



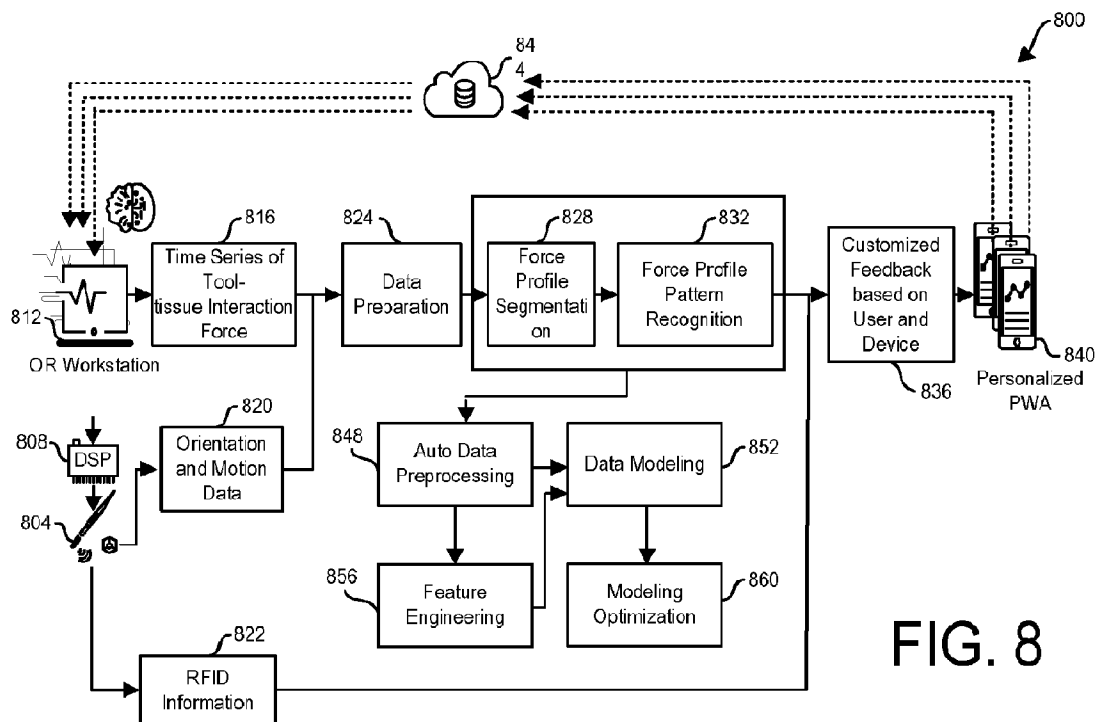
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(54) **Titre : CARACTERISATION D'INSTRUMENT CHIRURGICAL BASEE SUR APPRENTISSAGE AUTOMATIQUE**
(54) **Title: MACHINE LEARNING-BASED SURGICAL INSTRUMENT CHARACTERIZATION**



(57) **Abrégé/Abstract:**

Data is received that is generated by at least one sensor forming part of a surgical instrument. The sensor(s) on the surgical instrument can characterize use of the surgical instrument in relation to a patient. A first machine learning model can construct a force profile using the received data. The force profile includes a plurality of force patterns. In addition, a plurality of features are extracted from the received data. Thereafter, one or more attributes characterizing use of the surgical instrument are determined by a second machine learning model using the constructed force profile and the extracted features. Data characterizing the determination can be provided (e.g., displayed to a surgeon, etc.).

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Machine Learning-Based Surgical Instrument Characterization

RELATED APPLICATIONS

[0001] The current application claims priority to U.S. Pat. App. Ser. No. 17/318,975 filed on May 12, 2021 and to U.S. Pat. No. 17/540,966 filed on December 2, 2021, the contents of both of which are hereby fully incorporated by reference.

TECHNICAL FIELD

[0002] The subject matter described herein relates to machine learning-based techniques for characterizing the use of sensor-equipped surgical instruments to improve patient outcomes.

BACKGROUND

[0003] According to the World Health Organization (WHO), surgical procedures lead to complications in 25% of patients (around 7 million annually) among which 1 million die. Among surgical tasks responsible for error, tool-tissue force exertion is a common variable. Surgical simulation has shown that more than 50% of surgical errors are due to the inappropriate use of force contributing to an annual cost of over \$17 billion in the USA alone.

SUMMARY

[0004] In a first aspect, data is received that is generated by at least one sensor forming part of a surgical instrument. The surgical instrument can take various forms including being handheld, fully manual, and/or at least partially robotic. The sensor(s) on the surgical instrument can characterize use of the surgical instrument in relation to a patient. A first machine learning model can construct a force profile using the received data. The force profile includes a plurality of force patterns. The force

profile segmentation model includes at least one first machine learning trained using historical surgical instrument usage data. In addition, a plurality of features are extracted from the received data. Thereafter, one or more attributes characterizing use of the surgical instrument are determined by a second machine learning model using the constructed force profile and the extracted features. Data characterizing the determination can be provided.

[0005] The first machine learning model can include a force profile segmentation model trained using historical surgical instrument usage data.

[0006] The second machine learning model can include a force profile recognition model.

[0007] The sensor(s) forming part of the surgical instrument can take various forms including one or more of: an identification sensor, a force sensor, a motion sensor, a position sensor, an accelerometer, or an optical sensor. In one variation, the surgical instrument are forceps with right and/or left prongs having a sensor embedded or affixed thereto.

[0008] The sensor(s) forming part of the surgical instrument can generate different types of data including time-series based data characterizing use of the surgical instrument.

[0009] Noise in the received data can be reduced prior to the extraction of the features and/or use by the force profile segmentation model. The noise can be reduced by applying rule-based data point filtering to mitigate imbalances in the received data.

[0010] Outliers in the received data can be removed prior to the extraction of the features and/or use by the force profile segmentation model.

[0011] The force profile segmentation model can include an encoder network followed by a decoder network.

[0012] The second machine learning model can include multiple layers including a bottleneck layer to reduce dimensionality after a max pooling layer, a stacked series of convolutional layers to learn features followed by a concatenation layer.

[0013] The extracted features can be fused into the second machine learning model after resampling and normalization as a new dimension to the second machine learning model.

[0014] A synthetic time-series generation technique based on dynamic time warping (DTW) and Stochastic Subgradient (SSG) averaging can be applied to mitigate imbalance in the extracted features.

[0015] At least a part of the received data can include a waveform such that the extracted features characterize one or more of: maximum, range, coefficient of variance, peak counts, peak values, cycle length, signal fluctuations, entropy, or flat spots.

[0016] The force profile pattern recognition model can include at least one neural network.

[0017] The data characterizing the determination can identify a surgical task performed using the surgical instrument.

[0018] The data characterizing the determination can identify a skill level associated with use of the surgical instrument. The data characterizing the determination can identify a skill level associated with a particular surgical task using the surgical instrument.

[0019] At least one of the at least one first machine learning model and the at least one second machine learning model can be trained using data generated from a single type of surgical instrument and/or from a single surgeon. Further, at least one of the at least one first machine learning model and the at least one second machine learning model can be trained using data generated from a plurality of surgeons.

[0020] The surgical instrument can include an identification element. Such an identification element can be associated with one of a plurality of machine learning models such that at least one of the at least one first machine learning model and the at least one second machine learning model is selected from the plurality of available machine learning models based on the associating. The identification element can take various forms including a radio frequency identification (RFID).

[0021] Providing data characterizing the determination can include one or more of: causing the data characterizing the determination to be displayed in an electronic visual display, storing the data characterizing the determination in physical persistence, loading the data characterizing the determination in memory, or transmitting the data characterizing the determination to a remote computing system.

[0022] The provided data can characterize various actions including a completion time for a surgical task, a range of force applications in connection with a surgical task, a force variability index, or a force uncertainty index compared to one or more other surgical instrument users.

[0023] The provided data can include conveying feedback to a user of the surgical instrument. The feedback can take various forms including one or more of haptic, visual, or audio feedback.

[0024] The feedback can be conveyed on a heads-up display worn or in view of a user of the surgical instrument.

[0025] At least one of the force profile segmentation model or the force profile recognition model can be trained locally on an endpoint computing instrument executing both such models. In other variations, at least one of the force profile segmentation model or the force profile recognition model is trained at least in part by a cloud-based computing service.

[0026] In some variations, feature extracted from the data are anonymized and then encrypted. The encrypted, anonymized features can be transmitted to a remote computing system to train one or more models corresponding to at least one of the force profile segmentation model or the force profile recognition model. The features can be anonymized using various techniques including using k-anonymity privacy. Various encryption technologies can be utilized including homomorphic encryption

[0027] In some variations, at least one of the force profile segmentation model or the force profile pattern recognition model through federated learning using a combination of an edge device executing such models and a cloud-based system.

[0028] In an interrelated aspect, one or more data streams are received that generated by at least one sensor forming part of a surgical instrument. The at least one sensor characterizes use of the surgical instrument by a surgeon in relation to a patient. Thereafter, a force profile is constructed by a force profile segmentation using the received data streams. The force profile includes a plurality of force patterns and the force profile segmentation model can include at least one first machine learning trained using historical surgical instrument usage data. A plurality of features can be continually extracted from the received data. Based on these features, one or more attributes characterizing use of the surgical instrument can be determined by a force profile pattern recognition model. The force profile pattern recognition model can

include at least one second machine learning model. Real-time feedback can be provided to the surgeon based on the one or more determined attributes characterizing use of the surgical instrument.

[0029] In a further interrelated aspect, a system includes a plurality of edge computing devices and a cloud-based system. The plurality of edge computing devices are each configured to receive one or more data streams generated by at least one sensor forming part of a respective surgical instrument. The at least one sensor characterizing use of the respective surgical instrument by a particular surgeon in relation to a particular patient, each of the edge computing devices executing a local force profile segmentation model and a force profile recognition model. The cloud-based system is configured for training and updating each of a master force profile segmentation model and a master force profile pattern recognition model based on model parameter data received from the plurality of edge computing devices which has been anonymized and encrypted using homomorphic encryption prior to it being transmitted over a network by the edge computing devices. The cloud-based system sends updates over the network to each of the respective local force profile segmentation models and to each of the force profile recognition models.

[0030] Non-transitory computer program products (i.e., physically embodied computer program products) are also described that store instructions, which when executed by one or more data processors of one or more computing systems, cause at least one data processor to perform operations herein. Similarly, computer systems are also described that may include one or more data processors and memory coupled to the one or more data processors. The memory may temporarily or permanently store instructions that cause at least one processor to perform one or more of the operations described herein. In addition, methods can be implemented by one or

more data processors either within a single computing system or distributed among two or more computing systems. Such computing systems can be connected and can exchange data and/or commands or other instructions or the like via one or more connections, including but not limited to a connection over a network (e.g., the Internet, a wireless wide area network, a local area network, a wide area network, a wired network, or the like), via a direct connection between one or more of the multiple computing systems, etc.

[0031] The details of one or more variations of the subject matter described herein are set forth in the accompanying drawings and the description below. Other features and advantages of the subject matter described herein will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

[0032] FIG. 1 is a first diagram illustrating force signals generated from a sensor-equipped surgical instrument over five different surgical tasks;

[0033] FIG. 2 is a second diagram illustrating force signals generated from a sensor-equipped surgical instrument over five different surgical tasks;

[0034] FIGs. 3-7 are diagrams illustrating views of a graphical user interface dashboard characterizing use of one or more surgical instruments;

[0035] FIG. 8 is a diagram illustrating a sample architecture for characterizing the use of a surgical instrument using machine learning;

[0036] FIG. 9 is a diagram illustrating a first machine learning model architecture;

[0037] FIG. 10 is a diagram illustrating a second machine learning model architecture; and

[0038] FIG. 11 is a process flow diagram illustrating the characterization of use of a surgical instrument using machine learning.

