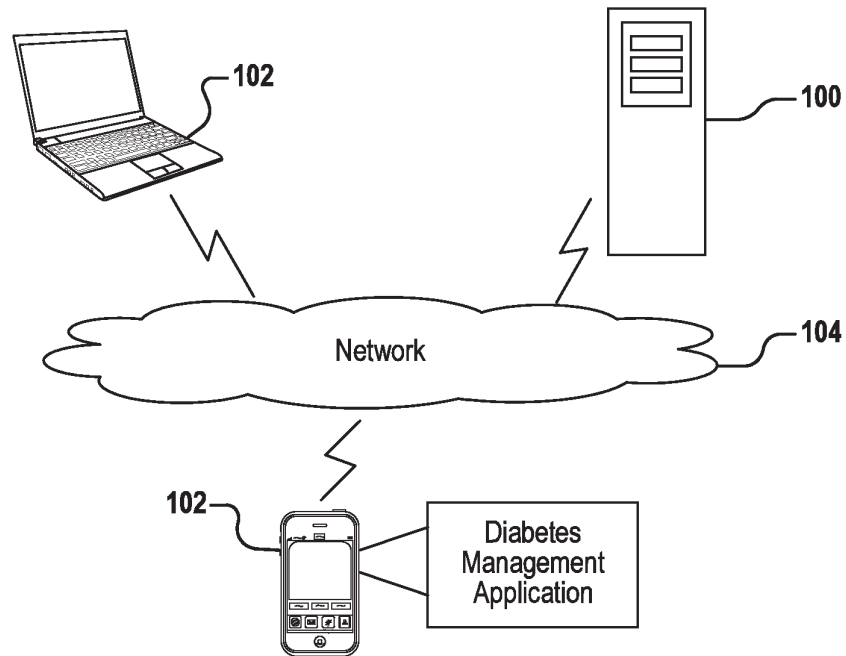
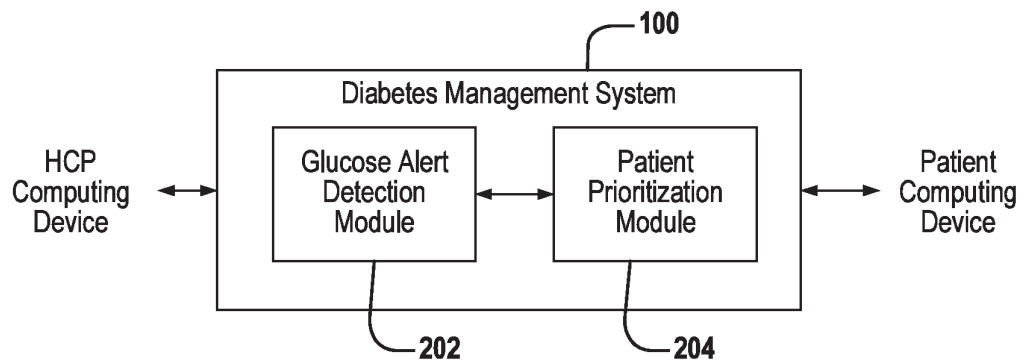




