TECHNOLOGY, INC.

DGH

DGH 550 (PACHETTE 2)

ULTRASONIC PACHYMETER

OPERATOR'S MANUAL

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I. INTRODUCTION

Ultrasonic Pachymetry is an integral part of refractive corneal surgery as well as certain screening procedures that are a function of corneal thickness. The DGH 550 (*Pachette 2*) is an ultrasonic pachymeter that uses echo spike techniques to measure the thickness of the cornea. This is the recommended method for obtaining corneal thickness measurements because it offers the following advantages:

- Reproducibility
- High accuracy
- Ability to take measurements anywhere on the cornea
- Measurements are not dependent upon patient fixation
- Ease of use

The corneal thickness measurement may then be used in many different ways including: Lasik and glaucoma screening, Lasik flap measurement, corneal edema check for extended wear contact lens patients, and pre-operative data for intrastromal ring implantation and radial/arcuate keratotomy.

The *Pachette 2* was designed to provide a means of obtaining fast, accurate, corneal thickness measurements with an instrument that is simple to use, economical, and ultra-portable. We invite you to read this manual carefully to discover how quickly and easily the *Pachette 2* can be integrated into your practice.

II.   FEATURES

The *Pachette 2* is manufactured with high quality components that are designed and built using the latest technological concepts. The result is an advanced and powerful pachymeter that offers practicality and reliability. The following features are just a sample of the characteristics and capabilities of the *Pachette 2*.

Standard Features

- Simple to use. Turn on power and the *Pachette 2* is ready to take measurements.
- Automatic measurement mode for operation without a foot switch.
- Rapidly obtains and stores up to 50 measurements at a single location.
- Displays the current measurement, the average, and the standard deviation of all measurements taken.
- Mapping mode for obtaining and storing up to 33 actual and biased corneal mapped measurements.
- Large 16 x 2 LCD character display allows easy visibility from a distance over a large viewing angle and in all lighting conditions.
- Proven measurement algorithm which yields accurate, reproducible measurements in a fraction of a second.
- Ultra-Portable. Compact and light weight to allow easy transfer from the office to the hospital. Adjustable tilt stand/handle for ease of viewing.
- Operator feedback. Audible signal indicates when a valid measurement is complete.
- Personalized configuration. User-friendly front panel allows selection of number of measurements to be obtained, and selection of delay time between measurements.
- Configuration memory. Once personally configured for the operator, non-volatile memory provides permanent storage of configuration data, even when the *Pachette 2* is turned off.

Optional Features

- FLAP option for measuring Lasik flaps as thin as 95 microns.
- Printer interface for sending pachymetry data to a serial printer.
- Data transfer interface for sending pachymetry data to a personal computer.
- IrDA interface for sending pachymetry data to other IrDA compatible devices.

III. GENERAL DESCRIPTION

Front Panel
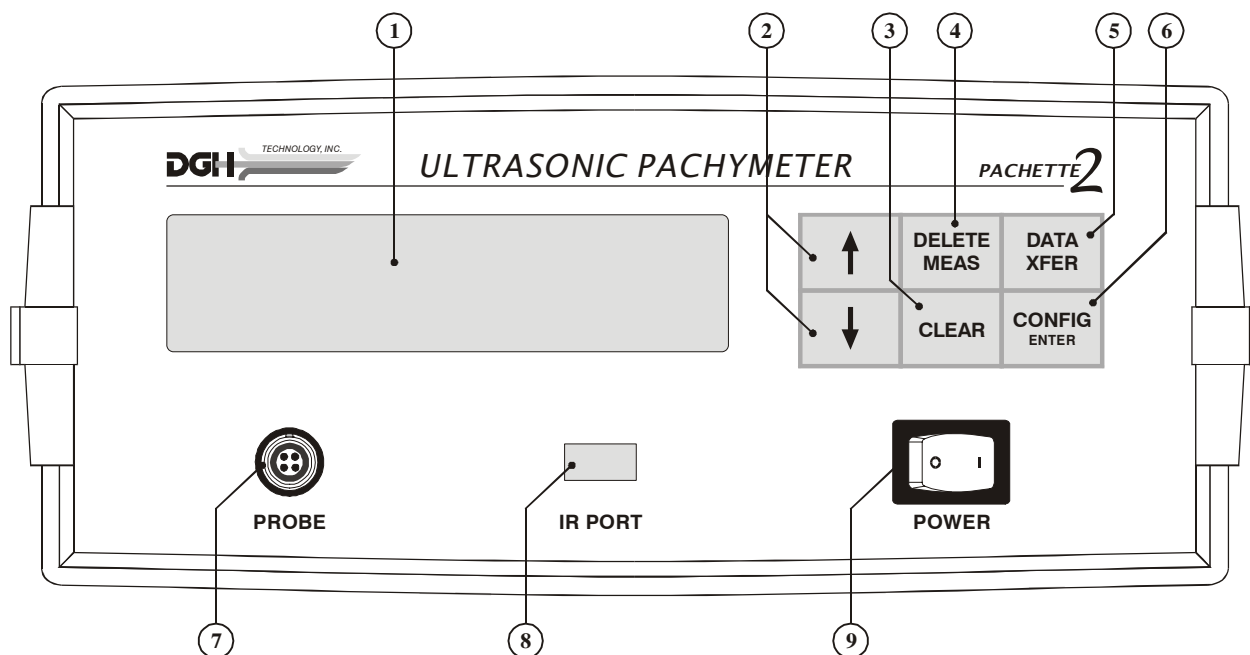
Figure III-A *DGH 550 Front Panel.*

① **LCD Display**
     Large 16 x 2 character display used to present measurement data and/or configuration parameters to the operator.

② **↑ / ↓ Keys**
     Used to review measurements or to program options and numerical values presented on the display. The ↑ key is also used to enter the CalBox mode which permits the operator to verify calibration of the pachymeter.

③ **"CLEAR" Key**
     This key is used to erase all obtained measurements whenever it is desired to begin a new measurement sequence. Also used to exit the CalBox mode or to exit the configuration menu.

④ **"DELETE MEAS" Key**

Used to erase a single measurement from a group of measurements.

⑤ **"DATA XFER" Key**

When a data transfer option is installed, this key is used to transfer pachymetry data to a printer or a computer.

⑥ **"CONFIG/ENTER" Key**

This key is used to activate the configuration menu for the purpose of changing configuration parameters. After the menu has been activated, the ↑ / ↓ keys can be used to select the desired value for the current configuration parameter. Parameters values are then chosen by pressing **ENTER**.

⑦ **Probe Connector**

Front panel connector which mates to the connector on the Probe cable.

⑧ **Infrared Port**

Infrared port that can be used for wireless transfer of pachymetry data to another device that is IrDA compatible. (This feature is optional)

⑨ **Power switch**

Pressing "1" side of switch turns the *Pachette 2* on. Pressing "0" side of switch turns the *Pachette 2* off.