DETAILED DESCRIPTION

[0039] The current subject matter is directed to enhanced techniques and systems for monitoring or otherwise characterizing use of a surgical instrument during one or more surgical procedures. While the current subject matter is described, as an example, in connection with sensor-equipped forceps, it will be appreciated that the current subject matter can also be used with other sensor-equipped surgical instruments including, electrosurgical (bipolar or monopolar) or otherwise, without limitation, cutting instruments, grasping instruments, and/or retractors.

[0040] As noted above, the current subject matter can be used with sensor-equipped forceps such as that described in U.S. Pat. Pub. No. 20150005768A1 and entitled: “Bipolar Forceps with Force Measurement”, the contents of which are hereby incorporated by reference. The surgical instruments used herein can include one or more sensors such as an identification sensor (e.g., RFID, etc.), force sensors, motion sensors, position sensors. The data generated from such sensors can be connected to a developed signal conditioning unit interfaced through a software with machine learning algorithm (federated and global) deployed to the cloud (or in some cases executing at a local endpoint). The machine learning algorithms can interface with a unique federated learning architecture such that tool, sensor and surgeon specific data, are recognized, segmented and analyzed (signal, task, skill, pattern (position, orientation, force profile) – all based on sensor signal), such that high fidelity feedback can be generated and provided in real-time (warning) or performance reporting (via secure application or online user profile).

[0041] For data modeling to validate and/or otherwise inform the advances provided herein, 50 neurosurgery cases that used sensor-equipped forceps (herein after sensor-equipped forceps) for tumor resection of various types in adult patients including meningioma, glioma, hemangioblastoma, and schwannoma was employed. Twelve surgeons performed the cases, which included one Expert surgeon with 30+ years of experience and 11 Novice surgeons ranging across 3 levels of post-graduate years (PGY) 1-2 (n=4), 3-4 (n=3) and >4 years (n=4). The surgical team adopted and used the sensor-equipped forceps system, similar to and instead of, a conventional bipolar forceps. The recorded data includes time-series of tool-tissue interaction force through sensor-equipped forceps, transcribed voices of the surgical team, and microscopic video data to label the training dataset for surgical error incidents and neurosurgical maneuvers categorized into 5 main different tasks, i.e. (1) coagulation (cessation of blood loss from a damaged vessel), (2) dissection (cutting or separation of tissues), (3) pulling (moving and retaining tissues in one direction), (4) retracting (grasping and retaining tissue for surgical exposure), and (5) manipulating (moving cotton or other non-tissue objects). The added advantage was the provision of real-time tool-tissue force measurement, display, and recording. A snapshot of aggregated force data over the 50 cases of neurosurgery is illustrated in diagram 100 of FIG. 1. The graph in FIG. 1 highlights the differences in completion time and range of forces across the 5 surgical tasks. In particular, FIG. 1 illustrates sensor-equipped forceps timeseries data of the Right prong across the 5 surgical tasks of Retracting, Manipulation, Dissecting, Pulling, and Coagulation overlaid for 50 cases. Differences in the range and duration of force are shown in the overlaid data profiles.

[0042] A data management framework as used herein can include a curing pipeline and reporting structure incorporating a data ingestion point where the

segmented force profiles representing a consolidated period of force application in a specific surgical task was imported. The force segments were identified through the processing of operating room voice data and were concatenated into a structured data frame containing various information including timestamp, surgeon and experience level, surgical task type, and high/low force error or bleeding instances. In the next step, 37 time-series-related features were calculated from the manually segmented task force data in each prong among which a subset of 25 with a combination of average, minimum, or maximum value of features for each prong was selected for the subsequent analysis based on statistical tests to monitor their representation power in different surgeon skill and task categories. The aim was to have the best explain of patterns and behaviors for force profiles over the timespan of each data segment. These time-series features included:

[0043] Force Duration: duration of force application in one task segment.

[0044] Force Average: average of force values in one task segment.

[0045] Force Max: maximum of force values in one task segment.

[0046] Force Min: minimum of force values in one task segment.

[0047] Force Range: range of force values in one task segment.

[0048] Force Median: median of force values in one task segment.

[0049] Force SD: standard deviation of force values in one task segment.

[0050] Force CV: coefficient of variation of force values in one task

segment.

[0051] Force Mean CI (0.95): confidence interval on the mean with 95%

probability.

[0052] Force Data Skewness: the extent to which the force data

distribution deviates from a normal distribution.

[0053] **Force Data Skewness 2SE**: the significance of skewness in force data based on dividing by 2 standards errors (significant when > 1).

[0054] **Force Data Kurtosis**: the extent to which the force data distribution is tailed in a normal distribution.

[0055] **Force Data Kurtosis 2SE**: the significance of kurtosis in force data based on dividing by 2 standards errors (significant when > 1).

[0056] **Force Data Normality**: Shapiro-Wilk test of normality in force data distribution.

[0057] **Force Data Significance of Normality**: significance of Shapiro-Wilk test of normality.

[0058] **Force Peak Value**: peak force value in one task segment.

[0059] **Force Peak Counts**: number of force peaks in one task segment.

[0060] **1st Derivative SD**: standard deviation for the first derivative of the force signal in one task segment.

[0061] **Force Signal Flat Spots**: maximum run length for each section of force time-series when divided into ten equal-sized intervals.

[0062] **Force Signal Frequency**: dominant time-series harmonics extracted from Fast Fourier Transform (FFT) of force value in one task segment.

[0063] **Force Cycle Length**: average time length of force cycles in one task segment.

[0064] **Force Signal Trend**: force time-series trend in one task segment.

[0065] **Force Signal Fluctuations**: force time-series fluctuation index in one task segment.

[0066] **Force Signal Spikiness**: force time series spikiness index (variance of the leave-one-out variances of the remainder component) in one task segment.

[0067] **Force Signal Linearity:** force time-series linearity index (from Teräsvirta's nonlinearity test) in one task segment.

[0068] **Force Signal Stability:** force time-series stability index (variance of the means) in one task segment.

[0069] **Force Signal Lumpiness:** force time-series lumpiness index (variance of the variances) in one task segment.

[0070] **Force Signal Curvature:** force time-series curvature index in one task segment (calculated based on the coefficients of an orthogonal quadratic regression).

[0071] **Force Signal Mean Shift:** force time-series largest mean shift between two consecutive windows in one task segment.

[0072] **Force Signal Variance Shift:** force time-series largest variance shift between two consecutive windows in one task segment.

[0073] **Force Signal Divergence:** force time-series divergence index in one task segment (largest shift in Kulback-Leibler divergence between two consecutive windows).

[0074] **Force Signal Stationary Index:** force time-series stationary index around a deterministic trend in one task segment (based on Kwiatkowski-Phillips-Schmidt-Shin (KPSS) unit root test with linear trend and lag one).

[0075] **Force Signal Entropy:** force time-series forecastability in one task segment (low values indicate a high signal-to-noise ratio).

[0076] **First Autocorrelation Minimum:** time of first minimum of the autocorrelation function in force time-series signal from one task segment.

[0077] **First Autocorrelation Zero:** time of first zero crossing of the autocorrelation function in force time-series signal from one task segment.

[0078] Autocorrelation Function E1: first autocorrelation coefficient from force time-series signal in one task segment.

[0079] Autocorrelation Function E10: sum of the first ten squared autocorrelation coefficients from force time-series signal in one task segment.

[0080] To find accurate force peaks within each task segment, the signals were smoothed by passing through a digital 4th order Butterworth low-pass filter with a cutoff frequency of 0.1 Hz. Further, the outlier segmented data were identified based on 1st and 99th percentiles of either maximum force, minimum force, or task completion time from all trials of the expert surgeon as <1% error was assumed to occur by experienced surgeons. The force segments for which the maximum force peak, minimum force valley, or task completion time exceeded the upper threshold (99th percentile) or fell short of the lower threshold (1st percentile) were labeled as outliers and removed (~11%).

[0081] Interactive figures of the force time-series features extracted from all 50 cases were categorized in 5 different tasks. FIG. 2 is a diagram 200 illustrating a sample result. FIG. 2 shows the relationship between different skill levels and across different tasks. In particular, FIG. 2 illustrates aggregative data distribution of both Expert and Novice surgeons across the surgical tasks for each time-series extracted feature.

[0082] Again, to validate the current innovations, data was analyzed prior to exploring machine learning models for a better behavior understanding of the force profiles. Summary statistics were extracted for each task and surgeon experience that included the number of force segments and mean (SD) of the force features across all available segments.

[0083] The number of force segments were 2085 for Coagulation (Expert: 1108; Novice: 977), 303 for Pulling (Expert: 192; Novice: 111), 296 for Manipulation (Expert: 210; Novice: 86), 89 for Dissecting (Expert: 64; Novice: 25), and 122 for Retracting (Expert: 71; Novice: 51), with a total value of 1645 for Expert and 1250 for Novice surgeons. The mean (SD: Standard Deviation) for Force Duration in Coagulation was 12.1 (7.2) seconds – around 58% higher than the average of completion time in other tasks – while the completion time in Pulling, Manipulation, Dissecting, and Retracting tasks were 7.6 (5.3), 5.4 (2.5), 10.1 (8.6), and 7.6 (5.1) seconds, respectively. The mean (SD) for Force Range in Manipulation was 1.2 (0.5) N – around 52% higher than the average of completion time in other tasks – while the range of forces in Coagulation, Pulling, Dissecting, and Retracting tasks were 0.7 (0.5), 1 (0.6), 0.9 (0.5), and 0.7 (0.4) N, respectively. For presenting the level of force variability, Standard Deviation was calculated across the tasks and surgeons. The mean (SD) across all tasks were 0.23 (0.14) for Expert and 0.27 (0.14) for Novice surgeons. For materializing the unsafe force application risk, Force Peak Values were identified across the tasks and surgeons. The mean (SD) across all tasks were 0.35 (0.27) for Expert and 0.39 (0.29) for Novice surgeons. Level of Force Signal Entropy was used to measure the level of randomness in force application for among different surgical experience. Mean (SD) of this feature for Expert surgeon was 0.67 (0.09) and for Novice surgeons was 0.65 (0.07).

[0084] To understand the pattern of force data in various conditions under investigation, independent measures two-way ANOVA was performed that simultaneously evaluates the effect of experience and task type as two different grouping variables on the continuous variable of tool-tissue interaction force. The results showed significant difference between experience levels in various features

including Force Maximum ($p < 0.001$), Force Range ($p < 0.001$), Force Standard Deviation ($p < 0.001$), Force Distribution Kurtosis ($p < 0.001$), Force Peak Values ($p < 0.001$), Force Flat Spots ($p < 0.001$), Force Signal Frequency ($p < 0.001$), Force Signal Fluctuations ($p = 0.02$), Force Signal Stability ($p < 0.001$), Force Signal Mean Shift ($p < 0.001$), and Force Signal Entropy ($p < 0.001$). Among various tasks, several features were significantly different, e.g., Force Duration ($p < 0.001$), Force Average ($p < 0.001$), Force Maximum ($p < 0.001$), Force Range ($p < 0.001$), Force Peak Values ($p < 0.001$), Force Peak Counts ($p < 0.001$), Force Signal Flat Spots ($p < 0.001$), Force Signal Frequency ($p < 0.001$), Force Signal Fluctuations ($p < 0.001$), and Force Signal Stability ($p < 0.001$), and Force Signal Curvature ($p < 0.001$). The results showed no significant difference for Force Coefficient of Variation and Force Signal Cycle Length among tasks, experience levels, and their interaction.

