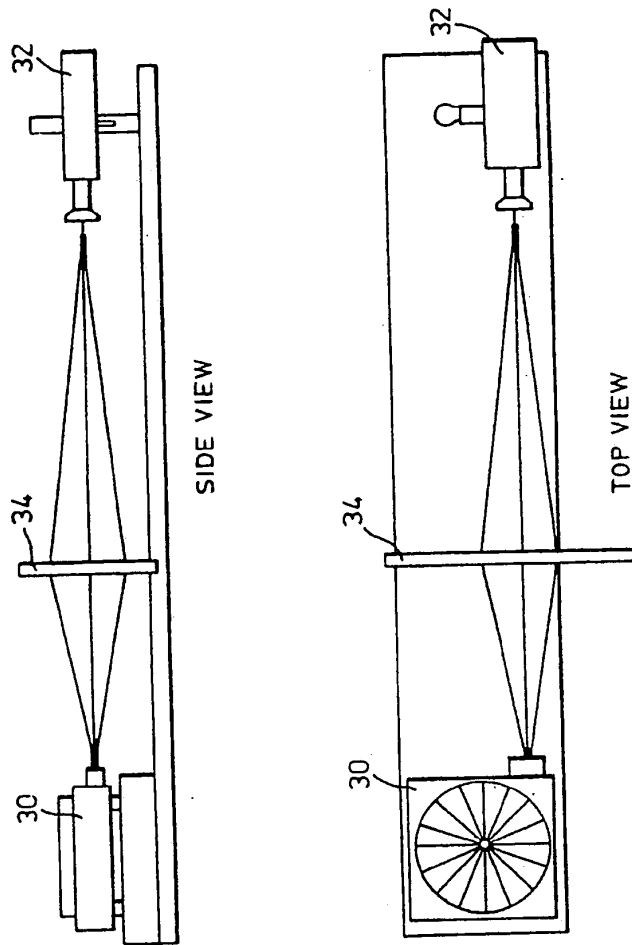


FIG.1

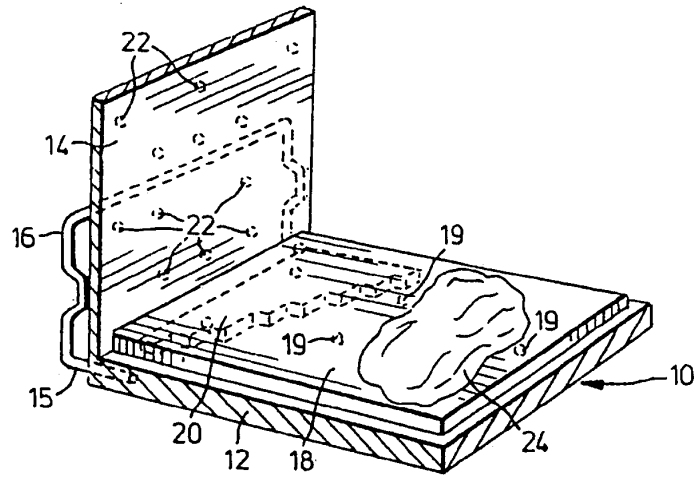


FIG. 2

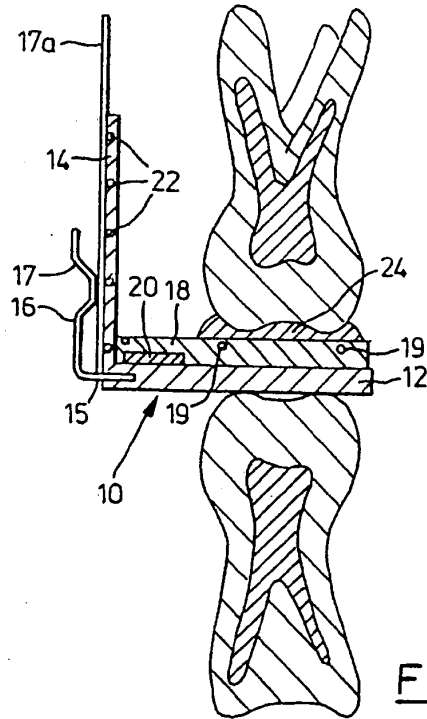


FIG. 3

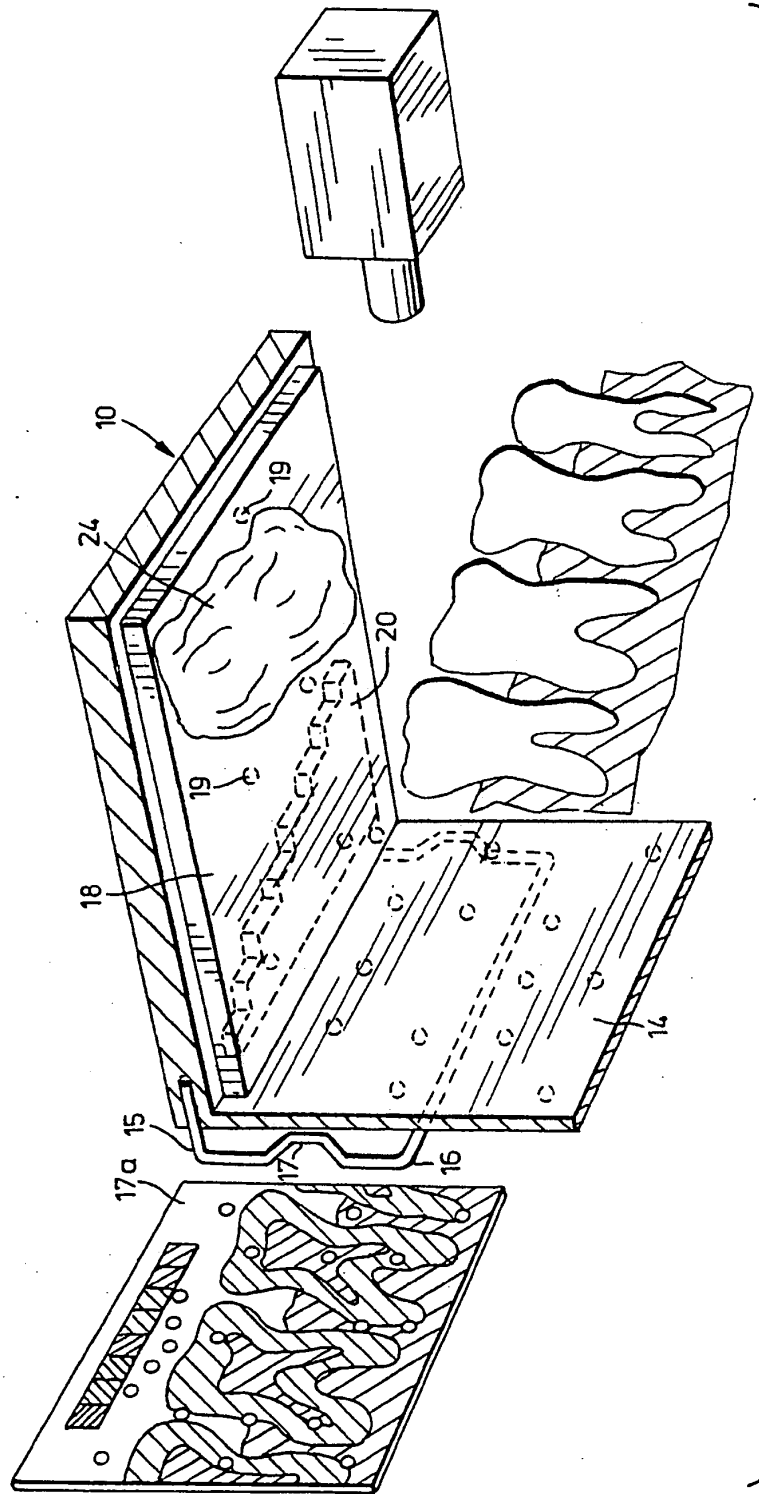


FIG. 4

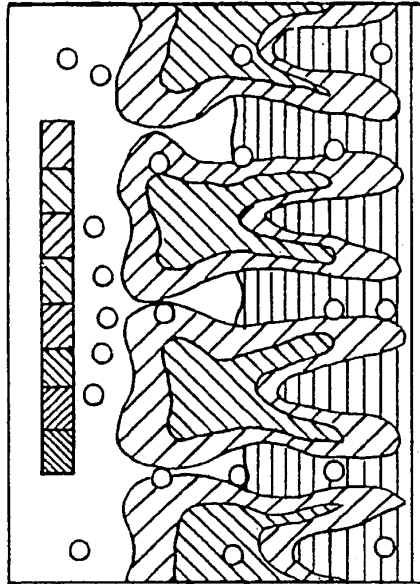