Back Panel
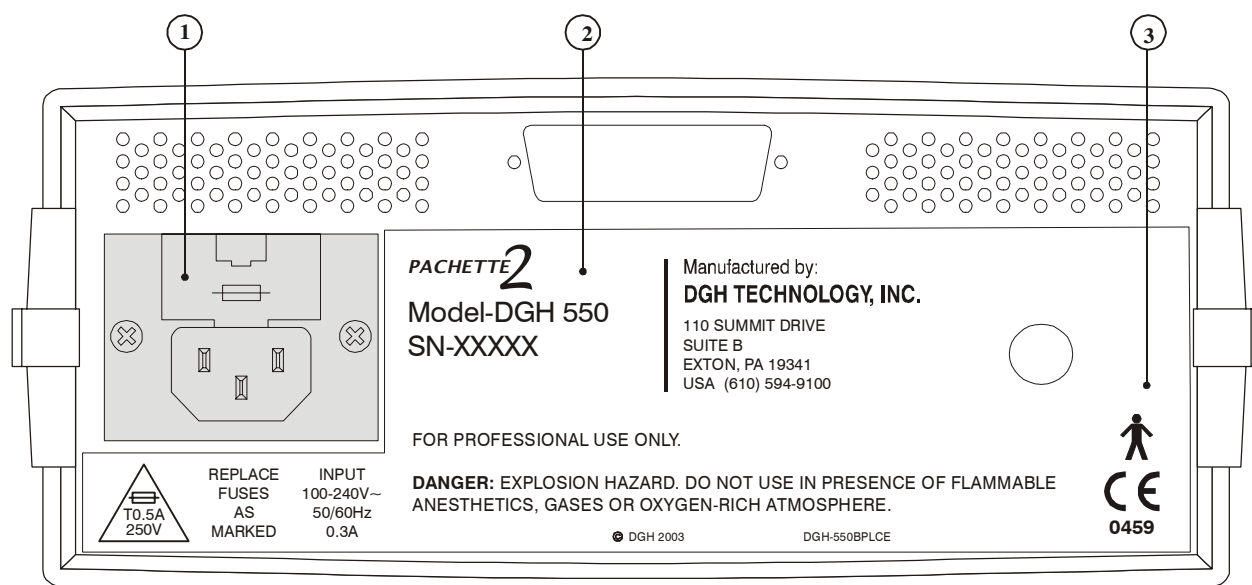
Figure III-B *DGH 550 Back Panel.*

① **Fuse Holder**
  Location of AC input fuse(s). If a fuse needs replacing, always replace the fuse as marked.

② **Model & Serial Numbers**
  Location of model and serial numbers used to identify the unit

③ **CE Certification Marks**
  These marks are used to identify CE certified units. (CE certification is optional)

Calibration Standard

To check Pachymeter calibration, an electronic CalBox (below) is used to simulate the thickness of the cornea. Instructions for using the CalBox are given in section VIII and they are also printed on the Calbox label.
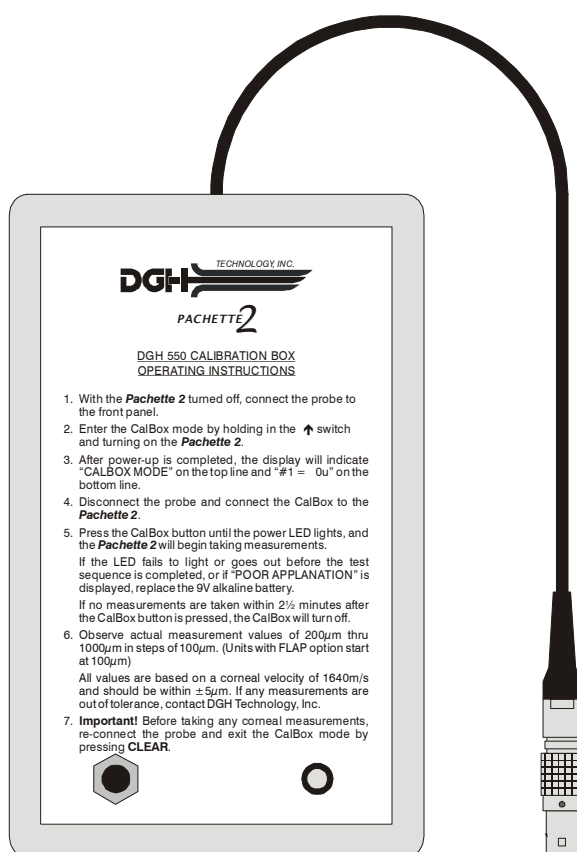
Figure III-C *Electronic CalBox*

IV. POWER-UP SEQUENCE

1. Plug the AC cord into a three-prong outlet.

2. Verify that the probe is connected to the front panel.

3. Turn on the unit.

4. The *Pachette 2* performs an internal self-test function.

5. When the power-up sequence is finished, the display will indicate:

```
Avg of  0 =    0u
   Std Dev = 0.0u
```

The *Pachette 2* is now ready to take corneal measurements. If any default parameters need to be modified, refer to section V. Otherwise, refer to section VI for a detailed description of the proper method for obtaining measurements.

V. CONFIGURING THE PACHETTE 2

Configuration Overview

When shipped from the factory, the *Pachette 2* is ready to take corneal measurements. It is not necessary to setup or configure anything. The operator only needs to connect the probe to the front panel and then apply power to the unit. However, the *Pachette 2* has been designed to allow the operator to modify certain default parameters to tailor the instrument to meet one's needs. Once modified, these parameters are permanently stored in non-volatile memory and are automatically recalled each time the unit is powered up. To change a parameter, the operator must access the configuration menu. The following procedure explains how to access the configuration menu and modify the default parameters.

Changing Parameters On The Configuration Menu

A complete list of all the possible parameters on the configuration menu is given in Table 1. The unshaded sections of this table identify parameters that are accessible on the basic *Pachette 2*. The shaded sections of the table identify parameters that are only accessible when optional features have been added to the unit. The procedure below shows how to activate the configuration menu and modify the parameters on the basic *Pachette 2*. For a detailed description of any parameters associated with optional features, refer to section IX.

1.   Press the **CONFIG** key and the display will briefly indicate:

```
        PACHETTE 2
          CONFIG
```

then the display will briefly show the Software Version and then show:

```
    OPERATIONAL MODE
     Continuous Avg
```

2.   Press **ENTER** to continue in Continuous Avg mode or press the ↑ or ↓ key to change the operational mode from Continuous Avg to Mapping. Refer to section IX.A to continue in Mapping Mode. In Continuous Avg mode display will show:

```
┌─────────────────────────┐
│     STD DEVIATION       │
│       Enabled           │
└─────────────────────────┘
```

3. Use the ↑ or ↓ keys to enable or disable standard deviation. Press the **ENTER** key to confirm your selection and the display will then indicate:

```
┌─────────────────────────┐
│      NUMB OF MEAS       │
│          25             │
└─────────────────────────┘
```

4. Use the ↑ or ↓ keys to select the total number of measurements that you wish to obtain. Press and release either key to change the current value slowly, one number at a time, or press and hold the key to scroll through the values more quickly. To confirm your selection press **ENTER** and the display will then indicate:

```
┌─────────────────────────┐
│     AUTO REP DELAY      │
│       100 msec          │
└─────────────────────────┘
```

5. Use the ↑ or ↓ keys to select the desired value for the auto repeat delay. This is the period of time that the unit will wait between consecutive measurements while the probe is properly applanated to the cornea. Press **ENTER** to confirm your selection.

6. If no options have been installed, the unit will save the current configuration and then exit the configuration menu. The display will briefly indicate:

```
┌─────────────────────────┐
│        SAVING           │
│        CONFIG           │
└─────────────────────────┘
```

and then the unit will return to the measurement mode.