[0085] Based on the ANOVA test results, a subset of features was extracted for developing machine learning models. In this subset, Force Duration, Force Minimum, Force Coefficient of Variance, Force Data Skewness, Force Data Skewness 2SE, 1st Derivative SD, Force Peak Counts, Force Cycle Length, Force Signal Spikiness, Force Signal Stationary Index, First Autocorrelation Zero, and Autocorrelation Function E10 were excluded. In addition, the surgical tasks were classified as 5 main categories of Retracting [the tumor or tissues], Manipulation [of cotton], Dissecting [the tumor or tissues], Pulling [the tumor or tissues], and Coagulation [the vessels/veins in tumor or tissues].

[0086] To quantify the behavior of force profiles for pattern recognition and performance analysis, machine learning models for segmenting and recognizing the patterns of intra-operative force profiles were developed. The models can be configured so as to make no assumption about the underlying pattern in force data and

hence are robust to noise. The framework enables modeling a complex structure in non-stationary time-series data, where data characteristics including mean, variance, and frequency change over time. With reference to FIG. 8 which is described in further detail below, the AI modeling architecture can include Auto Data Preprocessing 848 (e.g., Data Balancing and Augmentation, Outlier Removal, Data Transformation, etc.), Feature Engineering 856, Data Modeling 852 (U-Net for force profile segmentation; LSTM and InceptionTime for pattern recognition), and Modeling Optimization and Performance Evaluation 860 which can be integrated into a cloud platform 844 to generate performance evaluation reports to the surgical team.

[0087] For force profile segmentation, a first machine learning model 828 can take the pre-processed data after applying a rule-based data balance mechanism and perform point-wise data classification as *ON* and *OFF* regarded as the segments of force data through the U-Net model which showed the best results for 0.0001 learning rate, 128 as the filter size, moving window size of 224, and batch size of 128. The mean inference time was 1.51 seconds, and the minimum validation loss value occurred at epoch 28 was 0.0878 (training loss = 0.0827). The final performance accuracy was 0.98 in training and 0.97 in validation. The average accuracy derived from confusion matrix for classification was 0.95 (sensitivity = 0.96, specificity = 0.94). Both macro and weighted by prevalence AUC of ROC were 0.99. Note that One-vs-One and One-vs-Rest class AUC has identical results given the 2-class problem at hand. The micro-averaged precision-recall score for both classes was 0.99. When testing the model, the accuracy showed 0.95 (F1-score: 0.95 in class *ON*, and 0.95 in class *OFF*, weighted value = 0.96).

[0088] During the initial model developments, experiments were conducted for skill classification based on the available data of 50 cases using a support vector

machine (SVM) model on 25 extracted features after dimensionality reduction by principal component analysis (PCA) showed the highest area under the curve (AUC) of 0.65, training accuracy of 0.60, testing accuracy of 0.62 with the sensitivity of 0.66 and specificity of 0.57. The optimal model parameters were radial basis kernel function with both cost and gamma values of $0.1 \times 10^{0.1}$.

[0089] During the initial model developments, experiments were also conducted using a recurrent neural network based on LSTM that had an input layer with 100 inputs, a single layer hidden layer with 100 LSTM neurons, a dropout layer with the ratio of 0.5 to reduce overfitting of the model to the training data, a dense fully connected layer with 100 neurons and ReLU activation function to interpret the extracted features by the LSTM hidden layer, and an output layer with Softmax activation to make predictions for the 5 classes. In this variation, the optimizer used to train the network was the adam version of stochastic gradient descent with categorical cross entropy as the loss function. The network was trained for 1000 epochs and a batch size of 20 samples was used for the optimal results that showed mean (SD) loss of 0.598 (0.001), mean (SD) accuracy of 0.828 (0.001), and mean squared error of 0.055 (0.001).

[0090] For skill classification and task recognition, deep learning model (e.g., InceptionTime, etc.) can be utilized. In particular, this deep learning model can be configured to classify or otherwise characterize surgeon experience level (i.e., novice, intermediate, and expert) and allocate surgical competency scores based on descriptive force patterns including, high force error, low force error, variable force, and other unsafe force instances. A deep neural network model for time series classification based on InceptionTime can be used to obtain the learned features that together with the engineered features described above was used for surgeon experience

classification. The time-series classification for the classes of surgeons performed best in InceptionTime with no hand-crafted features added to the network (AUC = 0.85; p-value < 0.0001). The model was characterized with a learning rate of 0.001, a network depth size of 8, moving window size of 200, and batch size of 128. The testing time for each sample happened in an average of 0.5 seconds, and the model reached minimum validation loss at epoch 23 (validation loss = 0.4760 and training loss = 0.4362). The final performance accuracy was 0.98 in training and 0.68 in validation. The model confusion matrix revealed an average classification accuracy of 0.77 (sensitivity = 0.80, specificity = 0.73). AUC for ROC graph showed 0.85 in both macro and weighted by prevalence and One-vs-One and One-vs-Rest settings in this 2-class problem. Micro-averaged precision-recall score for both classes was 0.85. During testing the model for unseen instances of force data, the accuracy was 0.77 with the F1-score of 0.78 in the *Expert*, and 0.75 in the *Novice* classes, respectively (weighted value = 0.77).

[0091] The data framework can include a HIPAA and PIEPDA compliant cloud architecture for retaining and processing the intraoperative de-identified data through a cloud platform with secure authentication and an interactive web/mobile application which interfaced with a progressive web application (PWA) to make it installable on mobile devices. Data characterizing the use of the surgical instruments can be displayed in various dashboards rendered in one or more graphical user interface. The dashboards can be personalized for data scientists as well as each surgeon's view who need to login through their personified credentials to perform data analysis or track their performance by comparing to expert surgeon(s) in the "Expert Room" (FIGs, 3-8).

[0092] The application can render multiple graphical user interfaces for different aspects including for 1) For both data scientist and surgeon: Geospatial Information for sensor-equipped forceps cases across the world with multiple choice selection lists and interactive maps to display the information in a searchable table; 2) For both data scientist and surgeon: Surgical Force Data for visualizing different engineered features across each task through interactive distribution plots showing detailed statistics for Expert or Novice surgeons to compare and reproduce each force segment through mouse hover and click; 3) For surgeon: Performance Comparison Dashboard for tracking of individual performance over time characterized by task completion time, range of force application, force variability index, and force uncertainty index (level of entropy in time series data) compared to the average and range of an expert surgeon; 4) For data scientist: Skill Prediction Tool for step-by-step training and testing of models with parameter fine-tuning and generating results to distinguish surgical expertise; and 5) For data scientist: Task Recognition Tool for visualizing, training and testing of models with parameter fine-tuning and generating results to perform surgical task classification. Through this platform, personalized performance data will be available for each surgeon through their user-specific account to view, compare, or share their case data with other colleagues in the field.

[0093] With reference to diagram 300 of FIG. 3, a geospatial information tab can include an interactive map to select each surgical center along with dropdown lists to adjust the map view based on each country and region selection. The case summary including hospital information, number of sensor-equipped forceps systems available, cases completed, and active surgeons appears in an interactive table.

[0094] With reference to diagram 400 of FIG. 4, a surgical force data tab includes interactive graphics that show aggregative data distribution of both Expert and

Novice surgeons across the surgical tasks based on a feature selected from the dropdown menu (left column chart). The actual force profiles for left (red time-series plot) and right (blue time-series plot) prong of sensor-equipped forceps (right column chart) can be shown by hover + click on each data point of the violin distribution plots.

[0095] FIG. 5 is a diagram 500 illustrating a data analytics dashboard in "Surgeon" view. The current view includes three tabs of "Geospatial Information", "Surgical Force Data", and "Performance Comparison Dashboard". These charts have fully interactive capability including zoom, pan, download, etc. This figure, as an example, shows the overtime performance report (with the slide bar at the top to select range of cases) for a Novice surgeon with PGY > 4. The name is deidentified for privacy reasons. The gauge charts show the performance compared to the Expert surgeon.

[0096] FIG. 6 is a diagram 600 illustrating a graphical user interface view corresponding to a task recognition tool tab which incorporates an interactive tool for a data scientist to view the reduced feature map after applying dimensionality reduction (e.g., principal component analysis, etc.) on the full feature set portraying the force profiles of sensor-equipped forceps and characterizing the surgical skill levels (the scatter contour plot in the middle column – purple points belong to Novice and green points to Expert; the circular and triangular points indicate training and testing data), interactive panel for selecting the machine learning model (e.g., SVM, etc.) parameters (left column), and graphical results of the machine learning model including ROC curve and confusion matrix (right column) along with the training and testing accuracies (middle column – under the scatter contour plot).

[0097] FIG. 7 is a diagram 700 that includes a graphical user interface view of a skill prediction tool tab that incorporates an interactive tool for a data scientist to

view the reduced feature map after applying dimensionality on the full feature set portraying the force profiles of sensor-equipped forceps marked by different colors for each surgical task (the scatter contour plot in the middle column), interactive panel for selecting the parameters and running the LSTM model (left column), and the results of the deep learning model on the actual force profile in terms of mean loss, mean accuracy, and mean squared error (right column).

[0098] To quantify the behavior of force profiles for pattern recognition and performance analysis, one or more machine-learning models can be provided for segmenting and recognizing the patterns of intra-operative force profiles. Deep learning models can be used that include multiple layers of feature representation as a stacked neural network. Such a model can be configured so that it does not make any assumptions about the underlying pattern in the force data so that it is robust to noise. This framework can model a more complex structure in non-stationary time-series data, where data characteristics including mean, variance, and frequency change over time.

[0099] FIG. 8 is an example architecture diagram 800 which comprises a sequence two or more machine learning models that can interact with a surgical instrument. In this example, the surgical instrument is a sensor-equipped forceps 804; however, it will be appreciated that other types of surgical instruments can be used. In addition, while the example of FIG. 8 includes two machine learning models executing in sequence, it will be appreciated that a different ensemble and/or architecture of two or more machine learning models can be used depending on the desired configuration including, for example, the type of data being generated by the surgical instrument and/or other types of complementary data being generated by other medical devices or instruments within a surgical setting (e.g., an operating room).

[00100] Referring again to FIG. 8, a surgical instrument 804 (i.e., a sensor-equipped surgical can communicate with one or more computing devices including an operating room workstation 812 by way of a communications interface 808 such as a digital signal processor (e.g., a DSP for conditioning data generated by strain gauge sensor). The surgical instrument 804 through its sensors, generates one or more data streams that characterize the use of the surgical instrument (in general and in relation to a patient). These data streams can take various forms and can be provided directly, or indirectly (e.g., via the operating room workstation 812) to a consuming application or process. A first data stream 816 can provide time-series data characterizing tool-tissue interaction force (e.g., derived from a strain gauge sensor on the surgical instrument 804, etc.). A second data stream 820 can provide data characterizing the orientation and motion of the surgical instrument 804 (e.g., derived from an inertial measurement unit sensor on the surgical instrument, etc.). In addition, identification information 822 can also be provided. This identification information can, for example, be derived from an RFID or similar sensor on the surgical instrument.

