CLAIMS

1. A medical device, comprising:

at least one memory device storing data;

a communication interface defining a first communication path to allow communications between the medical device and an external device or network; and

a hardware key interface configured to receive a hardware key, the hardware key interface defining a second communication path that is separate from the first communication path,

wherein the data on the at least one memory device cannot be modified unless the hardware key interface is physically coupled to the hardware key.

2. The medical device of claim 1, wherein the medical device is a meter that determines an analyte concentration in a sample provided on a test sensor, the meter including a test sensor port to receive the test sensor, and the test sensor port acts as the hardware key interface.

3. The medical device of claim 2, further comprising:

a plurality of contacts configured to connect with electrodes on the test sensor and receive, via the electrodes, an electrochemical signal from a reaction between a reagent and the sample on the test sensor, the electrochemical signal indicating the analyte concentration, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

4. The medical device of claim 3, wherein the hardware key includes conducting lines that provide a resistance that is detected by the plurality of contacts, the resistance defining the key code.

5. The medical device of claim 2, further comprising:

a plurality of contacts configured to connect with conducting lines on the test sensor and receive, via the conducting lines, a calibration code corresponding to the reaction between the reagent and the sample on the test sensor, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one

memory device cannot be modified unless the key code provided by the hardware key is validated.

6. The medical device of claim 1, further comprising a detector configured to detect the hardware key coupled to the hardware key interface.

7. The medical device of claim 1, wherein the hardware key includes a key code component and conducting lines, the hardware key interface receiving the key code via the conducting lines, and the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

8. A medical device system, comprising:

a medical device comprising:

at least one memory device storing data;

a communication interface defining a first communication path to allow communications between the medical device and an external device or network; and

a hardware key interface defining a second communication path that is separate from the first communication path; and

a hardware key that is configured to be coupled to the meter via the second communication path defined by the hardware key interface,

wherein the data on the at least one memory device cannot be modified unless the hardware key interface is physically coupled to the hardware key.

9. The medical device system of claim 8, wherein the medical device is a meter that determines an analyte concentration in a sample provided on a test sensor, the meter including a test sensor port to receive the test sensor, and the test sensor port acts as the hardware key interface.

10. The medical device system of claim 9, wherein the meter further comprises a plurality of contacts configured to connect with electrodes on the test sensor and receive, via the electrodes, an electrochemical signal from a reaction between a reagent and the sample on the test sensor, the electrochemical signal indicating the analyte concentration, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the

data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

11. The medical device system of claim 10, wherein the hardware key includes conducting lines that provide a resistance that is detected by the plurality of contacts, the resistance defining the key code.

12. The medical device system of claim 9, wherein the meter further comprises a plurality of contacts configured to connect with conducting lines on the test sensor and receive, via the conducting lines, a calibration code corresponding to the reaction between the reagent and the sample on the test sensor, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

13. The medical device system of claim 8, wherein the medical device further comprises a detector configured to detect the hardware key coupled to the hardware key interface.

14. The medical device system of claim 8, wherein the hardware key includes a key code component and conducting lines, the hardware key interface receiving the key code via the conducting lines, and the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

15. A method for a medical device system, comprising:

establishing a connection between a medical device and an external device or network via a first communication path defined by a communication interface;

initiating a modification process, including executing a command sequence;

detecting a physical coupling between the medical device and a hardware key, the hardware key being coupled to the medical device via a second communication path defined by a hardware key interface, the second communication path being separate from the first communication path; and

modifying data stored on at least one memory device on the medical device according to the modification process,

wherein the data on the at least one memory device cannot be modified unless the hardware key interface is physically coupled to the hardware key.

16. The method of claim 15, further comprising detecting a key code from the hardware key and validating the key code, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

17. The method of claim 15, wherein executing the command sequence includes entering authorization information.

18. The method of claim 15, wherein the medical device is a meter that determines an analyte concentration in a sample provided on a test sensor, the meter including a test sensor port to receive the test sensor, and the test sensor port acts as the hardware key interface.

19. The method of claim 18, wherein the meter further comprises a plurality of contacts configured to connect with electrodes on the test sensor and receive, via the electrodes, an electrochemical signal from a reaction between a reagent and the sample on the test sensor, the electrochemical signal indicating the analyte concentration, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

20. The method of claim 18, wherein the meter further comprises a plurality of contacts configured to connect with conducting lines on the test sensor and receive, via the conducting lines, a calibration code corresponding to the reaction between the reagent and the sample on the test sensor, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

CLAIMS

1. A medical device, comprising:

at least one memory device storing data;

a test sensor port to receive a test sensor;

a communication interface defining a first communication path to allow communications between the medical device and an external device or network; and

a hardware key interface configured to receive a hardware key, the hardware key interface defining a second communication path that is separate from the first communication path, wherein the test sensor port acts as the hardware key interface, and

wherein the medical device prevents data on the at least one memory device from being modified unless the hardware key interface is physically coupled to the hardware key.