However, if other options have been installed, the configuration menu will advance to the next configurable parameter. Modify any remaining parameters by using the same procedure as above, i.e. press the ↑ or ↓ keys to select a new parameter value and then press **ENTER** to confirm your selection and advance to the next parameter.

Note: To save a current parameter value and exit the configuration menu without advancing to the next parameter, press the **CLEAR** key.

7. Pachymetry measurements may now be taken. Refer to section VI for a detailed description of the proper method for obtaining measurements.

Table 1 *Parameters On The Configuration Menu And Associated Options*

Parameter [default value]	Range	Description	Associated Option(s)
OPERATIONAL MODE [Continuous Avg]	Continuous Avg Mapping	Selects how the *Pachette 2* should operate. Continuous Avg = multiple measurements at a single location. Mapping = single measurement at different positions.	Continuous Avg with Mapping
STD. DEVIATION [Enabled]	Enabled Disabled	Enables or Disables the presentation of standard deviation on the display.	Continuous Avg
NUMB OF MEAS [25]	1 to 50	Selects the number of measurements to be obtained.	Continuous Avg
AUTO REP DELAY [100 msec]	100 to 950 msec	Period of time between consecutive measurements while the probe is applanated to the cornea.	Continuous Avg
NUMB OF POSN [33]	1 to 33	Selects the number of positions to be obtained.	Mapping
AMOUNT OF BIAS [100%]	1 to 199	Selects the percentage used to calculate biased measurements.	Mapping
GOOD MEAS DELAY [1.0 sec]	1.0 to 9.5 seconds	Period of time before the unit will automatically store the current measurement and advance to the next measurement position.	Mapping
POOR APPL DELAY [2.0 sec]	1.0 to 9.5 seconds	Period of time after a poor applanation occurs before the unit will automatically advance to the next measurement position.	Mapping
EXT. INTERFACE [Disabled]	Disabled Prnt Enabled Xfer Enabled IrDA Enabled	Mode of operation for the external interface: Disabled = no interface is enabled. Prnt Enabled = RS232C serial connection to printer. Xfer Enabled = RS232C serial data transfer to a computer. IrDA Enabled = wireless connection for IrDA device.	Printer Data Transfer IrDA
BAUD RATE [9600 bps]	300 600 1200 2400 4800 9600	Sets the data transfer rate in bits per second (bps) for the RS232C serial interface.	Printer Data Transfer IrDA
PRINT NOTES [Enabled]	Enabled Disabled	Enables or Disables the Notes box on printout.	Printer

VI.   OBTAINING PACHYMETRY MEASUREMENTS

The *Pachette 2* does not require a foot switch to obtain pachymetry measurements. Instead, measurements are automatically taken whenever the tip of the probe is properly applanated onto the cornea. This feature allows the operator to concentrate on probe tip alignment and positioning. In addition, the *Pachette 2* was designed (in Continuous Avg mode) to take multiple measurements very rapidly at a single location and display the total average. Therefore, as long as the probe is properly applanated onto the cornea, the unit will continue taking measurements until a predetermined number of measurements has been reached. This number can be selected by the operator before beginning the measurement sequence. The following procedure may be used to obtain pachymetry measurements.

1.   Perform the Power-Up Sequence as described in section IV.

2.   Select the number of measurements to be obtained by accessing the configuration menu as described in section V.

3.   Position the *Pachette 2* for easy visibility during patient examination.

4.   With the patient in supine position and visualizing a fixation spot on the ceiling, position the tip of the probe onto the cornea. Once the probe tip is aligned properly, the *Pachette 2* will automatically begin to take a series of measurements.

     If a measurement is not obtained within 3 seconds, a long "beep" will occur and the display will indicate:

```
       POOR
    APPLANATION
```

     If the message of "POOR APPLANATION" keeps appearing, check to insure the probe tip actually touches the cornea and is perpendicular to the corneal surface.

5.   For each measurement that is obtained, a short "beep" will occur to indicate that the measurement has been stored in memory. After all measurements have been taken, a long "beep" will occur, the display will briefly indicate:

```
    All Meas Taken
    Press ↑/↓ or CLR
```

and then the display will look like example #1:

```
Avg of 25 = 540u
 Std Dev = 0.3u
```

Note: In example #1, the *Pachette 2* was pre-configured to obtain 25 measurements with standard deviation enabled. See section V for configuration details. If standard deviation is disabled the display will look like example #2:

```
Meas  #21 = 540u
Avg of 25 = 541u
```

The top line of the display in example #1 shows the average of the 25 measurements (in microns). The top line of the display in example #2 shows the thickness of Measurement #21.   All thickness measurements are based on a corneal velocity of 1640 m/sec. The bottom line of the display in example #1 shows the standard deviation of the 25 measurements.   The bottom line of the display in example #2 shows the average of the 25 measurements.

6. To display and review each measurement and the standard deviation (if enabled), use the ↑ or ↓ keys. If any measurement seems questionable to the operator, it can be erased from memory by pressing the **DELETE MEAS** key.   The standard deviation will be updated with each deletion.

7. After the measurements have been reviewed, the operator can take more measurements to replace the ones that were deleted or just accept the ones that remain. In either case, the total average and standard deviation will be updated accordingly.

Note: Once the measurement memory is filled (i.e. 25 measurements have been taken when the *Pachette 2* was pre-configured to obtain 25 measurements), no more measurements can be taken unless a measurement is deleted or all measurements are cleared from memory.

8. To begin a new measurement sequence, press the **CLEAR** key to erase all measurements and re-initialize the *Pachette 2*. Measurements are also erased from memory whenever the unit is turned off.

VII. PROBE QUALITY

Whenever the *Pachette 2* is initialized, a self-test is automatically performed that checks the quality of the ultrasonic probe. Ultrasonic waves are emitted from the piezoelectric element in the transducer housing and transmitted through the plastic cone. A return signal (echo) is created when the ultrasonic waves pass through the end of the plastic cone into free air. This echo signal is received by the piezoelectric element, and then amplified and measured within the unit. The magnitude of the echo signal is compared to the magnitude of the echo signal when the unit was originally calibrated at the factory.

If the probe quality is satisfactory, the *Pachette 2* is ready to take measurements and the operator is unaware that the self-test has occurred. However, if the probe quality is not satisfactory, one of the following messages will be displayed on the front panel.

```
CHECK
PROBE
```

This message usually means the tip of the probe is wet. However, if drying the tip of the probe fails to make this message go away, then the probe may have degraded to the point that it will require replacement.

```
PLUG IN
PROBE
```

This message occurs when: (1) the probe connector is not mated or is improperly mated to the connector on the front panel, or (2) the probe is defective.

```
PQF
FAILED
```

This message usually indicates a hardware failure occurred within the unit and the unit must be returned for repair. See page 27 section X.E for service.

VIII. VERIFYING PACHETTE 2 CALIBRATION

Pachymeter calibration is verified by using the electronic calibration box (CalBox) that is supplied with the *Pachette 2* (see Figure III-C). It is important to realize that the CalBox does **not** calibrate the pachymeter. The CalBox generates a sequence of precise, predetermined thicknesses that can be measured by the pachymeter. The values of these thicknesses have been purposely selected to span the full measurement range of the unit. Therefore, by measuring these predetermined thicknesses, the operator can quickly verify that the pachymeter is properly calibrated.