FIG. 5(a) IMAGE 1

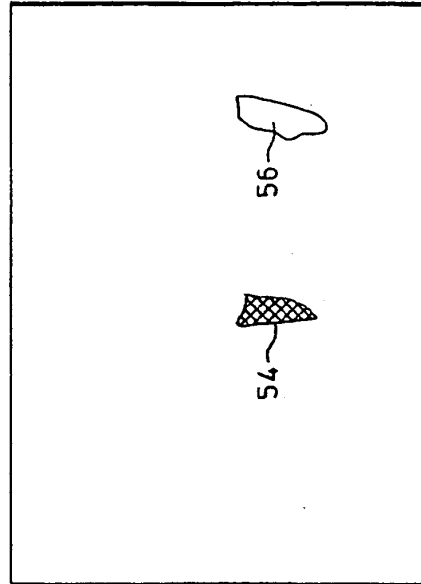


FIG. 5(c) IMAGE 3

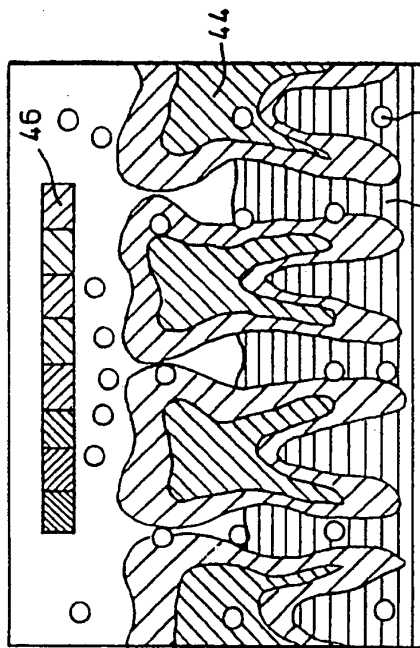


FIG. 5

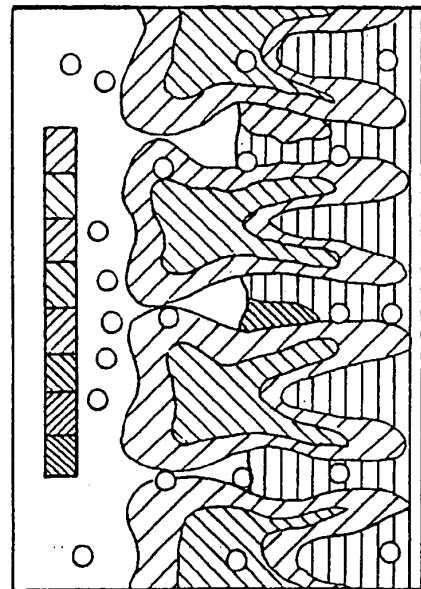
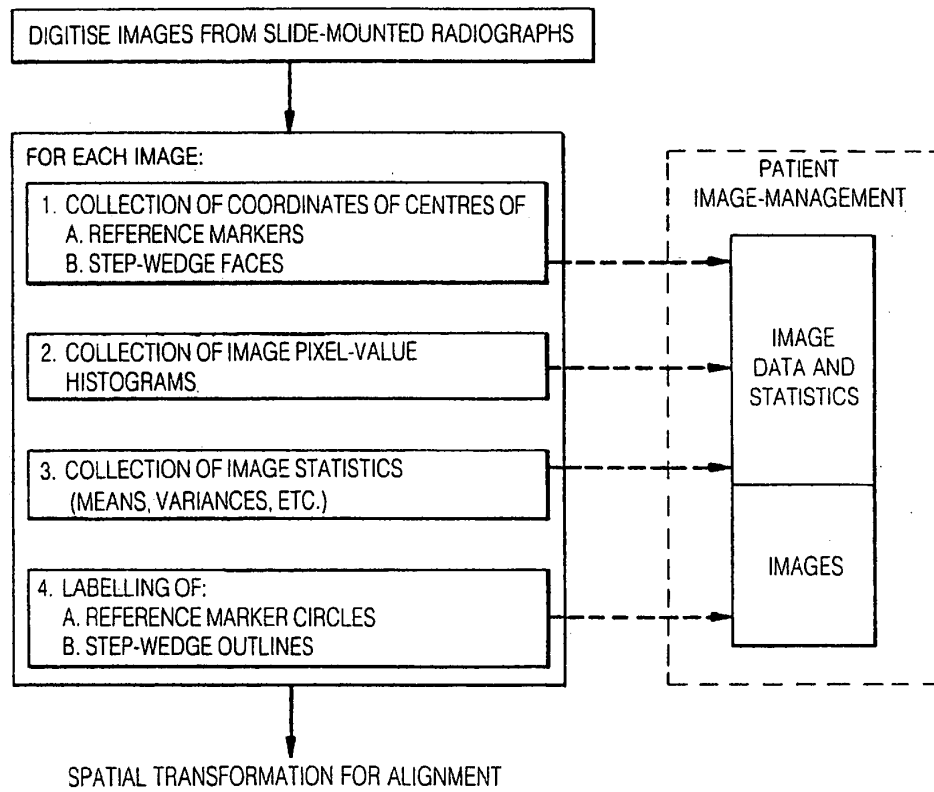
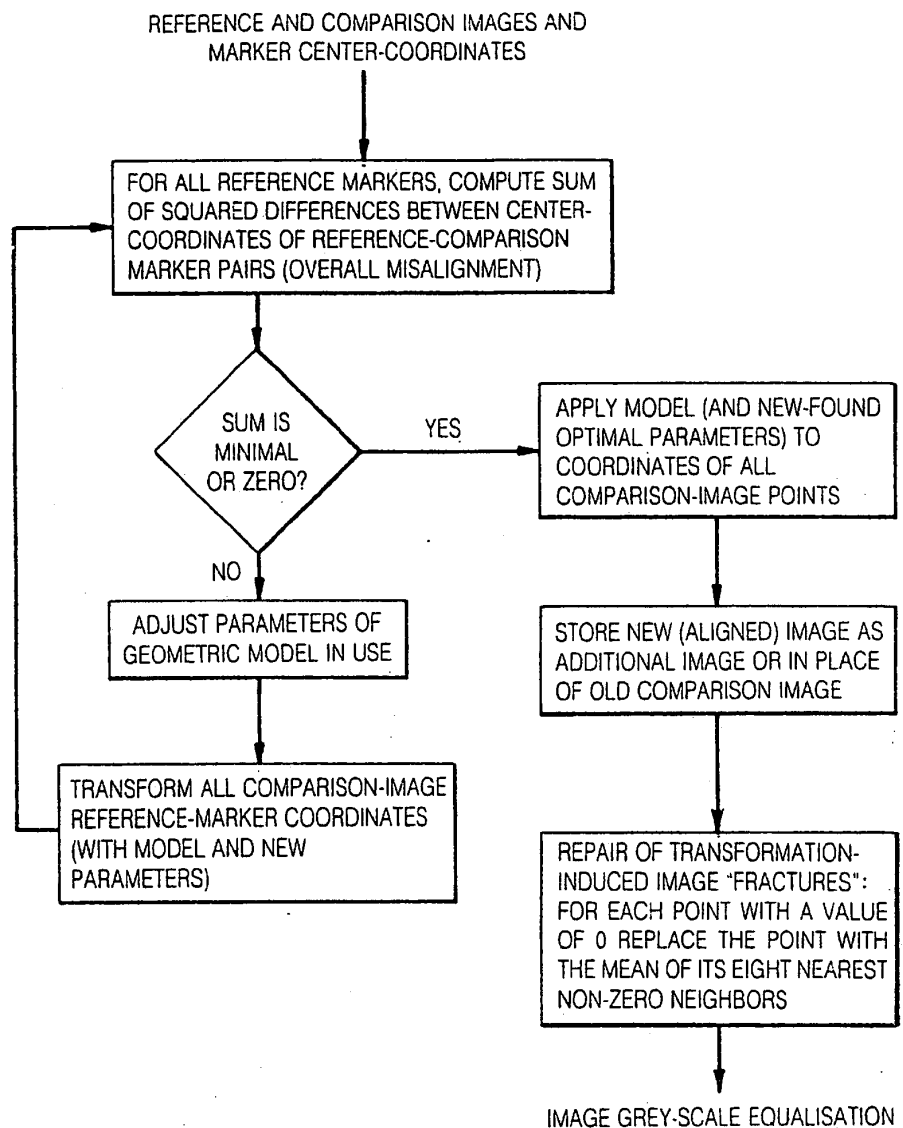


