The patient was given a User card file for Evaluation. After data collection, the User card file was sent to Patient Data Analysis.

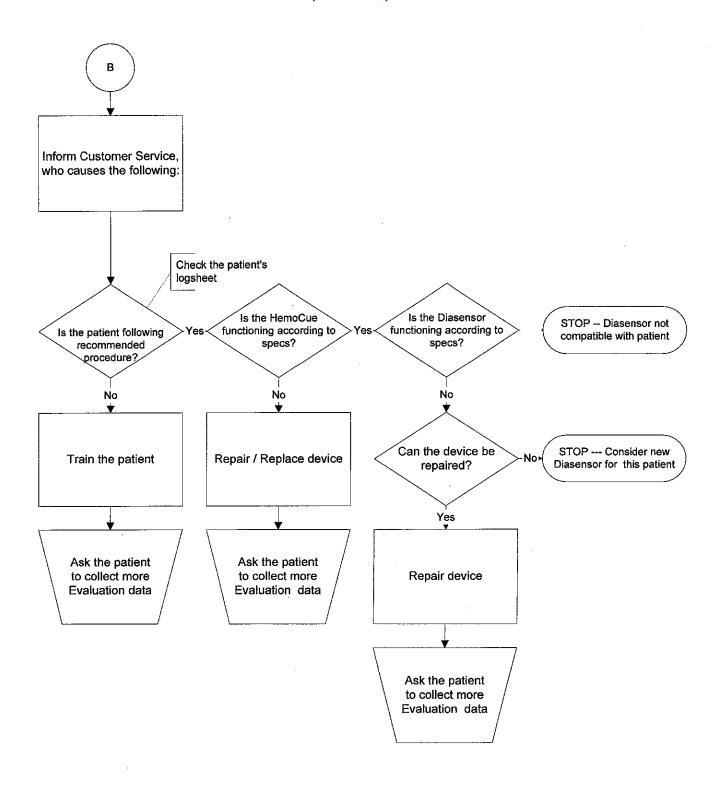1. Items appearing in a "predefined process" box are defined in the Diasensor 2000 Algorithm Product Specification.

```
        ( Start )
            |
            v
+---------------------------+
| Receive notification that |
| we now have "enough"      |
| D2000 data                |
+---------------------------+
            |
            v
+---------------------------+
| Unzip the binary data,    |
| concatenate the files, and|
| convert the data to ASCII |
+---------------------------+
            |
            v
      < Are there sufficient >---No--->( B )
      < measurements?        >
            |
           Yes
            |
            v
          ( A )
```

```
          ( A )
            |
            v
+---------------------------+
| Perform the Threshold     |
| Test.                     |
+---------------------------+
            |
            v
      < Did Threshold Test >---No--->( B )
      < pass?              >
            |
           Yes
            |
            v
+---------------------------+
| Create and send a         |
| physician's report to     |
| Customer Service          |
+---------------------------+
            |
            v
+---------------------------+        Customer Service will ensure
| Make a  User card file in |........ that the patient receives the
| Measurement mode          |        PCMCIA User card file.
| available.                |
+---------------------------+
            |
            v
        ( Stop )
```

(**B**)

Inform Customer Service, who causes the following:

Check the patient's logsheet

Is the patient following recommended procedure? —Yes→ Is the HemoCue functioning according to specs? —Yes→ Is the Diasensor functioning according to specs?

(STOP -- Diasensor not compatible with patient)

No (patient) ↓   No (HemoCue) ↓   No (Diasensor) ↓

Train the patient   **Repair / Replace device**

Can the device be repaired? —No→ (STOP --- Consider new Diasensor for this patient)

Ask the patient to collect more Evaluation data

Ask the patient to collect more Evaluation data

Yes ↓

Repair device

Ask the patient to collect more Evaluation data