Procedure For Verifying Calibration

1. With the *Pachette 2* turned off, connect the probe to the front panel.

2. Enter the CalBox mode by holding in the ↑ key and turning on the *Pachette 2*.

3. After power-up is completed, the display will indicate "CALBOX MODE" on the top line and "#1 = 0u" on the bottom line.

4. Disconnect the probe and connect the CalBox to the *Pachette 2*.

5. Press the CalBox button until the LED lights, and the *Pachette 2* will begin taking measurements.

   If the LED fails to light or goes out before the test sequence has completed, or if "POOR APPLANATION" is displayed, then replace the 9V alkaline battery.

   If no measurements are taken within 2½ minutes after the CalBox button is pressed, the CalBox will automatically turn off.

6. Observe actual measurement values of 200μm thru 1000μm in steps of 100μm. (Units with FLAP option start at 100μm)

   All values are based on a corneal velocity of 1640m/s and should be within $\pm 5\mu$m. If any measurements are out of tolerance, contact DGH Technology, Inc.

7. **Important!** Before taking any corneal measurements, re-connect the probe and exit the CalBox mode by pressing **CLEAR**.

IX.   OPTIONAL FEATURES FOR THE PACHETTE 2

The *Pachette 2* has been designed as an economical and easy to use instrument. A basic unit contains a variety of features that the operator will find useful when obtaining pachymetry measurements. To further enhance the functionality of the *Pachette 2*, DGH Technology, Inc. also offers five additional options that can be installed when the unit is purchased. Any combination of options may be selected to tailor the unit to fit one's particular requirements. The options that are available for the *Pachette 2* are:

1. Mapping Mode Option – Permits the operator to obtain actual and biased corneal mapped measurements. Included in the base *Pachette 2*
2. FLAP Option* – Permits the measuring of Lasik flaps as thin as 95 microns.
3. Printer Interface Option* – A serial RS232C interface that allows a serial printer to be connected to the *Pachette 2* for obtaining a hard copy of pachymetry data.
4. Data Transfer Interface Option* – A serial RS232C interface that allows pachymetry data to be transferred to a personal computer for the purpose of archiving, display formatting, computations, etc.
5. IrDA Interface Option* – A wireless infrared interface that allows pachymetry data to be transferred to an IrDA compatible device for the purpose of archiving, display formatting, computations, etc. **NOTE**: This option is not available as of release date 06/2003 of the DGH 550 Operator's Manual

    *Additional hardware and software required.

The following sections give a description of each option and also explain how to use them.

IX.A. Mapping Mode Option

The basic *Pachette 2* was designed to obtain multiple corneal measurements at a single location and generate an average for those measurements. In contrast, the mapping mode option permits the operator to take a single measurement at different positions on the cornea. With this option enabled, the *Pachette 2* can be programmed to record measurements from a maximum of 33 different positions. However, the operator must

keep track of which measurement belongs to each corneal position. This can be achieved with the help of corneal thickness charts, which are available upon request from DGH Technology, Inc.

Configuring The Mapping Mode Option

A complete list of all configurable parameters for the mapping mode option is given in Table 2. Use the following procedure to access the configuration menu and modify the mapping mode parameters.

8. Press the **CONFIG** key and the display will briefly indicate:

```
        PACHETTE 2
          CONFIG
```

and then the display will indicate:

```
     OPERATIONAL MODE
       Continuous Avg
```

9. Press the ↑ or ↓ keys to change the operational mode from Continuous Avg to Mapping. Press the **ENTER** key to confirm your selection and the display will then indicate:

```
       NUMB OF POSN
            33
```

10. Use the ↑ or ↓ keys to select the number of positions that will be measured. Press **ENTER** to confirm your selection and the display will then indicate:

```
      AMOUNT OF BIAS
           100%
```

11. Use the ↑ or ↓ keys to select the percentage that will be used to calculate the biased measurement. Press **ENTER** to confirm your selection and the display will then indicate:

```
GOOD MEAS DELAY
    1.0 sec
```

12. Use the ↑ or ↓ keys to select the time (in seconds) that the unit will wait before storing the current measurement and advancing to the next measurement position. Press **ENTER** to confirm your selection and the display will then indicate:

```
POOR APPL DELAY
    2.0 sec
```

13. Use the ↑ or ↓ keys to select the time (in seconds) that the unit will wait after a poor applanation before advancing to the next measurement position. Press **ENTER** to confirm your selection.

At this point, the *Pachette 2* will either exit the configuration menu or advance to the next configurable parameter. More parameters will only be available if other options have been installed.

Note 1: To save a changed parameter and immediately exit the configuration menu without advancing to the next parameter, press the **CLEAR** key.

Note 2: When changing from Continuous Avg to Mapping mode, any measurements obtained in Continuous Avg mode will be deleted before the Mapping mode becomes active. This is necessary because the two operational modes are very different and measurements from the previous mode would have no relevance if carried over to the new mode.

Table 2 *Configurable Parameters For The Mapping Mode Option*

Parameter [default value]	Range	Description
OPERATIONAL MODE [Continuous Avg]	Continuous Avg Mapping	Selects how the *Pachette 2* should operate. Continuous Avg = multiple measurements at a single location. Mapping = single measurement at different positions.
NUMB OF POSN [33]	1 to 33	Selects the number of positions to be obtained.
AMOUNT OF BIAS [100%]	1 to 199	Selects the percentage to be used for calculating biased measurements.
GOOD MEAS DELAY [1.0 sec]	1.0 to 9.5 seconds	Period of time before the unit will automatically store the current measurement and advance to the next measurement position.
POOR APPL DELAY [2.0 sec]	1.0 to 9.5 seconds	Period of time after a poor applanation occurs before the unit will automatically advance to the next measurement position.

Obtaining Measurements With The Mapping Mode Option

1. Perform the Power-Up Sequence as described in section IV.

2. Position the *Pachette 2* for easy visibility during patient examination.

3. With the patient in supine position and visualizing a fixation spot on the ceiling, position the tip of the probe onto the cornea at the location the operator has defined as position #1. Once the probe tip is aligned properly, the *Pachette 2* will automatically attempt to take a measurement.

4. When a measurement is obtained, a short "beep" will occur to indicate that the measurement has been displayed. The measurement is shown on the top line of the display for a time interval known as the "Good Measurement Delay" (default = 1 sec.). After the delay expires, the measurement will be stored, the display will advance to position #2 and two short "beeps" will occur to indicate that the unit is ready to take the next measurement.

    If a measurement is not obtained within 3 seconds, a long "beep" will occur to indicate that a poor applanation has happened. The message of "POOR APPLANATION" is also displayed for a time interval known as the "Poor Applanation Delay" (default = 2 sec.). After this delay expires, the display will advance to position #2 and two short "beeps" will occur to indicate that the unit is ready to take the next measurement.

    Note: The audible feedback is provided so that the operator can concentrate on

probe tip alignment and positioning. For instructions on changing the length of the Good Measurement and Poor Applanation delays, see the beginning of this section.

If the message of "POOR APLANATION" keeps appearing on the display, check to insure the probe tip actually touches the cornea and is perpendicular to the corneal surface.