FIG. 5(b) IMAGE 2



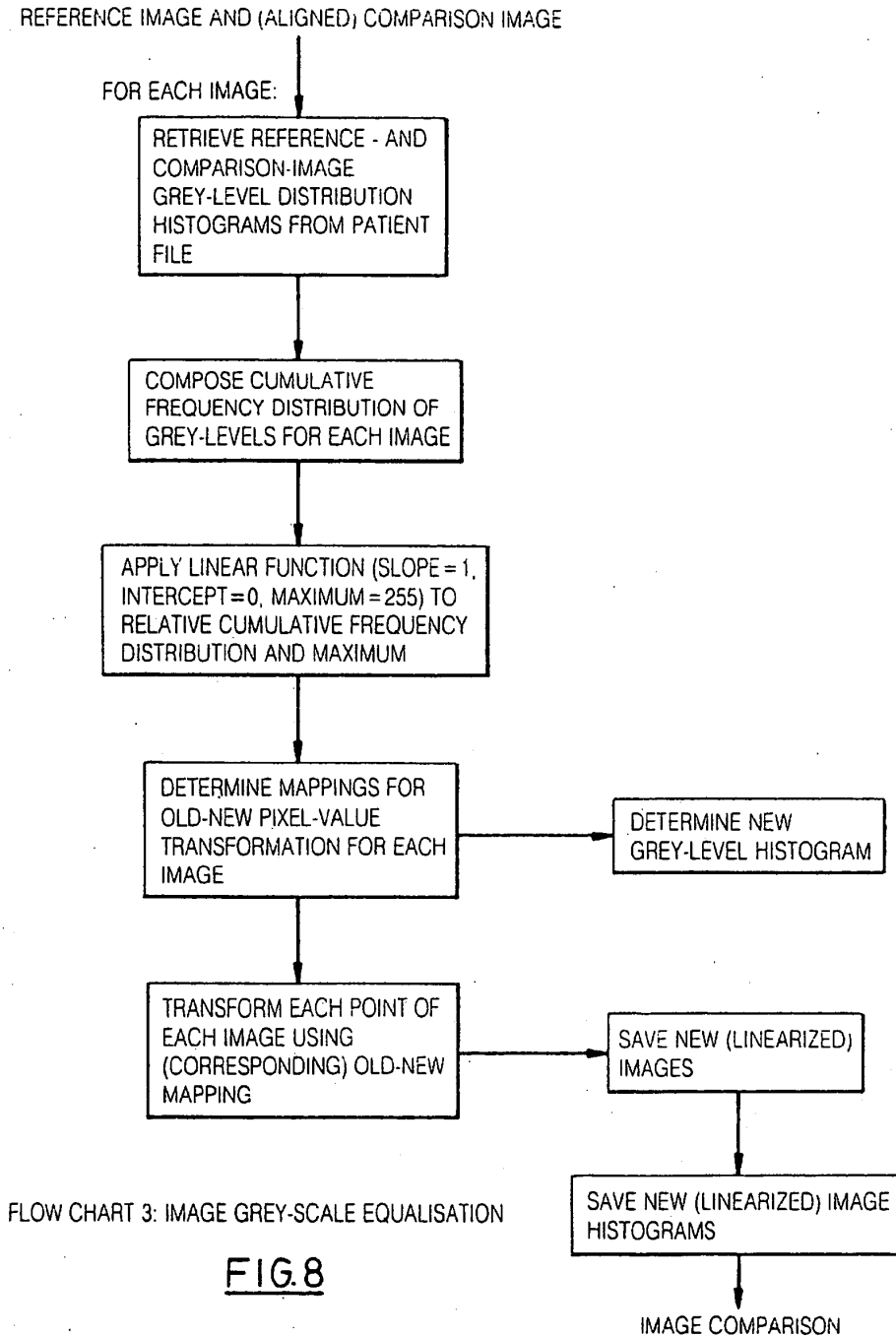
FLOW-CHART 1: IMAGE DIGITISATION AND CHARACTERIZATION