[00101] Data from the first and second data streams 816, 820 can be pre-processed in a variety of manners. The data preparation 824 can include labeling the data, filtering out noise, removing outliers, and/or extracting features from the data streams. The noise reduction can, for example, be performed as part of a feature engineering operation 856 using a Butterworth low-pass filter and outliers can be removed based on the 1st and 99th percentile thresholds of expert force profiles as <1% error was assumed to occur by experienced surgeons. Features that can be extracted include those referred to above as well as one or more of e.g., force maximum, range, coefficient of variance, peak counts and values, cycle length, signal fluctuations and entropy, and flat spots, and the like.

[00102] As part of data preprocessing operation 848, a rule-based data point filtering can be applied to mitigate the problem of imbalance data in *On* and *OFF* conditions for the recorded force data. In one experiment, 93.7% of the force data points were labeled as *OFF* (among a total of 11.6 million records), meaning that inactive status constructs most operating room times for the surgical instrument 804 (e.g., the SMARTFORCEPS device). A rule-based algorithm for inactive state removal can be used to eliminate the excessive idle time points when the rolling average with a window of 5 for the left and right prong forces was less than or equal to 0.3N. The points with overlapping *OFF* labels in both rule-based and manually labeled data can be removed from the analysis.

[00103] A first machine learning model 828 (e.g., a force profile segmentation model, etc.) can take the pre-processed data (i.e., the cleaned force time-series data, extracted features, etc.) to construct force profile comprising a plurality of force patterns which can form part of a data modeling operation 852. The first machine learning model 828 can take various forms and, in one example, can be a custom-designed U-Net model was implemented that consists of a convolutional encoder and decoder structure to capture the properties and reconstruct the force profile ($X_{in} \in \mathbb{R}^{(S_0 \times i \times C)}$; S_0 fixed-length segment interval each containing i data points through $C=2$ channels for left and right prong) through a deep stack of feature maps followed by a mean-pooling-based classifier on point-wise confidence scores for interval-wise timeseries segmentation ($X_{(seg.)} \in \mathbb{R}^{(S \times K)}$; S : final segment intervals containing $K=2$ segment classes, i.e. device ON/OFF). For the training parameters, 50 epochs were used with batch sizes of 128, *Adam* as the optimizer, *Categorical Cross-Entropy* as the loss function, and *accuracy* and *validation loss* as the evaluation metrics for a random 10% subset of training data as

the validation data. Grid search was performed as part of a modelling optimization and performance evaluation operation 860 over the learning rate, i.e., within [0.0001-0.1], and U-Net filter values, i.e., within [16-64], for hyperparameter tuning.

[00104] FIG. 9 is a diagram 900 illustrating a first model architecture having a plurality of convolution layers which are used to process input force data (i.e., the input force profile). This model architecture can illustrate the first machine learning model 828. The model architecture can include a convolution encoder operations stage 910 which takes the extracted data / features corresponding to the sensor-equipped instrument 804, a deconvolution decoder operations stage 920, and a segment classifier 930 which generates a segmented force profile. In convolutional operations 911, feature extraction can be performed using a filter that sweeps across the data matrix within a receptive field. Batch normalization 912 can be performed to reduce the internal covariance shift and stabilizing the network while being trained. ReLu activation function 913 can be used to introduce non-linearity to the data. The max pooling operation 914 can reduce the size of extracted features maps so that the computational costs are reduced and/or over-fitting is avoided. Upsampling 921 and concatenation 922 can be performed to reconstruct the original data pattern through the decoding procedure. In the segment classifier stage 930, dropout operation 931 can be utilized for regularization and Sigmoid 932 can be used as the activation function for classification.

[00105] A second machine learning model 832 can characterize force profile pattern recognition. The output of this second machine learning model 832 can be used to characterize surgical experience level directly or indirectly. In other words, the output of the second machine learning model 832 can be used as part of an algorithm to classify surgeon experience level (i.e., novice, intermediate, and expert) and allocate

surgical competency scores based on descriptive force patterns, high force error, low force error, variable force, and other unsafe force instances.

[00106] The second machine learning model 832 can, for example, be a neural network or ensemble of neural networks. In one variation, the second machine learning model 832 comprises a deep neural network model for time series classification based on InceptionTime 33 to obtain learned features that together with engineered features 1001 such as described above can be used in a surgeon experience classification.

[00107] FIG. 10 is a diagram 1000 illustrating a second machine learning architecture corresponding to the second machine learning model 832. With this architecture, the input to the network can be a segmented force time-series series ($X_{\text{(seg.)}} \in \mathbb{R}^{(S \times C)}$): S intervals over $C=2$ channels of left and right prong data in SMARTFORCEPS from OrbSurgical, Ltd.). The network can include multiple layers including a *bottleneck layer* 1002 to reduce the dimensionality after a *max pooling layer* 1003, a stacked series of *convolutional layers* 1004 to learn the features followed by a *concatenation layer* 1005. The extracted features can be fused into the network after *resampling and normalization* 1006 as a new dimension to the network 1007. The output of the network can be the probabilities of different classes, i.e., surgical proficiency 1008. 100 epochs can be used in the training parameters along with *Adam* optimizer, *Categorical Cross-Entropy* with a customized loss function, and *accuracy* and *validation loss* as the evaluation metrics. For hyperparameter tuning, grid search can be applied over the learning rate, i.e., within [0.001-0.1], network depth, i.e., within [6-12] layers, input data window size, i.e., within [96-200], and batch size, i.e., within [32-128].

[00108] In addition or in some variations, the output of the second machine learning model 832 can be used to identify or otherwise characterize surgical task type. This can be based on a time-series based surgeon activity recognition while performing a specific task (i.e., coagulation, dissection, pulling, retracting, and manipulating). A recurrent neural network based on InceptionTime 33 with similar or close characteristics can be used in this regard. The output of the network can be the probabilities of different surgical tasks 1008. 150 epochs can be used in the training parameters along with Adam optimizer, Categorical Cross-Entropy with a customized loss function, and accuracy and validation loss as the evaluation metrics. For hyperparameter tuning, grid search can be applied over the learning rate, i.e., within [0.001-0.1], network depth, i.e., within [6-12] layers, input data window size, i.e., within [96-200], and batch size, i.e., within [32-128].

[00109] To mitigate the imbalance data issue for the task recognition procedure, a synthetic time-series generation technique based on dynamic time warping (DTW) and Stochastic Subgradient (SSG) averaging can be utilized. In this technique, new time-series samples can be generated for each class carrying their characteristics based on a modified k-means clustering algorithm, in which the clustering was applied separately for each class and the cluster centroids were used as new data points for the respective classes. To assign data to each centroid, DTW, a point-to-point measure for similarity comparison between two temporal sequence of data which may vary in speed, was used as the distance measure, and to calculate new centroids, Schultz and Jain's stochastic subgradient mean algorithm can be used as the averaging mechanism. To obtain the desired augmented time-series, the following can be used: $k = 1$ (number of k-means iterations), $ssg_epochs = 1$ (number of iterations for the SSG algorithm), $n_base = 2$ (controls the number of centroids to be generated), and

$n_reps - 10$ (number of iterations the algorithm is called). The generated data in each iteration can be fed back to the model to create new data.

[00110] For the output of the first and second machine learning models 828, 832, the loss and accuracy values for both training and validation data in each epoch, the model summary including the type, shape, and parameter counts for each layer, classification report including macro and weighted average accuracy, precision, recall, F1-score during training and validation was reported. Furthermore, for the testing phase, the average time required for testing, confusion matrix, accuracy, [weighted] F1-score, macro and weighted average values of *one-vs-one* and *one-vs-rest* area under the curve (AUC) for receiver operating characteristic (ROC), and an average precision score (micro-averaged over all classes) with the corresponding charts and graphs were generated and saved in the log files. Additionally, data distribution charts loss/accuracy histories, all-class and single-class graphs of ROC with AUC values, and precision-recall visualizations were created for model evaluations.

[00111] The output of the first and second machine learning models 828, 832 can be used to provide feedback to the user of the surgical instrument 804 (e.g., a surgeon, etc.). The feedback can be provided in various manners including haptic, audio, visual (e.g., a heads up display, etc.) and/or on an endpoint computing device 940 (e.g., a mobile phone, a tablet, a computer, etc.). The real-time feedback can be generated after incorporating the sensory input data (IMU: orientation and motion details - Strain Gauge: tool-tissue interaction force - RFID: radio-frequency identification for the unique tool specs (tool type (forceps, dissector, suction device, etc.), tool length, tip size, calibration factor, manufacturing date, etc.)) into the first and second machine learning models 828, 832 and the output can be customized based on

the user skill and tool type. The feedback can be provided, for example, when there is an unsafe event so that the surgeon can take appropriate remedial action.

[00112] The feedback provided by the current subject matter can take various forms and have different granularity. The output of one or more of the first and second machine learning models 828, 832 can be used to specify how a particular user is performing relative to their own past performance, how that particular user is performing relative to his or her peers within a particular group (e.g., hospital), how that particular user is performing across all surgeons, and the like. In some cases, there can be different levels / groupings such as trainee - master – peers and that these groups may have their own associated first and second machine learning models 828, 832 which are used to provide feedback (whether in real-time or post-surgery procedure).

[00113] One or more of the first and second machine learning models 828, 832 can be updated or otherwise trained using a federated learning procedure which utilizes data generated by multiple surgical instruments 804 across different users and/or across different locations. The machine learning model parameters transported to the cloud as part of the federated learning procedure 844 can be de-identified, encrypted (e.g., homomorphically encrypted, etc.) prior to being transported over the network.

[00114] FIG. 11 is a process flow diagram 1100 in which, at 1110, data is received that is generated by at least one sensor forming part of a surgical instrument which characterizes use of the surgical instrument in relation to a patient. Subsequently, at 1120, a force profile is constructed by a first machine learning model using the received data that includes a plurality of force patterns. The first machine learning can be trained using historical surgical instrument usage data. In addition, at

1130, features are extracted from the received data. These extracted features can be used, at 1140, by a second machine learning model which determines one or more attributes characterizing use of the surgical instrument model using the constructed force profile. Data characterizing the determination can, at 1150, be provided (e.g., displayed, loaded into memory, stored in physical persistence, transmitted to a remote computing device, etc.),

[00115] Various implementations of the subject matter described herein may be realized in digital electronic circuitry, integrated circuitry, specially designed ASICs (application specific integrated circuits), computer hardware, firmware, software, and/or combinations thereof. These various implementations may include implementation in one or more computer programs that are executable and/or interpretable on a programmable system including at least one programmable processor, which may be special or general purpose, coupled to receive data and instructions from, and to transmit data and instructions to, a storage system, at least one input device, and at least one output device.

[00116] These computer programs (also known as programs, software, software applications or code) include machine instructions for a programmable processor, and may be implemented in a high-level procedural and/or object-oriented programming language, and/or in assembly/machine language. As used herein, the term “machine-readable medium” refers to any computer program product, apparatus and/or device (e.g., magnetic discs, solid state drives, optical disks, memory, Programmable Logic Devices (PLDs)) used to provide machine instructions and/or data to a programmable processor, including a machine-readable medium that receives machine instructions as a machine-readable signal. The term “machine-readable

signal” refers to any signal used to provide machine instructions and/or data to a programmable processor.