**FIG. 1**



**FIG. 2**

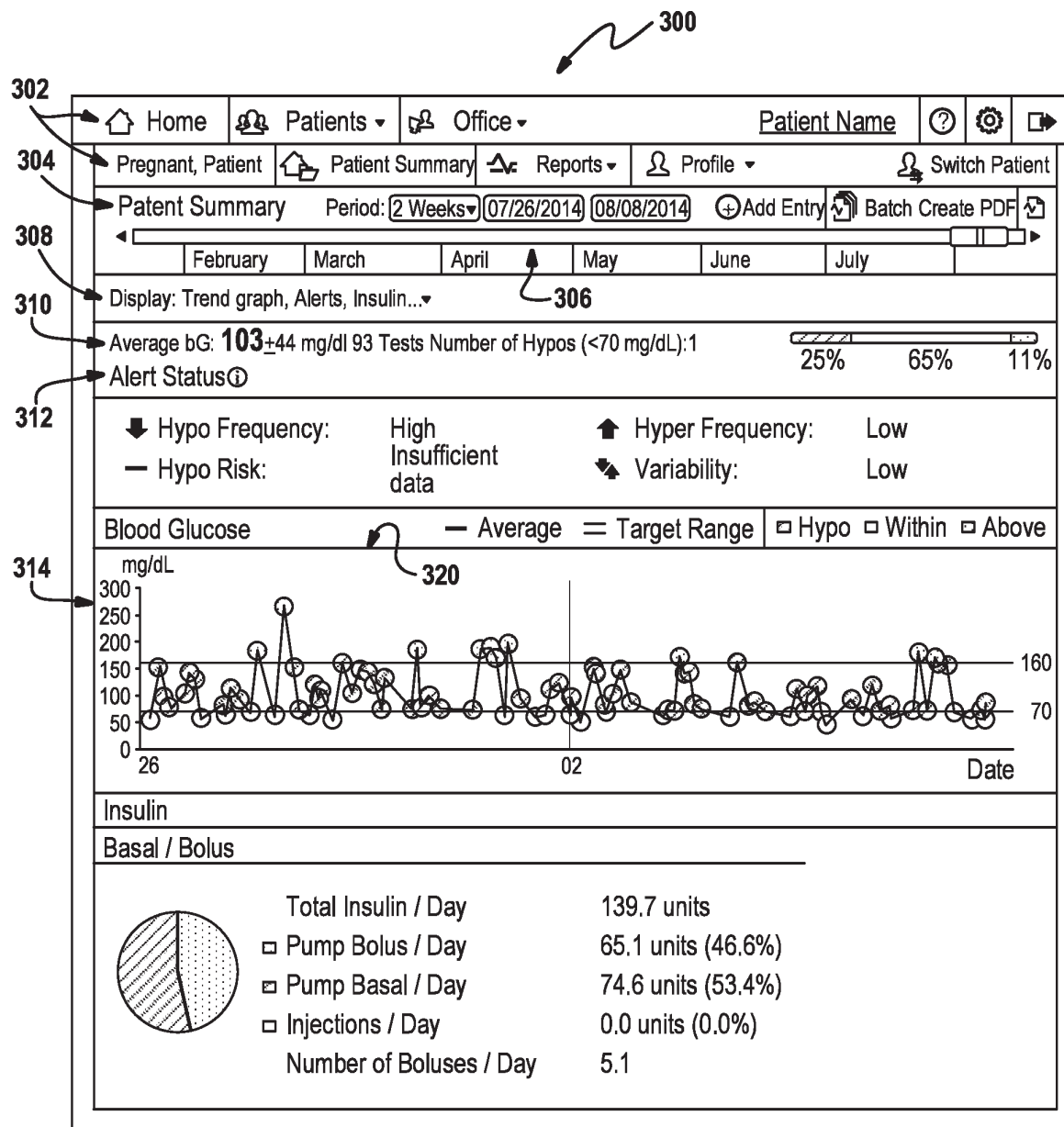
