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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 June 2017 (15.06.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/098503 A1

(54) Title: DATABASE MANAGEMENT FOR LAPAROSCOPIC SURGERY

Fig. 1

(57) **Abstract**: The present invention provides a computer-implemented system for providing database management for laparoscopic surgery comprising: a. at least two records, each one of said records is of at least one procedure, each record is characterized by at least one attribute; b. at least one processor configured to compare each of said at least two records and to determine if there exists at least one attribute common to both of said at least two records; wherein, if there exists at least one said attribute common to both of said at least two records, an outcome of at least one said procedure is predictable

DATABASE MANAGEMENT FOR LAPAROSCOPIC SURGERY

FIELD OF THE INVENTION

The present invention generally pertains to a system and method for providing database management for laparoscopic surgery.

BACKGROUND OF THE INVENTION

Large amounts of data on the progress of a surgical procedure can be collected during the procedure. In addition, information can be collected about the patient, the surgeon, surgical assistants, equipment used, as well as data about outcomes of the surgery.

At present, little use is made of these data.

It is therefore a long felt need to provide system and method for correlating the collected data and thus increasing its usefulness.

SUMMARY OF THE INVENTION

It is an object of the present invention to disclose a computer-implemented system and method for providing database management for laparoscopic surgery.
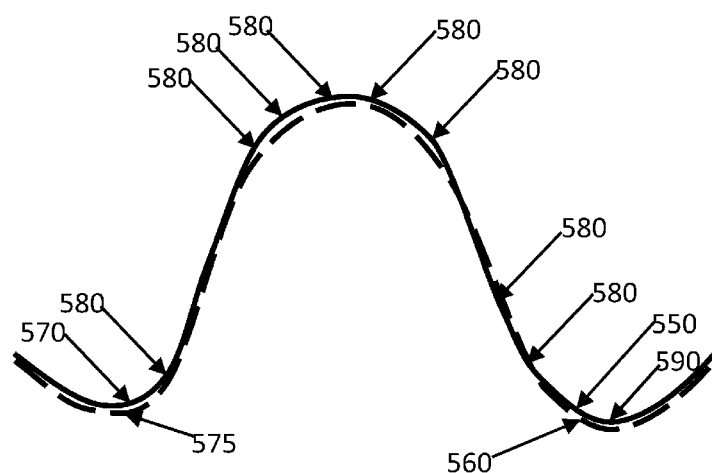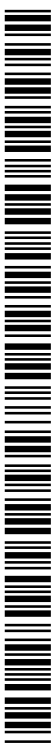
It is another object of the present invention to disclose a computer-implemented system for providing database management for laparoscopic surgery comprising:

    a.   at least two records, each one of said records is of at least one procedure, each record is characterized by at least one attribute;

    b.   at least one processor configured to compare each of said at least two records and to determine if there exists at least one attribute common to both of said at least two records;

wherein, if there exists at least one said attribute common to both of said at least two records, an outcome of at least one said procedure is predictable.

It is another object of the present invention to disclose the system as described above, wherein said comparison is a real-time comparison.

It is another object of the present invention to disclose the system as described above, wherein said at least one procedure is selected from a group consisting of: an identifiable

1

unit, a surgical task, a complete procedure and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said attribute is selected from a group consisting of a pre-procedure datum, an intra-procedure datum and a post-procedure datum.

It is another object of the present invention to disclose the system as described above, wherein said pre-procedure datum is selected from a group consisting of: an identifier of a patient; a datum from a patient's medical history, number of said at least one procedures carried out by an operator, cleaning status of an operating room, a general datum, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said datum from a patient's medical history is selected from a group consisting of: an illness, an outcome of an illness, a previous procedure, an outcome of a previous procedure, a genetic factor, an effect on said patient of said genetic factor, a predicted effect on said patient of said genetic factor, a medical treatment, an allergy, a medical condition, a psychological factor, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said cleaning status of an operating room is selected from a group consisting of: time of last cleaning, date of last cleaning, cleaning procedure, cleaning material and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said intra-procedure datum is selected from a general datum.

It is another object of the present invention to disclose the system as described above, wherein said post-procedure datum is selected from a group consisting of: an outcome of a procedure, length of hospital stay for a patient, a readmission for a patient, a medical treatment for a patient, a subsequent procedure, number of subsequent procedures carried out an operator, a general datum, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said outcome is selected from a group consisting of: a successful aspect, a partially successful aspect, a partial failure in an aspect, a complete failure in an aspect, and any combination thereof.

It is another object of the present invention to disclose the system as described above,

2

wherein said aspect is selected from a group consisting of: a complication during a procedure, a complication during another procedure, a component where recovery is smooth and uncomplicated, a rate of recovery from a procedure, a rate of recovery from a complication, a long-term effect of a procedure, a long-term effect of a complication, amount of bleeding during a procedure, amount of bleeding during another procedure, return of an abnormality, speed of healing, an adhesion, patient discomfort, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said general datum is selected from a group consisting of: an image of at least a portion of a surgical field, an identifier of an operator, a rating for an operator, a physical characteristic of a patient, a physical characteristic of an operating room, an identifier of a procedure, type of procedure, time of a beginning of a procedure, time of an intermediate point of a procedure, time of an end point of a procedure, duration of a procedure, time between end of a procedure and beginning of another procedure, time of creation of a critical point, location of a critical point, time of creation of a fixed point, location of a fixed point, a medication, a medical device, an identifier of a surgical object, a type of a surgical object, a number used for a surgical object, a cleaning status for a surgical object, a comment, a parameter, a metric, occurrence of a malfunction, severity of a malfunction, start time of a malfunction, end time of a malfunction, reason for start of a malfunction, reason for end of a malfunction, occurrence of an adverse event, a test, an image from another modality, an overlay, a label, a note, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said parameter is selected from a group consisting of: 2D position of at least a portion of at least one item, 2D orientation of at least a portion of at least one item, 3D position of at least a portion of at least one item, 3D orientation of at least a portion of at least one item, 2D projection of a 3D position of at least a portion of said at least one item, movement of at least a portion of at least one said item, energy use; idle time, approach time, speed, maximum speed, speed profile, acceleration, motion smoothness, path length, distance efficiency, depth perception, transit profile, deviation on horizontal plane, deviation on vertical plane, response orientation, economy of area (EOA), economy of volume (EOV), number of movements, force range, interquartile force range, integral of the force, integral of the grasping force, integral of the Cartesian force, first derivative of the force, second derivative of the force, third derivative of the force, lighting level, amount of suction, amount of fluid flow, heating level in an ablator, amount of defogging, amount of smoke removal,

3

activation of an item, deactivation of an item, bleeding, change in heart rate, change in blood pressure, change in color of an organ,

It is another object of the present invention to disclose the system as described above, wherein said physical characteristic of an operating room is selected from a group consisting of: temperature, humidity, type of lighting, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said medical device is selected from a group consisting of: a heating blanket, a pump, a catheter, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said occurrence of an adverse event is selected from a group consisting of: unexpected bleeding, undesirable change in blood pressure, undesirable change in heart rate, undesirable change in consciousness state, pain, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said physical characteristic of said patient is selected from a group consisting of: age, height, weight, body mass index, physical parameter of said patient, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said physical parameter of said patient is selected from a group consisting of: health status, blood pressure, heart rate, blood gasses, blood volume, blood hemoglobin, breathing rate, breath depth, EEG, ECG, sweating, and any combination thereof,

It is another object of the present invention to disclose the system as described above, wherein said medication is selected from a group consisting of: an antibiotic, an anesthetic, plasma, blood, saline, coagulant, anticoagulant, blood pressure medication, heart medication, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said medical treatment is selected from a group consisting of: administering a medication, applying a medical device, prescribing a course of exercise, administering physiotherapy, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said test is selected from a group consisting of: a blood test, a blood pressure measurement, an EEG, and ECG, and any combination thereof.

4

It is another object of the present invention to disclose the system as described above, wherein said other modality is selected from a group consisting of: MRI, CT, ultrasound, X-ray, fluorography, fluoroscopy, molecular imaging, scintigraphy, SPECT, positron emission tomography (PET), other types of tomography, elastography, tactile imaging, photoacoustic imaging, thermography, functional near-infrared spectroscopy (FNIR) and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said image from said other modality can be stored or real-time.

It is another object of the present invention to disclose the system as described above, wherein said note is selected from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said comment is selected from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said critical point is selected from a group consisting of: a location in said surgical field, a beginning of a procedure, an end of a procedure, an intermediate point in a procedure and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said at least one image of at least a portion of a surgical field is selected from a group consisting of: a 2D image, a 3D image, a panoramic image, a high resolution image, a 3D image reconstructed from at least one 2D image, a 3D stereo image and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said second modality image thereof is selected from a group consisting of: a 2D image, a 3D image, a panoramic image, a high resolution image, a 3D image reconstructed

5

from at least one 2D image, a 3D stereo image and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein at least one said attribute in at least one of said at least two records is a function of time.

It is another object of the present invention to disclose the system as described above, wherein said comparing comprises comparing as a function of time at least one parameter, said at least one parameter being in both said at least two records.

It is another object of the present invention to disclose the system as described above, wherein said at least one critical point is identifiable from a comparison selected from a group consisting of: a comparison between at least one first parameter at time t and at least one first parameter at time $t + \Delta t$, and a comparison between at least one first parameter at time t and at least one second parameter at time t.

It is another object of the present invention to disclose the system as described above, wherein said at least one critical point is identifiable from a comparison of a plurality of consecutive said at least one first parameters to a plurality of consecutive said at least one second parameters.

It is another object of the present invention to disclose the system as described above, wherein said comparison is made by determining existence of a difference between a member of a group consisting of said at least one first parameter at time t and said at least one first parameter at time $t + \Delta t$, said at least one first parameter at time t and said at least one second parameter at time t, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said difference is detectable for a member of a group consisting of: said at least one first parameter at time t differs from said at least one first parameter at time $t + \Delta t$ by an amount greater than a predetermined value, said at least one first parameter at time t differs from said at least one second parameter at time t by an amount greater than a predetermined value, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said predetermined value is in a range of about 0.1% to about 15%.

It is another object of the present invention to disclose the system as described above, wherein said predetermined value is about 5%.

It is another object of the present invention to disclose the system as described above, wherein said system is in communication with a system for controlling laparoscopic surgery.

It is another object of the present invention to disclose the system as described above, wherein a searchable tag is providable for at least one said attribute.

It is another object of the present invention to disclose the system as described above, wherein said searchable tag is providable in a manner selected from a group consisting of manually, semi-automatically, automatically and any combination thereof.

It is another object of the present invention to disclose the system as described above, additionally comprising at least one sensor configured to determine at least one said attribute.

It is another object of the present invention to disclose the system as described above, wherein said at least one sensor is selected from a group consisting of: an electromagnetic sensor; an ultrasound sensor; an inertial sensor to sense the angular velocity and the acceleration of the surgical object; a gyroscope, an accelerometer, an inertial measurement unit (IMU), a motion sensor, a sensor wearable by an operator, a sensor attachable to a surgical object, an RFID tag attachable to a surgical object, an ultrasound sensor, an infrared sensor, a gyroscope, a tachometer, a shaft encoder, a rotary encoder, a strain gauge and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein a member of a group consisting of: said at least one critical point, a suggestion, an instruction, a warning, a distance, an angle, an area, a volume, a size scale, information on a medical history of a patient, and any combination thereof is overlayable on at least a portion of at least one said image.

It is another object of the present invention to disclose the system as described above, wherein a member of a group consisting of a suggestion, an instruction, a warning and any combination thereof is providable if, during a procedure, at least one said attribute is correlatable with an at least one second attribute in a stored record

It is another object of the present invention to disclose the system as described above, wherein said processor is additionally configured to real time generate a display image by at least one of a group consisting of: (a) marking at least one virtual marker at at least one predetermined position within at least a portion of said image of at least a portion of a surgical field; (b) rendered superimposition of said image of at least a portion of a surgical field and at least a portion of said second imaging modality.

7

It is another object of the present invention to disclose the system as described above, wherein said marking provides information selected from a group consisting of: a distance between predetermined points, an area between predetermined points, a volume between predetermined points, an orientation relative to a predetermined direction, a physical identifier, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said physical identifier identifies a member of a group consisting of: at least one portion of tissue of a predetermined type, a predetermined location, a surgical object, and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said tissue of a predetermined type is selected from a group consisting of: an organ, a blood vessel, a bone, a nerve, a ligament, abnormal tissue and any combination thereof.

It is another object of the present invention to disclose the system as described above, wherein said physical identifier comprises a mark of predetermined shape.

It is another object of the present invention to disclose the system as described above, wherein said predetermined shape is selected from a group consisting of: a word, a geometric shape, an outline of a predetermined area, a patch covering said predetermined area, an outline of predetermined shape, a patch of predetermined shape, and any combination thereof.

It is another object of the present invention to disclose a computer-implemented method for providing database management for laparoscopic surgery comprising:

    a.   providing a computer-implemented system for database management for laparoscopic surgery comprising:

        i.   at least two records, each one of said records is of at least one procedure, each record is characterized by at least one attribute; and;

        ii.   at least one processor configured to to compare each of said at least two records and to determine if there exists at least one attribute common to both of said at least two records;

    b.   comparing said at least two records;

    c.   selecting, from said at least two said records, at least one first record and at least one second record having at least one attribute in common; and

8

d.   if there exists at least one said attribute common to both of said at least two records, generating a prediction as to at least one outcome of at least one said procedure.