[00117] To provide for interaction with a user, the subject matter described herein may be implemented on a computer having a display device (e.g., a CRT (cathode ray tube) or LCD (liquid crystal display) monitor) for displaying information to the user and a keyboard and a pointing device (e.g., a mouse or a trackball) by which the user may provide input to the computer. Other kinds of devices may be used to provide for interaction with a user as well; for example, feedback provided to the user may be any form of sensory feedback (e.g., visual feedback, auditory feedback, or tactile feedback); and input from the user may be received in any form, including acoustic, speech, or tactile input.

[00118] The subject matter described herein may be implemented in a computing system that includes a back-end component (e.g., as a data server), or that includes a middleware component (e.g., an application server), or that includes a front-end component (e.g., a client computer having a graphical user interface or a Web browser through which a user may interact with an implementation of the subject matter described herein), or any combination of such back-end, middleware, or front-end components. The components of the system may be interconnected by any form or medium of digital data communication (e.g., a communication network). Examples of communication networks include a local area network (“LAN”), a wide area network (“WAN”), and the Internet.

[00119] The computing system may include clients and servers. A client and server are generally remote from each other and typically interact through a communication network. The relationship of client and server arises by virtue of

computer programs running on the respective computers and having a client-server relationship to each other.

[00120] Although a few variations have been described in detail above, other modifications are possible. For example, the logic flow depicted in the accompanying figures and described herein do not require the particular order shown, or sequential order, to achieve desirable results. Other embodiments may be within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A computer-implemented method for characterizing surgeon skill level comprising:

receiving data generated by at least one sensor forming part of a manually operable handheld surgical instrument, the at least one sensor characterizing use of the surgical instrument in relation to a patient;

constructing, by a first machine learning model using the received data, a force profile comprising a plurality of force patterns;

extracting a plurality of features from the received data;

determining, by a second machine learning model using the constructed force profile and the extracted features, one or more attributes characterizing a skill of a surgeon while using the surgical instrument; and

providing data characterizing the determination.

2. The method of claim 1, wherein the first machine learning model comprises a force profile segmentation model trained using historical surgical instrument usage data.

3. The method of claim 2, wherein the second machine learning model comprises a force profile recognition model.

4. The method of any of the preceding claims, wherein the at least one sensor comprises one or more of: an identification sensor, a force sensor, a motion sensor, a position sensor, an accelerometer, or an optical sensor.

5. The method of any of the preceding claims, wherein the surgical instrument comprises forceps with right and/or left prongs having a sensor embedded or affixed thereto.

6. The method of any of the preceding claims, wherein the at least sensor generates time-series based data characterizing use of the surgical instrument.

7. The method of any of the preceding claims further comprising:
reducing noise in the received data prior the extraction of the features and/or use
by the second machine learning model.
8. The method of claim 7 further comprising:
applying rule-based data point filtering to mitigate imbalances in the received
data.
9. The method any of the preceding claims further comprising:
removing outliers in the received data prior to the extraction of the features.
10. The method of any of the preceding claims, wherein the first machine
learning model comprises:
an encoder network followed by a decoder network.
11. The method of any of the preceding claims, wherein the second machine
learning model comprises:
multiple layers including a bottleneck layer to reduce dimensionality after a max
pooling layer, a stacked series of convolutional layers to learn features followed by a
concatenation layer.
12. The method of claim 11 further comprising:
fusing the extracted features into the second machine learning model after
resampling and normalization as a new dimension to the second machine learning model.
13. The method of any of the preceding claims further comprising:
applying a synthetic time-series generation technique based on dynamic time
warping (DTW) and Stochastic Subgradient (SSG) averaging to mitigate imbalance in the
extracted features.

14. The method of any of the preceding claims, wherein the received data comprises a waveform and the extracted features characterize one or more of: maximum, range, coefficient of variance, peak counts, peak values, cycle length, signal fluctuations, entropy, and flat spots.

15. The method of any of the preceding claims further comprising:
normalizing a distribution of the extracted features to minimize a dominant effect of data variances.

16. The method any of the preceding claims, wherein the first machine learning model comprises at least one neural network.

17. The method any of the preceding claims, wherein the data characterizing the determination identifies a skill level associated with a particular surgical task using the surgical instrument.

18. The method any of the preceding claims, wherein at least one of the at least one first machine learning model and the at least one second machine learning model is trained using data generated from a single type of surgical instrument.

19. The method any of the preceding claims, wherein at least one of the at least one first machine learning model and the at least one second machine learning model is trained using data generated from a single surgeon.

20. The method of any of claims 1 to 19, wherein at least one of the at least one first machine learning model and the at least one second machine learning model is trained using data generated from a plurality of surgeons.

21. The method of any of the preceding claims, wherein the surgical instrument comprises an identification element, and the method further comprises:

associating the identification element with one of a plurality of machine learning models; and

selecting at least one of the at least one first machine learning model and the at least one second machine learning model from the plurality of available machine learning models based on the associating.

22. The method of claim 16, wherein the identification element comprises a radio frequency identification (RFID).

23. The method of any of the preceding claims, wherein providing data characterizing the determination comprises one or more of: causing the data characterizing the determination to be displayed in an electronic visual display, storing the data characterizing the determination in physical persistence, loading the data characterizing the determination in memory, or transmitting the data characterizing the determination to a remote computing system.

24. The method of any of the preceding claims, wherein the provided data comprises conveying feedback to a user of the surgical instrument.

25. The method of claim 24, wherein the conveyed feedback comprises one or more of: haptic, visual, or audio feedback.

26. The method of claim 24, wherein the feedback is conveyed on a heads-up display worn or in view of a user of the surgical instrument.

27. The method any of the preceding claims, wherein at least one of the first machine learning model or the second machine learning model is trained on an endpoint computing instrument executing both such models.

28. The method of any of the preceding claims, wherein at least one of the first machine learning model or the second machine learning model is trained at least in part by a cloud-based computing service.

29. The method of any of the preceding claims further comprising:
anonymizing features extracted from the data;
encrypting the anonymized features; and
transmitting the encrypted, anonymized features to a remote computing system to train one or more models corresponding to at least one of the first machine learning model or the second machine learning model.

30. A computer-implemented method for characterizing surgeon skill level comprising:

receiving data generated by at least one sensor forming part of a surgical instrument, the at least one sensor characterizing use of the surgical instrument in a surgical setting in relation to a patient;

extracting a plurality of features from the received data;

determining, by a sequential operation by a first machine learning model followed by a second machine learning model and based on the extracted features, one or more attributes characterizing a skill of a surgeon while using the surgical instrument; and
providing data characterizing the determination.

31. A system comprising:
at least one data processor; and
memory including instructions which, when executed by the at least one data processor, result in a method as in any of the preceding claims.

32. A non-transitory computer program product storing instructions which, when executed by at least one processor, result in a method as in any of claim 1 to 29.