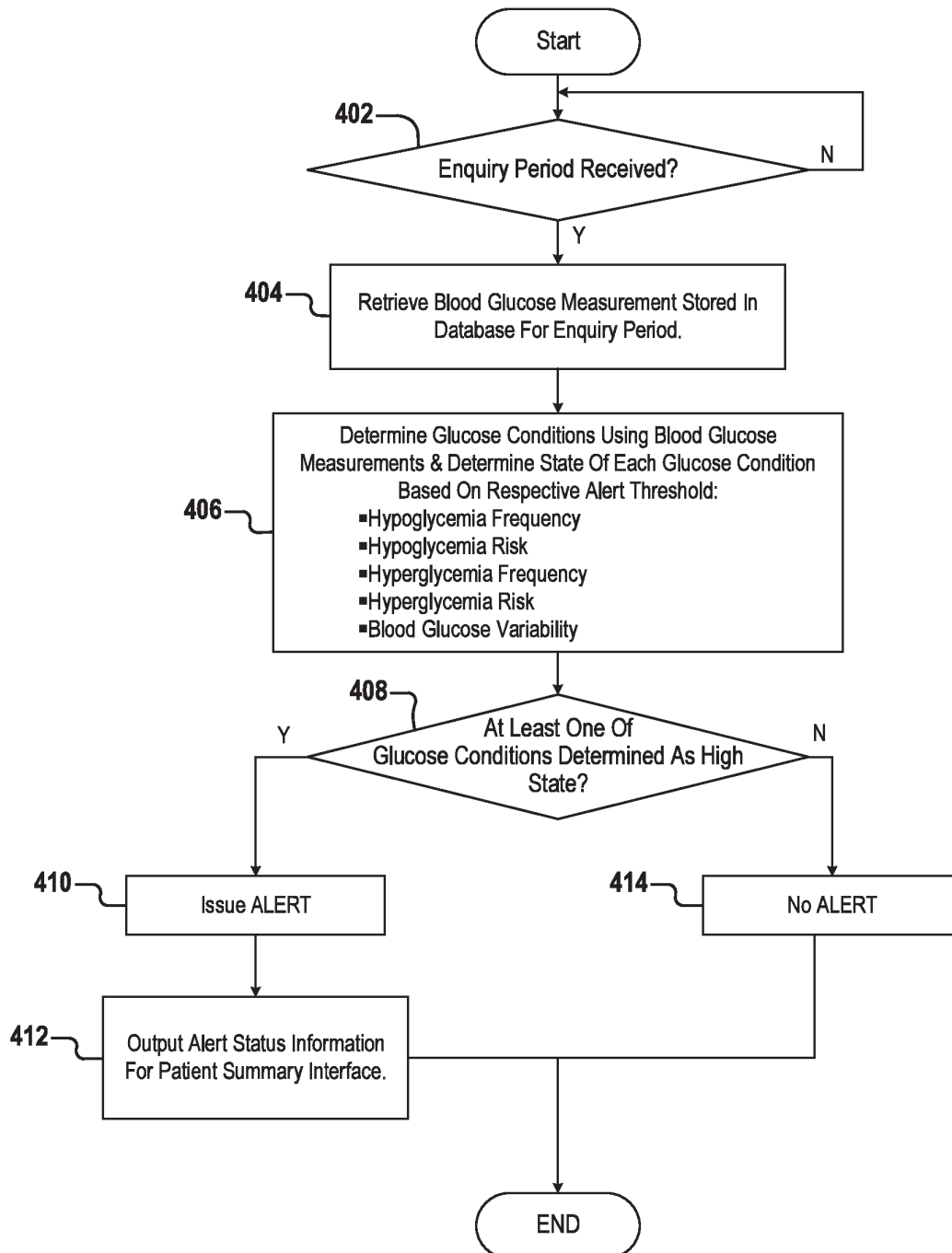