5.   Whenever an acceptable measurement has been made, the top line of the display will indicate the corneal thickness in microns. All thickness measurements are based on a corneal velocity of 1640 m/sec. Simultaneously, the bottom line of the display indicates a biased corneal thickness (in microns) that is based on surgical requirements as defined by the operator. Refer to the beginning of this section for instructions on changing the percentage that determines the biased measurement.

6.   All measurements can be reviewed on the display by using the ↑ or ↓ keys on the front panel. A new measurement may be taken at any position by causing the appropriate position number to appear on the display and then retaking the new measurement. Any measurement that is suspect may also be erased by pressing the **DELETE MEAS** key.

7.   All measurements remain in memory until the **CLEAR** key is pressed or the *Pachette 2* is turned off. Press **CLEAR** to erase all measurements and re-initialize the *Pachette 2* for a new measurement sequence starting at position #1.

IX.B. FLAP Option

The basic *Pachette 2* can obtain corneal measurements as thin as 200 microns. However, if Lasik flap measurements need to be obtained, then the FLAP option should be installed. This option allows corneal measurements as thin as 95 microns to be obtained. When the FLAP option is installed, the *Pachette 2* operates exactly the same way as it did without the option. The only difference is that the unit is now capable of taking thinner measurements. To identify a *Pachette 2* with the FLAP option installed, check for a label that says "FLAP" located on the back panel of the unit next to the serial number.

IX.C. Printer Interface Option

The printer interface option is a software/hardware interface that allows the *Pachette 2* to be connected to a serial printer. The hardware interface that is utilized is the industry

standard serial data communication protocol designated as RS232C. Refer to appendix A for a technical description of the RS232C interface as it relates to the *Pachette 2*. Once the printer interface is installed, a serial printer and interface cable must also be purchased before a hardcopy of pachymetry data can be obtained. A compatible printer and interface cable can either be purchased from DGH Technology, Inc. or the operator can supply them. DGH currently offers the SII DPU-414 thermal printer by Seiko Instruments, Inc. for use with the *Pachette 2*. Please contact DGH before attempting to interface your own printer. DGH maintains a list of printers that have already been tested for compatibility with the *Pachette 2*.

The intent of this section is to provide the operator with information for using the SII DPU-414 printer with the *Pachette 2*. Where applicable, the SII DPU-414 User's Guide that was shipped with the printer will be referenced.

Configuring The Printer Interface

Before the *Pachette 2* can send any data to a serial printer, the printer interface parameters must be properly set. The interface must first be enabled, and then the baud rate (or data transmission rate) must be set to match the RS232C interface on the printer. Once configured, it is not necessary to repeat this procedure since the parameter settings are stored in non-volatile memory. However, if it becomes necessary to reset or check the initial configuration, use the procedure below to access the configuration menu and gain access to the printer interface parameters.

Note: When the SII DPU-414 printer is purchased along with the printer interface option, the interface will already be configured by DGH Technology, Inc. However, if no printer is purchased with the printer interface option, then the operator must configure the interface when a printer is connected to the *Pachette 2*.

1. Plug the probe into the front panel, turn on the unit, and wait until the unit is ready to take a measurement.

2. Press the **CONFIG** key and the display will briefly indicate:

> ```
> PACHETTE 2
> CONFIG
> ```

and then the first configurable parameter will be displayed.

3. Press the **ENTER** key repetitively until the display indicates:

```
  ┌─────────────────────────────┐
  │       EXT. INTERFACE        │
  │          Disabled           │
  └─────────────────────────────┘
```

4.   Press the ↑ or ↓ keys to select "Prnt Enabled" on the bottom line of the display.

5.   Press the **ENTER** key to enable the printer interface. The display will now indicate:

```
  ┌─────────────────────────────┐
  │         BAUD RATE           │
  │         9600 bps            │
  └─────────────────────────────┘
```

Note: To disable the printer interface, follow steps 1 thru 3 above, select "Disabled" in step 4, and then press **ENTER** .

6.   Use the ↑ or ↓ keys, if necessary, to select a baud rate for the *Pachette 2* that matches the baud rate of the printer (9600 is the default setting for the SII DPU-414 printer). Press **ENTER** to confirm selection, then display will indicate:

```
  ┌─────────────────────────────┐
  │        PRINT NOTES          │
  │          Enabled            │
  └─────────────────────────────┘
```

7.   Use the ↑ or ↓ keys to enable or disable the Notes box on the printout.

8.   Press the **ENTER** or **CLEAR** key to save and exit the configuration menu.

Connecting The Printer To The *Pachette 2* And Loading Paper

1.   Turn off the power switch on the *Pachette 2* and the SII DPU-414 printer.

2.   Plug the *Pachette 2* AC power cord into the back panel of the *Pachette 2* and into a three-prong AC outlet.

3.   Connect the printer AC adapter to the back of the SII DPU-414 printer and to an AC outlet as described in section 2.1 of the SII DPU-414 Operation Manual.

4.   Plug the RS232C, 25-pin, "D-Type" connector on the end of the printer cable into the mating connector on the rear of the *Pachette 2*.

Note: If the printer is to be mated to the *Pachette 2* for extended periods of time, it is recommended that the "D-Type" connector be secured to the *Pachette 2* using

the (2) screws on the connector.

5. Plug the RS232C, 9-pin, "D-Type" connector on the opposite end of the printer cable into the mating connector on the rear of the SII DPU-414 printer.

6. Turn on the *Pachette 2* power switch.

7. Turn on the printer power switch. When the SII DPU-414 printer is powered up for the first time, the yellow "OFF LINE" LED will blink. This indicates that paper needs to be loaded into the printer.

8. Load the thermal paper into the printer as described in section 2.2 of the SII DPU-414 Operation Manual. When the paper is loaded correctly, the "OFF LINE" LED stops blinking and remains on to indicate that the printer is still off-line.

9. Bring the printer on-line by pressing the **ON LINE** button. The printer is now ready to accept data from the *Pachette 2*.

    Note: If the printer has been previously loaded with paper, the printer will automatically be brought on-line when the power switch is turned on.

Obtaining A Printout

1. Verify that the printer is on-line (the green "OFF LINE" LED should be lit). If the printer is off-line, it can be brought on-line by pressing the **ON LINE** button.

2. Obtain pachymetry measurements as described in section VI.

3. Initiate the printout by pressing the **DATA XFER** key on the *Pachette 2* front panel. During the printout, the *Pachette 2* display will indicate "PLEASE WAIT".

    Note: If no printout occurs and the display indicates "NO INTERFACE DETECTED", check the printer cable to make sure that it is properly mated. Also, make sure that the printer is on-line (as explained above).

4. After the printout is completed, the *Pachette 2* will retain a copy of all measurements in memory. The operator can either initiate another printout or press the **CLEAR** key to erase all measurements and begin a new measurement session.

Printer Troubleshooting

If the printer malfunctions or does not operate at all, go to the troubleshooting guide that is given in section 7 of the SII DPU-414 Operation Manual. In addition, the printer can also perform a self-test printout to verify that the print head is operating properly. Refer to section 2.6 of the SII DPU-414 Operation Manual to run the test print.