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100

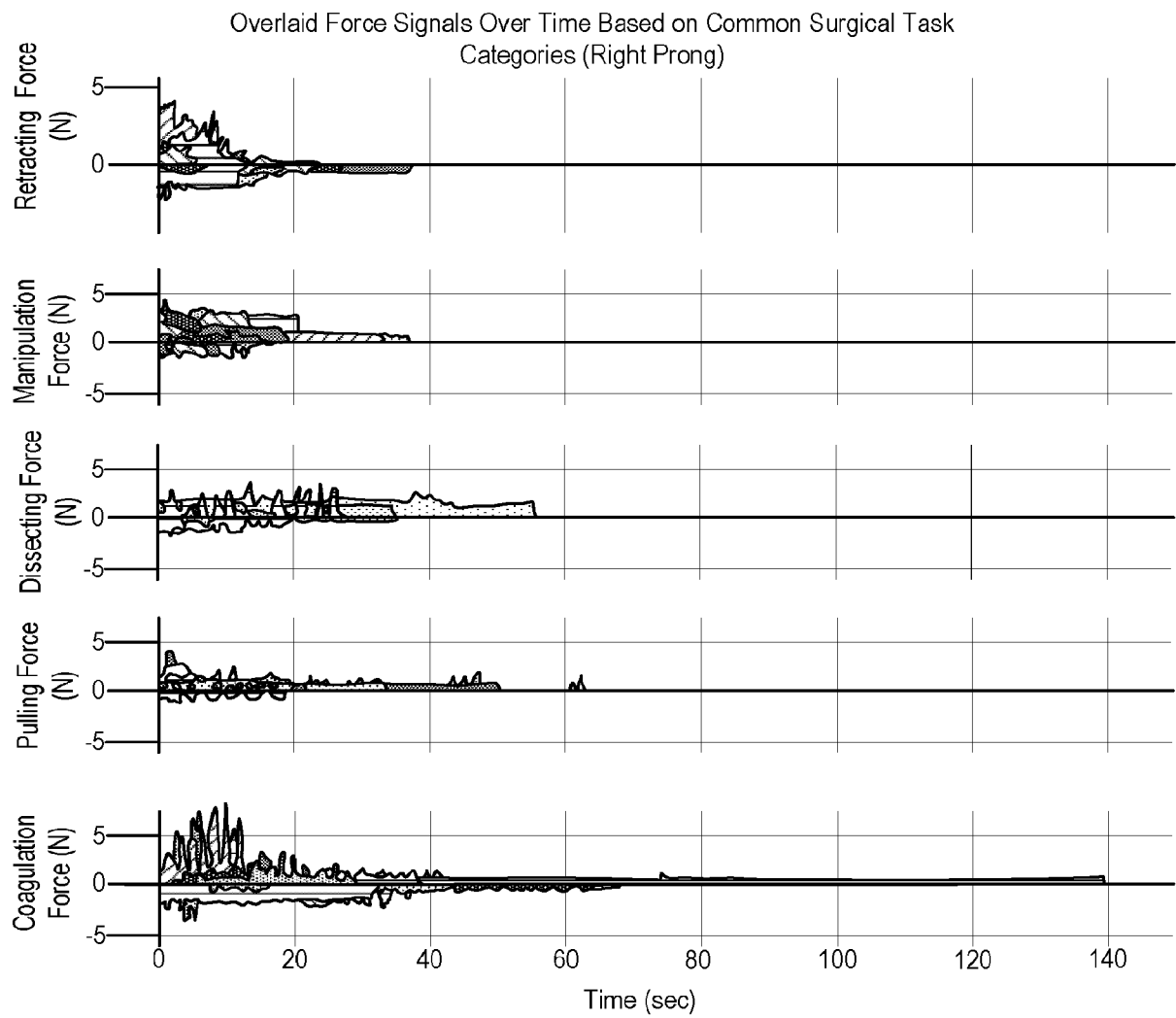


FIG. 1

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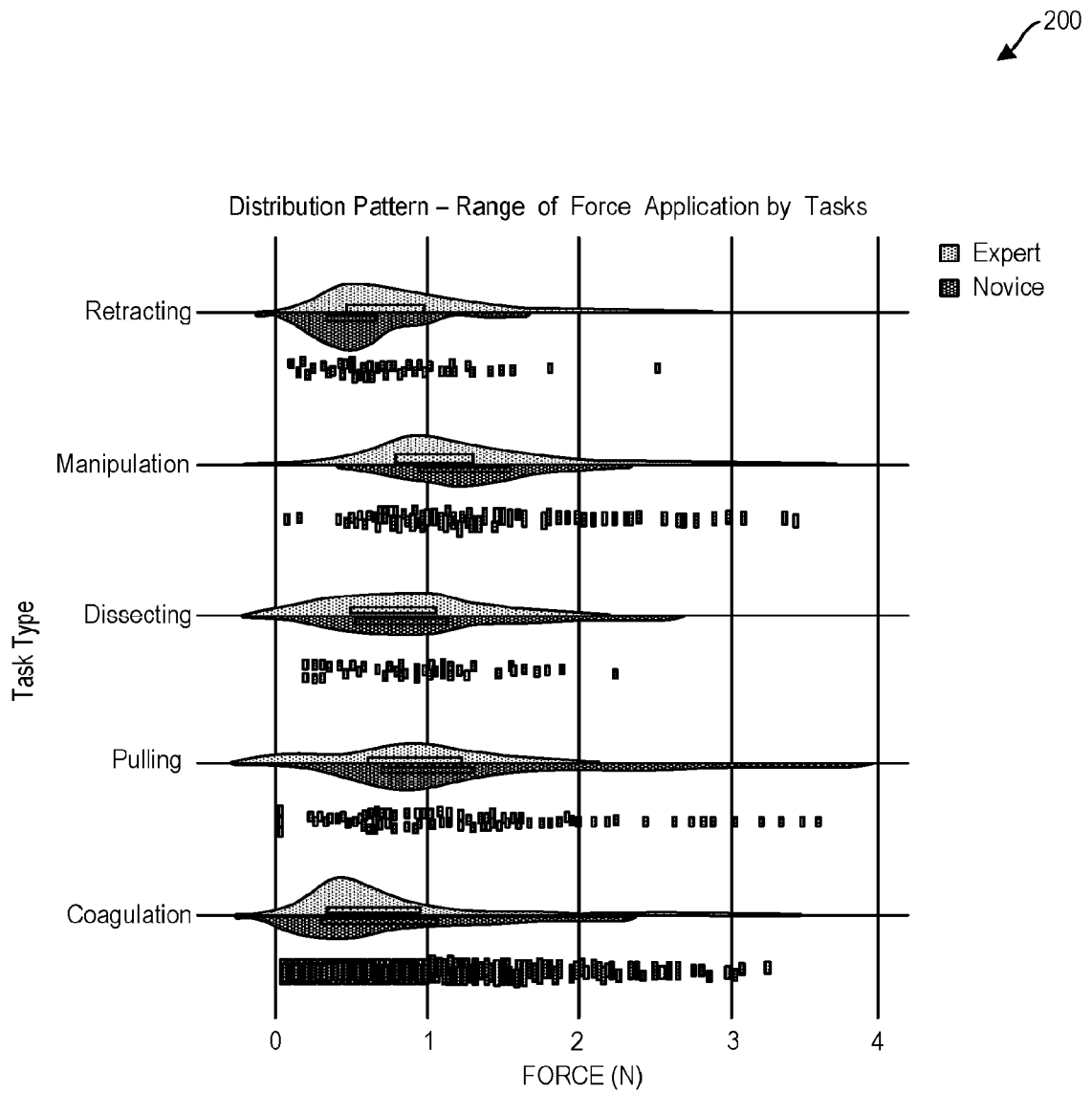


