



## PHT eSense™ Sensors

### Prevent false self-reported data with wirelessly integrated measurement devices

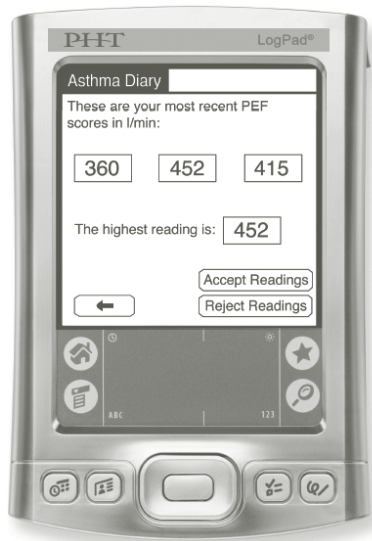


Whether recording peak expiratory flow (PEF) values or blood sugar levels, precise physiological measurements are essential for the success of many clinical trials. Numerous measurement devices (such as spirometers, glucometers and activity monitors) store data electronically, but they are rarely part of a fully integrated electronic patient reported outcome (ePRO) system. **PHT's eSense Sensors**, are changing that. ESense enables scientific researchers to ask new questions by collecting precise objective physiological data in conjunction with high-quality subjective eDiary reports (e.g. pain vs. activity level).

eSense Sensors use wireless sensor technology that enables PHT's LogPads and StudyPads to interact – without cables, wires or any other encumbrances – directly with measurement devices. Subjects simply use the measurement device in the proximity of the eDiary, and the data is automatically transmitted to the eDiary – it's that simple. Since subjects are prevented from entering measurement data manually, such integration ensures subjects are using the devices per the terms of the protocol. This integration also enables clinical trial leaders and investigators to see real-time data streams of attributable, time-stamped data collected electronically from the devices. The result is an ePRO system that's powerful, easy-to-use and 21 CFR Part 11 compliant.

### How eSense Works

eSense uses special radio sensor technology based on the IEEE 802.15.4 standard. This ultra low-power wireless technology allows devices that are within ten feet of each other to communicate directly, with or without line of sight. Since eSense devices consume such low battery power, the measuring devices and the LogPads/StudyPads maintain the long battery life that helps make them so easy and dependable for subjects to use. eSense works with any electronic measuring device that can export data through a serial interface. In addition, unlike other wireless protocols, eSense sensors are light-weight and capable of storing and sending data, thus allowing sponsors to use tiny, wearable devices which are more convenient for subjects. PHT can work with you to ensure the eSense Sensor technology is fully integrated with any other patient data measurement devices used in your trial. Data collection via the easy-to-use LogPad and StudyPad Systems is always FDA compliant and fully accessible in real-time by sponsors and sites.



*The exclusive PHT eSense™ PiKo® (above) provides sponsors with a more complete view of a patient by collecting objective PEF and FEV<sub>1</sub> data in conjunction with subjective eDiary reports. Though fully integrated, both the electronic diary and the measuring device are mobile, independent devices - so subjects can conveniently use each separately depending on the protocol.*

## Automatic Tools for Easy Data Capture

Consider an asthma patient in a respiratory clinical trial. She's tasked with peak flow readings four times a day, but only needs to fill out a handheld diary once, before bed. With eSense, she takes her spirometer with her for the day and leaves her LogPad at home. During the day, she takes her peak flow readings, and at nighttime she takes her final reading and completes her diary. By simply placing the spirometer near the eSense LogPad, the sensors in the LogPad and the spirometer recognize each other and automatically and securely transmit all the day's time-stamped spirometer readings directly into the eDiary. She then reviews and signs a complete day's worth of data and transmits it over her home phone line or via a wireless connection to a central server, where it is instantly made available for review by study sponsors and site personnel.

## Key Features of PHT's eSense Sensors:

- ❖ Automatic wireless capture of objective and subjective patient readings
- ❖ Support for date/time stamps for every reading
- ❖ Light-weight and portable devices
- ❖ Wireless transmission of data between measurement device and LogPad
- ❖ Low power consumption for long battery life on the LogPad and measurement device
- ❖ eSense Sensors support a wide variety of measurement devices

## Benefits of Using PHT's eSense Sensors:

- ❖ High-quality data with no opportunity for invented data, user input error or transcription error
- ❖ Worldwide dependable telecom coverage
- ❖ Real-time access to all data collected for proactive trial and safety monitoring
- ❖ Full integration with an FDA compliant ePRO system that provides real-time access to data
- ❖ Real-time interactive reporting that integrates subject reports with objective physiological data to provide a 360-degree view of the patient to both sites and sponsors
- ❖ Increased scientific value of the trial due to high-quality, accurate and time-stamped data

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