It is another object of the present invention to disclose the method as described above, wherein said step of comparing comprises real-time comparing.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said at least one procedure from a group consisting of: an identifiable unit, a surgical task, a complete procedure and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said attribute from a group consisting of a pre-procedure datum, an intra-procedure datum and a post-procedure datum.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said pre-procedure datum from a group consisting of: an identifier of a patient; a datum from a patient's medical history, number of said at least one procedures carried out by an operator, cleaning status of an operating room, a general datum, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said datum from a patient's medical history from a group consisting of: an illness, an outcome of an illness, a previous procedure, an outcome of a previous procedure, a genetic factor, an effect on said patient of said genetic factor, a predicted effect on said patient of said genetic factor, a medical treatment, an allergy, a medical condition, a psychological factor, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said cleaning status of an operating room from a group consisting of: time of last cleaning, date of last cleaning, cleaning procedure, cleaning materials and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said intra-procedure datum from a general datum.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said post-procedure datum from a group consisting of: an outcome of a procedure, length of hospital stay for said patient, a readmission for a patient, a medical treatment for a patient, a subsequent procedure, number of subsequent

9

procedures carried out by an operator, a general datum and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said outcome from a group consisting of: a successful aspect, a partially successful aspect, a partial failure in an aspect, a complete failure in an aspect, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said aspect from a group consisting of: a complication during a procedure, a complication during another procedure, a component where recovery is smooth and uncomplicated, a rate of recovery from a procedure, a rate of recovery from a complication, a long-term effect of a procedure, a long-term effect of a complication, amount of bleeding during said at least one procedure, amount of bleeding during a procedure, amount of bleeding during another procedure, return of an abnormality, speed of healing, an adhesion, patient discomfort, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said general datum from a group consisting of: an image of at least a portion of a surgical field, an identifier of an operator, a rating for an operator, a physical characteristic of a patient, an identifier of an operating room, a physical characteristic of an operating room, an identifier of a procedure, type of procedure, time of a beginning of a procedure, time of an intermediate point of a procedure, time of an end point of a procedure, duration of a procedure, time between end of a procedure and beginning of another procedure, time of creation of a critical point, location of a critical point, time of creation of a fixed point, location of a fixed point, a medication, a medical device, an identifier of a surgical object, a type of a surgical object, a number used for a surgical object, a cleaning status for a surgical object, a comment, a parameter, a metric, occurrence of a malfunction, severity of a malfunction, start time of a malfunction, end time of a malfunction, reason for start of a malfunction, reason for end of a malfunction, occurrence of an adverse event, a test, an image from another modality, an overlay, a label, a note, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising a step of selecting said parameter from a group consisting of: 2D position of at least a portion of at least one item, 2D orientation of at least a portion of at least one item, 3D position of at least a portion of at least one item, 3D orientation of at least a

10

portion of at least one item, 2D projection of a 3D position of at least a portion of said at least one item, movement of at least a portion of at least one said item, energy use; idle time, approach time, speed, maximum speed, speed profile, acceleration, motion smoothness, path length, distance efficiency, depth perception, transit profile, deviation on horizontal plane, deviation on vertical plane, response orientation, economy of area (EOA), economy of volume (EOV), number of movements, force range, interquartile force range, integral of the force, integral of the grasping force, integral of the Cartesian force, first derivative of the force, second derivative of the force, third derivative of the force, lighting level, amount of suction, amount of fluid flow, heating level in an ablator, amount of defogging, amount of smoke removal, activation of an item, deactivation of an item, bleeding, change in heart rate, change in blood pressure, change in color of an organ, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said physical characteristic of an operating room from a group consisting of: temperature, humidity, type of lighting, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said medical device from a group consisting of: a heating blanket, a pump, a catheter, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said occurrence of an adverse event from a group consisting of: unexpected bleeding, undesirable change in blood pressure, undesirable change in heart rate, undesirable change in consciousness state, pain, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said physical characteristic of said patient from a group consisting of: age, height, weight, body mass index, physical parameter of said patient, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said physical parameter of said patient from a group consisting of: health status, blood pressure, heart rate, blood gasses, blood volume, blood hemoglobin, breathing rate, breath depth, EEG, ECG, sweating, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said medication from a group consisting of: an

11

antibiotic, an anesthetic, plasma, blood, saline, coagulant, anticoagulant, blood pressure medication, heart medication, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said medical treatment from a group consisting of: a medication, a medical device, prescribing a course of exercise, administering physiotherapy, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said test from a group consisting of:, but not limited to, a blood test, a blood pressure measurement, an EEG, and ECG, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said other modality from a group consisting of: MRI, CT, ultrasound, X-ray, fluorography, fluoroscopy, molecular imaging, scintigraphy, SPECT, positron emission tomography (PET), other types of tomography, elastography, tactile imaging, photoacoustic imaging, thermography, functional near-infrared spectroscopy (FNIR) and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of providing said image from said other modality either stored or real-time.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said note from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said comment from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

It is another object of the present invention to disclose the method as described above,

12

additionally comprising step of selecting said critical point from a group consisting of: a location in said surgical field, a beginning of a procedure, an end of a procedure, an intermediate point in a procedure and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting a member of a group consisting of said at least one image of at least a portion of a surgical field, said second modality image and any combination thereof from a group consisting of: a 2D image, a 3D image, a panoramic image, a high resolution image, a 3D image reconstructed from at least one 2D image, a 3D stereo image and any combination thereof.

It is another object of the present invention to disclose the method as described above, wherein at least one said attribute in at least one of said at least two records is a function of time.

It is another object of the present invention to disclose the method as described above, additionally comprising step of comparing as a function of time at least one parameter in both said at least two records.

It is another object of the present invention to disclose the method as described above, additionally comprising step of identifying said at least one critical point from a comparison selected from a group consisting of: a comparison between at least one first parameter at time t and at least one first parameter at time $t + \Delta t$, and a comparison between at least one first parameter at time t and at least one second parameter at time t.

It is another object of the present invention to disclose the method as described above, additionally comprising step of identifying said at least one critical point from a comparison of a plurality of consecutive said at least one first parameters to a plurality of consecutive said at least one second parameters.

It is another object of the present invention to disclose the method as described above, wherein said step of comparing comprises determining existence of a difference between a member of a group consisting of said at least one first parameter at time t and said at least one first parameter at time $t + \Delta t$, said at least one first parameter at time t and said at least one second parameter at time t, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of detecting said difference for a member of a group consisting

13

of: said at least one first parameter at time t differs from said at least one first parameter at time $t + \Delta t$ by an amount greater than a predetermined value, said at least one first parameter at time t differs from said at least one second parameter at time t by an amount greater than a predetermined value, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said predetermined value to be in a range of about 0.1% to about 15%.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said predetermined value to be about 5%.

It is another object of the present invention to disclose the method as described above, additionally comprising step of providing said system in communication with a system for controlling laparoscopic surgery.

It is another object of the present invention to disclose the method as described above, additionally comprising step of providing a searchable tag for at least one said attribute.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting a manner of providing said searchable tag from a group consisting of manually, semi-automatically, automatically and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising steps of providing at least one sensor and determining, by means of said sensor, at least one said attribute.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said at least one sensor from a group consisting of: an electromagnetic sensor; an ultrasound sensor; an inertial sensor to sense the angular velocity and the acceleration of the surgical object; a gyroscope, an accelerometer, an inertial measurement unit (IMU), a motion sensor, a sensor wearable by an operator, a sensor attachable to a surgical object, an RFID tag attachable to a surgical object, an ultrasound sensor, an infrared sensor, a gyroscope, a tachometer, a shaft encoder, a rotary encoder, a strain gauge and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of overlaying a member of a group consisting of: said at least

14

one critical point, a suggestion, an instruction, a warning, a distance, an angle, an area, a volume, a size scale, information on a medical history of a patient, and any combination thereof on at least a portion of at least one said image.

It is another object of the present invention to disclose the method as described above, additionally comprising step of a providing a member of a group consisting of a suggestion, an instruction, a warning and any combination thereof if, during a procedure, at least one said attribute is correlatable with an at least one second attribute in a stored record

It is another object of the present invention to disclose the method as described above, additionally comprising step of real time generating a display image by at least one of a group consisting of: (a) marking at least one virtual marker at at least one predetermined position within at least a portion of said image of at least a portion of a surgical field; (b) rendered superimposition of said image of at least a portion of a surgical field and at least a portion of said second imaging modality.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting information provided by said marking from a group consisting of: a distance between predetermined points, an area between predetermined points, a volume between predetermined points, an orientation relative to a predetermined direction, an identifier, and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of identifying, by means of said identifier, a member of a group consisting of: at least one portion of tissue of a predetermined type, a predetermined location, a surgical object, and any combination thereof,

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said tissue of a predetermined type from a group consisting of: an organ, a blood vessel, a bone, a nerve, a ligament, abnormal tissue and any combination thereof.

It is another object of the present invention to disclose the method as described above, additionally comprising step of providing said identifier comprising a mark of predetermined shape.

It is another object of the present invention to disclose the method as described above, additionally comprising step of selecting said predetermined shape from a group consisting of: a word, a geometric shape, an outline of a predetermined area, a patch covering said

15

predetermined area, an outline of predetermined shape, a patch of predetermined shape, and any combination thereof.

BRIEF DESCRIPTION OF THE FIGURES

In order to better understand the invention and its implementation in practice, a plurality of embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, wherein

Fig. 1 schematically illustrates an idealized example of movement of a tool, showing critical points;

Fig. 2 shows an interior of a uterus with endometriosis lesions highlighted;

Fig. 3A-B schematically illustrates an embodiment of a flexible robotic arm which includes IMUs;

Fig. 4 schematically illustrates the 3D movements, over time, of the tip of a surgical tool during a procedure;

Fig. 5A schematically illustrates the speed of the tool tip during the procedure;

Fig. 5B schematically illustrates the acceleration of the tool tip during the procedure;

Fig. 6A schematically illustrates the speed of the tool tip for part of the procedure;

Fig. 6B schematically illustrates the acceleration of the tool tip for part of the procedure;

Fig. 6C schematically illustrates the jerk of the tool tip for part of the procedure; and

Fig. 7 illustrates a label applied to a bile duct.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description is provided, alongside all chapters of the present invention, so as to enable any person skilled in the art to make use of said invention and sets forth the best modes contemplated by the inventor of carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide a means and method for providing database management for laparoscopic surgery.

16

The term **"item"** hereinafter refers to any identifiable thing within a field of view of an imaging device. An item can be something belonging to a body or something introduced into the body. Items also comprise things such as, for non-limiting example, shrapnel or parasites and non-physical things such as fixed points.

The term **"object"** hereinafter refers to an item naturally found within a body cavity. Non-limiting examples of an object include a blood vessel, an organ, a nerve, and a ligament, as well as an abnormality such as a lesion and a tumor.

The term **"tool"** or **"surgical tool"** hereinafter refers to an item mechanically introducible into a body cavity. Non-limiting examples of a tool include a laparoscope, a light, a suction device, a grasper, a suture material, a needle, and a swab.

The term **"surgical object"** hereinafter refers to a surgical tool, a robotic manipulator or other maneuvering system configured to manipulate a surgical tool, at least a portion of a light source, and at least a portion of an ablator.

The term **"fixed point"** hereinafter refers to a location in a surgical field which is fixed relative to a known location. The known location can be, for non-limiting example, an insertion point, a known location in or on a patient, a known location in an environment around a patient (e.g., an operating table, a hospital bed, or the walls of a room), a known location in a manipulation system, a practice dummy, or a demonstrator.

The term **"operator"** hereinafter refers to any of: a principal operator such as, but not limited to, the surgeon carrying out the main parts of the procedure, an assistant such as, but not limited to, a nurse and an observer such as, but not limited to, a senior surgeon providing instruction to or assessing a principal operator. An identifier for an operator can include, but is not limited to, a name, an ID number, a function and any combination thereof.

The term **"identifiable unit"** hereinafter refers to an identifiable purposive activity during a surgical operation, typically a minimal identifiable activity. Examples include, but are not limited to, movement of a needle and forceps to the site where a suture is to be made, making a knot in suture thread, activating fluid flow, and making an incision.

The term **"surgical task"** hereinafter refers to a connected series of at least one identifiable unit which comprises an identifiable activity. Non-limiting examples of surgical tasks that comprise more than one identifiable unit include, but are not limited to, making one suture, removing incised tissue from a surgical field, and clearing debris from a surgical field. A

17

non-limiting example of a surgical task that comprises a single identifiable unit is making an incision.

The term "**complete procedure**" hereinafter refers to a connected series of at least one surgical task which forms an independent unit. For non-limiting example, closing an incision with one or more sutures will be referred to as a complete procedure.

The term "**procedure**" or "**surgical procedure**" hereinafter refers to at least a portion of a surgical operation, with the portion of the surgical operation including at least one identifiable unit. For non-limiting example, in increasing order of complexity, a procedure can comprise tying the knot in a suture, making a single suture, or closing an incision with a series of sutures.

The term "**attribute**" hereinafter refers to a datum which is associable with a particular instance of a procedure. An attribute can be an identifier of an identifiable unit (moving a needle and grasper to a site of a suture, inserting a needle through tissue, making a tie in a knot, etc.), a surgical task (a single suture, a series of sutures to close an incision, incising, tissue removal, number of tasks previously performed, etc.), a complete procedure (tumor removal, appendectomy, etc.), an identifier of an operator (name, age, skill level, movement metric, etc.), an identifier of an operation room (location, cleaning status, size), an identifier of a patient (name, age, weight, previous procedures, health status, etc.), an identifier of a tool (type, brand, usage status, etc.), an identifier of a tool manipulation system (brand, age, usage status, time since maintenance, etc.), a time-related identifier (time of day, date, etc.) or any other datum that can differentiate a given instance of a procedure from another instance of the same procedure.

The term "**about**" hereinafter refers to a range of 25% around the quoted number.

The system disclosed herein provides means and method for database management for surgery, especially laparoscopic surgery.

In the database management system a group of surgical procedures can be selected, stratified according to attributes that correlate to a specific surgical outcome, and assigned relative weights to components based on their stratified positions. The attributes are selected from a universe of possible values. Further biases (positive or negative) can be applied at any arbitrary point or stratified position, including to individual procedures, groups of procedures or arbitrary stratification.

18

A surgical procedure, as used herein, comprises an identifiable portion of a surgical operation. This identifiable portion can be as small as a single identifiable unit, for non-limiting example, a movement of a tool to the location of a suture or activation of flow of fluid, or as large as a complete operation. Typically, however, a complete operation will not be stored. Typically, a stored procedure will be at one of three levels of complexity, with the simplest level being an identifiable unit such as, but not limited to, movement of a tool to a predetermined location such as the location of a suture or the start of an incision, execution of a single tie in a suture, a single change in a lighting level, or activation of fluid flow; the second level being a surgical task, such as, but not limited to, a single suture, a single use of fluid to clear a portion of a surgical field, or an incision; and the most complex level being a complete procedure, such as, but not limited to, a series of sutures to close an entire incision, a series of incisions to remove tissue, or a combined use of fluid and suction, perhaps with alteration of lighting, to clear a substantial portion of a surgical field.

In the prior art, typically, a relationship between attribute of a procedure and outcome was determined by experience, usually the experience of a single operator or a small pool of operators. An operator would observe outcomes of procedures in his own experience and, based on the attributes of these procedures, as he observed them, he would separate the procedures into classes. For example, one class might consist of "generally recommended procedures", those procedures which, for broad sets of attributes, generally had a good outcome. A second class might be "specific use procedures" those procedures which, for a narrow set of attributes or for only a few sets of attributes, generally had a good outcome. Another class might be "indifferent procedures", those procedures for which outcome appeared not to be correlated with attribute for known sets of attributes. Yet another class might be "not recommended procedures", those procedures which, for broad sets of attributes, generally had a bad outcome.

In the prior art, there was little control over selection of attributes, or over the size of the pool of procedures from which selection could be made. The prior art generally worked reasonably well when the choice of procedure was fairly narrow, the recorded (or remembered) attributes were fairly narrow and the differences in outcome were fairly wide.

However, there are now a very much greater number of operators, it is possible to store a much larger number of attributes, and the range of outcomes is generally narrower since procedures with the worst outcomes have been, in general weeded out.