FIG. 2

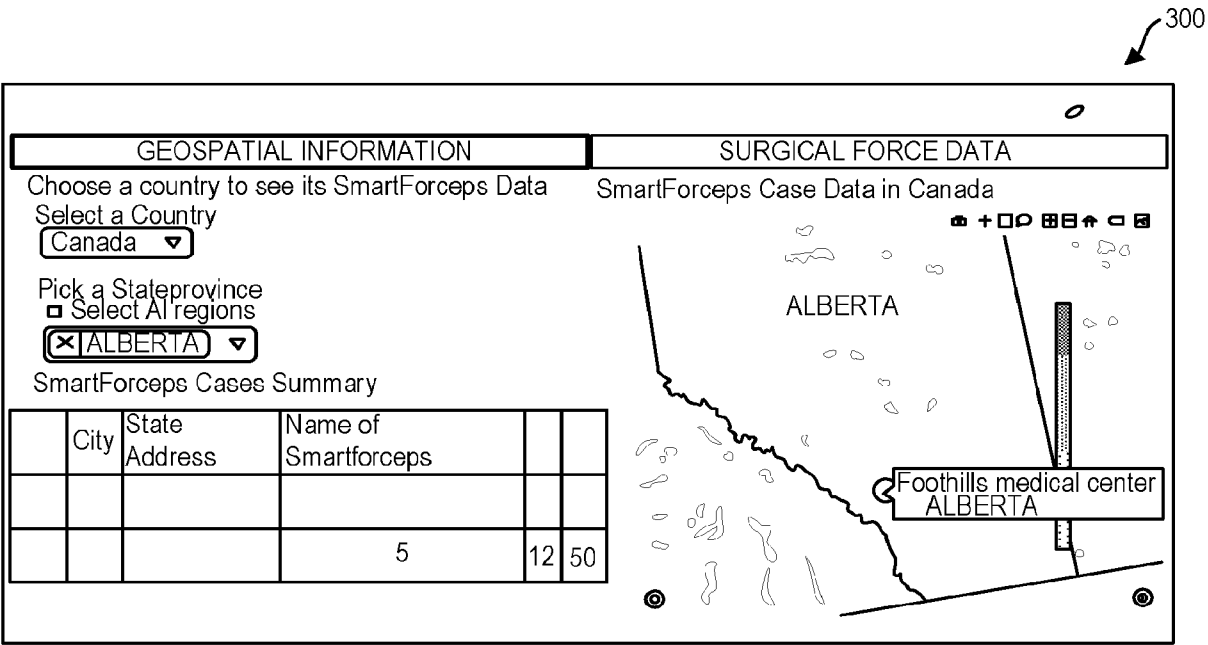


FIG. 3

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400

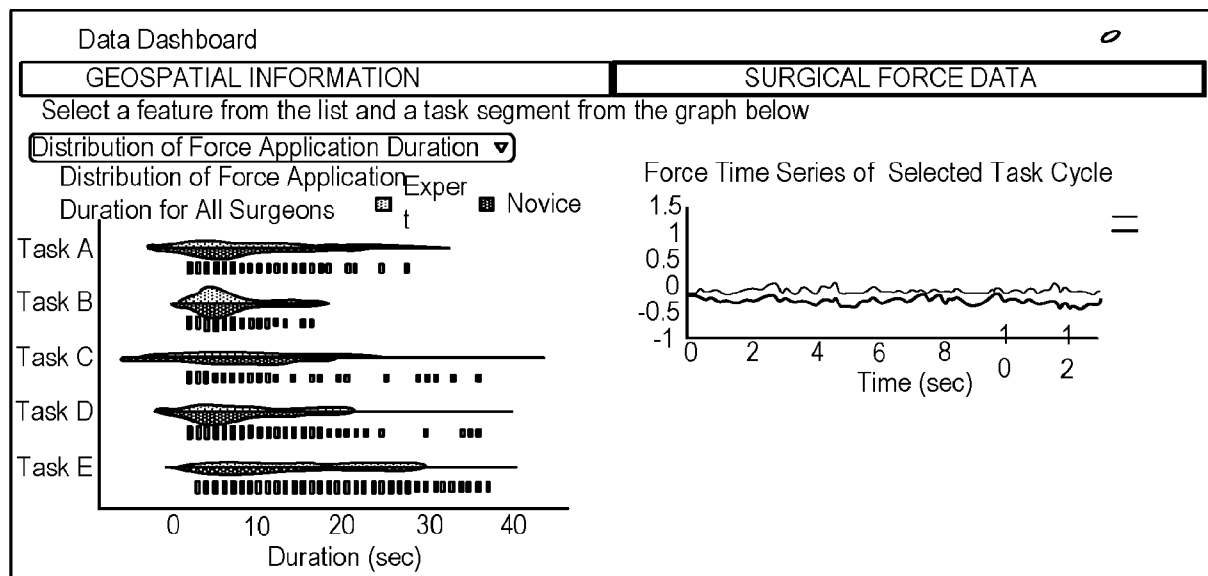


FIG. 4

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500

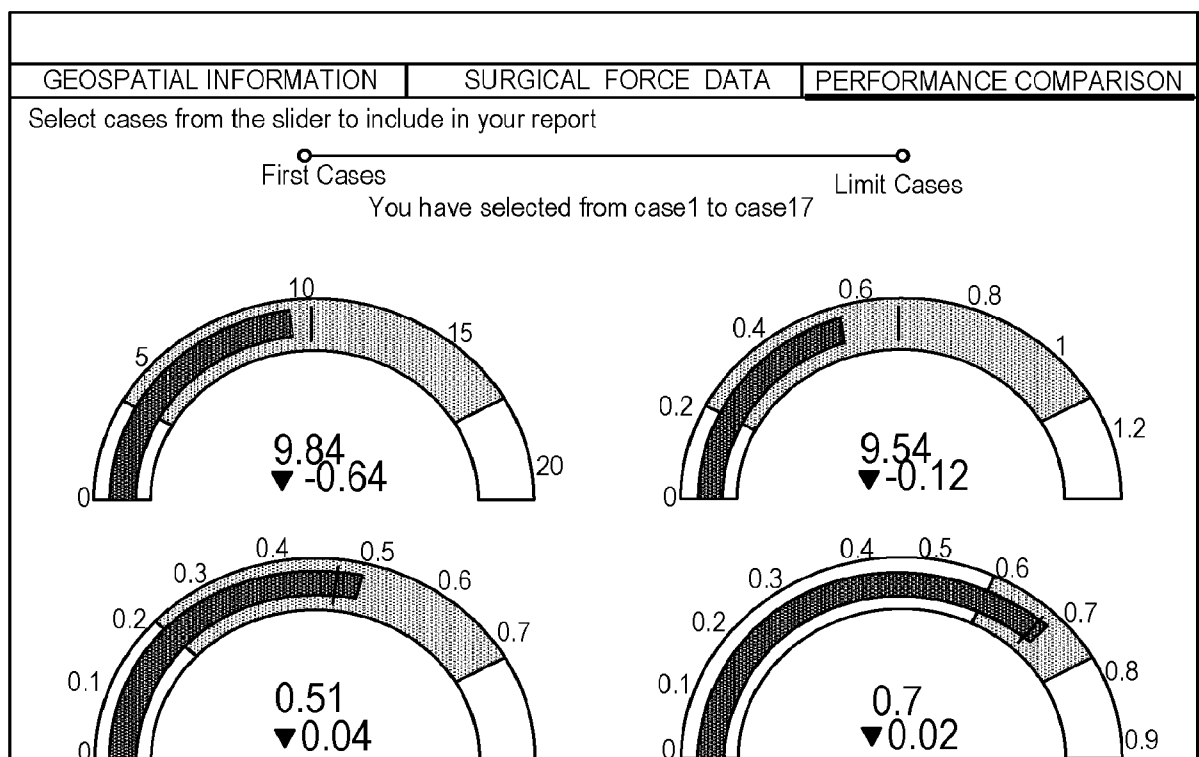


FIG. 5

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600

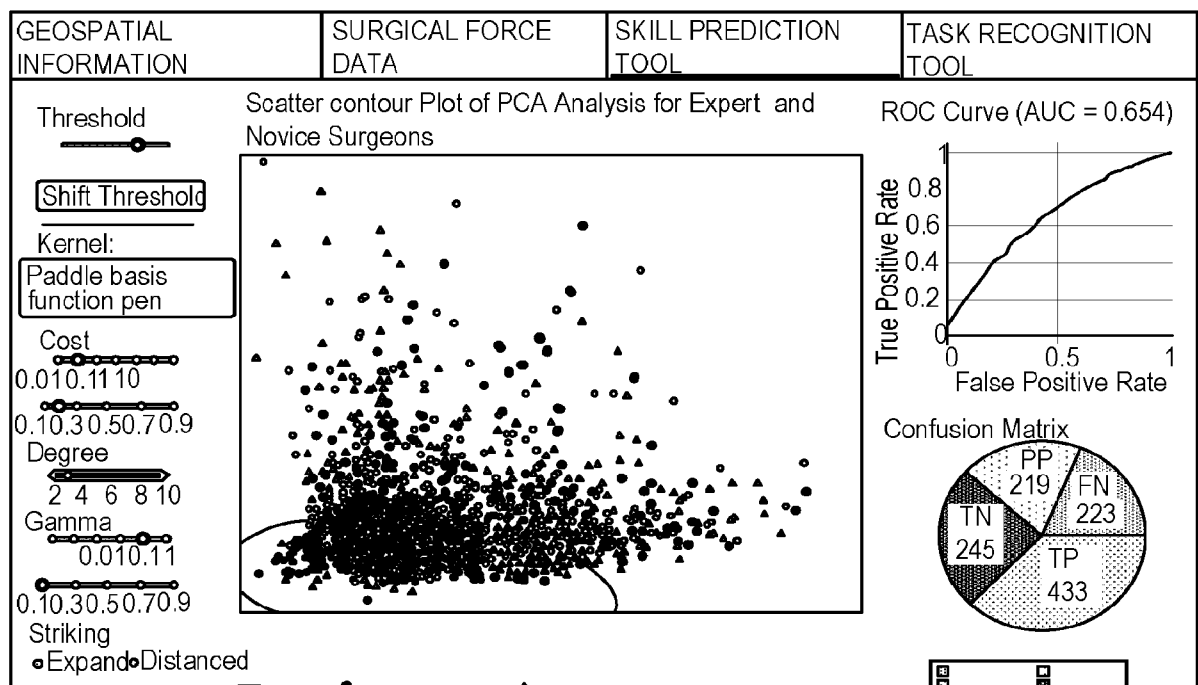


FIG. 6

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700

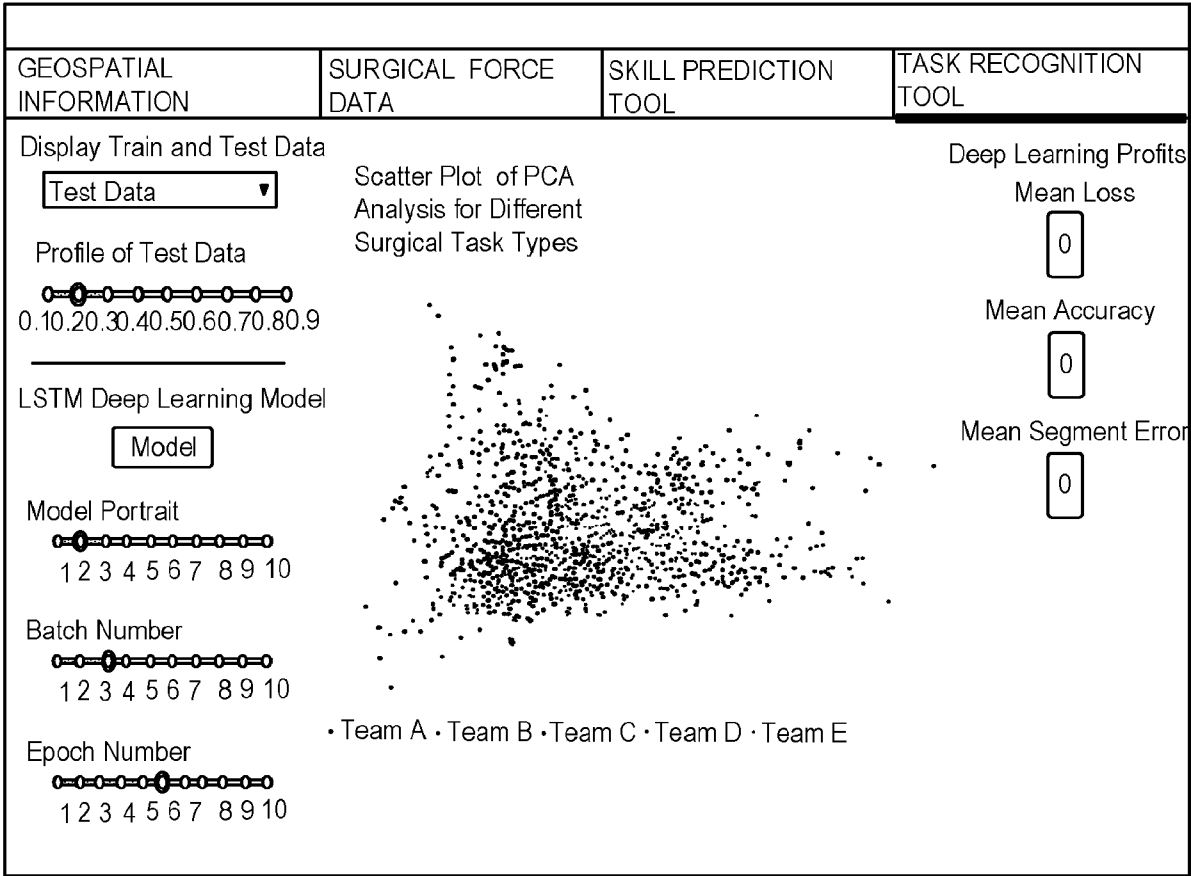


FIG. 7

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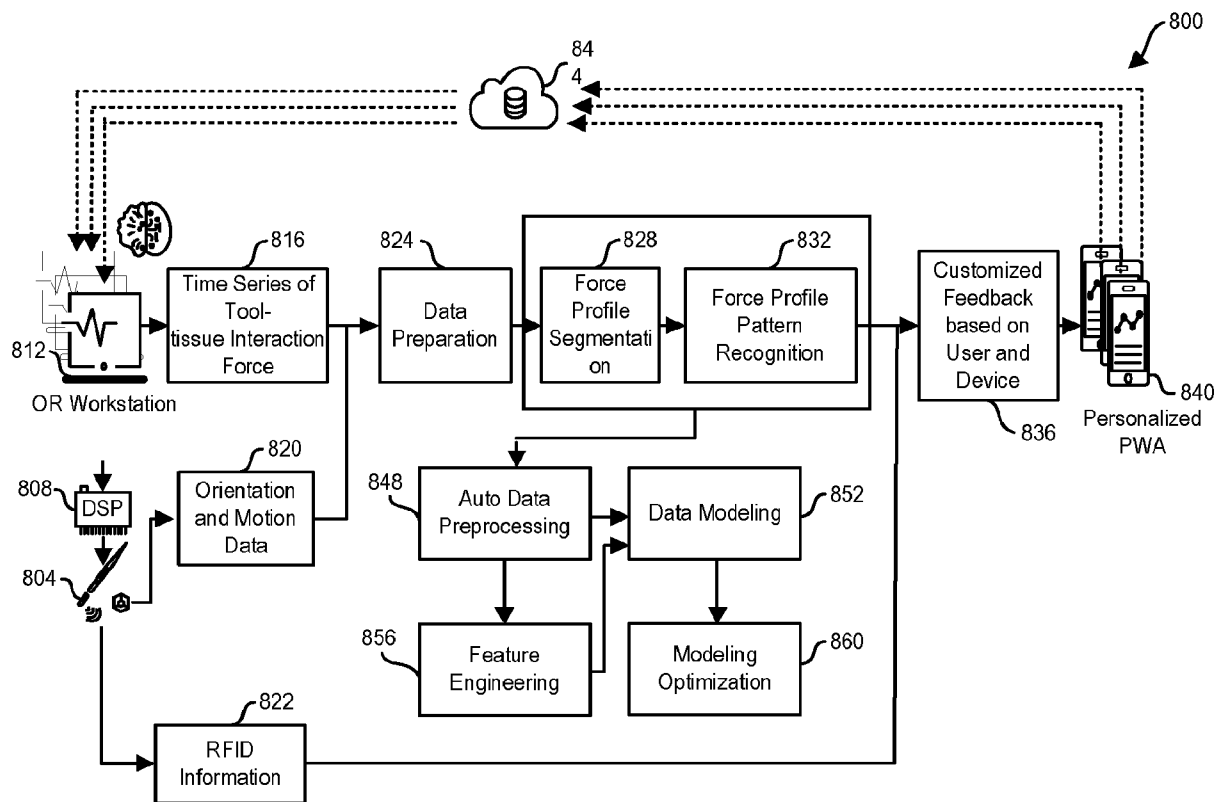


FIG. 8

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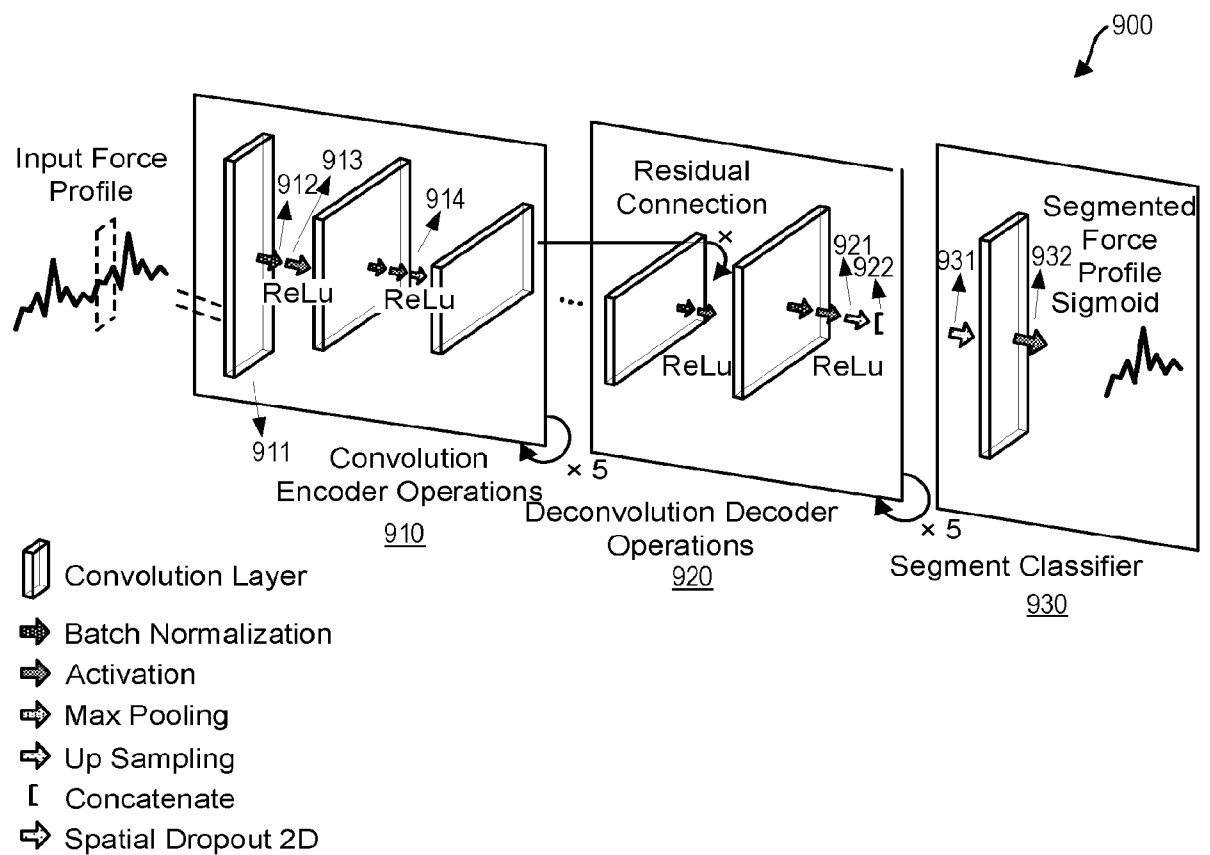