FIG. 3

**FIG. 4**

## bG Hypoglycemia Frequency

| Frequency Type   | Rule                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Alert Threshold |
|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| % of Occurrences | <p>Within the selected date range (i.e., enquiry period):</p> <ol style="list-style-type: none"> <li>1. Numerator: Count the number of bG_DATA, excluding bG HI, that are less than the Patient's bG Hypo Target Threshold.</li> <li>2. Denominator: Count the total number of bG_DATA.</li> <li>3. Compute the % of occurrences by dividing the numerator result by the denominator result, and multiplying by 100.</li> <li>4. State of bG Hypo Frequency is determined as HIGH if the result from Step 3 is greater than or equal to the Alert Threshold for bG Hypo % Occurrences Value.</li> <li>5. State of bG Hypo Frequency is determined as LOW if the result from Step 3 is less than the Alert Threshold for bG Hypo % of Occurrences Value.</li> </ol> | Adjustable      |
| # of Occurrences | <p>Within the selected date range (i.e., enquiry period):</p> <ol style="list-style-type: none"> <li>1. Count the number of bG_DATA excluding bG HI, that are less than the Patient's bG Hypo Target Threshold.</li> <li>2. State of bG Hypo Frequency is determined as HIGH if the result from Step 1 is greater than or equal to the Alert Threshold for bG Hypo # of Occurrences Value.</li> <li>3. State of bG Hypo Frequency is determined as HIGH if the result from Step 1 is less than the Alert Threshold for bG Hypo # of Occurrences Value.</li> </ol>                                                                                                                                                                                                  | Adjustable      |

**FIG. 5A**

## bG Hyperglycemia Frequency

| Frequency Type   | Rule                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Alert Threshold |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| % of Occurrences | <p>Within the selected date range:</p> <ol style="list-style-type: none"><li>1. Numerator: Count the number of bG_DATA, excluding bG LO, that are greater than the Patient's Single bG Target Range Threshold.</li><li>2. Denominator: Count the total number of bG_DATA.</li><li>3. Compute the % of occurrences by dividing the numerator result by the denominator result, and multiplying by 100.</li><li>4. State of bG Hypo Frequency is determined as HIGH if the result from Step 3 is greater than or equal to the Alert Threshold for bG Hyper % Occurrences Value.</li><li>5. State of bG Hypo Frequency is determined as LOW if the result from Step 3 is less than the Alert Threshold for bG Hyper % of Occurrences Value.</li></ol> | Adjustable      |

**FIG. 5B**

## bG Hypoglycemia Risk

| Rule                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Alert Threshold  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| <p>Within the selected date range:</p> <ol style="list-style-type: none"> <li>1. If the Data Range is less than or equal to 3 weeks, AND <ol style="list-style-type: none"> <li>i. At least one 3-Day Profile structured test exists with at least 17 bG results that have occurred within this date range, THEN proceed to Step 3.</li> </ol> </li> <li>OR</li> <li>2. At least 28 patient's bG_DATA values exist, AND <ol style="list-style-type: none"> <li>i. For all bG_DATA that occur at time equal to or greater than the patient's Wakeup Meal Time and less than the patient's After Lunch Meal Time, compute the Mean number of Tests per Day using the formula: <math display="block">\frac{\text{Number of bG\_All\_DATA}}{\text{Number of Days in Date\_Range}}</math> </li> <li>ii. For all bG_DATA that occur at time equal to or greater than the patient's After Lunch Meal and less than the patient's Wakeup Meal Time, compute the Mean number of Tests per Day using the formula: <math display="block">\frac{\text{Number of bG\_All\_DATA}}{\text{Number of Days in Date\_Range}}</math> </li> <li>iii. If the results from Step (a) AND Step (b) are greater than or equal to 1, THEN proceed to Step 3.</li> </ol> </li> <li>3. Using the following formula, compute the r(bG) values for all the patient's bG_Data. <math display="block">r(bG) = 10 * [1.509 * (\ln(bG)^{1.084} - 5.381)]^2</math> <ol style="list-style-type: none"> <li>i. For bG values &lt;20 mg/dL or bG LO, record a score of 100 for the rl(bG) value.</li> <li>ii. For bG values &gt;600 mg/dL or bG HI, record a score of 0 for the rl(bG) value.</li> </ol> </li> <li>4. Compute Low bG [Risk] Index (LBGI) value using the following formula: <math display="block">LBGI = \frac{1}{n} \sum_{i=1}^n rl(bG_i)</math> </li> <li>5. State of bG Hypo Risk is determined as HIGH if the result from Step 4 is greater than 2.5 (i.e., Alert Threshold).</li> <li>6. State of bG Hypo Risk is determined as LOW if the result from Step 4 is greater than 2.5 (i.e., Alert Threshold).</li> <li>7. If less than 28 patient's bG_DATA values available, then state of bG Hypo Risk is not available due to insufficient data.</li> </ol> | Fixed and Preset |