Therefore, there is need for the present system, in which attributes can be stratified and weighted in order to establish associations between sets of attributes and outcomes.

In the present system, procedures and their attributes are searchably stored in at least one database. Attributes and can be stratified, where top-level strata comprise more general sets of attributes, and lower-level strata comprise more specific sets of attributes. It should be noted that a set of attributes can comprise a single attribute or a plurality of attributes. Lower-level attributes form child attributes of higher-level attributes.

Stratification provides controls that can: 1) ensure an unbiased sample set that is representative of the entire population; or, 2) ensure a specific bias to create an outcome that is desired but not necessarily representative of the underlying population. An example of the former is in clinical trials or experiments in the social sciences. In those cases, the experimenter is attempting to form a representative sample set against which assumptions can be varied to investigate how they affect the controlled population. An example of the latter is in risk management, where different population subsets can have little or no correlation and can have highly divergent standard deviations and highly divergent outcomes. In that case, the statistician may want to bias the sample set toward a specific subclass such as subsets that have relatively better or worse outcomes. In both cases, stratification enables the statistician to build sample sets with outcomes, based on the type of stratification model being implemented, that provide predictions which can be applied to other members of the selected subclass. In stratified sampling, the strata are formed based on members' shared attributes or characteristics. These attributes could be based on relative quantitative metrics of members of a population, such as size, average age or ethnicity of a population. In addition, an attribute can be based on a physically identifiable characteristic of an operator or patient such as color of hair, skin or eyes, right-handedness or left-handedness (especially of an operator), weight, age or body mass index of either an operator or a patient.

The system can recognize multiple types of attributes associated with an entity. As non-exclusive examples, the system can operate on classes of attributes that are: (a) relative-to-universe, or (b) intrinsic. Relative-to-universe attributes may be, for example, scoring systems or designations as common/uncommon procedures. The system can be configured to recognize multiple types of intrinsic attributes. As non-limiting examples, types of intrinsic attributes can be: syntactically structured intrinsic attributes, contextual attributes, accounting attributes, and market-based attributes. Some intrinsic attributes may also be considered to be absolute. An example accounting attribute may be cost of a procedure and an example

20

market-based attribute may be popularity among a class of physician. Examples of contextual attributes may include: (a) location attributes (e.g., attributes of the operating room), (b) attributes related to an operator (e.g., "experienced" vs. "inexperienced", (c) attributes related to a patient (e.g., "young" vs. "old"), (d) attributes related to tools (e.g., shape of a tool), and (e) attributes related to procedures (e.g., automatic vs. manual). The system can recognize any combination of different types of attributes.

Any combination of multiple attributes can be formed as a compound attribute. Any combination of intrinsic attributes can be considered to be a compound intrinsic attribute while any combination of relative attributes or intrinsic and relative attributes together can be formed as a compound relative attribute. Compound attributes can be defined as a new single attribute.

In some cases, attributes can be defined to include attributes relating to the patient, such as the patient's health status, and correspondingly exclude attributes of the procedure itself. For those embodiments, the system can be configured to define attributes so as to specifically exclude attributes relating to: the operating room, the operator, the tools, or procedures in the operation, or the degree of automation of the procedure. In those configurations, those excluded attributes are not considered to be attributes because the included attributes relate to the patient, not the procedure.

Similarly, attributes can be defined to include attributes relating to the operator, while excluding attributes related to the patient, the tools, or the operating room. In such embodiments, tools or degree of automation would only be considered attributes if specifically selected by the operator, whereupon they would be treated as attributes of the operator.

In some embodiments, relative-to-universe attributes can be defined to include qualities based on any of: a rating system; a scoring system that compares entities at a point in time and then groups the entities by their relative scores; or any system of identification, through any type of scoring system, that would give the same entity, a different identification value at a different time based its score; and ranking systems. In these systems, the same entity or the same group of entities can be assigned a different value at a different point in time because these systems are point-in-time measurements that group entities based on a measurement at a given point in time.

A stratified composite unit is a stratified organization for procedures comprising: 1) a parent

21

group that is defined by one or more attributes where all members of the parent group have in common the attributes used to define the parent group; and 2) at least two sub-groups of the parent group, which may be considered to be children of the parent group and/or siblings of each other. All members of a sub-group have in common the attributes used to define the sub-group. Additionally, all members of the sub-group have in common the attributes used to define the parent group of the sub-group. Any stratified composite units and sub-units in a stratified composite unit can include an arbitrary number of other sub-units that follow the rules of its parent unit or sub-unit. In some cases, a stratified composite unit may be comprised of only a parent group and two sub-units. In other cases, a stratified composite unit may be comprised of as many parts as the size and diversity of the original composite unit parent will support.

By stratifying the database, the procedures or groups of procedures can be selected for varying user-defined criteria. For non-limiting example, the criteria can be safety and class of patient. A non-limiting example is that the likelihood is high that certain outcomes are avoided for diabetic patients. In another non-limiting example, a criterion can be success, where success is defined as successful or partly-successful outcomes, class of operator, and class of a second operator. For non-limiting example, selection can be for procedures likely to be successful for less-experienced surgeons when no experienced surgeon is present.

Procedures are defined as at least a portion of a surgical operation, where a procedure can be an identifiable task, a surgical task, a complete procedure and any combination thereof. The procedure, once identified, is stored in a database. Identification of a procedure can be manual, semi-automatic, automatic and any combination thereof, and can take place in real time, off-line and any combination thereof.

As described hereinbelow, a stored procedure will typically contain a video clip or other visual recording of at least part, and preferably substantially all, of the procedure. Preferably, it will also include identifying data ("attributes") and identifying tags related to the identifying data, so that each stored procedure is classifiable and selectable based on its attributes.

Attributes can be entered into a database manually, semi-automatically or automatically, as can the video of the procedure and its start point, end point and critical points. Entering of attributes can be real-time, off line, and any combination thereof.

The system can comprise a number of functions, which will be discussed in more detail hereinbelow. These functions can include one or more of, but are not limited to:

- An advanced artificial intelligence (AI) system and/or information from at least one sensor, where the AI system is capable of analyzing a scene in a field of view (FOV) and, from the analysis (and possibly from other provided information) forming an understanding of what is occurring. For non-limiting example, analysis of the FOV can indicate that a surgeon is performing suturing. A sensor can be internal (within the surgical field), external, and any combination thereof.

- Image processing can also be used to identify body structures such as nerves, ligaments and blood vessels and to distinguish between arteries and veins. From blood movement, the heartbeat can be identified, so that the pulse rate can be determined and, from changes in the heartbeat and/or the pulse rate, adverse events can be determined. Adverse events can include, but are not limited to, cardiac events; increases in blood pressure; decreases in blood pressure, which can indicate bleeding or onset of shock; and any combination thereof.

- Augmented reality can be used to enhance a displayed image. This can include a marker, a label, a registered image from another modality (such as, but not limited to, MRI), a warning, advice, a recommendation, and any combination thereof. A marker can indicate a critical point or a size. For non-limiting example, one or more points of interest (the tip of a tool, an organ, a location in space) can be selected and the system can display the actual distance between the two marked points. A label can include, but is not limited to, an object to be avoided such as, but not limited to, an organ, a nerve a blood vessel, a suspect lesion or other object to be investigated or approached, and any combination thereof.

   A displayed image, of an FOV or from another modality, can be a 2D image, a 3D image and any combination thereof.

   An image, of an FOV or from another modality, can be a panoramic image, it can be limited to a specific area and any combination thereof.

- Fixed points in the surgical field can also be identified and marked. Marked fixed points can identify critical points for extraction of procedures. They can also be used to assist an operator, for example so that a surgical object such as an endoscope or other surgical tool can later be directed to return to a selected fixed point. Other uses

23

of fixed points include finding a preferred path between two or more fixed points. These fixed points can mark, for non-limiting example, a beginning and end of a suture, either for an autonomic suturing procedure or as an indication of a path for an operator to follow during a manual suturing procedure. The path can mark the line of an incision, which can take into account the contours of an organ being sutured, possible movement of the organ, and ensuring that the suturing tool or tools can bypass any obstacles in the path.

In preferred embodiments, a procedure can be stored, preferably as a function of time and preferably with at least one identifying tag to enhance and simplify searching at least one database of stored procedures, so that the procedure is searchably available for observation and/or analysis. A procedure can be an identifiable unit, a surgical task, a complete procedure and any combination thereof.

The procedure can include an image, an overlay, a label, augmented reality, information from another imaging modality, a fixed point, position data, orientation data, and any combination thereof. The position and orientation data can be a 2D position, for non-limiting example, in the plane of the FOV, of at least a portion of at least one item; a 2D orientation, for non-limiting example, in the plane of the FOV, of at least a portion of at least one item; a 3D position of at least a portion of at least one item; a 3D orientation of at least a portion of at least one item; a 2D projection of a 3D position of at least a portion of at least one item; a velocity of at least a portion of at least one item; an acceleration of at least a portion of at least one item; an angle of at least a portion of at least one item; a state of at least a portion of at least one item; as well as a first parameter, a second parameter, and any combination thereof.

A procedure can also searchably include an identifier for an operator, a location for the procedure, the type of procedure, the type of surgical operation, a characteristic of the location, an identifier of an item in the surgical environment, a medical history of the patient, a characteristic of the patient, an outcome of a procedure and any combination thereof.

Any of the information above can be used as an identifier. For non-limiting example, identifying tags can be used to determine the quality of outcome for appendectomies performed by Dr. Jones.

Advanced artificial intelligence (AI) system

The AI system is capable of analyzing a scene in an FOV and, from the analysis (and

24

possibly from other provided information) forming an understanding of what is occurring.

In some embodiments, the system identifies surgical tools in the working area; in preferred embodiments, objects including, but not limited to, organs, lesions, bleeding and other items related to the patient can be identified. In some embodiments, items related to the operation including, but not limited to, tools, smoke, flowing fluid, and the quality of the lighting (level, dark spots, obscured spots, etc.) can be identified.

Identification of tools is preferably by means of image recognition, it can be by means of tags associated with the tools, and any combination thereof. Tags can comprise color-coding or other mechanical labels, electronic coding, such as, but not limited to radiofrequency signals, and any combination thereof. Radiofrequency signals can be the same for the different tools or they can differ for at least one tool. The system can recognize a labelled tool from its mechanical or radiofrequency coding, a tool can be identified by an operator, and any combination thereof.

In preferred embodiments, the system identifies a procedure by means of analysis of at least one image, where the analysis can include, but is not limited to, organ position, tool movement, tool position, tool orientation and any combination thereof.

In some embodiments, commands can be entered via a touchscreen and a procedure can be identified by means of the entered command. The touchscreen can be in a monitor, a tablet, a phone, or any other device comprising a touchscreen and configured to communicate with the system.

In some embodiments, a command can be entered and a procedure can be identified from a gesture pattern consisting of at least one body movement and can respond appropriately to the gesture pattern. The body movement can be an arm movement, a hand movement, an eye movement, a head movement, a torso movement and any combination thereof. The gesture pattern can be detected within the FOV, outside the FOV, and any combination thereof. A gesture pattern can be identifiable from analysis of at least one image of a FOV, from analysis of at least one signal from at least one sensor, and any combination thereof.

The gesture pattern can be related to a surgical activity (e.g., recognizing a gesture pattern related to suturing), not related to a surgical activity (e.g., crossing tools to indicate that the system is to acquire an image of the FOV), and any combination thereof. A response to a gesture pattern can be a fixed response (e.g., taking a picture, zooming in or out, identifying a start of a procedure, identifying an end of a procedure) or it can be a flexible response (e.g.,

25

adjusting zoom and location of an endoscope to provide optimum viewing for a suturing procedure, automatically identifying start, end and critical points in a procedure from a series of gesture patterns).

In some embodiments, the AI-based software can have full connectivity with a member of a group consisting of: digital documentation, PACS, navigation, other health IT systems, and any combination thereof.

In some embodiments, the AI-based software can empower "big data" systems with analytic capabilities.

In some embodiments, the AI-based software can support advanced instruments and imaging for a range of surgical procedures.

At least the database and preferably both the tracking subsystem and the database are in communication with at least one processor configured to analyze the spatiotemporal 3-dimensional surgical database. The result of the analysis can be determining a path for movement of at least one tool, determining a path start point, determining a path end point, identifying a start of a procedure, identifying a start of a feature, identifying an end of a procedure, identifying an end of a feature, and any combination thereof.

A non-limiting example of a procedure comprising a number of surgical tasks, with each surgical task comprising at least one identifiable unit is suturing an incision, where the suturing process comprises a plurality of sutures. In this example, the process of suturing the incision comprises a number of surgical tasks, each comprising at least one identifiable unit. Movement of the tools to the site of the first suture could be treated as a first identifiable unit. Each suture, comprising several identifiable units, would be a surgical task; each movement of the tools from a completed suture to a next suture would comprise another identifiable task, and movement of the tools away from last suture could constitute the final identifiable task. Therefore, in this example, if the incision is closed with 4 sutures, the procedure could comprise 1 (move-to-first-suture-site) + 4 (suture) +3 (move between sutures) + 1 (move away from last suture) = 9 subprocedures. It would also comprise 8 critical points, namely 2 critical points for each suture. During the first surgical task, a single identifiable unit, the tools would be moved to the first critical point; during the second surgical task, the tools would be moved from the first critical point through the set of identifiable tasks comprising a suture to a second critical point; during the third surgical task, the tools are moved from the

26

second critical point to the third critical point, which is the first critical point of the second suture, and so on.

Similarly, a surgical task can be broken down into individual units, and critical points assigned to each of the individual units. For non-limiting example, creating a single suture can comprise several individual units, including at least some of the following: (1) inserting a needle through the tissue, (2) pulling suturing thread through the tissue, (3) grasping one end of the suturing thread with a grasper, (4) cutting one end of the thread, (5) passing one end of the thread around the other to make a first tie, (6) pulling the first tie tight, (7), passing one end of the thread around the other to make a second tie, thus forming a knot, (8) pulling the knot tight, (7) and (8) clipping short the thread ends, and (9) removing the clipped ends. In this example, the procedure of creating a suture would comprise a minimum of 18 critical points, namely, a critical point at the beginning and end of each individual unit.

Critical points can also be established at a point where there is a change in movement. For non-limiting example, movement of a tool from the location of a completed suture to the location of a next suture often involves a smooth movement upward and laterally away from both the completed suture and the tissue, followed by a downward, lateral movement to the location of the next suture. A critical point can be established at the beginning of the upward, lateral movement, at the end of the smooth movement, where the speed and direction of movement change, at the beginning of the downward, lateral movement and at the end of the downward, lateral movement, where the speed of movement again changes.

