Application Specification

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Intended Use

The My GrandCare Monitoring System Product Family is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It is a software application running on a Commercial Off The Shelf (COTS) Personal Computer (PC). It collects measurements captured on commercially available wireless medical devices which are designed for home use and connection to a COTS PC. It displays the collected measurement on the PC, and securely stores the collected information locally on a memory device installed in the PC for the patient to view, and for the caregiver to view remotely via a host server. The My GrandCare Monitoring System Family can be used to display educational and motivational content from the caregiver and can facilitate communication between the caregiver and patient via health wellness surveys and optional video conferencing.

The My GrandCare Monitoring System Product Family is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

The software application captures, stores, and displays information in a secure local database, and transmits information to caregivers who are authenticated on a secure host server running My GrandCare software, via a secure connection over a standard telephone line or internet connection.

The software application allows caregivers to review patient vital signs on the secure website. The My GrandCare System Monitoring Product Family Care Management Suite allows for predefining upper and lower limits, and, when either limit is exceeded, or when readings are or are not taken, the system notifies the caregiver using emails, phone calls, or text messages. Caregivers can add automated medication reminders, and appointment reminders, and receive notifications when the patient does or does not report that medications have been taken.

The system can also be used for social interaction between caregivers and patients, and to collect non-medical information from commercially available activity of daily living sensors, such as motion, door, bed and temperature sensors, caller ID modems, and action buttons, which can be reviewed by caregivers, and which can trigger rule-based notifications to caregivers.

Indications for Use

The My GrandCare Monitoring System Product Family is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the, caregivers' questions by participating in surveys.

The My GrandCare Monitoring System Product Family allows the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients.

The My GrandCare Monitoring System Product Family is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

The My GrandCare Monitoring System Product Family is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

How Used

The system collects measurements captured on commercially available personal computers, from commercially available wireless medical devices which are designed for home and assisted living center use, and displays the information on the computer screen for the patient, and through an Internet interface for the caregiver. The system can provide alerts to caregivers when health readings have been taken or not taken, or medication has been accessed or not accessed. It can provide prompts to patients when it is time to taken medications, and information about the medication.

Intended Users

End users are home-based patients or assisted living-based patients with long-term monitoring needs and their caregivers.

Intended Use Environment(s)

Patient homes, private homes or assisted living centers.

Targeted Patient Populations

Home-based patients with chronic conditions that require long-term, retrospective monitoring.

Contraindications	
See Indication for Use.	
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