**FIG. 5C**

## bG Hyperglycemia Risk

| Rule                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Alert Threshold  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| <p>Within the selected date range:</p> <ol style="list-style-type: none"> <li>1. If the Data Range is less than or equal to 3 weeks, AND               <ol style="list-style-type: none"> <li>i. At least one 3-Day Profile structured test exists with at least 17 bG results that have occurred within this date range, THEN proceed to Step 3.</li> </ol> </li> <li>OR</li> <li>2. At least 28 patient's bG_DATA values exist, AND               <ol style="list-style-type: none"> <li>i. For all bG_DATA that occur at time equal to or greater than the patient's Wakeup Meal Time and less than the patient's After Lunch Meal Time, compute the Mean number of Tests per Day using the formula:                   <math display="block">\frac{\text{Number of bG\_All\_DATA}}{\text{Number of Days in Date\_Range}}</math> </li> <li>ii. For all bG_DATA that occur at time equal to or greater than the patient's After Lunch Meal and less than the patient's Wakeup Meal Time, compute the Mean number of Tests per Day using the formula:                   <math display="block">\frac{\text{Number of bG\_All\_DATA}}{\text{Number of Days in Date\_Range}}</math> </li> <li>iii. if the results from Step (a) AND Step (b) are greater than or equal to 1, THEN proceed to Step 3.</li> </ol> </li> <li>3. Using the following formula, compute the r(bG) values for all the patient's bG_Data.                   <math display="block">r(bG) = 10 * [1.509 * (\ln(bG)^{1.084} - 5.381)]^2</math> <ol style="list-style-type: none"> <li>i. For bG values &lt;20 mg/dL or bG LO, record a score of 0 for the rh(bG) value.</li> <li>ii. For bG values &gt;600 mg/dL or bG HI, record a score of 100 for the rh(bG) value.</li> </ol> </li> <li>4. Compute High bG [Risk] Index (HBGI) value using the following formula:                   <math display="block">HBGI = \frac{1}{n} \sum_{i=1}^n rh(bG_i)</math> </li> <li>5. State of bG Hyper Risk is determined as HIGH if the result from Step 4 is greater than 10 (i.e., Alert Threshold).</li> <li>6. State of bG Hyper Risk is determined as LOW if the result from Step 4 is greater than 10 (i.e., Alert Threshold).</li> <li>7. If less than 28 patient's bG_DATA values available, then state of bG Hyper Risk is not available due to insufficient data.</li> </ol> | Fixed and Preset |

**FIG. 5D**

## bG Variability

| Variability Type                   | Rule                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Alert Threshold |
|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Standard Deviation<br>% of Mean bG | <p>Within the selected date range:</p> <ol style="list-style-type: none"> <li>1. Compute the Standard Deviation using the following formula for the patient's bG_DATA. <math display="block">SD = \sqrt{\frac{1}{n-1} \sum_{i=1}^n (X_i - MX)^2}</math> <p>When the number of bG_DATA &lt; 2, then the standard deviation shall not be calculated, due to insufficient data available. Thus, the state of bG Variability is not available.</p> </li> <li>2. Compute the Mean bG value using the following formula for the patient's bG_DATA. <p>N = number of selected X values<br/> Xi = the i<sup>th</sup> selected X value</p> <math display="block">MX = \frac{1}{n} \sum_{i=1}^n X_i</math> </li> <li>3. Compute the Standard Deviation % of the Mean by dividing the results from Step 1 by the result from Step 2 and then multiplying the result by 100.</li> <li>4. State of bG Variability is determined as HIGH if the result from Step 3 "Computed Standard Deviation % of Mean" is greater than the Alert Threshold for bG Standard Deviation % of Mean Value.</li> <li>5. State of bG Variability is determined as LOW if the result from Step 3 "Computed Standard Deviation % of Mean" is less than or equal to the Alert Threshold for bG Standard Deviation % of Mean Value.</li> </ol> | Adjustable      |