An idealized example of movement of a tool is shown in **Fig. 1**. In this example, the movement of the tool is shown by the solid line (**550**), and an idealized movement of the tool is shown by the dashed line (**560**). The dashed line is displaced downward slightly for clarity. Each critical point critical point (**580**) in the actual movement (**550**) indicates where the slope of the curve (**550**) changes.

The beginning of a procedure can be determined if at least one calculated first parameter is substantially equal to at least one stored second parameter. A beginning of a procedure can similarly be determined if at least one calculated first parameter at a time $t + \Delta t$ is substantially different from the same at least one first parameter at time t.

In the example of **Fig. 1**, the beginning of the procedure occurs when the position, speed and acceleration of the tool (**570**) are substantially the same as the stored second parameters of position, speed and acceleration (**575**).

27

The exemplary tool movement shown in **Fig. 1** can comprise a single procedure with a single beginning (**570**), a single end (**590**) and a number of critical points, or it can comprise up to 9 sub-procedures, each comprising the minimum number, 2, of critical points.

In preferred embodiments, two first parameters or a first parameter and a second parameter are deemed to be different if the difference between the two is greater than a predetermined amount. In some embodiments, the predetermined amount can be in the range of about 0.1% to about 15%. In a preferred embodiment, the predetermined amount is about 5%. The two first parameters or the first parameter and the second parameter are deemed to be substantially the same if the difference between the first parameter and the second parameter is no greater than the predetermined amount.

The exemplary tool movement shown in **Fig. 1** can comprise a single procedure with a single beginning (**570**), a single end (**590**) and a number of critical points, or it can comprise up to 9 sub-procedures, each comprising the minimum number, 2, of critical points.

A critical point can be established based on any of: 2D position of at least a portion of at least one item, 2D orientation of at least a portion of at least one item, 3D position of at least a portion of at least one item, 3D orientation of at least a portion of at least one item, 2D projection of a 3D position of at least a portion of said at least one item, movement of at least a portion of at least one said item, energy use; idle time, approach time, speed, maximum speed, speed profile, acceleration, motion smoothness, path length, distance efficiency, depth perception, transit profile, deviation on horizontal plane, deviation on vertical plane, response orientation, economy of area (EOA), economy of volume (EOV), number of movements, force range, interquartile force range, integral of the force, integral of the grasping force, integral of the Cartesian force, first derivative of the force, second derivative of the force, third derivative of the force, lighting level, amount of suction, amount of fluid flow, heating level in an ablator, amount of defogging, amount of smoke removal, activation of an item, deactivation of an item, bleeding, change in heart rate, change in blood pressure, change in color of an organ, and any combination thereof.

A critical point, including a critical point defining a beginning of a procedure or an end of a procedure can be determined if the difference between a first parameter at any given time t and the first parameter at a different time $t + \Delta t$ is greater than a predetermined value.

In some embodiments, a critical point, including a critical point defining a beginning of a procedure or an end of a procedure can be determined if the difference between a first

parameter (that of the current procedure) and a second parameter (that of the stored procedure) is less than a predetermined value. In some embodiments, the critical point is determinable when the first parameter matches a stored second parameter tagged as a critical point.

In some embodiments, a critical point, including a critical point defining a beginning of a procedure or an end of a procedure can be determined if the difference between a first parameter (that of the current procedure) and a second parameter (that of the stored procedure) is greater than a predetermined value.

At least the database and preferably both the tracking subsystem and the database are in communication with at least one processor configured to analyze the spatiotemporal 3-dimensional surgical database. The result of the analysis can be determining a path for movement of at least one tool, determining a path start point, determining a path end point, identifying a start of a procedure, identifying a start of a feature, identifying an end of a procedure, identifying an end of a feature, and any combination thereof.

In some embodiments, the system can provide analytics, for non–limiting example, at least one of:

- An objective skills assessment system for evaluating the quality of a procedure, either as part of a training system or as part of an evaluation of an operator. A procedure, either in real time or recorded, can be observed, to determine the skill level of the operator. Recorded procedures can be compared with outcomes, so as to determine which variants of a procedure have the better outcomes, thereby improving training and skill levels. [i.e., Global Operative Assessment of Laparoscopic Skills (GOALS)]

- In real time, feedback can be given to an operator, either from an intelligent system or from a human advisor (Gesture/Task Classification). The advisor, whether human or an intelligent system, can be local or remote.

- Risk assessments can be performed, in order to reduce risk and/or, based on video data, to estimate the risk of possible liability claims.

- Information can be aggregated from a number of videos of robotic and/or laparoscopic procedures. These data can be used for:
  o Benchmarking – determining best practice.
  o Training effectivity – showing examples of good practice vs. bad practice.

29

o Skills progress during training – determining improvements in practice over time and identifying areas where progress is not adequate.

o Standardization – ensuring that best-practice regimes are followed.

o Repeatability – ensuring that best practice regimes are consistently achieved.

* Records can comprise identifiable units, surgical tasks, complete procedures, and any combination thereof, preferably in 3D.

* A record will typically comprise pre-procedure data, intra-procedure data, and post procedure data, as described hereinbelow.

Preferably, all of the data in the record are tagged so as to be searchable, so that records can be searched and analyses such as, but not limited to, statistical analyses can be made for stored records.

Preferably, a record will include a plurality of images forming a 3D video of at least part of the procedure of the record. Preferably, substantially all of the procedure will be included in the video. Preferably, a video or other visual portion of a record can be edited so that short clips can be shown and/or stored. This can be useful to highlight good practice, to indicate areas of suboptimal practice, to enhance searchability and any combination thereof.

* Stored records can become part of "big data" analyses of any combination of the above, for individual operators, for individual patients, for groups of operators, for groups of patients, and for the hospital or medical center as a whole.

A pre-procedure datum can include, but is not limited to, an attribute such as a patient's name or other identifier; a patient's medical history; number of previous similar procedures carried out by an operator; a cleaning status of an operating room (such as, but not limited to, time and date of last cleaning, cleaning procedure and cleaning materials); a start time for the operation; any of the general data described hereinbelow, preferably including name, duration, and time between procedures for each procedure previous to the procedure of the record; and any combination thereof.

An intra-procedure datum can include any general datum described hereinbelow, as well as time between beginning of an operation and start of a procedure, time between end of a previous procedure and start of a procedure, time until the end of an operation, and any combination thereof.

A post-procedure datum can include, but is not limited to, an outcome of the procedure or of

the operation as a whole, length of hospital stay for the patient, a readmission for the patient, subsequent medical treatment of the patient, subsequent procedures in the operation, the number of subsequent similar procedures carried out by at least one of the operators, and any combination thereof.

Records, including any of pre-procedure data, intra-procedure data, and post-procedure data can include an attribute of the procedure such as: an image of at least a portion of a surgical field, preferably in 3D, a name or other identifier of an operator, a rating (such as, but not limited to) a GOALS score for an operator, a physical characteristic of the patient, an identifier of an operating room, a physical characteristic of the operating room (e.g., temperature, humidity, type of lighting), a name or other identifier of a procedure, a type of procedure, time of a beginning of a procedure, time of an intermediate point of a procedure, time of an end point of a procedure, duration of a procedure, time between end of a procedure and beginning of a next procedure, time of creation of a critical point, location of a critical point, time of creation of a fixed point, location of a fixed point, a medication or medical device (such as, but not limited to, a heating blanket, a pump or a catheter), an identifier of a surgical object, a type of surgical object, a total number used for a surgical object, a cleaning status for a surgical object, a comment by an operator, a parameter, a metric, occurrence of a malfunction, severity of malfunction, start time of malfunction, end time of malfunction, reason for start of malfunction, reason for end of malfunction, occurrence of an adverse event (such as, but not limited to, unexpected bleeding, undesirable change in blood pressure, undesirable change in heart rate, undesirable change in consciousness state, pain), a test, any other item of medical interest and any combination thereof, and can further comprise an image from another modality, an overlay, a label, a note, a comment, and any combination thereof.

An attribute of a patient, such as a physical characteristic of the patient, can include, but is not limited to, the patient's age, height, weight, body mass index, health status, medical status, a physical parameter of the patient and any combination thereof.

A physical parameter of the patient can include, but is not limited to: blood pressure, heart rate, blood gasses, blood volume, blood hemoglobin, breathing rate, breath depth, EEG, ECG, sweating, any other measureable physical data indicating a patient's condition and any combination thereof.

A medical history can comprise: an illness and its outcome, a genetic factor, including an

31

effect on the patient and a predicted effect on the patient, a medical treatment previously undergone, a medical treatment in progress, a medication used in the past, a medication in current use, an allergy, a medical condition, a psychological factor, and any combination thereof.

A medication can include, but is not limited to: an antibiotic, an anesthetic, plasma, blood, saline, coagulant, anticoagulant, an antiviral, a steroid, a blood pressure treatment, and any combination thereof.

A medical treatment can include, but is not limited to, a medication, a medical device, a course of exercise, physiotherapy, and any combination thereof.

A medical condition is a chronic physical syndrome in a patient. A medical condition can be curable or incurable, treatable or untreatable. Non-limiting examples of a medical condition include: diabetes, asthma, lupus, a heart condition, an ulcer, scabies and psoriasis. An illness is a medical condition that is self-limiting, such as, but not limited to, measles, influenza, or warts. There are obviously overlaps between medical conditions and illnesses. For example, only 2/3 of untreated warts disappear within two years; a long-lasting wart could be classified either as a medical condition or as an illness.

A test can be a test of a patient's chemistry, such as, but not limited to, a blood test, an image such as, but not limited to, MRI, X-ray, PET, fluorography, fluoroscopy, a blood pressure measurement, an EEG, and ECG, and any combination thereof.

A note or comment can include, but is not limited to: a procedure that was were performed, a sequence of procedures performed, how each procedure was executed, why each procedure was chosen, an assessment of a patient, a prediction, an item not in a medical history (for non-limiting example, if an unexpected medical condition is discovered during the course of a procedure) and any combination thereof.

A record can also include a method of executing a procedure, for example, if a new method is used.

An outcome of a procedure can include, but is not limited to: a successful aspect, a partially successful aspect, a partial failure in an aspect, a complete failure in an aspect, and any combination thereof.

An aspect can include, but is not limited to: a complication during the procedure, a complication during another portion of the operation, a component where recovery was

32

smooth and uncomplicated, the rate of recovery, the rate of recovery from a complication, a long-term effect of a procedure, a long-term effect of a complication, a long-term effect of a complication, amount of bleeding during said procedure, amount of bleeding during another portion of the same operation, return of an abnormality, speed of healing, an adhesion, patient discomfort and any combination thereof.

The outcome of a procedure can have more than one aspect. Non-limiting examples of a successful aspect include: minimal bleeding after completion of a procedure, minimal bleeding during a procedure, no return of the abnormality, rapid healing, no adhesions and minimal patient discomfort. Non-limiting examples of a partially successful aspect include: some bleeding after completion of a procedure, some bleeding during a procedure, minimal return of the abnormality, moderately rapid healing, a few small adhesions and some patient discomfort. Non-limiting examples of a partial failure in an aspect include: significant bleeding after completion of a procedure, significant bleeding during a procedure, return of a significant amount of the abnormality, slow healing, significant adhesions and significant patient discomfort. Non-limiting examples of complete failure in an aspect include: serious or life-threatening bleeding after completion of a procedure, serious or life-threatening bleeding during a procedure, rapid return of the abnormality, very slow healing or failure to heal, serious adhesions and great patient discomfort.

It is clear that an outcome can include any combination of aspects. For non-limiting example, a procedure could have minimal bleeding, both during and after the procedure (successful) with a few adhesions (partial success), but significant patient discomfort (partial failure) and rapid return of the abnormality (complete failure).

Tagging, supplying an identifier, can be manual, semi-automatic, automatic and any combination thereof. For non-limiting example, typically, names or other identifiers of operators will be entered manually, although automatic entry is possible, for non-limiting example, by reading an RFID tag worn by an operator. In another non-limiting example, a critical point or a fixed point can be tagged manually, semi-automatically, or automatically. For non-limiting example, manual tagging can be by an operator indicating, by word, by gesture, or by touching a touchscreen, that a given point, such as the current position of a tool, is to be tagged as a critical point or as a fixed point. For non-limiting example, automatic tagging can occur when a system identifies a point as a critical point or a fixed point. For non-limiting example, in semi-automatic tagging, the system automatically identifies a point as a possible critical point or fixed point and provides an indication of the

33

possible existence of a critical point or fixed point. The operator then manually confirms (or denies) the existence of the critical point or fixed point.

Preferably, tagging during a procedure is automatic and is done in real time so that, for non-limiting example, the start, critical points and end of a procedure are determined automatically and in real time.

In a big data analysis, the tags can be used to enable rapid and accurate searching of recorded procedures, for non-limiting example, to identify comparable procedures, for comparing a current procedure to previously recorded procedures, for training purposes, for assessment purposes, and any combination thereof.

For non-limiting example, the outcome is known for stored procedures, so a comparable procedure with a best outcome can be shown, either during a procedure or afterward, for example on a pop-up in a display, as a separate display, or as an augmented reality display to provide a comparison between a procedure as executed and best practice.

The stored histories can be tagged with identifiers, to enhance and simplify big data analyses such as, but not limited to, searching libraries of stored procedures, identifying similar procedures, identifying similarities in procedures, determining more and less optimal variants of procedures, and any combination thereof. For non-limiting example, a procedure can be tagged with the names of members of the operating team, with the type(s) of procedure carried out, and with characteristics of the patient. For non-limiting example, this could be used to determine the quality of outcome for appendectomies performed by Dr. Jones.

It should be emphasized that it is within the scope of the present invention wherein identification of a position, orientation or other metric of a surgical object, or determination of a critical point can include additional information. Typically, this additional information can be obtained from a sensor such as an accelerometer, a motion sensor, an IMU, a sensor wearable by an operator, a sensor attachable to a surgical object, an RFID tag attachable to a surgical object, an ultrasound sensor, an infrared sensor, a gyroscope, a tachometer, a shaft encoder, a rotary encoder, a strain gauge and any combination thereof, or from at least one image from another modality such as: MRI, CT, ultrasound, X-ray, fluorography image, fluoroscopy, molecular imaging, scintigraphy, SPECT, positron emission tomography (PET), other types of tomography, elastography, tactile imaging, photoacoustic imaging, thermography, functional near-infrared spectroscopy (FNIR) and any combination thereof.

During analyses, multiple records, including pre-procedure records, intra-procedure records and post-procedure records, can be analyzed to emphasize patterns in the data. Any of the

34

stored data, as described hereinabove, can be used for a comparison. For non-limiting example, a comparison could be made using the attributes of operator handedness (a physical characteristic of the operator), operating room and occurrence of the complication of adhesions. The result of the analysis could be that an appendectomy by a left-handed principal operator should be scheduled for a room other than Operating Room 5. (The analysis would, of course, be completely silent on why Operating Room 5 is unsuited to appendectomies by left-handed surgeons.)