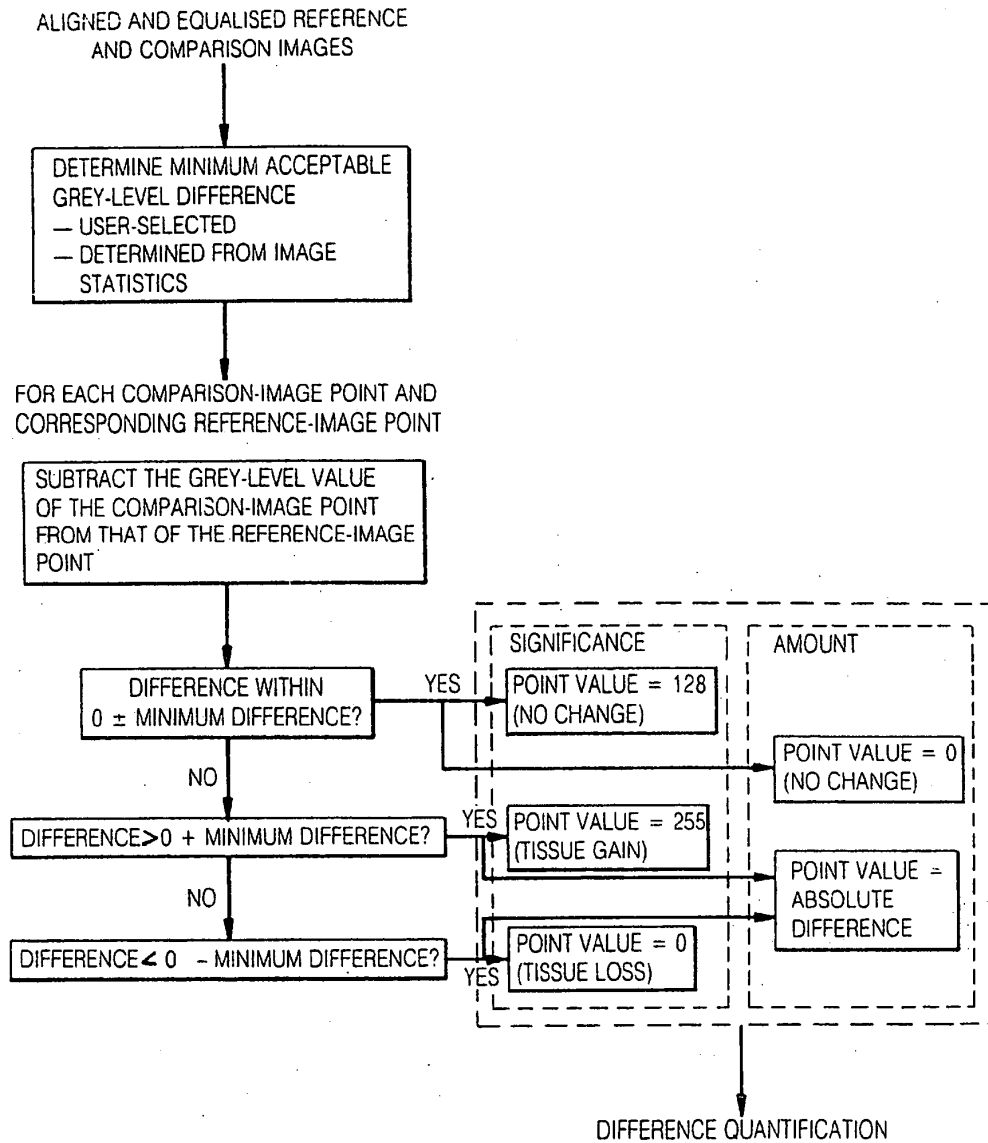
FIG. 6



FLOW CHART 2: SPATIAL TRANSFORMATION FOR ALIGNMENT

FIG. 7





FLOW CHART 4: IMAGE COMPARISON

FIG.9

SIGNIFICANCE - AND AMOUNT-MAPS
OF REFERENCE-COMPARISON
DIFFERENCES

USER SELECTS REGION(S) OF
"INTERESTING" DIFFERENCE
ON SIGNIFICANCE MAP

AREAS OF DIFFERENCE ARE
RANK-ORDERED ACCORDING
TO DIRECTION AND MEAN
AMOUNT OF DIFFERENCE

CALCULATE MEAN GREY-LEVEL VALUES
OF 7 X 7 SQUARES CENTERED ON
STEP-WEDGE FACES OF (ALIGNED AND
EQUALISED) REFERENCE - AND
COMPARISON-IMAGES

PLOT MEAN VALUES AGAINST
(KNOWN) VOLUMES OF
IMAGED ALUMINUM

INDICATE MEAN
REFERENCE-COMPARISON
DIFFERENCE VALUES

USER INTERPOLATES VOLUME
OF ALUMINUM EQUIVALENT
TO MEAN DIFFERENCE VALUES
AND CONVERTS TO VOLUME OF
HYDROXYAPATITE

FLOW CHART 5 DIFFERENCE QUANTIFICATION

FIG.10



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
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	G 03 B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 07-02-1989	Examiner CHEN A.H.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 (03.83) (P0401)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	("6690761").PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2004/11/18 13:34
L2	19	("4251732" "4782502" "4922915" "4985906" "5001738" "5222021" "5235628" "5335260" "5493601" "5769072" "5852647" "6077224" "6205348" "6226393" "6246745" "6248063" "6302582" "6320931" "6411729").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2004/11/18 13:35
L3	27	"378"/\$.ccls. and lang.in.	US-PGPUB; USPAT; USOCR	OR	ON	2004/11/18 13:37
L4	379	"378"/\$.ccls. and (dental and compar\$4)	US-PGPUB; USPAT; USOCR	OR	ON	2004/11/18 13:43
L5	33	"378"/\$.ccls. and (dental and (compar\$4 near image))	US-PGPUB; USPAT; USOCR	OR	ON	2004/11/18 14:20
L6	0	"378"/\$.ccls. and (intra-oral near6 sourc)	US-PGPUB; USPAT; USOCR	OR	ON	2004/11/18 14:21
L7	5	"378"/\$.ccls. and (intra-oral near6 source)	US-PGPUB; USPAT; USOCR	OR	ON	2004/11/18 14:21
L8	16	((("4,813,060") or ("5,306,306") or ("5,335,260") or ("5,480,439") or ("5,995,583") or ("6,069,935") or ("6,381,301") or ("6,496,558"))). PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	OFF	2004/11/18 14:40
S1	247	(378/38-40).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/17 14:36
S2	51	(378/191).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/02/04 12:39
S3	395	(378/168-170).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/02/04 12:39