**FIG. 5E**

600

|                                                                                                                          |            |          |                                                                                                  |   |   |   |
|--------------------------------------------------------------------------------------------------------------------------|------------|----------|--------------------------------------------------------------------------------------------------|---|---|---|
| Home                                                                                                                     | Patients ▾ | Office ▾ | Patient Name                                                                                     | ? | ⚙ | ▶ |
| <b>Alert Settings</b>                                                                                                    |            |          |                                                                                                  |   |   |   |
| Time Range: <span style="border: 1px solid black; padding: 2px;">2 Weeks</span> ▾                                        |            |          |                                                                                                  |   |   |   |
| <b>Blood Glucose Alerts</b>                                                                                              |            |          |                                                                                                  |   |   |   |
| <div style="display: flex; justify-content: space-between;"> <span>⏴ Hypo Frequency Alert</span> <span>602</span> </div> |            |          |                                                                                                  |   |   |   |
| <input checked="" type="radio"/> Hypo Frequency: % of bG values below hypo limit                                         |            |          | more than <span style="border: 1px solid black; padding: 2px;">10</span> % of all bG values      |   |   |   |
| <input checked="" type="radio"/> Hypo Frequency: Number of bG values below hypo limit                                    |            |          | more than <span style="border: 1px solid black; padding: 2px;">1</span> or more of all bG values |   |   |   |
| <div style="display: flex; justify-content: space-between;"> <span>⏵ Hypo Risk Alert</span> <span>602</span> </div>      |            |          |                                                                                                  |   |   |   |
| <input checked="" type="checkbox"/> Hypo Risk: LBGI                                                                      |            |          | more than 2.5                                                                                    |   |   |   |
| <div style="display: flex; justify-content: space-between;"> <span>Hyper Alert</span> <span>602</span> </div>            |            |          |                                                                                                  |   |   |   |
| <input checked="" type="radio"/> Hypo Frequency: % of bG values above target range                                       |            |          | more than <span style="border: 1px solid black; padding: 2px;">30</span> % of all bG values      |   |   |   |
| <input checked="" type="radio"/> Hypo Frequency: HBGI                                                                    |            |          | more than 10.0                                                                                   |   |   |   |
| <div style="display: flex; justify-content: space-between;"> <span>⚙ Variability Alert</span> <span>602</span> </div>    |            |          |                                                                                                  |   |   |   |
| <input checked="" type="radio"/> Variability: Standard Deviation (SD)                                                    |            |          | more than <span style="border: 1px solid black; padding: 2px;">50</span> % of Average bG         |   |   |   |
| <input checked="" type="radio"/> Variability: Standard Deviation (SD)                                                    |            |          | more than <span style="border: 1px solid black; padding: 2px;">75</span> mg/dL                   |   |   |   |
| <div style="border: 1px solid black; padding: 5px; display: inline-block;">Save</div>                                    |            |          |                                                                                                  |   |   |   |

**FIG. 6**

700

Home

Patients

Office

Patient Name

Welcome, SAMPLEPATIENTHCPAUGUST2014!