2. The medical device of claim 1, wherein the medical device is a meter that determines an analyte concentration in a sample provided on the test sensor.

3. The medical device of claim 2, further comprising:

a plurality of contacts configured to connect with electrodes on the test sensor and receive, via the electrodes, an electrochemical signal from a reaction between a reagent and the sample on the test sensor, the electrochemical signal indicating the analyte concentration, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

4. The medical device of claim 3, wherein the hardware key includes conducting lines that provide a resistance that is detected by the plurality of contacts, the resistance defining the key code.

5. The medical device of claim 2, further comprising:

a plurality of contacts configured to connect with conducting lines on the test sensor and receive, via the conducting lines, a calibration code corresponding to the reaction between the reagent and the sample on the test sensor, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

6. The medical device of claim 1, further comprising a detector configured to detect the hardware key coupled to the hardware key interface.

7. The medical device of claim 1, wherein the hardware key includes a key code component and conducting lines, the hardware key interface receiving the key code via the conducting lines, and the

data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

8. A medical device system, comprising:

a medical device comprising:

at least one memory device storing data;

a test sensor port to receive a test sensor;

a communication interface defining a first communication path to allow communications between the medical device and an external device or network; and

a hardware key interface defining a second communication path that is separate from the first communication path; and

a hardware key that is configured to be coupled to the medical device via the second communication path defined by the hardware key interface, wherein the test sensor port acts as the hardware key interface,

wherein the medical device prevents data on the at least one memory device from being modified unless the hardware key interface is physically coupled to the hardware key.

9. The medical device system of claim 8, wherein the medical device is a meter that determines an analyte concentration in a sample provided on the test sensor.

10. The medical device system of claim 9, wherein the meter further comprises a plurality of contacts configured to connect with electrodes on the test sensor and receive, via the electrodes, an electrochemical signal from a reaction between a reagent and the sample on the test sensor, the electrochemical signal indicating the analyte concentration, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

11. The medical device system of claim 10, wherein the hardware key includes conducting lines that provide a resistance that is detected by the plurality of contacts, the resistance defining the key code.

12. The medical device system of claim 9, wherein the meter further comprises a plurality of contacts configured to connect with conducting lines on the test sensor and receive, via the conducting lines, a calibration code corresponding to the reaction between the reagent and the sample on the test sensor, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

13. The medical device system of claim 8, wherein the medical device further comprises a detector configured to detect the hardware key coupled to the hardware key interface.

14. The medical device system of claim 8, wherein the hardware key includes a key code component and conducting lines, the hardware key interface receiving the key code via the conducting lines, and the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

15. A method for a medical device system, comprising:

establishing a connection between a medical device and an external device or network via a first communication path defined by a communication interface;

initiating a modification process, including executing a command sequence;

detecting a physical coupling between the medical device and a hardware key, the hardware key being coupled to the medical device via a second communication path defined by a hardware key interface, the second communication path being separate from the first communication path, wherein the medical device includes a test sensor port to receive a test sensor, and the test sensor port acts as the hardware key interface; and

modifying data stored on at least one memory device on the medical device according to the modification process,

wherein the medical device prevents data on the at least one memory device from being modified unless the hardware key interface is physically coupled to the hardware key.

16. The method of claim 15, further comprising detecting a key code from the hardware key and validating the key code, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

17. The method of claim 15, wherein executing the command sequence includes entering authorization information.

18. The method of claim 15, wherein the medical device is a meter that determines an analyte concentration in a sample provided on a test sensor.

19. The method of claim 18, wherein the meter further comprises a plurality of contacts configured to connect with electrodes on the test sensor and receive, via the electrodes, an electrochemical signal from a reaction between a reagent and the sample on the test sensor, the electrochemical signal indicating the analyte concentration, the plurality of contacts being further configured to receive a key

code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.

20. The method of claim 18, wherein the meter further comprises a plurality of contacts configured to connect with conducting lines on the test sensor and receive, via the conducting lines, a calibration code corresponding to the reaction between the reagent and the sample on the test sensor, the plurality of contacts being further configured to receive a key code from the hardware key, wherein the data on the at least one memory device cannot be modified unless the key code provided by the hardware key is validated.