Search History 11/18/04 2:41:00 PM Page 1
C:\APPS\EAST\Workspaces\351567.wsp

S4	613	((378/38-40).CCLS.) or ((378/191).CCLS.) or ((378/168-170).CCLS.)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/02/04 12:39
S5	41	(("3949229") or ("4188537") or ("4239971") or ("4259853") or ("4628356") or ("4783793") or ("4823369") or ("4856038") or ("5093852") or ("5195114") or ("5214686") or ("5503559") or ("5528645") or ("5533080") or ("5579361") or ("5677940") or ("5784429") or ("5793837") or ("5828720") or ("5828721")).PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/16 14:08
S6	13	(("5828722") or ("5838765") or ("5917882") or ("5917883") or ("5930327") or ("6424694") or ("re35423") or ("re36162")).PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/16 15:41
S7	388	dental and densitom\$	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 15:52
S8	27	("3949229" "4188537" "4239971" "4259853" "4628356" "4783793" "4823369" "4856038" "5093852" "5195114" "5214686" "5503559" "5528645" "5533080" "5579361" "RE35423" "5677940" "5784429" "5793837" "5828720" "5828721" "5828722" "5838765" "RE36162" "5917882" "5917883" "5930327").PN.	USPAT	OR	ON	2004/06/16 15:43
S9	173	"378"/\$.ccls. and (densitom\$ or densit\$) and database	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 16:25
S10	494	(378/54).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/16 16:25
S11	751	(378/54-56).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/16 16:27

S12	25	((378/54-56).CCLS.) and database	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 16:30
S13	11	("4811373" "4829549" "5673298" "5771272" "5778045" "5785041" "5835555" "5838765" "5850836" "6029078" "6102567").PN.	USPAT	OR	ON	2004/06/16 16:28
S14	0	"378"/\$.ccls and (current near6 densit\$)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 16:30
S15	308	"378"/\$.ccls. and (current near6 densit\$)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 16:46
S16	26	"378"/\$.ccls. and (den\$6 same compar\$5 same database)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 17:05
S17	96	"378"/\$.ccls. and (updat\$4 near image)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 17:08
S18	871	"378"/\$.ccls. and (compar\$4 same image same differen\$6)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 17:08
S19	25	"378"/\$.ccls. and (compar\$4 same image same differen\$6 same database)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 18:45
S20	0	"378"/\$.ccls. and (dental near densitometer)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 17:42
S21	8	"378"/\$.ccls. and (dental near density)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 17:42
S22	59	"378"/\$.ccls. and (dental same density)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 17:57
S23	2	("5995583").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/16 18:23

S24	2	("6320931").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/16 18:23
S25	32	"378"/\$.ccls. and dental and database	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 18:26
S26	15	"378"/\$.ccls. and (compar\$4 same previous same density)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 10:47
S27	18	"378"/\$.ccls. and dental and database and age	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/16 18:53
S28	2	("5995583").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/17 10:35
S29	2	("6415048").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/17 10:35
S30	0	"378"/\$.ccls. and (upate near database)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 10:47
S31	3	"378"/\$.ccls. and (update near database)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:32
S32	251	(378/38-40).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/17 14:33
S33	33	((378/38-40).CCLS.) and density	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:34
S34	5	((378/38-40).CCLS.) and (patient near information)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:34

S35	4	((378/38-40).CCLS.) and decay	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:36
S36	161	dental and x-ray and (patient near information)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:47
S37	20	("4489387" "5011405" "5338198" "5395238" "RE35169" "5518397" "5528735" "5533895" "5618176" "5826237" "5879158" "5975893" "6014629" "6063028" "6068482" "6099314" "6217325" "6227850" "6227851" "6236878").PN.	USPAT	OR	ON	2004/06/17 14:40
S38	20	((378/38-40).CCLS.) and keyboard	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:51
S39	13	"5533080"	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:51
S40	2	("5533080").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/17 14:53
S41	175	dental and densitometry	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 14:58
S42	2	("6246745").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2004/06/17 14:59
S43	7	((378/38-40).CCLS.) and database	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 15:01
S44	29	dental near densit\$	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 15:02

S45	254	teeth near densit\$	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 15:03
S46	15	(teeth near densit\$) and x-ray	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/06/17 15:03
S47	35	"378"/\$.ccls. and dental and database	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/11/18 11:16
S48	102	compar\$4 same ((dental or densitome\$6) near model)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2004/11/18 13:34



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/351,567	01/24/2003	Ronald E. Massie	3097	4505
	7590	12/01/2004	EXAMINER	
Mark E. Brown Chase Law Firm, L.C. 4400 College Boulevard, Suite 130 Overland Park, KS 66211			SONG, HOON K	
			ART UNIT	PAPER NUMBER
			2882	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/351,567		Applicant(s) MASSIE, RONALD E.	
	Examiner Hoon Song		Art Unit 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) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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 ____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ 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

4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.

5) ☐ Claim(s) ____ is/are allowed.

6) ☒ Claim(s) 1-6 is/are rejected.

7) ☐ Claim(s) ____ is/are objected to.

8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 24 January 2003 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).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. ____
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/24/04</u> .	6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a digital densitometry generating system, classified in class 378, subclass 168.
- II. Claims 7-20, drawn to a dental database management method, classified in class 707, subclass 100.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the digital densitometry generating system does not require the specific database management. The subcombination has separate utility such as database management system for health insurance claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Brown on 11/18/2004 a provisional election was made without traverse to prosecute the invention of I, claims 1-6.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 7-20 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 102(b) 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.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable 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).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hoon Song whose telephone number is (571) 272-2494. The examiner can normally be reached on 8:30 AM - 5 PM, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272 - 2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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).

HKS

11/27/04

HKS



EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER

Notice of References Cited	Application/Control No. 10/351,567	Applicant(s)/Patent Under Reexamination MASSIE, RONALD E.	
	Examiner Hoon Song	Art Unit 2882	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-4,941,164	07-1990	Schuller et al.	378/205
	B	US-4,104,532	08-1978	Weiss, Mortimer E.	378/38
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/08A (02-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1
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Complete if Known

Application Number	10/351,567
Filing Date	01/24/2003
First Named Inventor	Ronald E. Massie
Art Unit	2882
Examiner Name	
Attorney Docket Number	3097

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	†
		Country Code ² Number ⁴ Kind Code ³ (if known)	MM-DD-YYYY			
HES		EP88310182.6	05-01-1989	Governors of Univ of Alberta		
HKS		EP1237483	09-11-2002	Massie		

**Examiner
Signature**

Hoon Song

Date
Considered

4/18164

*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 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of Information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	
Filing Date	
First Named Inventor	Ronald E. Massie
Group Art Unit	
Examiner Name	
Attorney Docket Number	3097

10/351567
01/24/03
24 Apr 03
R. Tall

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
HBS		3,949,229		Albert	04/06/1976	
		4,188,537		Franke	02/12/1980	
		4,239,971		Cushman	12/16/1980	
		4,259,853		Fleissner	04/07/1981	
		4,628,356		Spillman et al.	12/09/1986	
		4,783,793		Virta et al	11/08/1988	
		4,823,369		Guenther et al.	04/18/1989	
		4,856,038		Guenther et al.	08/08/1989	
		5,093,852		Nishikawa et al.	03/03/1992	
		5,195,114		Sairenji et al.	03/16/1993	
		5,214,686		Webber	05/25/1993	
		5,503,559		Vari	04/02/1996	
		5,528,645		Koivisto	06/18/1996	
		5,533,080		Pelc	07/02/1996	
		5,579,361		Augais et al.	12/26/1996	
		5,677,940		Suzuki et al.	10/14/1997	
	5,784,429		Arai	07/21/1998		
	5,793,837		Mezhinsky et al.	08/11/1998		
	5,828,720		Syrjanen	10/27/1998		
HBS		5,828,721		Schulze-Ganzlin et al.	10/27/1998	