Your last visit was on 08/19/2014 08:28 AM

Patients

Display: Date of Birth, Patient ID, Therapy Type, Average bG and Standard Deviation, ...

| Last Name | First Name | Date of Birth | Person with Diabetes ID | Therapy Type | Average bG +/- SD | Tests / Day | Most Recent Data | Alerts |
|-----------|------------|---------------|-------------------------|--------------|-------------------|-------------|------------------|--------|
| Adams     | Nick       | 05/03/1964    |                         | MDI (ICT)    | 187 +/- 102 mg/dL | 4.7         | 08/08/2014       |        |
| Andrews   | Larry      | 11/18/1943    |                         | Other        | 155 +/- 66 mg/dL  | 7.0         | 08/08/2014       |        |
| Brock     | Patient    | 08/31/1989    |                         | Other        | 103 +/- 44 mg/dL  | 6.6         | 08/08/2014       |        |
| Davis     | Lydia      | 08/26/1961    |                         | Other        | 81 +/- 27 mg/dL   | 0.1         | 08/13/2014       |        |
| Franklin  | Cody       | 02/20/2008    |                         | Other        | 178 +/- 87 mg/dL  | 7.9         | 08/08/2014       |        |

5

of 10 patients

<<

<

1

2

>

>>

702

704

FIG. 7

| Glucose Condition       | Weight Factor |
|-------------------------|---------------|
| Hypoglycemia Frequency  | 8             |
| Hypoglycemia Risk       | 4             |
| Hyperglycemia Frequency | 2             |
| Hyperglycemia Risk      | 2             |
| Variability             | 1             |

**FIG. 8A**

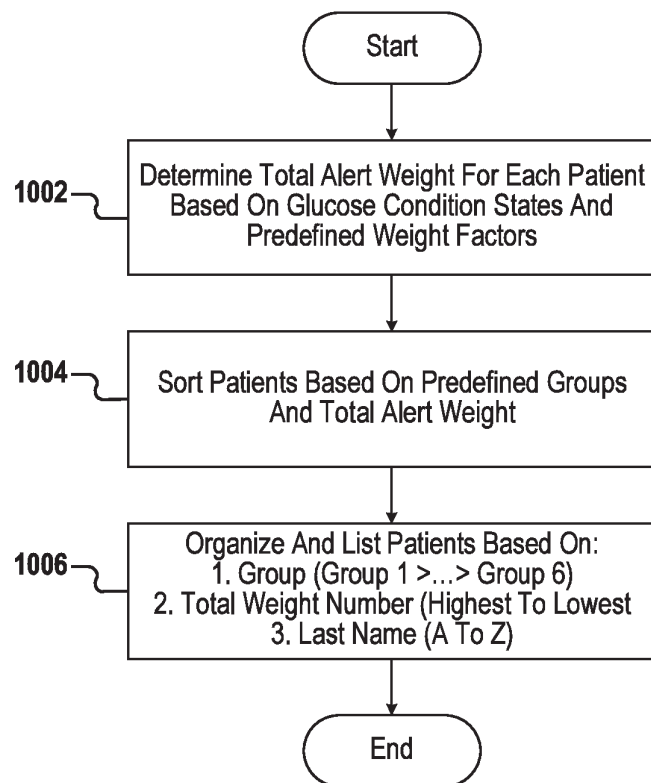
| State             | Weight Factor |
|-------------------|---------------|
| HIGH              | 10000         |
| LOW               | 100           |
| Insufficient Data | 1             |

**FIG. 8B**

|                   |               | Hypo-Frequency | Hypo-Risk | Hyper-Frequency | Hyper-Risk | Variability |
|-------------------|---------------|----------------|-----------|-----------------|------------|-------------|
|                   | Weight Factor | 8              | 4         | 2               | 2          | 1           |
| HIGH              | 10000         | 80000          | 40000     | 20000           | 20000      | 10000       |
| LOW               | 100           | 800            | 400       | 200             | 200        | 100         |
| Insufficient Data | 1             | 8              | 4         | 2               | 2          | 1           |

**FIG. 8C**

| Group No. | Minimum Alert Weight | Maximum Alert Weight |
|-----------|----------------------|----------------------|
| Group 1   | 80000                | -                    |
| Group 2   | 40000                | 79999                |
| Group 3   | 20000                | 39999                |
| Group 4   | 10000                | 19999                |
| Group 5   | 100                  | 9999                 |
| Group 6   | -                    | 99                   |

**FIG. 9****FIG. 10**