IX.D. Data Transfer Interface Option

The data transfer interface option is a software/hardware interface that allows the *Pachette 2* to transfer pachymetry data to a personal computer (PC). The hardware interface that is utilized is the industry standard serial data communication protocol designated as RS232C. A 25-pin connector on the rear panel of the *Pachette 2* conforms to the RS232C standard. It is the operator's responsibility to provide a cable from this connector to a comparable RS232C connector on the operator's PC. These cables are available from a variety of stores that retail computers. The specific type of cable required depends upon the configuration of the RS232C interface of the particular computer. Refer to appendix A for a technical description of the RS232C interface as it relates to the *Pachette 2*.

Software is also required to implement the data transfer. All software required on the pachymeter end of the interface is supplied within the *Pachette 2*. It's the operator's responsibility to provide the software for the PC end of the interface. This software will vary depending upon the type and configuration of PC, as well as what the operator intends to do with the data transferred from the *Pachette 2*. All information required by a programmer to determine the format of the data sent by the *Pachette 2* is given in appendix B.

Configuring The Data Transfer Interface

Before the *Pachette 2* can transfer any data to a PC, the data transfer interface parameters must be properly set. The interface must first be enabled, and then the baud rate (or data transmission rate) must be set to match the RS232C interface on the PC. Once configured, it is not necessary to repeat this procedure since the parameter settings are stored in non-volatile memory. However, if it becomes necessary to reset or check the initial configuration, use the following procedure to access the configuration menu and gain access to the data transfer parameters.

1. Plug the probe into the front panel, turn on the unit, and wait until the unit is ready to take a measurement.

2. Press the **CONFIG** key and the display will briefly indicate:

    > **PACHETTE 2**
    > **CONFIG**

    and then the first configurable parameter will be displayed.

3. Press the **ENTER** key repetitively until the display indicates:

    > **EXT. INTERFACE**
    > **Disabled**

4. Use the ↑ or ↓ keys to select "Xfer Enabled" on the bottom line of the display.

5. Press the **ENTER** key to enable the data transfer interface. The display will now indicate:

    > **BAUD RATE**
    > **9600 bps**

    Note: To disable the data transfer interface, follow steps 1 thru 3 above, select "Disabled" in step 4, and then press **ENTER** .

6. Use the ↑ or ↓ keys, if necessary, to select a baud rate for the *Pachette 2* (9600 is the default setting) that matches the baud rate of the computer interface.

7. Press the **CLEAR** key to save and exit the configuration menu.

Connecting The *Pachette 2* To A Personal Computer

1. Turn off the power switch on the *Pachette 2* and on the computer.

2. Plug the *Pachette 2* AC power cord into the back panel of the *Pachette 2* and into a three-prong AC outlet.

3. Connect the computer AC power cord into a three-prong AC outlet.

4. Connect the RS232C data cable between the *Pachette 2* and the computer. A 25-PIN, "D-Type" connector mates to the rear of the *Pachette 2*, and either a 9-pin or 25-pin "D-Type" connector mates to the computer RS232C interface (also

called a COM port).

> **Note:** If the computer is to be mated to the *Pachette 2* for extended periods of time, it is recommended that the "D-Type" connectors be secured to the computer and the *Pachette 2* by using the (2) screws on each connector.

5. Turn on the *Pachette 2* power switch and the computer power switch.

Transferring Pachymetry Data To A Computer

As explained above, DGH Technology, Inc. does not provide software for a personal computer that will accept a data transfer from the *Pachette 2*. However, no matter what software is developed by the operator or a third party, the following general guidelines can be used when transferring pachymetry data to a personal computer.

1. Start an appropriate computer software program that is capable of communicating with the *Pachette 2* through the designated COM port.

2. Adjust the computer COM port settings to the following: parity = none, data bits = 8, stop bits = 1, baud rate = 9600.

3. Obtain pachymetry measurements as described in section VI.

4. Start the data transfer by pressing the **DATA XFER** key on the *Pachette 2* front panel.

    > **Note:** If no data transfer occurs and the display indicates "NO INTERFACE DETECTED", check the data cable to make sure that it is properly mated.

5. After the data transfer is completed, the *Pachette 2* will retain a copy of all measurements in memory. The operator can either initiate another data transfer or press the **CLEAR** key to erase all measurements and begin a new measurement session.

IX.E. IrDA Interface Option

This option is not available as of release date 06/2003 of the DGH 550 Operator's Manual.

X.   CARE AND MAINTENANCE

X.A.   Cleaning Instructions

Keep the probe tip clean. To prevent patient-to-patient infection, after each patient wipe the probe with a Q-tip soaked in 70% isopropyl alcohol, and then immerse the probe tip for 10 minutes in 70% isopropyl alcohol. The tip should be rinsed in sterile distilled water before using. The electronic console can be cleaned by wiping with a damp cloth with mild soap. Do not immerse in water.

---

* * * CAUTION * * *

The probe should **NEVER** be autoclaved or subjected to intense heat. As a general rule, the above cleaning instructions are sufficient to disinfect the probe in ordinary use. Do not scratch or chip the conical probe tip, which makes contact with the cornea.

X.B.   Transport and Storage Conditions

The *Pachette 2* is capable, while packed for transport or storage, of being exposed for a period not exceeding 15 weeks to environmental conditions not outside the following ranges:

1. An ambient temperature range of -40°C to 70°C.
2. A relative humidity range of 10% to 100%, including condensation.
3. An atmospheric pressure range of 500 hPa to 1060 hPa.

X.C.   Operating Conditions

The *Pachette 2* should be operated between temperatures of +18°C. to +40°C.

X.D. Warranty

DGH Technology, Inc. "DGH" warrants each new DGH 550 and its accompanying accessories (hereinafter called "Equipment") to be free from defects in material and workmanship for twelve (12) months from the date of delivery to the original purchaser. This warranty is not applicable to any defect which is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than DGH. This warranty does not apply if the Equipment has not been operated and maintained in accordance with the operating and maintenance manuals and instructions or bulletins issued in respect thereof by DGH. It is further understood that the cost of servicing replaceable and expandable items including parts and labor made in connection with the routine maintenance services as described in such Operator's Manual is not covered under this warranty and is the responsibility of the purchaser.

This warranty is strictly limited to replacement or repair of the part that is found to be defective in material and workmanship. At the option of DGH, said part shall be replaced or repaired free of charge, F.O.B. our factory by DGH.

DGH reserves the right to make changes in the design and material of Equipment without incurring any obligations to incorporate such changes in Equipment already completed on the effective date of any such change or changes.

This is the only warranty of this product and is expressly in lieu of all other warranties, expressed or implied by law or otherwise, including any implied warranties of merchantability and of fitness for a particular purpose. Without regard to the alleged defect, DGH does not, under any circumstances, assume any responsibility for the loss of time, inconvenience or other consequential damages, including but not limited to, loss or damage of personal property, or loss of revenue. DGH has neither assumed nor authorized any other person (including any distributor authorized to sell its Equipment) to assume for it any other liability in the connection with the sale of Equipment.

X.E. Service

If you are having problems with this unit, please refer to the appropriate sections of this manual. Most service calls result from a misinterpretation of the operation of the instrument, as described in the manual.

However, if you feel there is a problem with the unit or a probe, please contact the Customer Service Department at the address below. DGH Technology, Inc. can also be

contacted via our web page at www.dghkoi.com. When contacting us, please provide the model and serial number for the unit. These numbers are located on the back panel.