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner
Signature

Hoon Song

Date	
Considered	

6116104

*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 Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



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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	
				Filing Date	
				First Named Inventor	Ronald E. Massie
				Group Art Unit	
				Examiner Name	
Sheet	2	of	2	Attorney Docket Number	3097

[illegible][illegible]

Examiner Signature	Hoon Song	Date Considered	6/16/04
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Signature _____

*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 Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

possible. * Applicant is to place a check mark here if English language translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Index of Claims 	Application No.		Applicant(s)	
	10/351,567		MASSIE, RONALD E.	
	Examiner		Art Unit	
	Hoon Song		2882	

✓	Rejected
=	Allowed

—	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
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Claim		Date									
Final	Original	11/18/04									
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BIBDATASHEET**CONFIRMATION NO. 4505**

Bib Data Sheet

SERIAL NUMBER 10/351,567	FILING DATE 01/24/2003 RULE	CLASS 378	GROUP ART UNIT 2882	ATTORNEY DOCKET NO. 3097
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APPLICANTS

Ronald E. Massie, Four Seasons, MO; *verified*

**** CONTINUING DATA *******

This application 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 *verified*

**** FOREIGN APPLICATIONS ******* *none*

IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** SMALL ENTITY ****
**** 04/14/2003**

Foreign Priority claimed ☐ yes ☒ no	35 USC 119 (a-d) conditions met ☐ yes ☒ no ☐ Met after Allowance	STATE OR COUNTRY MO	SHEETS DRAWING 11	TOTAL CLAIMS 20	INDEPENDENT CLAIMS 3
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Verified and Acknowledged *Mark E. Brown* Examiner's Signature Initials

ADDRESS

Mark E. Brown
 Chase Law Firm, L.C.
 4400 College Boulevard, Suite 130
 Overland Park, KS
 66211

TITLE

Dental and orthopedic densitometry modeling system and method

FILING FEE RECEIVED 375	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
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Search Notes 	Application No.		Applicant(s)	
	10/351,567		MASSIE, RONALD E.	
	Examiner		Art Unit	
	Hoon Song		2882	

SEARCHED			
Class	Subclass	Date	Examiner
378/	38-40	11/18/2004	HKS
	191		
	168-170		
	54-56		

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
east	11/18/2004	HKS



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/351,567	01/24/2003	Ronald E. Massie	3097	4505
7590	02/18/2005		EXAMINER	
Mark E. Brown Chase Law Firm, L.C. 4400 College Boulevard, Suite 130 Overland Park, KS 66211			SONG, HOON K	
			ART UNIT	PAPER NUMBER
			2882	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.		Applicant(s)	
	10/351,567		MASSIE, RONALD E.	
	Examiner		Art Unit	
	Hoon Song		2882	

All participants (applicant, applicant's representative, PTO personnel):

(1) Hoon Song.

(3) David Bruce.

(2) Mark Brown.

(4) _____.

Date of Interview: 09 February 2005.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.

If Yes, brief description: _____.

Claim(s) discussed: attached.

Identification of prior art discussed: Schuller et al. (US 4941164).

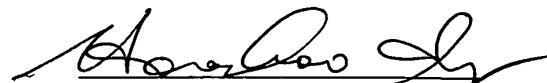
Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The applicant discussed Schuller referee does not teaches a three-dimensional image or model. Also Schuller uses fiducial marker to align both images but the invention does not used the fiducial marker. As amended, attached claim 1 distinguishes over the art of record.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

CHASE LAW FIRM, L.C.

4400 COLLEGE BOULEVARD
SUITE 130
OVERLAND PARK, KANSAS 66211
Tel. 913.339.9666
Fax 913.339.6061

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MAR 01 2005

FACSIMILE TRANSMISSION

We are sending a total of 6 pages including this cover sheet.

Re: Ronald E. Massie, Applicant
SN 10/351,567
Filed 01/24/2003
Hoon K. Song, Examiner

To: Commissioner for Patents

Facsimile No.: 703-872-9306

From: Mark Brown

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MAR 01 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/351,567	Confirmation No.	4505
Applicant	:	Ronald E. Massie, D.D.S.		
Filed	:	January 24, 2003		
TC/AU.	:	2882		
Examiner	:	Hoon K. Song		
Docket No.	:	3097		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the outstanding Office action and pursuant to the discussion at the interview conducted on February 10, 2005, please amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

Serial No. 10/351,567
Amdt. dated March 1, 2005
Reply to Office action of December 1, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (currently amended) A digital modeling system for creating dental or orthopedic models of patients, which system comprises:
 - a computer including a digital memory ~~adapted for~~ storing patient densitometry information, an input and an output;
 - a dental or orthopedic input device including an energy source and an energy sensor; said source and said sensor being ~~adapted for placement~~ placed with at least a portion of the patient's dental or orthopedic structure therebetween;
 - said sensor ~~being adapted for~~ transferring signals to the computer input;
 - said signals representing densitometry of the patient's dental or orthopedic structure;
 - said computer ~~being adapted for~~ creating, storing and comparing three-dimensional digital densitometry models without the use of fiducial markers of patient dental or orthopedic structure; and
 - an output device connected to said computer output and ~~adapted for~~ communicating densitometry model comparison information[.];
 - imaging software associated with said computer; and
 - a display associated with said output device and displaying information pertaining to said densitometry model.
2. (original) The system according to claim 1 wherein said source is external.

Serial No. 10/351,567
Amdt. dated March 1, 2005
Reply to Office action of December 1, 2004

3. (original) The system according to claim 1 wherein said source is
intraoral.

4. (original) The system according to claim 1 wherein said sensor is external.

5. (original) The system according to claim 1 wherein said sensor is intraoral.

6. (currently amended) The system according to claim 1, which includes:
said energy being collimated[;]
~~imaging software associated with said computer; and~~
~~a display associated with said output device and adapted for displaying densitometry~~
model information.

7-20. (withdrawn)

Serial No. 10/351,567
Amdt. dated March 1, 2005
Reply to Office action of December 1, 2004

Remarks

Applicant sincerely appreciates the courtesy extended by examiners Bruce and Song at the interview conducted on February 10, 2005. Pursuant to the discussion at the interview and in response to the outstanding Office action, the above application has been amended to more particularly point out and distinctly claim what applicant regards as his invention.