Analysis can include, but is not limited to:

- synchronizing at least two records, where the records can be synchronized by: time since the beginning of a procedure, time since the beginning of an operation, length of a procedure, length of an operation, time until the end of a procedure, time until the end of an operation, type of procedure, type of operation, time between the beginning of an operation and the onset of a complication, time between the beginning of a procedure and the onset of a complication, time from the onset of a complication to the beginning of a procedure, time from the onset of a complication to the beginning of an operation, operator, patient, operator characteristic, as disclosed above, patient physical characteristic, as disclosed above, and any combination thereof;

- analyzing each of the records, to determine, for non-limiting example, attributes of the operator, attributes of the patient, attributes of the operating room, attributes of an assistant, outcome of a procedure, outcome of an operation, length of procedure, length of operation, length of time until the onset of a complication, and any combination thereof;

- selecting a subset of the records based upon at least one attribute in common between the records;

- determining whether there exists at least one common factor in at least one outcome of the procedure or procedures between the records with the common attribute; and

- generating a prediction as to at least one future outcome of that procedure or portion thereof or those procedures that have the at least one attribute in common.

The results of an analysis can include, for non-limiting example, for a given set of attributes, the likelihood of a complication, the type of complication which is likely, when a complication is likely to occur, the likelihood of a plurality of complications, the likelihood of a series of complications, likely recovery time, and any combination thereof.

A possible result of an analysis can be, but is not limited to, at least one procedure that, for patients with a given set of physical characteristics, the set comprising at least one physical characteristic, is the least likely to result in any complications. A linkage can be established

35

between a procedure, a given set of physical characteristics, the set comprising at least one physical characteristic, and at least one procedure which is the least likely to result in at least one complication or at least one specific complication. Similarly, a linkage can be established between a procedure, a given set of physical characteristics, the set comprising at least one physical characteristic, and at least one procedure which is likely to result in at least one of: the fewest complications, the fewest complications of a given type, or the fewest complications in a specified set of complications.

A non-limiting example of possible complications for a patient with a set of physical characteristics when the patient undergoes a surgical procedure is: The set of attributes is females over the age of menopause who are overweight but not obese and who, before menopause, had had heavy bleeding during menstruation for at least 10 years. The surgical procedure is removal of fibroid tumors. Likely complications could include: heavy bleeding during the procedure, perforation of the uterus during the procedure, heavy bleeding after the procedure, pain during sex after recovery, adhesions in the uterus, and adhesions between the uterus and other abdominal organs. Procedures that are least likely to result in heavy bleeding could include: ablation rather than excision of the fibroid tumors, ablation of the excision site after tumor removal, or use of an anticoagulant after excision. Tissue grafting or seeding of prepared tissue might be recommended to avoid contractures and thereby avoid pain during sex. Avoidance of heavy lifting can be recommended to avoid adhesions. Gentle exercise, might be prescribed, possibly including specific exercises.

In some embodiments, the system can interface with other tools, such as, but not limited to, suction devices, lighting, ablators, and fluid suppliers. For non-limiting example, if the system determines that there is effusion of blood from an incision, it could command that a suction device be brought into the region of blood effusion and that suction be applied to the blood.

Image processing

Preferably, at least one patient object, such as at least a portion of at least one organ, suspect location, lesion, vein, artery, cyst, cystic duct, bile duct, bowel and any combination thereof can be identified by means of image analysis. In some variants of these embodiments, the patient object can be automatically classified. In some variants of these embodiments, the patient object can be identified manually, for example, by an operator pointing at or touching an image of the patient object.

In some embodiments, automatic detection of a suspect location, lesion and any combination thereof results in: an alert being automatically provided that a suspect location, lesion and any

combination thereof has been found; a label being automatically attached to the suspect location, lesion and any combination thereof; and any combination thereof. The alert can be a voice message, a text message, a pop-up, a symbol, and any combination thereof. The label can be an identifier for the suspect location, lesion and any combination thereof; a classification of the suspect location, lesion and any combination thereof; and any combination thereof. In some embodiments, upon automatic detection of at event, a suggestion can be provided. The event can be start of a procedure, completion of a procedure, or an occurrence during a procedure. The event can be correlatable with an attribute of the procedure. For non-limiting example, if it is detected that a suture has been completed, a suggestion can be provided that a next suture be carried out. For non-limiting example, if it is detected that a suture is to be made for an obese patient, a suggestion can be provided as to the type of suture, so that a suture appropriate for an obese patient be used, or, upon detection of completion of a first suture, a suggestion can be made of a distance between sutures, so that the distance between sutures is appropriate for an obese patient.

In some embodiments, upon automatic detection of an event, an instruction can be provided. The event can be start of a procedure, completion of a procedure, or an occurrence during a procedure. For non-limiting example, if it is detected that a lighting level is low, an instruction can be provided to increase the lighting level, or an instruction can be provided to move a light to illuminate a dark area.

A lesion, a suspect location, and any combination thereof can be identified, for non-limiting example, using data stored in a database, or, after a first identification of a suspicious area by an operator, by identifying a subsequent suspect location, lesion and any combination thereof by comparison to the first one.

Fig. 2 shows an interior of a uterus with endometriosis lesions (110) highlighted.

In some embodiments, missed tools can be identified and at least one of the operator alerted to the missing tool or the missing tool labelled.

An image captured by the imaging device can be a 2D image, a 3D image, a panoramic image, a high resolution image, a 3D image reconstructed from at least one 2D image, a 3D stereo image (typically constructed from at least two 2D images, one for each eye), and any combination thereof.

Additional information can be obtained from an accelerometer, a motion sensor, an IMU, a sensor wearable by an operator, a sensor attachable to a surgical object, an RFID tag

attachable to a surgical object, an ultrasound sensor, an infrared sensor, a CT image, an MRI image, and X-ray image, a gyro-meter, tachometer, shaft encoder, rotary encoder, strain gauge and any combination thereof.

A sensor can be an internal or external integrated sensor. A non-limiting example of an integrated sensor is an inertial measurement unit (IMU). An IMU can incorporate multiple sensors, such accelerometers, gyroscopes, and magnetometers, to track the orientation, position, or velocity of a surgical object. An IMU can be relatively small and be designed to transmit data wirelessly. However, these devices experience increasing error over time (especially in position), and some of the sensors may be sensitive to interference from other devices in an operating room.

In some embodiments, one IMU can be mounted internally, in conjunction with a tool such as a laparoscope, with a second IMU mounted on a base unit for the device used to control positioning of the tool. This improves the robustness of the determination of the position, orientation and movement of the tool.

The sensor can be in mechanical communication with a surgical object, in electrical communication, and any combination thereof. The electrical communication can be wired communication, wireless communication and any combination thereof.

The state of an item such as a surgical tool includes general properties such as its position, orientation, speed, and acceleration. It can also include tool-specific properties, such as location or relative location of a movable part of a surgical tool, such as, for non-limiting example, the locations of the faces of a gripper relative to each other (e.g., whether a gripper is open or closed). There are various mechanisms by which these properties can be determined. Some of these mechanisms are described hereinbelow.

The state of other items can include a lighting level, an amount of suction, an amount of fluid flow, a heating level in an ablator, an amount of defogging, an amount of smoke removal and any combination thereof.

Image-based tracking can identify the properties of tools, including tools attached to a robotic arm, tools controlled directly by an operator and static tools in the surgical environment. It can also track items in the environment besides the surgical tools.

The tracking subsystem can comprise at least one sensor (such as, for non-limiting example, a motion sensor) on at least one tool, at least one sensor (such as, for non-limiting example, an RFID tag) in communication with at least one tool, at least one processor to determine

38

movement of at least one tool by determining change in position of at least one robot arm and any combination thereof.

There are many techniques for tracking items in a camera image. Items of interest can be tracked by identifying inherent, distinguishing characteristics of a surgical object. For example, this could include the shape, color, texture, and movement of a surgical object. To enhance the tracking, a surgical object can be modified to make it more recognizable in a camera image. For instance, at least one colored marker or at least one tracking pattern can be affixed to a surgical tool to aid in detection by a computer algorithm or to aid in providing an instruction to an operator.

Other tracking technologies include sensor-based technologies. There are many different types of sensors that can be used to track an item. Optical techniques, such as an infrared tracking system, can locate a surgcial object that has at least one infrared marker attached to it. The surgical object being tracked does not require any wires, but the line of sight from the tracking system to a tracked surgical object must be kept clear.

A magnetic tracking system can also be used to locate surgical objects or other objects of interest. At least one magnetic sensors can be affixed to a surgical object, and a magnetic transmitter emits a field that a magnetic sensor can detect. Unfortunately, the presence of objects in the operating room that affect or are affected by magnetic fields can make this technology infeasible.

In some embodiments of autonomic robotic control of surgical tools, two IMUs are used for dead reckoning, one at the base, the proximal end, of a flexible robotic arm and one at or near the distal end of the flexible robotic arm. The distal IMU can be mounted to a laparoscope or other surgical tool or it can be mounted on the distal end of the flexible robotic arm itself. In some embodiments, other IMUs are provided at intermediate positions along the flexible robotic arm. **Fig. 3A** schematically indicates an embodiment of a flexible robotic arm (**100**) which includes proximal and distal IMUs (**110**). **Fig. 3B** schematically indicates an embodiment of a flexible robotic arm (**100**) with intermediate IMUs (**115**) in addition to the proximal and distal IMUs (**110**).

From the image analysis, in some embodiments, physiological parameters of individuals can be observed in real time via video stream from in vivo information. Physiological parameters can include pulse rate, pulse intensity, quality of oxygenation of the blood, quality of oxygenation of tissue, turgidity of tissue, and any combination thereof. Changes in any of the

39

above can also be determined and enhanced, suppressed, or the operator alerted to a change.

For non-limiting example, from analysis of the reflected light from within operating field, it is possible to identify information about physiological fluctuations of the patient which are too small to be seen by the human eye.

Phase differences, pressure differences or both can be used to differentiate veins from arteries. Arteries will show greater pressure changes than veins, and pressure pulses will appear sooner in arteries than in veins (arteries lead in phase, veins lag). The position $x(t)$ of the surface of a blood vessel at time t is given by

$$x(t) = x_0 + A \sin(2\pi f t + \phi)$$

where x_0 is the position at time $t=0$, A is the amplitude of the movement, f is the frequency of the pulsation, and ϕ is the phase of the pulsation at the point x on the blood vessel. A vein, will, in general, be distinguishable from an artery by having a smaller amplitude A and a larger phase ϕ.

In an exemplary embodiment, position, orientation, velocity, acceleration, motion smoothness, and force applied by the tool can be accurately measured, thereby enabling measurement of and assessment of movement metrics such as those, for non-limiting example, listed in Table I.

In embodiments where the motion of at least one tool is tracked, Table I gives a non-limiting example of metrics which can be measured and stored. From such metrics, procedure start points, critical points and end points, can be determined Metrics can also be used to assess performance, and to identify malfunctions, as discussed below. In a given embodiment, any combination of metrics can be used.

Table I Motion-based Metrics

Parameter (Metric)	Description
Time related	
Time	Total time taken to perform a procedure
Idle time	Percentage of time where the surgical object is considered to be non-moving
Approach time	Time taken to reach the target point
Speed	Rate of change of the i surgical object's position
Maximum speed	Maximum of measured speeds
Speed profile	Shape of the speed curve
Acceleration	Rate of change of the surgical object's speed
Motion smoothness	Motion analysis parameter based on the third time-derivative of position, which represents a change in acceleration
Search time	Percentage of time spent in a "search zone"
Space-related	
Path length	Length of the curve described by the tip of the surgical object while performing the task
Distance efficiency	Relationship between measured path length and shortest path. Describes the economy of movements
Depth perception	Total distance travelled by the surgical object along its axis
Transit profile	2D transit trajectory projected onto a plane
Deviation on horizontal plane and vertical plane	Deviation from the ideal course in the horizontal and vertical directions
Response orientation	Characterizes the amount of rotation about the axis of the surgical object
Economy of area (EOA)	Relationship between the maximum area occupied by the surgical object and the total path length
Economy of volume (EOV)	Relationship between the maximum volume occupied by the surgical object and the total path length
Number of movements	Number of movements made to complete a task (measured as number of zero crossings on the acceleration/time profile)

41

Force-related	
Force range	Difference between the minimum and the maximum force applied during a task
Interquartile force range	Selects the 50 % of the data closest to the median so that outliers do not have an effect on the overall metric.
Integral of the force	Provides a measure of high forces and the amount of time that forces are high.
Integral of the grasping force	Provides a measure of high forces and the amount of time that forces are high.
Integral of the Cartesian force	Provides a measure of high forces and the amount of time that forces are high.
First derivative of the force	Indicates consistency of force application.
Second derivative of the force	Indicates consistency of force application.
Third derivative of the force	Indicates smoothness of force application

Fig. 4 shows, schematically, the 3D movements, over time, of the tip of a surgical tool during a procedure. **Fig. 5A** shows the speed of the tool tip during the procedure, while **Fig. 5B** shows the acceleration of the tool tip during the procedure. The speed, acceleration and jerk for the first part of the procedure are shown in **Figs. 6A, B** and **C**, respectively. From these, the metrics of Table II can be calculated.

Table II shows exemplary means of calculating the metrics of Table I.