DGH Technology, Inc.
110 Summit Drive, Suite B
Exton, PA 19341
Phone: (610) 594-9100
Fax: (610) 594-0390

XI. IMPORTANT NOTES

XI.A. Prescription Device

The *Pachette 2* is a prescription device and is to be used only by or under the supervision of a licensed physician.

XI.B. Tissue Exposure To Ultrasound Energy

The ultrasound energy emitted by the *Pachette 2* is low intensity and will have no adverse effects on the patient and/or operator. However, the operator is still cautioned to perform examinations using the principle of **ALARA** (As Low As Reasonably Achievable). All examinations should be done so that the patient receives as little ultrasound radiation as possible. Do not hold the probe against the eye or other tissue with the system activated except when making a measurement. Do not make unnecessary measurements.

XI.C. Ultrasonic Intensities

The *Pachette 2* has only one mode, and ultrasonic intensity settings are not under the control of the operator. Thus, the values below are the values to be expected for a typical transducer.

	In Water	In the Eye*
I SPTA,mw/cm²	8.17	7.47
I SPPA,W/cm²	13.10	12.00
I M,W/cm²	22.90	20.90

* At transducer focus (1 mm from probe tip)

Since the *Pachette 2* is a contact scanner, the energy will always be attenuated by the tissue when used as recommended. However, since the focal length (point of maximum intensity) is very short (1 mm), and thus penetration into the eye is limited, the water values are effectively the same as the tissue values, for all practical purposes.

If more accuracy is desired, the intensity in the eye at the transducer focus (corresponding to maximum intensity) may be calculated according to the formula recommended by the FDA:

$$It = Iw \times e^{\left(-0.069 \times f \times z\right)}$$

where *It* is the estimated in situ intensity, *Iw* is the measured intensity in water at the focus of the transducer (indicated in the above chart), *f* is the ultrasonic frequency, and *z* is the distance from the face of the probe to the transducer focus, which is the point of measurement (1 millimeter). The nominal frequency of these transducers is 20 MHz. The actual frequency of a particular transducer may vary from this value. The tissue calculations above were done with the measured frequency of the transducer used for the tests.

XI.D. Biometric Measurement Capabilities

The DGH 550 can be ordered with one of three different measurement options. Therefore, the biometric measurement capabilities of a particular unit will depend upon which option is installed. The following table shows the measurement range for each option.

Measurement Option	Range (μm)	Accuracy (μm)	Display Resolution (μm)
Standard Unit	200 - 1000	± 5	1
FLAP Option	95 - 1000	± 5	1
Extended Option	200 - 2000	± 5	1

XI.E. Classification

According to the degree of protection against electric shock, the *Pachette 2* is classified as type B equipment. On CE units this is indicated by the ✟ symbol on the back panel.

XI.F. EMI / EMC Compliance (CE Units Only)

The Electro Magnetic Interference and Compatibility testing of the DGH 550 Ultrasonic Pachymeter (*Pachette 2)* was performed to determine compliance with emissions and immunity requirements set forth by the European Community under the requirements of the EMC Directive (89/336/EEC).

Tests for radiated and conducted emissions were performed. Tests were performed according to:

EN55011:1998   Radiated Emissions

EN55011:1998   Conducted Emissions

The system complied with the radiated and conducted emissions requirements throughout the test.

Tests for power harmonics and flicker were performed. Tests were performed according to:

EN61000-3-2:1995   Harmonics

EN61000-3-3:1995   Flicker

The system complied with the harmonics and flicker requirements throughout the test.

Tests for radiated and conducted immunity were performed per EN60601-1-1-2: 2002 requirements. Tests were performed according to:

IEC 61000-4-2:1995   Electrostatic Discharge

IEC 61000-4-3:1995   RF Susceptibility

IEC 61000-4-4:1995   Electrical Fast Transient/Burst

IEC 61000-4-5:1995   Voltage Surge

IEC 61000-4-6:1996   Conducted RF Immunity

IEC 61000-4-8:1993   Magnetic Immunity

IEC 61000-4-11:1994   Voltage Dips and Interrupts

The system complied with the radiated and conducted immunity requirements throughout the test.

XII. APPENDIX A

RS232C HARDWARE INTERFACE

There are three interface options currently available for the *Pachette 2*: (1) printer interface, (2) data transfer interface, and (3) IrDA interface. Utilization of one or more of these options requires a hardware interface to the *Pachette 2*. An RS232C standard serial interface is provided for the printer and data transfer options. A 25-pin D-Type female connector is located on the rear panel of the *Pachette 2*. This connector has the following pin out assignment.

PIN	NAME	EIA NAME	FUNCTION
1	FG	AA	Frame ground
3	TD	BA	Transit data
2	RD	BB	Receive data
7	SG	AB	Signal ground
20	DTR	CD	Data terminal ready

The *Pachette 2* is configured as a Data Communication Equipment (DCE) device as defined by the RS232C specification. This means that data leaves the *Pachette 2* on pin 3 and enters the *Pachette 2* on pin 2 of the interface.

A third signal active in the interface is Data Terminal Ready (DTR). This is an input to the *Pachette 2* that, when active, indicates that the interface is ready to accept data from the *Pachette 2*. When the signal is deactivated by the receiving device, the *Pachette 2* will temporarily suspend data transmission until the DTR goes active again. This allows slower devices, such as printers and personal computers, to "hold-off" data transmission from the *Pachette 2* until they are ready to receive the data.

When the *Pachette 2* is attempting to transmit data across the RS232C interface and DTR remains inactive for more than 30 seconds, the message "NO INTERFACE DETECTED" will appear on the front panel display, the alarm will sound, and the transmission will be aborted. This is usually an indication that the interface is not plugged in, or that the printer is not "on-line".

All signals within the interface are RS232C standard loads and ±10V levels. All other pins on the connector have no connection.

> ### * * * WARNING * * *
>
> Interfacing the *Pachette 2* with voltages in excess of ±10V will cause permanent damage to the *Pachette 2*. DGH Technology, Inc. assumes no liability for damage to the *Pachette 2* or any user equipment in the event of improper use of the RS232C interface.

RS232C Interface Cables

There are generally two different interface cables that are used with the *Pachette 2*. The first cable is needed when connecting the *Pachette 2* to the SII DPU-414 printer. This cable can be purchased from DGH Technology, Inc. when the SII DPU-414 printer is ordered. The second cable is used when connecting the *Pachette 2* to a personal computer. It is usually the operator's responsibility to obtain this cable from a computer outlet store. For reference, the wiring diagrams for both of these cables are given in Figure XII-A and Figure XII-B.