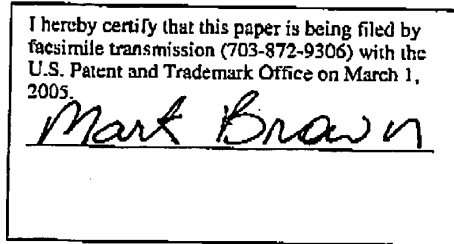
Currently amended claim 1 is the only independent claim remaining in the application. As amended, it was indicated that it would distinguish over the art of record. The other pending claims, all of which depend directly from claim 1, are claims 2-6. Claim 6 has been amended to delete subject matter added to claim 1 by this amendment.

In view of the foregoing, the application is in condition for allowance. Notice to this effect is respectfully solicited. The Examiner is invited to contact the undersigned by telephone if prosecution of this application can be expedited thereby.

Substance of the Interview

- 1) No exhibits were shown or demonstrations conducted.
- 2) Claim 1 was discussed.
- 3) Schuller et al. US 4,941,164 was discussed.
- 4) The principal proposed amendments are shown in the claim attached to the Interview Summary.
- 5) Applicant's principal argument was that the primary reference does not teach a three-dimensional image or model. Also, unlike the applicant's invention, Shuler uses fiducial markers to align both images.
- 6) No other pertinent matters were discussed.
- 7) The outcome of the interview is described on the Interview Summary.

Serial No. 10/351,567
Amdt. dated March 1, 2005
Reply to Office action of December 1, 2004



Respectfully Submitted,

Mark Brown

MARK E. BROWN
Patent Office Reg. No. 30,361

CHASE LAW FIRM, L.C.
4400 College Boulevard, Suite 130
Overland Park, Kansas 66211
Telephone: (913) 339-9666

Attorneys for Applicant

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

10/351567

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS		
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	minus 20=	*
INDEPENDENT CLAIMS	minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

31.05

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	* 6	Minus ** 20	=
Independent	* 1	Minus *** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	395.00
X\$ 25=	
X100=	
+180=	
TOTAL	

RATE	FEE
BASIC FEE	790.00
X\$50=	
X200=	
+360=	
TOTAL	

SMALL ENTITY OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL	
ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL	
ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL	
ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL	
ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL	
ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL	
ADDIT. 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 number found in the appropriate box in column 1.

Index of Claims 	Application No.		Applicant(s)	
	10/351,567		MASSIE, RONALD E.	
	Examiner		Art Unit	
	Hoon Song		2882	

✓	Rejected
=	Allowed

-	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date											
Final	Original	11/18/04											
1	✓												
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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
10/351,567		2882	28M1

Change of Address/Power of Attorney

The following fields have been set to Customer Number 23618 on 03/03/2005

- Correspondence Address
- Power of Attorney
- Maintenance Fee Address

The address of record for Customer Number 23618 is:

CHASE LAW FIRM L.C
4400 COLLEGE BOULEVARD, SUITE 130
OVERLAND PARK, KS 66211

The Practitioners of record for Customer Number 23618 are:

PTO INSTRUCTIONS:

Please take the following action when the correspondence address has been changed to a customer number:

- 1) Add 'ADDRESS CHANGE TO CUSTOMER NUMBER' on the next available content line of the File Jacket.
- 2) Put a line through the old address on the File Jacket and enter the Customer Number as the new address.
- 3) File this Notice in the File Jacket.

Please take the following action when the correspondence address has NOT been changed:

- 1) File this Notice in the File Jacket



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NOTICE OF ALLOWANCE AND FEE(S) DUE

23618 7590 05/12/2005
CHASE LAW FIRM L.C
4400 COLLEGE BOULEVARD, SUITE 130
OVERLAND PARK, KS 66211

EXAMINER

SONG, HOON K

ART UNIT PAPER NUMBER

2882

DATE MAILED: 05/12/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/351,567	01/24/2003	Ronald E. Massie	3097	4505

TITLE OF INVENTION: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	08/12/2005

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 REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. 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.

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
(703) 746-4000**

or Fax

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)

23618 7590 05/12/2005

**CHASE LAW FIRM L.C
4400 COLLEGE BOULEVARD, SUITE 130
OVERLAND PARK, KS 66211**

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 (703) 746-4000, on the date indicated below.

_____ (Depositor's name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/351,567	01/24/2003	Ronald E. Massie	3097	4505

TITLE OF INVENTION: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	08/12/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
SONG, HOON K	2882	378-038000

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, _____ 1
 (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. _____ 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 enclosed:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

- ☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. **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.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/351,567	01/24/2003	Ronald E. Massie	3097	4505
23618	7590	05/12/2005		
CHASE LAW FIRM L.C. 4400 COLLEGE BOULEVARD, SUITE 130 OVERLAND PARK, KS 66211			EXAMINER SONG, HOON K	
			ART UNIT 2882	PAPER NUMBER

DATE MAILED: 05/12/2005

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 252 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 252 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 (703) 305-8283.

SM

Notice of Allowability	Application No.	Applicant(s)	
	10/351,567	MASSIE, RONALD E.	
	Examiner	Art Unit	
	Hoon Song	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 response filed on 3/1/2005.
2. ☒ The allowed claim(s) is/are 1-6.
3. ☒ The drawings filed on 24 January 2003 are accepted by the Examiner.
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. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ 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).
7. ☐ 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. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date <u>1/24/03</u> 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. ☐ Notice of Informal Patent Application (PTO-152) 6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ 7. ☒ Examiner's Amendment/Comment 8. ☒ Examiner's Statement of Reasons for Allowance 9. ☐ Other _____
--	---

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Brown on 5/2/2005.

The application has been amended as follows:

Cancel claims 7-20.

Allowable Subject Matter

Claims 1-6 are allowed over prior art.

The following is an examiner's statement of reasons for allowance:

Regarding claims 1-6, the prior art fails to teach a digital modeling system for creating dental or orthopedic models of patients having a computer for creating, storing and comparing three-dimensional digital densitometry models without the use of fiducial markers of patient dental or orthopedic structure as claimed in independent claim 1.

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."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Schuller et al. (US 4941164) teaches a method for alignment of radiographic images but fails to teach three-dimensional models nor without the using fiducial markers.

Lang et al. (US 6690761B2) teaches a method for creating a dental densitometry image but fails to teach that the densitometry image is three dimensional nor the models are compared three dimensionally without use of fiducial marker.

Barry et al. (US 5835555) teaches an x-ray bone densitometry apparatus but fails to teach a computer for creating three-dimensional densitometry models to be compared without the use fiducial markers.

Stein et al. (US 6385283B1) teaches a method for determining future fracture risk but fails to teach a computer for creating three-dimensional densitometry models to be compared without the use fiducial markers.

Kopelman et al. (US 6664986B1) teaches a computer for creating dental model but fails to teach the model is densitometry model.

Analoui (US 6405071B1) teaches a method of creating and storing a three dimensional images but fails to teach the image is densitometry model nor comparing the models.

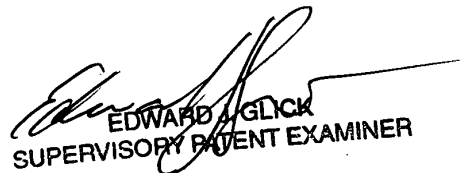
Serverance (US 6821116B2) teaches a computer for generating a dental structure database but fails to teach the data is densitometry models.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hoon Song whose telephone number is (571) 272-2494. The examiner can normally be reached on 8:30 AM - 5 PM, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272 - 2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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).