Metric	Units	
Time T	(s)	$T = t_f - t_0$
Idle time δ	(%)	$\dfrac{|\delta|}{T} : \delta = \left\{ t \in (0, \dots T) \, \middle| \, \sqrt{\left(\dfrac{dr_x}{dt}\right)^2 + \left(\dfrac{dr_y}{dt}\right)^2 + \left(\dfrac{dr_z}{dt}\right)^2} \leq 5 \right\}$
Speed v	(mm/s)	$v = \dfrac{1}{T} \displaystyle\int_{t=0}^{T} \sqrt{\left(\dfrac{dr_x}{dt}\right)^2 + \left(\dfrac{dr_y}{dt}\right)^2 + \left(\dfrac{dr_z}{dt}\right)^2}$
Acceleration a	(mm/s^2)	$a = \dfrac{1}{T} \displaystyle\int_{t=0}^{T} \sqrt{\left(\dfrac{d^2r_x}{dt^2}\right)^2 + \left(\dfrac{d^2r_y}{dt^2}\right)^2 + \left(\dfrac{d^2r_z}{dt^2}\right)^2}$
Motion smoothness S	(mm/s^3)	$S = \dfrac{1}{T} \displaystyle\int_{t=0}^{T} \sqrt{\left(\dfrac{d^3r_x}{dt^3}\right)^2 + \left(\dfrac{d^3r_y}{dt^3}\right)^2 + \left(\dfrac{d^3r_z}{dt^3}\right)^2}$
Normalized jerk J	(-)	$J = \sqrt{\dfrac{T^5}{2R^2} \displaystyle\int_0^T \left[\left(\dfrac{d^3r_x}{dt^3}\right)^2 + \left(\dfrac{d^3r_y}{dt^3}\right)^2 + \left(\dfrac{d^3r_z}{dt^3}\right)^2 \right] dt}$
Path length L	(mm)	$L = \displaystyle\int_{t=0}^{T} \sqrt{\left(\dfrac{dr(t)}{dt}\right)^2} \, dt$

42

Depth perception D	(mm)	$$D = \int_{t=0}^{T} \sqrt{\left\{\left(\frac{dr_y}{dt}\right)^2 + \left(\frac{dr_z}{dt}\right)^2\right\}}\, dt$$
EOA A	(-)	$$A = \frac{\sqrt{\left[\max_t r_x - \min_t r_x\right] \cdot \left[\max_t r_y - \min_t r_y\right]}}{L}$$
EOV V	(-)	$$V = \frac{\sqrt[3]{\left[\max_t r_x - \min_t r_x\right] \cdot \left[\max_t r_y - \min_t r_y\right] \cdot \left[\max_t r_z - \min_t r_z\right]}}{L}$$
First derivative of the force dF_{metric}		$$dF_{metric} = \sqrt{\frac{T}{2F_{iqr}^2}\int_0^T \left(\frac{df}{dt}\right)^2 dt}$$
Second derivative of the force d^2F_{metric}		$$d^2F_{metric} = \sqrt{\frac{T^3}{2F_{iqr}^2}\int_0^T \left(\frac{d^2f}{dt^2}\right)^2 dt}$$
Smoothness of the applied force d^3F_{metric}		$$d^3F_{metric} = \sqrt{\frac{T^5}{2F_{iqr}^2}\int_0^T \left(\frac{d^3f}{dt^3}\right)^2 dt}$$

In Table II, t_0 is the start time of the procedure, t_f is the end time, the motion has amplitude R and vector (r_x, r_y, r_z), where $R = \sqrt{r_x^2 + r_y^2 + r_z^2}$, S_{left} and S_{right} are, respectively, the time spent using the left hand and the time spent using the right hand, and f is a measured force.

Augmented reality

In some embodiments, augmented reality can be used, typically as an overlay on an image of at least part of the FOV. A grid can be provided, allowing an operator to estimate distances at a glance. Organs, lesions, veins, arteries, cysts, cystic ducts, bile ducts, bowels, tools and other items of interest can be highlighted or otherwise labelled. **Fig. 7** illustrates a label (a highlight) **(210)** applied to a bile duct.

Images from other modalities can be shown separately, superimposed on an image of the FOV, as an augmented reality image, with an image of the FOV as an augmented reality image and any combination thereof. An image from another modality can include, but is not limited to, an image generated by: MRI, CT, ultrasound, X-ray, a fluorography image, fluoroscopy, molecular imaging, scintigraphy, SPECT, positron emission tomography (PET), other types of tomography, elastography, tactile imaging, photoacoustic imaging, thermography, functional near-infrared spectroscopy (FNIR) and any combination thereof. Images from other modalities can be stored or real-time.

In some embodiments, a displayed image can be further augmented by information from at least one sensor. Such sensor information can be, but is not limited to, tool type, tool

43

identifier, tool activation state, tool activation level, tool position, tool orientation, tool speed, tool acceleration, heartbeat, heart rate, arterial blood pressure, venous blood pressure, EEG data, EKG data and any combination thereof. An item or point in space can be identified as a "fixed point" so that the system can, on command, return to a known known orientation and known zoom on a known fixed point. A fixed point can be stored in a database, can be displayed and any combination thereof.

In embodiments with a grid, preferably at least one distance marker is provided so that the operator knows the scale of the grid.

In some embodiments, the operator can touch at least one item in at least one image, preferably on a touchscreen, to label it, for distance measurement, for angle measurement, for forming a fixed point and any combination thereof. Preferably, each distance and angle measurement can be shown on the screen, more preferably, as a label between the selected points.

In some embodiments, an orientation indication can be provided, a horizon can be marked and any combination thereof. The orientation indication can be based on at least one item in a FOV such as, but not limited to, an organ, can be based on "dead reckoning", can be a direction relative to a region of interest, can be based on a position in a tool maneuvering system, can be based on a tool position determinable from a sensor signal, and any combination thereof.

Orientation can be determinable by providing a known orientation at a start of a procedure, by entering an orientation at a start of a procedure, by recognition of an orientation marker attached to a patient or to an operating table, and any combination thereof.

An orientation indication can allow an operator to remain aware of the orientation of a display view relative to a region of interest in the body, whatever the relative orientations of the body and the display view.

In preferred embodiments, an orientation marker remains within a fixed region in the display view.

A non-limiting example of an orientation marker is axes of a 3D coordinate system, with the axes labeled so that the identity of each axis is discernable at a glance. The axes are in a corner of the display view and rotate as the orientation of the display view changes.

44

Another non-limiting example of an orientation marker comprises an arrow with a fixed center, the direction of the arrow indicating a fixed (3D) direction in space. The point of the arrow will rotate around the center as the display view changes, while the color or texture of the arrow indicates whether the fixed direction is above or below the plane of the display image and the length of the arrow indicates the angle between the fixed direction and the plane of the display view.

Any means of indicating orientation known in the art can be used.

In some embodiments, at least one point in an FOV can be marked. A markable point can indicate an organ or tissue, be a location on an organ or tissue, be a location within the body not on an organ or tissue, indicate a tool or other surgical object (such as a swab) introduced by an operator, or be a location (such as a tool tip) on a tool or other surgical object.

Sets of points, such as but not limited to a set of points forming the outline of an item or the surface of an item can also be marked. A non-limiting example of an outline would be a line indicating the approximate extent of a tumor.

Marking can be by means of identifying a point in a display, which can be a 2D display or a 3D display; identifying a symbol representing an item, directing an indicator to a location by means of gestures or predetermined sounds, any other means known in the art of specifying a desired point, and any combination thereof. Identification can be by means of touching a point or item, touching an image of a point or item, pointing at a point or item, pointing at an image of a point or item and any combination thereof.

After marking, a point can be labeled; with the point indicated in an image by a virtual marker. A virtual marker can comprise any means of labeling images known in the art. Non-limiting examples of virtual markers include a predetermined geometrical shape, a predetermined word, a line encircling the image of a selected item, highlighting of the selected item (placing a patch of predetermined color or predetermined texture), and any combination thereof. Color-coding, with different colors indicating different types of virtual marker, can be used, either alone or in combination with any of the virtual markers described above.

In some embodiments, a virtual marker can indicate a selectable display view. In such embodiments, selection of a marker automatically alters the display view to the view specified by the marker. Such selectable display view markers can comprise, for non-limiting example, an outline of the selectable view, a point at the center of the selectable

45

view, a patch or different color or texture covering the selectable view, and any combination thereof.

In some embodiments, portions of the image are enhanced, typically in order to be seen or identified more easily. An object which can be enhanced can include, but is not limited to, a blood vessel, a nerve, an organ, a ligament, a bone, a muscle, a lesion a suspect location, and any combination thereof.

Enhancement can include, but is not limited to, for at least a portion of at least one image, increasing its brightness, altering its color, applying at least one color patch, applying at least one texture patch, applying a label, recoloring, and any combination thereof.

Markers can comprise a distance measurement, an angle measurement, an area measurement or a volume measurement. Two or more points can define a distance; multiple distances can be selected, both contiguous and non-contiguous. A marker can indicate a point, a distance, a path between points, a straight-line distance and any combination thereof. A numerical marker can indicate a total path length, a total straight-line distance, at least one pairwise distance, and any combination thereof.

Fixed points

Two or more points can define at least one distance. Distance can be displayed as an individual, pair-wise distance, as a total distance, and any combination thereof. A marker can indicate a point, a mark indicating the extent of distance, and any combination thereof.

Three or more points can define at least one angle. Angle size can be displayed as an individual, trio-wise angle, as a total angle, and any combination thereof. A marker can indicate a point, an edge, a mark indicating the extent of an angle, and any combination thereof.

Three or more points can also define an area; multiple areas can be defined. A marker can indicate a boundary for an area, the size of an area, a selected area, a cumulative size for selected areas, and any combination thereof.

Four or more points can define a volume; one or more volumes can be defined. A marker can indicate a volume, the size of a volume, a selected volume, the cumulative size of selected volumes, and any combination thereof.

Any combination of distance, angle, area and volume can be implemented. Any means known in the art of measuring distance, angle, area, volume known in the art can be

46

implemented. Non-limiting examples of such measurement means include the methods typically found in Computer Aided Design (CAD) systems.

Distance, angle, area and volume measurements are typically 3D measurements. In some embodiments, the distance marker can give the distance between the end points as a triple of values, typically the three distances (x, y, z) of a Euclidean coordinate system. Other typical coordinate systems include, but are not limited to, cylindrical coordinate systems (r, θ, z) and spherical coordinate systems (r, θ, φ).

At least two fixed points can indicate a preferred path. Two fixed points can mark the beginning and end of a path; additional fixed points can mark locations in the path. A path need not be a straight line. In some embodiments, a path can bypass obstacles. In some embodiments, a path can take into account non-flatness of, for example, an organ, if the path is to follow the surface of an organ. In some embodiments, a path can take into account movement such as, for non-limiting example, movement of an organ. In some embodiments, a path can take into account a desired distance between two tools at a point in a path, a desired orientation of at least one tool at at least one point in a path, and any combination thereof. Non-limiting examples include: if the path is that of a retractor, the end points of the path can define the distance between the blades of a retractor; a path can be defined so as to prevent collision between a tool and an organ; a path can be defined so as to prevent collision between two tools; a path can be defined so as to follow the contours of an organ; a path can be defined to follow contours of a lesion; and a path can be defined so as to avoid an item such as a nerve or blood vessel. A path can be stored in a database, can be displayed and any combination thereof.

In some embodiments, a path is constrained to go through fixed points marking the path; in some embodiments, a path can deviate from fixed points in order to avoid an obstacle.

In preferred embodiments of the system, sufficient depth information is provided so that the position and orientation of at least one item in the surgical field can be determined in true 3D, enabling the accurate determination of the distance between two items, the relative angle between two items, the angle between three items and any combination thereof.

The 3D position and orientations of an item can be determined using data from multiple cameras, from position sensors attached to tools, from position sensors attached to tool manipulators, from "dead reckoning" of tool positions and orientations coming from position and orientation commands to tool manipulators, for image analysis and any combination

thereof.

From the accurate determination of distance and angle in 3D, an accurate determination can be made as to whether the tool's position, orientation, speed, acceleration, smoothness of motion and other parameters are correct. It is also possible to determine if a tool is accurately following a desired path, whether a collision can occur between two items, and whether the distance between two items is small enough that one or both can be activated.

An item that can be activated or deactivated based on distance information can include, but is not limited to, an ablator, a gripper, a fluid source, a light source, a pair of scissors, and any combination thereof.

For non-limiting example, activation of an ablator is best delayed until the ablator is close to the tissue to be ablated so that heating does not occur away from the tissue to be ablated, to minimize the possibility of damage to other tissue. With 3D position information, the ablator can be automatically activated when the distance between the ablator and the tissue to be ablated is less than a predetermined distance, so that there is no unnecessary heating of fluid or tissue away from the tissue to be ablated and so that ablation is carried out efficiently.

If only 2D distance information is available, an ablator could be activated when the 2D distance was small, but the distance perpendicular to the 2D plane (upward) was still large. In this case, the operator could be ignorant of this until it was observed that the ablator was heating fluid rather than ablating tissue. An operator would then have to move the ablator downward until ablation could occur, but the operator would not have, nor could he be given, information on how far downward to move. At this point, either the ablator could be deactivated and moved until it contacted the tissue, or the ablator could be left activated until ablation began. In either case, unwanted damage to the tissue is likely.

In some embodiments, control of movement of a surgical tool or laparoscope can include a member of a group consisting of: changing arm movement and trajectory according to the FOV, changing velocity of movement according to the amount of zoom, closeness to an obstacle or stage in a procedure, and any combination thereof. Preferably, a rule-based approach will be used to determine movement or changes thereof.

In some embodiments, changes in performance can be used to identify incipient failure, to identify a need for maintenance, to correct motion until maintenance can be carried out, to improve force feedback, to improve operator stability, and any combination thereof.

48

Incipient failure can be of a tool, a motor, a bearing, another robot element and any combination thereof.

A change in performance can be uncommanded shaking or other vibration, noise, a change in sounds, a change in the smoothness of motion, a change in the quality of response, dirt on a lens, and any combination thereof. The change in quality of response can be a change in the actual speed or direction of motion following a command for a particular speed or direction of motion, a change in the response to a change in speed or direction (such as a change in a rate of change of speed or direction), and any combination thereof.

Performance, and therefore a change in performance, can be identified by image-based performance monitoring, by sensors in communication with a tool, a robot arm (manipulator), or any other part of the system, and any combination thereof. Sensors can be internal, external or any combination thereof. Sensors can be as motion sensors, temperature sensors, accelerometers, sound sensors, radiation sensors such as IR sensors, force sensors, torque sensors and any combination thereof. Sensors can be combined into a single unit, such as an Inertial Measurement Units (IMU), which typically combines at least one accelerometer and at lesat one gyroscope, and often includes at least one magnetometer. An IMU can measure and report specific force, angular rate, and, if a magnetometer is included, magnetic field. An IMU can be used to provide dead-reckoning control of a surgical object, where dead reckoning control is not provided via the processor calculating a a surgical object's position based on maneuvering commands issued by the processor. An IMU can be used to improve accuracy of dead reckoning control of a surgical object.

A fixed point can be used to determine malfunction. For non-limiting example, apparent movement of a fixed point can identify malfunction in at least one of a robotic manipulator and an endoscope. Apparent lateral movement of a fixed point during zooming is likely to indicate a malfunction in the endoscope, whereas apparent lateral movement during tracking is likely to indicate a malfunction in the maneuvering system.

A change in performance, and therefore incipient failure, can be identified if a parameter such as any of the metrics disclosed herein differs from a stored parameter by more than a predetermined amount, where the predetermined amount is in a range from about 0.1% to about 15%, preferably about 5%, a tool or a manipulator attached to the tool is identified as having a malfunction.

49

Response to a malfunction is typically based on: the type of malfunction, the size of the malfunction, the danger of the malfunction to the smooth completion of the procedure, and any combination thereof. The response can be: a warning to an operator, a correction applied to the activity of the tool or manipulator, a limit on a range of activity of the tool or manipulator, prevention of use of the tool or manipulator, and any combination thereof. Non-limiting examples of a limit on a range of activity of the tool or manipulator include: limiting to a predetermined range: the speed of the tool or manipulator, the orientation of the tool or manipulator, the position of the tool or manipulator, the acceleration of the tool or manipulator, the force exertable by the tool or manipulator, the force exertable on the tool or manipulator, and any combination thereof.