FIG. 9

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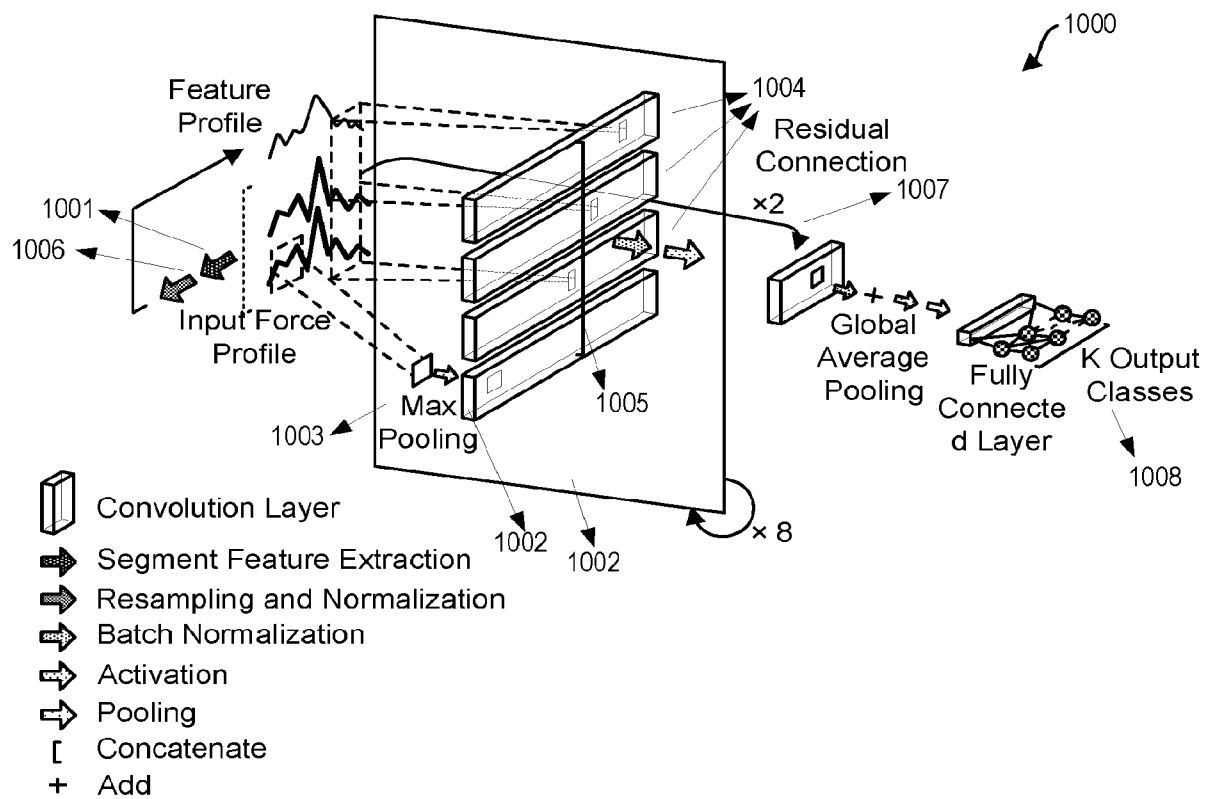


FIG. 10

11/11

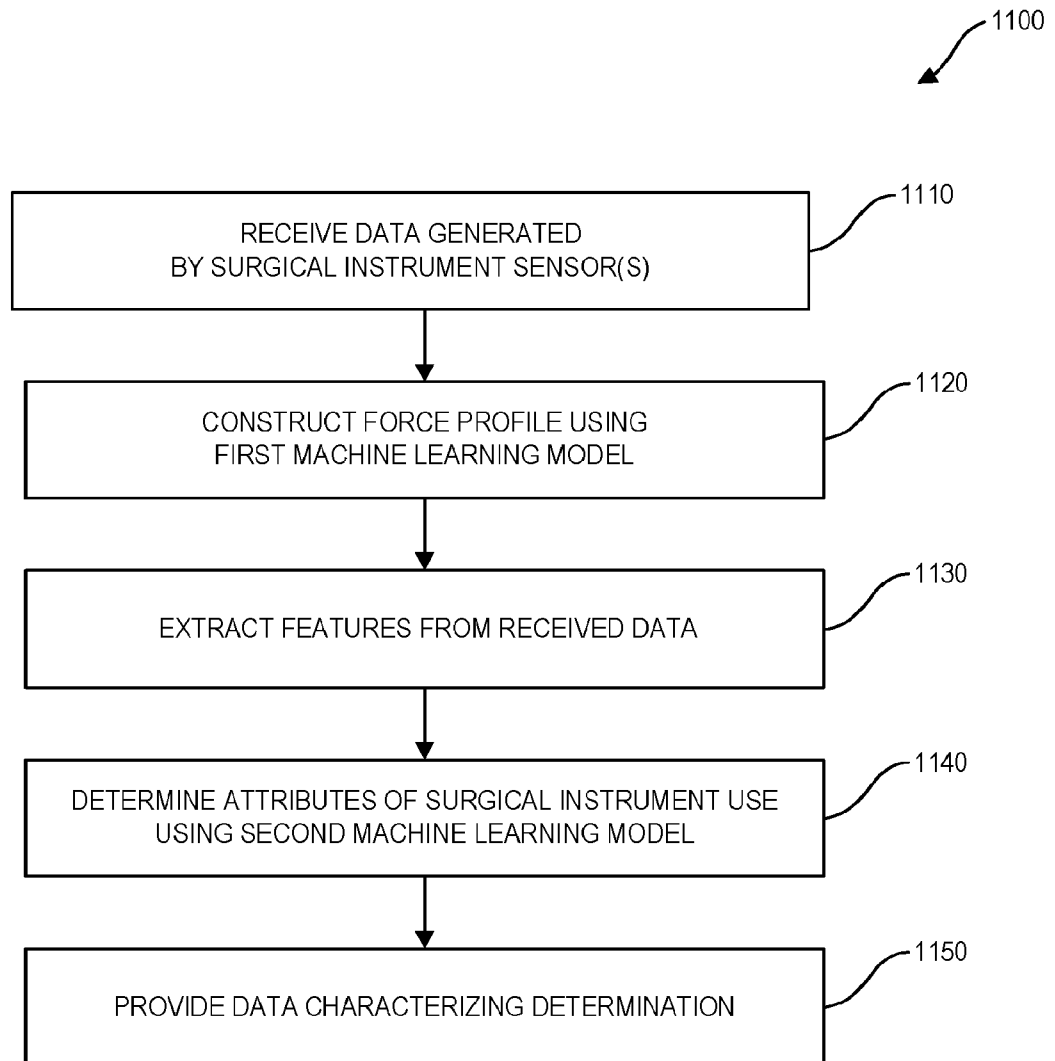


FIG. 11

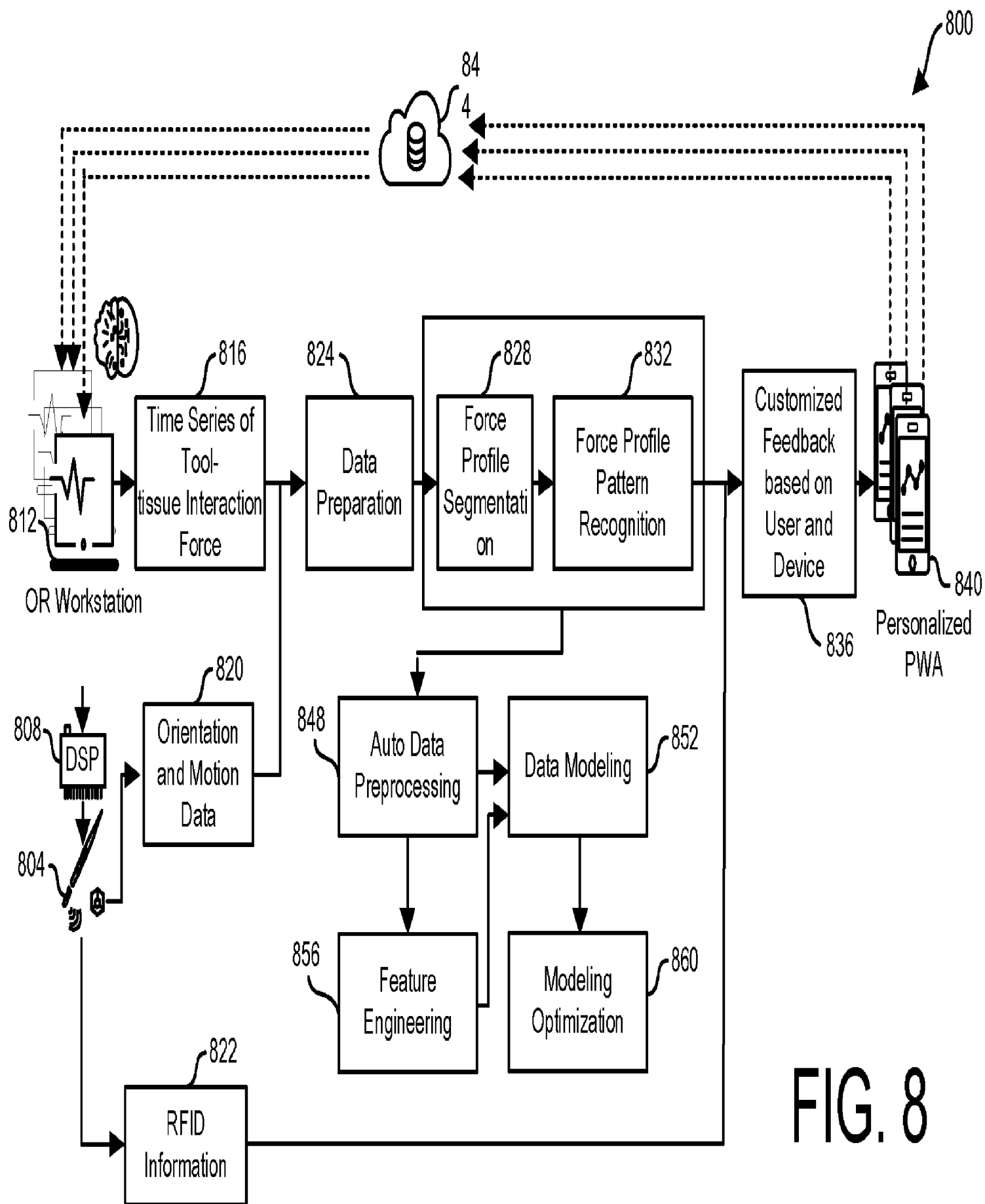


FIG. 8