HKS


EDWARD A. GLICK
SUPERVISORY PATENT EXAMINER



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	
				Filing Date	
				First Named Inventor	Ronald E. Massie
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	3097
Sheet	1	of	2		

U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ¹ (if known)			
HKS		3,949,229		Albert	04/06/1976	
		4,188,537		Franke	02/12/1980	
		4,239,971		Cushman	12/16/1980	
		4,259,853		Fleissner	04/07/1981	
		4,628,356		Spillman et al.	12/09/1986	
		4,783,793		Virta et al	11/08/1988	
		4,823,369		Guenther et al.	04/18/1989	
		4,856,038		Guenther et al.	08/08/1989	
		5,093,852		Nishikawa et al.	03/03/1992	
		5,195,114		Sairenji et al.	03/16/1993	
		5,214,686		Webber	05/25/1993	
		5,503,559		Vari	04/02/1996	
		5,528,645		Koivisto	06/18/1996	
		5,533,080		Pelc	07/02/1996	
		5,579,361		Augais et al.	12/26/1996	
		5,677,940		Suzuki et al.	10/14/1997	
	5,784,429		Arai	07/21/1998		
	5,793,837		Mezhinsky et al.	08/11/1998		
	5,828,720		Syrjanen	10/27/1998		
HKS		5,828,721		Schulze-Ganzlin et al.	10/27/1998	

[illegible]

Examiner Signature	Hoon Song	Date Considered	4/29/05
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*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 Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet

2

of

2

Complete if Known

Application Number

Filing Date

First Named Inventor	Ronald E. Massie
----------------------	------------------

Group Art Unit

Examiner Name

Attorney Docket Number

3097

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

**Examiner
Signature**

Hoon Song

Date _____

Considered

4/29/05

***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 Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

Notice of References Cited	Application/Control No. 10/351,567		Applicant(s)/Patent Under Reexamination MASSIE, RONALD E.	
	Examiner Hoon Song		Art Unit 2882	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,941,164	07-1990	Schuller et al.	378/205
*	B	US-6,690,761	02-2004	Lang et al.	378/56
*	C	US-5,835,555	11-1998	Barry et al.	378/146
*	D	US-6,385,283	05-2002	Stein et al.	378/54
*	E	US-6,664,986	12-2003	Kopelman et al.	715/849
*	F	US-6,405,071	06-2002	Analoui, Mostafa	600/425
*	G	US-6,821,116	11-2004	Severance, Gary L.	433/29
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Issue Classification 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/351,567	MASSIE, RONALD E.	
	Examiner	Art Unit	
	Hoon Song	2882	

ISSUE CLASSIFICATION									
ORIGINAL				CROSS REFERENCE(S)					
CLASS		SUBCLASS		CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
378		38		600	425				
INTERNATIONAL CLASSIFICATION									
A	6	1	B	6/14					
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				/					
 Hoon Song 4/29/2005 (Assistant Examiner) (Date)				EDWARD J. GLICK SUPERVISORY PATENT EXAMINER  (Patent Examiner) (Date)				Total Claims Allowed: 6	
 Christine Moore 5/3/05 (Legal Instruments Examiner) (Date)								O.G. Print Claim(s) 1	O.G. Print Fig. 4a

☒ 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
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	2		32		62		92		122		152		182		
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Index of Claims 	Application/Control No.		Applicant(s)/Patent under Reexamination	
	10/351,567		MASSIE, RONALD E.	
	Examiner		Art Unit	
	Hoon Song		2882	

✓	Rejected
=	Allowed

-	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date									
Final	Original	4/29/05									
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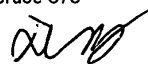
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Search Notes 	Application/Control No.		Applicant(s)/Patent under Reexamination	
	10/351,567		MASSIE, RONALD E.	
	Examiner		Art Unit	
	Hoon Song		2882	

SEARCHED			
Class	Subclass	Date	Examiner
378	38	4/27/2005	HKS
"	39	"	"
"	54-56	"	"
"	98.5	"	"
"	62	"	"
600	425	"	"
382	132	"	"

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
378	38	4/29/05	HKS
600	425	4/29/05	HKS

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
East	4/27/2005	HKS
David Bruce 378 	4/28/2005	HKS

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 (703) 746-4000

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 on the front of the application 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)

23618 7590 05/12/2005

CHASE LAW FIRM L.C.
 4400 COLLEGE BOULEVARD, SUITE 130
 OVERLAND PARK, KS 66211

08/11/2005 RHEBRAH1 00000006 503424 10351567

01 FC:1504 300.00 DA
 02 FC:2501 700.00 DA

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.

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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 (703) 746-4000, on the date indicated below.

Mark Brown (Depositor's name)
 Mark Brown (Signature)
 8/8/05 (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/351,567	01/24/2003	Ronald E. Massie	3097	4505

TITLE OF INVENTION: DENTAL AND ORTHOPEDIC DENSITOMETRY MODELING SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	08/12/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
SONG, HOON K	2882	378-038000

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.

Mark E. Brown

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 enclosed:

- ☒ Issue Fee
- ☒ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

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- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
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5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

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 8/8/05

Typed or printed name Mark Brown

Registration No. 30,361

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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www.uspto.gov

APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
10/351,567	6944262	2882	9200

Correspondence Address / Fee Address Change

The following fields have been set to Customer Number 63151 on 06/06/2006

- Correspondence Address
- Maintenance Fee Address

The address of record for Customer Number 63151 is:

MARK BROWN
125 LAKESHORE DRIVE SOUTH
LAKE QUIVIRA, KS 66217



TPW

Approved for use through 12/31/2008. OMB 0651-0035
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**CHANGE OF
CORRESPONDENCE ADDRESS
Patent**

Address to:
Mail Stop Post Issue
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Patent Number	6,944,262
Issue Date	September 13, 2005
Application Number	10/351,567
Filing Date	January 24, 2003
First Named Inventor	Ronald E. Massie
Attorney Docket Number	3097

Please change the Correspondence Address for the above-identified patent to:

☒ The address associated with Customer Number:

63151

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☐ Firm or
Individual Name

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This form cannot be used to change the data associated with a Customer Number. To change the data associated with an existing Customer Number use "Request for Customer Number Data Change" (PTO/SB/124).

This form will not affect any "fee address" provided for the above-identified patent. To change a "fee address" use the "Fee Address Indication Form" (PTO/SB/47).

I am the:

☒ Patentee.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☐ Attorney or agent of record. Registration Number _____

Signature

Typed or
Printed Name

Ronald E. Massie

Date

Telephone 573-365-0220

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 _____ forms are submitted.

This collection of information is required by 37 CFR 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: Mail Stop Post Issue, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

AO 120 (Rev. 08/10)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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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 10/3/2017	U.S. DISTRICT COURT for the District of Delaware
PLAINTIFF OSSEO IMAGING, LLC		DEFENDANT 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
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2		
3		
4		
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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