Monitoring, both of normal motion and of changes in performance can be used for safety monitoring. A change in performance related to the equipment can be flagged up and a procedure stopped or changed, or corrections applied to the movements to maintain a procedure within limits of safety. Applying a correction can be done automatically or upon request by an operator. If a correction is applied upon command, an indication will be provided to indicate that such correction is needed. The indication can be a visual signal, an audible signal, a tactile signal, and any combination thereof. In some embodiments, a warning, visual, audible, tactile and any combination thereof, can be provided when an automatic correction is applied.

The visual signal can be selected from a group consisting of a constant-color pattern, a varying-color pattern, a constant-shape pattern, a varying-shape pattern, constant-size pattern, a varying-size pattern, an arrow, a letter and any combination thereof.

The audible signal can be selected from a group consisting of a constant-pitch sound, a varying-pitch sound, a constant-loudness sound, a varying-loudness sound, a word and any combination thereof.

The tactile signal can be selected from a group consisting of a vibration, a constant-pressure signal, a varying-pressure signal, a stationary signal, a moving signal and any combination thereof.

The tactile signal can be applied to a member of a group consisting of: a head, a neck, a torso, an arm, a wrist, a hand, a finger, a leg, an ankle, a toe and any combination thereof.

Similarly, an operator's performance can be monitored and warnings can be flagged up if the operator's performance falls below a predetermined level of safety.

50

Monitoring, both of normal motion and of changes in performance can be used for safety monitoring. A change in performance related to the equipment can be flagged up and a procedure stopped or changed, or corrections applied to the movements to maintain a procedure within limits of safety. Similarly, an operator's performance can be monitored and warnings can be flagged up if the operator's performance falls below a predetermined level of safety.

In some embodiments, feedback is used to improve general robot accuracy. Feedback can be from operator movements, from image analysis (TRX & ALFX), from robot movements, and any combination thereof. Preferably, feedback enables closed-loop control of devices in the system, and enables more precise and more accurate control of robotic devices.

In some embodiments, at least one of the devices controllable by the system is bed-mounted. In preferred embodiments, this reduces the footprint of the system over the patient.

In some embodiments, the system comprises motorized control of a laparoscope. In some variants of these embodiments, the laparoscope has a wide-angle lens, preferably a high-definition lens. In some variants of these embodiments, the laparoscope is an articulated laparoscope; the system can comprise both the wide angle-lens and the articulated laparoscope. In some embodiments, with a wide-angle lens, the displayed FOV can be controlled by movement of the laparoscope, by virtual FOV control (computer control of the FOV by altering the displayed portion of the image), and any combination thereof. In some embodiments, at least one tool can be automatically tracked by the system.

In preferred embodiments, there is full automation of the control of the robot arms positioning the laparoscope or other surgical tool ("tool") in at least two degrees of freedom, and preferably in all 7 degrees of freedom.

In some embodiments, the robotic arms are snake-like robotic arms providing full control by visual servoing (adaptive control via aimage analytics). This enables closed-loop control of all DOF's and, therefore, closed loop control of locating the target. Closed loop control also enables optimization by building an adaptive kinematic model for control of the robotic arms.

In preferred embodiments, paths can be calculated in true 3D, enabling optimization of a path, and path and/or movement speed can be modified in real time, for example, to avoid obstacles, to move more slowly near items such as organs, to prevent collision between tools, and any combination thereof. Path calculation can also include use of information on the stage reached in a procedure and/or use of stored information on preferences of the operator,

51

based on stored information about the methods of a particular operator.

In embodiments with closed-loop control of robotic movement, lower cost components can be used, such as lower-cost gears, as image-based control enables the system to correct for backlash in gear trains in real time, thereby obviating the need to design systems with minimal backlash.

In preferred embodiments, the system can be in communication with other devices or systems. In some embodiments, for non-limiting example, the AI-based control software can control laparoscopes and/or other surgical tools. In some embodiments, it can be in communication with advanced imaging systems, and/or function as part of an integrated operating room.

52

CLAIMS:

1. A computer-implemented system for providing database management for laparoscopic surgery comprising:

    a. at least two records, each one of said records is of at least one procedure, each record is characterized by at least one attribute;

    b. at least one processor configured to compare each of said at least two records and to determine if there exists at least one attribute common to both of said at least two records;

    wherein, if there exists at least one said attribute common to both of said at least two records, an outcome of at least one said procedure is predictable.

2. The system of claim 1, wherein said comparison is a real-time comparison.

3. The system of claim 1, wherein said at least one procedure is selected from a group consisting of: an identifiable unit, a surgical task, a complete procedure and any combination thereof.

4. The system of claim 1, wherein said attribute is selected from a group consisting of a pre-procedure datum, an intra-procedure datum and a post-procedure datum.

5. The system of claim 4, wherein said pre-procedure datum is selected from a group consisting of: an identifier of a patient; a datum from a patient's medical history, number of said at least one procedures carried out by an operator, cleaning status of an operating room, a general datum, and any combination thereof.

6. The system of claim 5, wherein said datum from a patient's medical history is selected from a group consisting of: an illness, an outcome of an illness, a previous procedure, an outcome of a previous procedure, a genetic factor, an effect on said patient of said genetic factor, a predicted effect on said patient of said genetic factor, a medical treatment, an allergy, a medical condition, a psychological factor, and any combination thereof.

7. The system of claim 5, wherein said cleaning status of an operating room is selected from a group consisting of: time of last cleaning, date of last cleaning, cleaning procedure, cleaning material and any combination thereof.

8. The system of claim 4, wherein said intra-procedure datum is selected from a general datum.

9.   The system of claim 4, wherein said post-procedure datum is selected from a group consisting of: an outcome of a procedure, length of hospital stay for a patient, a readmission for a patient, a medical treatment for a patient, a subsequent procedure, number of subsequent procedures carried out an operator, a general datum, and any combination thereof.

10.   The system of claim 9, wherein said outcome is selected from a group consisting of: a successful aspect, a partially successful aspect, a partial failure in an aspect, a complete failure in an aspect, and any combination thereof.

11.   The system of claim 10, wherein said aspect is selected from a group consisting of: a complication during a procedure, a complication during another procedure, a component where recovery is smooth and uncomplicated, a rate of recovery from a procedure, a rate of recovery from a complication, a long-term effect of a procedure, a long-term effect of a complication, amount of bleeding during a procedure, amount of bleeding during another procedure, return of an abnormality, speed of healing, an adhesion, patient discomfort, and any combination thereof.

12.   The system of claim 9, wherein said general datum is selected from a group consisting of: an image of at least a portion of a surgical field, an identifier of an operator, a rating for an operator, a physical characteristic of a patient, a physical characteristic of an operating room, an identifier of a procedure, type of procedure, time of a beginning of a procedure, time of an intermediate point of a procedure, time of an end point of a procedure, duration of a procedure, time between end of a procedure and beginning of another procedure, time of creation of a critical point, location of a critical point, time of creation of a fixed point, location of a fixed point, a medication, a medical device, an identifier of a surgical object, a type of a surgical object, a number used for a surgical object, a cleaning status for a surgical object, a comment, a parameter, a metric, occurrence of a malfunction, severity of a malfunction, start time of a malfunction, end time of a malfunction, reason for start of a malfunction, reason for end of a malfunction, occurrence of an adverse event, a test, an image from another modality, an overlay, a label, a note, and any combination thereof.

13.   The system of claim 12, wherein said parameter is selected from a group consisting of: 2D position of at least a portion of at least one item, 2D orientation of at least a portion of at least one item, 3D position of at least a portion of at least one item, 3D orientation of at least a portion of at least one item, 2D projection of a 3D position of at least a portion of said at least one item, movement of at least a portion of at least one said

54

item, energy use; idle time, approach time, speed, maximum speed, speed profile, acceleration, motion smoothness, path length, distance efficiency, depth perception, transit profile, deviation on horizontal plane, deviation on vertical plane, response orientation, economy of area (EOA), economy of volume (EOV), number of movements, force range, interquartile force range, integral of the force, integral of the grasping force, integral of the Cartesian force, first derivative of the force, second derivative of the force, third derivative of the force, lighting level, amount of suction, amount of fluid flow, heating level in an ablator, amount of defogging, amount of smoke removal, activation of an item, deactivation of an item, bleeding, change in heart rate, change in blood pressure, change in color of an organ,

14. The system of claim 12, wherein said physical characteristic of an operating room is selected from a group consisting of: temperature, humidity, type of lighting, and any combination thereof.

15. The system of claim 12, wherein said medical device is selected from a group consisting of: a heating blanket, a pump, a catheter, and any combination thereof.

16. The system of claim 12, wherein said occurrence of an adverse event is selected from a group consisting of: unexpected bleeding, undesirable change in blood pressure, undesirable change in heart rate, undesirable change in consciousness state, pain, and any combination thereof.

17. The system of claim 12, wherein said physical characteristic of said patient is selected from a group consisting of: age, height, weight, body mass index, physical parameter of said patient, and any combination thereof.

18. The system of claim 17, wherein said physical parameter of said patient is selected from a group consisting of: health status, blood pressure, heart rate, blood gasses, blood volume, blood hemoglobin, breathing rate, breath depth, EEG, ECG, sweating, and any combination thereof,

19. The system of claim 12, wherein said medication is selected from a group consisting of: an antibiotic, an anesthetic, plasma, blood, saline, coagulant, anticoagulant, blood pressure medication, heart medication, and any combination thereof.

20. The system of claim 12, wherein said medical treatment is selected from a group consisting of: administering a medication, applying a medical device, prescribing a course of exercise, administering physiotherapy, and any combination thereof.

55

21.   The system of claim 12, wherein said test is selected from a group consisting of: a blood test, a blood pressure measurement, an EEG, and ECG, and any combination thereof.

22.   The system of claim 12, wherein said other modality is selected from a group consisting of: MRI, CT, ultrasound, X-ray, fluorography, fluoroscopy, molecular imaging, scintigraphy, SPECT, positron emission tomography (PET), other types of tomography, elastography, tactile imaging, photoacoustic imaging, thermography, functional near-infrared spectroscopy (FNIR) and any combination thereof.

23.   The system of claim 12, wherein said image from said other modality can be stored or real-time.

24.   The system of claim 12, wherein said note is selected from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

25.   The system of claim 12, wherein said comment is selected from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

26.   The system of claim 12, wherein said critical point is selected from a group consisting of: a location in said surgical field, a beginning of a procedure, an end of a procedure, an intermediate point in a procedure and any combination thereof.

27.   The system of claim 12, wherein said at least one image of at least a portion of a surgical field is selected from a group consisting of: a 2D image, a 3D image, a panoramic image, a high resolution image, a 3D image reconstructed from at least one 2D image, a 3D stereo image and any combination thereof.

28.   The system of claim 12, wherein said second modality image is selected from a group consisting of: a 2D image, a 3D image, a panoramic image, a high resolution image, a 3D image reconstructed from at least one 2D image, a 3D stereo image and any combination thereof.

29.   The system of claim 1, wherein at least one said attribute in at least one of said at least two records is a function of time.

30.   The system of claim 29, wherein said comparing comprises comparing as a function of time at least one parameter, said at least one parameter being in both said at least two records.

31.   The system of claim 29, wherein said at least one critical point is identifiable from a comparison selected from a group consisting of: a comparison between at least one first parameter at time t and at least one first parameter at time $t + \Delta t$, and a comparison between at least one first parameter at time t and at least one second parameter at time t.

32.   The system of claim 29, wherein said at least one critical point is identifiable from a comparison of a plurality of consecutive said at least one first parameters to a plurality of consecutive said at least one second parameters.

33.   The system of claim 29, wherein said comparison is made by determining existence of a difference between a member of a group consisting of said at least one first parameter at time t and said at least one first parameter at time $t + \Delta t$, said at least one first parameter at time t and said at least one second parameter at time t, and any combination thereof.

34.   The system of claim 29, wherein said difference is detectable for a member of a group consisting of: said at least one first parameter at time t differs from said at least one first parameter at time $t + \Delta t$ by an amount greater than a predetermined value, said at least one first parameter at time t differs from said at least one second parameter at time t by an amount greater than a predetermined value, and any combination thereof.

35.   The system of claim 34, wherein said predetermined value is in a range of about 0.1% to about 15%.

36.   The system of claim 34, wherein said predetermined value is about 5%.

37.   The system of claim 1, wherein said system is in communication with a system for controlling laparoscopic surgery.

38.   The system of claim 1, wherein a searchable tag is providable for at least one said attribute.

39.   The system of claim 38, wherein said searchable tag is providable in a manner selected from a group consisting of manually, semi-automatically, automatically and any combination thereof.

40.   The system of claim 1, additionally comprising at least one sensor configured to determine at least one said attribute.

41.   The system of claim 40, wherein said at least one sensor is selected from a group consisting of: an electromagnetic sensor; an ultrasound sensor; an inertial sensor to sense the angular velocity and the acceleration of the surgical object; a gyroscope, an

57

accelerometer, an inertial measurement unit (IMU), a motion sensor, a sensor wearable by an operator, a sensor attachable to a surgical object, an RFID tag attachable to a surgical object, an ultrasound sensor, an infrared sensor, a gyroscope, a tachometer, a shaft encoder, a rotary encoder, a strain gauge and any combination thereof.

42. The system of claim 1, wherein an overlay on at least a portion of said at least one image is selected from a member of a group consisting of: said at least one critical point, a suggestion, an instruction, a warning, a distance, an angle, an area, a volume, a size scale, information on a medical history of a patient, and any combination thereof.

43. The system of claim 42, wherein if, during a procedure, at least one said attribute is correlatable with an at least one second attribute in a stored record, a member of a group consisting of a suggestion, an instruction, a warning and any combination thereof is providable.

44. The system of claim 1, wherein said processor is additionally configured to real time generate a display image by at least one of a group consisting of: (a) marking at least one virtual marker at at least one predetermined position within at least a portion of said image of at least a portion of a surgical field; (b) rendered superimposition of said image of at least a portion of a surgical field and at least a portion of said second imaging modality.

45. The system of claim 44, wherein said marking provides information selected from a group consisting of: a distance between predetermined points, an area between predetermined points, a volume between predetermined points, an orientation relative to a predetermined direction, a physical identifier, and any combination thereof.

46. The system of claim 45, wherein said physical identifier identifies a member of a group consisting of: at least one portion of tissue of a predetermined type, a predetermined location, a surgical object, and any combination thereof,

47. The system of claim 46, wherein said tissue of a predetermined type is selected from a group consisting of: an organ, a blood vessel, a bone, a nerve, a ligament, abnormal tissue and any combination thereof.

48. The system of claim 45, wherein said physical identifier comprises a mark of predetermined shape.

49. The system of claim 48, wherein said predetermined shape is selected from a group consisting of: a word, a geometric shape, an outline of a predetermined area, a patch covering said predetermined area, an outline of predetermined shape, a patch of predetermined shape, and any combination thereof.

50. A computer-implemented method for providing database management for laparoscopic surgery comprising:

a.   providing a computer-implemented system for database management for laparoscopic surgery comprising:

   i.   at least two records, each one of said records is of at least one procedure, each record is characterized by at least one attribute; and;

   ii. at least one processor configured to to compare each of said at least two records and to determine if there exists at least one attribute common to both of said at least two records;

b.   comparing said at least two records;

c.   selecting, from said at least two said records, at least one first record and at least one second record having at least one attribute in common; and

d.   if there exists at least one said attribute common to both of said at least two records, generating a prediction as to at least one outcome of at least one said procedure.

51.   The method of claim 50, wherein said step of comparing comprises real-time comparing.

52.   The method of claim 50, additionally comprising step of selecting said at least one procedure from a group consisting of: an identifiable unit, a surgical task, a complete procedure and any combination thereof.

53.   The method of claim 50, additionally comprising step of selecting said attribute from a group consisting of a pre-procedure datum, an intra-procedure datum and a post-procedure datum.

54.   The method of claim 53, additionally comprising step of selecting said pre-procedure datum from a group consisting of: an identifier of a patient; a datum from a patient's medical history, number of said at least one procedures carried out by an operator, cleaning status of an operating room, a general datum, and any combination thereof.

55.   The method of claim 54, additionally comprising step of selecting said datum from a patient's medical history from a group consisting of: an illness, an outcome of an illness, a previous procedure, an outcome of a previous procedure, a genetic factor, an effect on said patient of said genetic factor, a predicted effect on said patient of said genetic factor, a medical treatment, an allergy, a medical condition, a psychological factor, and any combination thereof.

56.   The method of claim 54, additionally comprising step of selecting said cleaning status of an operating room from a group consisting of: time of last cleaning, date of last cleaning, cleaning procedure, cleaning materials and any combination thereof.

57.   The method of claim 50, additionally comprising step of selecting said intra-procedure datum from a general datum.

58. The method of claim 50, additionally comprising step of selecting said post-procedure datum from a group consisting of: an outcome of a procedure, length of hospital stay for said patient, a readmission for a patient, a medical treatment for a patient, a subsequent procedure, number of subsequent procedures carried out by an operator, a general datum and any combination thereof.

59. The method of claim 58, additionally comprising step of selecting said outcome from a group consisting of: a successful aspect, a partially successful aspect, a partial failure in an aspect, a complete failure in an aspect, and any combination thereof.

60. The method of claim 59, additionally comprising step of selecting said aspect from a group consisting of: a complication during a procedure, a complication during another procedure, a component where recovery is smooth and uncomplicated, a rate of recovery from a procedure, a rate of recovery from a complication, a long-term effect of a procedure, a long-term effect of a complication, amount of bleeding during said at least one procedure, amount of bleeding during a procedure, amount of bleeding during another procedure, return of an abnormality, speed of healing, an adhesion, patient discomfort, and any combination thereof.

61. The method of claim 58, additionally comprising step of selecting said general datum from a group consisting of: an image of at least a portion of a surgical field, an identifier of an operator, a rating for an operator, a physical characteristic of a patient, an identifier of an operating room, a physical characteristic of an operating room, an identifier of a procedure, type of procedure, time of a beginning of a procedure, time of an intermediate point of a procedure, time of an end point of a procedure, duration of a procedure, time between end of a procedure and beginning of another procedure, time of creation of a critical point, location of a critical point, time of creation of a fixed point, location of a fixed point, a medication, a medical device, an identifier of a surgical object, a type of a surgical object, a number used for a surgical object, a cleaning status for a surgical object, a comment, a parameter, a metric, occurrence of a malfunction, severity of a malfunction, start time of a malfunction, end time of a malfunction, reason for start of a malfunction, reason for end of a malfunction, occurrence of an adverse event, a test, an image from another modality, an overlay, a label, a note, and any combination thereof.

62. The method of claim 61, additionally comprising a step of selecting said parameter from a group consisting of: 2D position of at least a portion of at least one item, 2D orientation of at least a portion of at least one item, 3D position of at least a portion of

at least one item, 3D orientation of at least a portion of at least one item, 2D projection of a 3D position of at least a portion of said at least one item, movement of at least a portion of at least one said item, energy use; idle time, approach time, speed, maximum speed, speed profile, acceleration, motion smoothness, path length, distance efficiency, depth perception, transit profile, deviation on horizontal plane, deviation on vertical plane, response orientation, economy of area (EOA), economy of volume (EOV), number of movements, force range, interquartile force range, integral of the force, integral of the grasping force, integral of the Cartesian force, first derivative of the force, second derivative of the force, third derivative of the force, lighting level, amount of suction, amount of fluid flow, heating level in an ablator, amount of defogging, amount of smoke removal, activation of an item, deactivation of an item, bleeding, change in heart rate, change in blood pressure, change in color of an organ, and any combination thereof.

63. The method of claim 61, additionally comprising step of selecting said physical characteristic of an operating room from a group consisting of: temperature, humidity, type of lighting, and any combination thereof.

64. The method of claim 61, additionally comprising step of selecting said medical device from a group consisting of: a heating blanket, a pump, a catheter, and any combination thereof.

65. The method of claim 61, additionally comprising step of selecting said occurrence of an adverse event from a group consisting of: unexpected bleeding, undesirable change in blood pressure, undesirable change in heart rate, undesirable change in consciousness state, pain, and any combination thereof.

66. The system of claim 61, additionally comprising step of selecting said physical characteristic of said patient from a group consisting of: age, height, weight, body mass index, physical parameter of said patient, and any combination thereof.

67. The method of claim 66, additionally comprising step of selecting said physical parameter of said patient from a group consisting of: health status, blood pressure, heart rate, blood gasses, blood volume, blood hemoglobin, breathing rate, breath depth, EEG, ECG, sweating, and any combination thereof.

68. The method of claim 61, additionally comprising step of selecting said medication from a group consisting of: an antibiotic, an anesthetic, plasma, blood, saline, coagulant, anticoagulant, blood pressure medication, heart medication, and any combination thereof.

69. The method of claim 61, additionally comprising step of selecting said medical treatment from a group consisting of: a medication, a medical device, prescribing a course of exercise, administering physiotherapy, and any combination thereof.

70. The method of claim 61, additionally comprising step of selecting said test from a group consisting of:, but not limited to, a blood test, a blood pressure measurement, an EEG, and ECG, and any combination thereof.

71. The method of claim 61, additionally comprising step of selecting said other modality from a group consisting of: MRI, CT, ultrasound, X-ray, fluorography, fluoroscopy, molecular imaging, scintigraphy, SPECT, positron emission tomography (PET), other types of tomography, elastography, tactile imaging, photoacoustic imaging, thermography, functional near-infrared spectroscopy (FNIR) and any combination thereof.

72. The method of claim 61, additionally comprising step of providing said image from said other modality either stored or real-time.

73. The method of claim 61, additionally comprising step of selecting said note from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

74. The method of claim 61, additionally comprising step of selecting said comment from a group consisting of: a descriptor of a previously-performed procedure, a list of at least one previously performed procedure, how a procedure was executed, why a procedure was chosen, an assessment of a patient, a prediction, an item to be added to a medical history, a method of executing a procedure, and any combination thereof.

75. The method of claim 61, additionally comprising step of selecting said critical point from a group consisting of: a location in said surgical field, a beginning of a procedure, an end of a procedure, an intermediate point in a procedure and any combination thereof.

76. The method of claim 61, additionally comprising step of selecting said at least one image of at least a portion of a surgical field, from a group consisting of: a 2D image, a 3D image, a panoramic image, a high resolution image, a 3D image reconstructed from at least one 2D image, a 3D stereo image and any combination thereof.

77. The method of claim 61, additionally comprising step of selecting said second modality image from a group consisting of: a 2D image, a 3D image, a panoramic image, a high

62

resolution image, a 3D image reconstructed from at least one 2D image, a 3D stereo image and any combination thereof.

78. The method of claim 50, wherein at least one said attribute in at least one of said at least two records is a function of time.

79. The method of claim 78, additionally comprising step of comparing as a function of time at least one parameter in both said at least two records.

80. The method of claim 78, additionally comprising step of identifying said at least one critical point from a comparison selected from a group consisting of: a comparison between at least one first parameter at time t and at least one first parameter at time $t + \Delta t$, and a comparison between at least one first parameter at time t and at least one second parameter at time t.

81. The method of claim 78, additionally comprising step of identifying said at least one critical point from a comparison of a plurality of consecutive said at least one first parameters to a plurality of consecutive said at least one second parameters.

82. The method of claim 78, wherein said step of comparing comprises determining existence of a difference between a member of a group consisting of said at least one first parameter at time t and said at least one first parameter at time $t + \Delta t$, said at least one first parameter at time t and said at least one second parameter at time t, and any combination thereof.

83. The method of claim 78, additionally comprising step of detecting said difference for a member of a group consisting of: said at least one first parameter at time t differs from said at least one first parameter at time $t + \Delta t$ by an amount greater than a predetermined value, said at least one first parameter at time t differs from said at least one second parameter at time t by an amount greater than a predetermined value, and any combination thereof.

84. The method of claim 83, additionally comprising step of selecting said predetermined value to be in a range of about 0.1% to about 15%.

85. The method of claim 79, additionally comprising step of selecting said predetermined value to be about 5%.

86. The method of claim 50, additionally comprising step of providing said system in communication with a system for controlling laparoscopic surgery.

87. The method of claim 50, additionally comprising step of providing a searchable tag for at least one said attribute.

88.   The method of claim 87, additionally comprising step of selecting a manner of providing said searchable tag from a group consisting of manually, semi-automatically, automatically and any combination thereof.

89.   The method of claim 50, additionally comprising steps of providing at least one sensor and determining, by means of said sensor, at least one said attribute.

90.   The method of claim 89, additionally comprising step of selecting said at least one sensor from a group consisting of: an electromagnetic sensor; an ultrasound sensor; an inertial sensor to sense the angular velocity and the acceleration of the surgical object; a gyroscope, an accelerometer, an inertial measurement unit (IMU), a motion sensor, a sensor wearable by an operator, a sensor attachable to a surgical object, an RFID tag attachable to a surgical object, an ultrasound sensor, an infrared sensor, a gyroscope, a tachometer, a shaft encoder, a rotary encoder, a strain gauge and any combination thereof.

91.   The method of claim 50, additionally comprising step of overlaying on at least a portion of at least one said image a member of a group consisting of: said at least one critical point, a suggestion, an instruction, a warning, a distance, an angle, an area, a volume, a size scale, information on a medical history of a patient, and any combination thereof.

92.   The method of claim 91, additionally comprising step of providing if, during a procedure, at least one said attribute is correlatable with an at least one second attribute in a stored record, a member of a group consisting of a suggestion, an instruction, a warning and any combination thereof.

93.   The method of claim 50, additionally comprising step of real time generating a display image by at least one of a group consisting of: (a) marking at least one virtual marker at at least one predetermined position within at least a portion of said image of at least a portion of a surgical field; (b) rendered superimposition of said image of at least a portion of a surgical field and at least a portion of said second imaging modality.

94.   The method of claim 94, additionally comprising step of selecting information provided by said marking from a group consisting of: a distance between predetermined points, an area between predetermined points, a volume between predetermined points, an orientation relative to a predetermined direction, an identifier, and any combination thereof.

95.   The method of claim 95, additionally comprising step of identifying, by means of said identifier, a member of a group consisting of: at least one portion of tissue of a predetermined type, a predetermined location, a surgical object, and any combination thereof,

64

96.   The method of claim 96, additionally comprising step of selecting said tissue of a predetermined type from a group consisting of: an organ, a blood vessel, a bone, a nerve, a ligament, abnormal tissue and any combination thereof.

97.   The method of claim 95, additionally comprising step of providing said identifier comprising a mark of predetermined shape.

98.   The method of claim 97, additionally comprising step of selecting said predetermined shape from a group consisting of: a word, a geometric shape, an outline of a predetermined area, a patch covering said predetermined area, an outline of predetermined shape, a patch of predetermined shape, and any combination thereof.
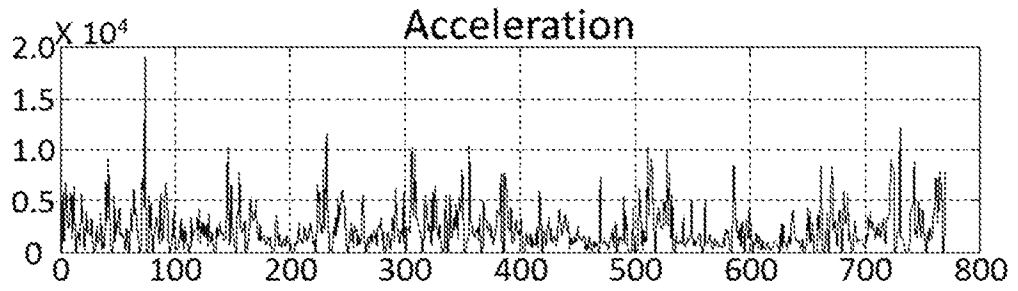
65

Fig. 1

Fig. 2

Fig. 3A

Fig. 3B

3/5

Fig. 4

4/5

Fig. 5A

Speed

Fig. 5B

Acceleration

Fig. 6A

Speed

Fig. 6B

Acceleration

Fig. 6C

Jerk

5/5

410

Fig. 7

A. CLASSIFICATION OF SUBJECT MATTER
IPC (2017.01) A61B 1/00, A61B 5/00, G06F 19/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC (2017.01) A61B 1/00, A61B 5/00, G06F 19/00

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Databases consulted: THOMSON INNOVATION, Esp@cenet, Google Patents, FamPat database
Search terms used: Laparoscopic, database, analysis, compare, common, features, predict

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0163359 A1 SHOLEV et al 12 Jun 2014 (2014/06/12) Abstract, pages 1-2, para.[0011]-,[0013],[0029], page 4 para. [0053]-[0059], page 19 para [0366],page 23 para. [0444]	1-98
A	US 2011/0046476 A1 CINQUIN et al 24 Feb 2011 (2011/02/24) Whole document	1-98
A	US 2015/0126894 A1 BENSON et al 07 May 2015 (2015/05/07) Whole document	1-98

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

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance		
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 Mar 2017	30 Mar 2017

| Name and mailing address of the ISA:
Israel Patent Office
Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel
Facsimile No. 972-2-5651616 | Authorized officer
BRODET Eyal

Telephone No. 972-5651778 |

Form PCT/ISA/210 (second sheet) (January 2015)

Patent document cited search report	Publication date	Patent family member(s)	Publication Date
US 2014/0163359 A1	12 Jun 2014	NONE	
US 2011/0046476 A1	24 Feb 2011	NONE	
US 2015/0126894 A1	07 May 2015	NONE	