Note: If a printer other than the SII DPU-414 is used with the *Pachette 2*, or if the *Pachette 2* is interfaced to a personal computer that uses a non-standard RS232C port, then a different interface cable may be required in each case.
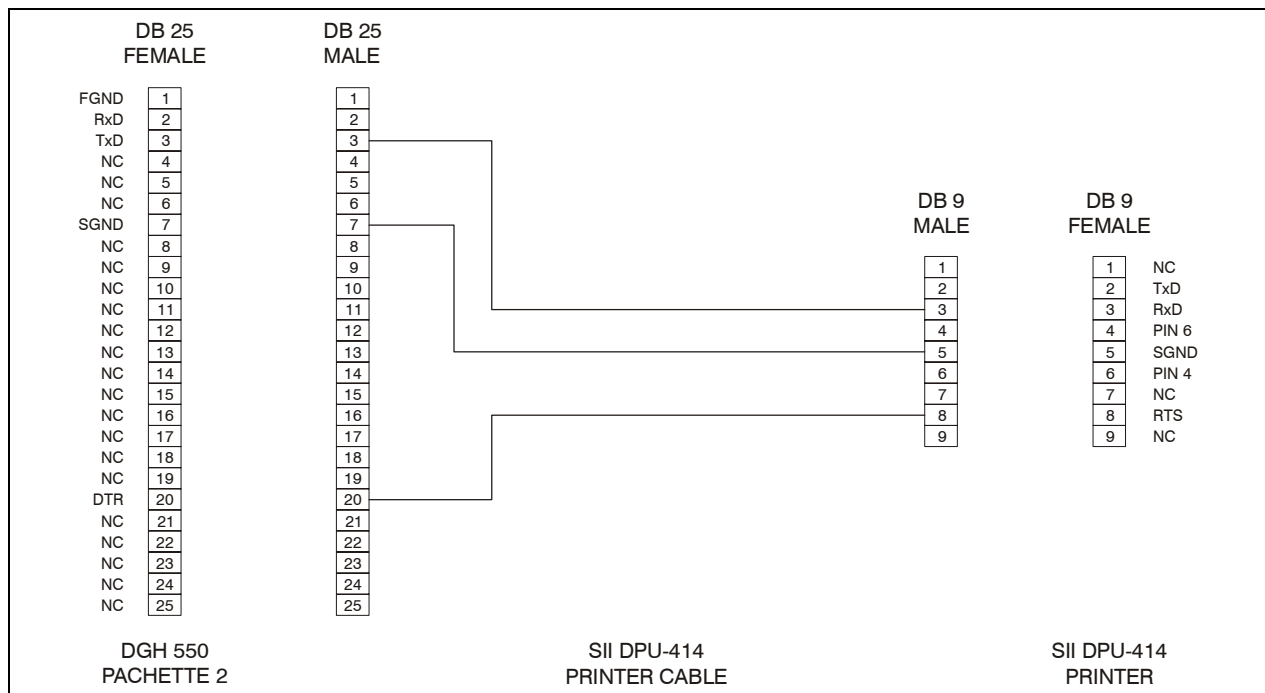
DB 25
FEMALE

DB 25
MALE

FGND	1
RxD	2
TxD	3
NC	4
NC	5
NC	6
SGND	7
NC	8
NC	9
NC	10
NC	11
NC	12
NC	13
NC	14
NC	15
NC	16
NC	17
NC	18
NC	19
DTR	20
NC	21
NC	22
NC	23
NC	24
NC	25

DB 9
MALE

DB 9
FEMALE

1	1	NC
2	2	TxD
3	3	RxD
4	4	PIN 6
5	5	SGND
6	6	PIN 4
7	7	NC
8	8	RTS
9	9	NC

DGH 550
PACHETTE 2

SII DPU-414
PRINTER CABLE

SII DPU-414
PRINTER

Figure XII-A *Wiring diagram for the SII DPU-414 printer interface cable.*

DB 25
FEMALE

DB 25
MALE

FGND	1
RxD	2
TxD	3
NC	4
NC	5
NC	6
SGND	7
NC	8
NC	9
NC	10
NC	11
NC	12
NC	13
NC	14
NC	15
NC	16
NC	17
NC	18
NC	19
DTR	20
NC	21
NC	22
NC	23
NC	24
NC	25

DB 9
MALE

DB 9
FEMALE

1	1	CD
2	2	RxD
3	3	TxD
4	4	DTR
5	5	SGND
6	6	DSR
7	7	RTS
8	8	CTS
9	9	RI

DGH 550
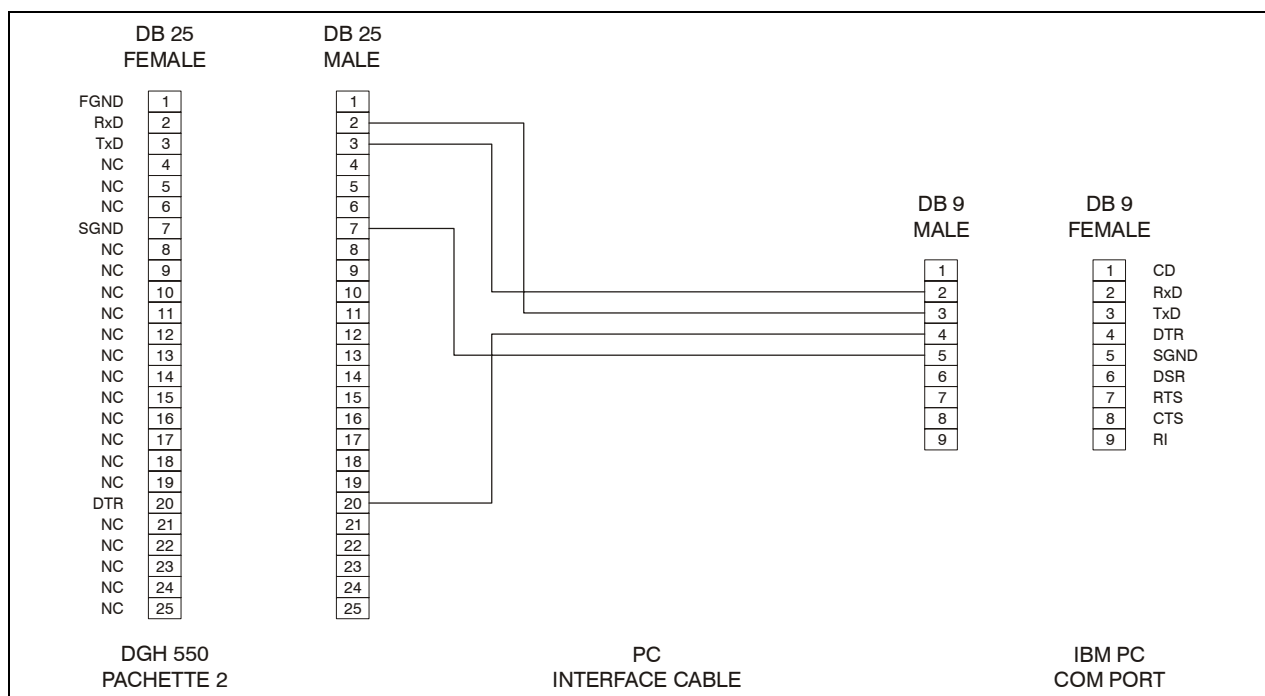PACHETTE 2

PC
INTERFACE CABLE

IBM PC
COM PORT

Figure XII-B *Wiring diagram for a typical PC interface cable.*

XIII. APPENDIX B

DATA TRANSFER FORMAT

When the data transfer interface is implemented, a specific data format is used to transfer data from the *Pachette 2* to a personal computer. This appendix provides the necessary information for a programmer to interpret and utilize the data stream sent by the *Pachette 2*.

The format of the data sent to the personal computer is shown in Figure XIII-A. Each character in the data stream, represented by "X", is a 7-bit ASCII encoded decimal digit (e.g. "1" is encoded as "31" hex, "2" as "32" hex, etc.). The first value transmitted is a four-digit number representing the velocity used to calculate all measurements. The second number contains two-digits and it represents the total number of measurements obtained. The next four-digit number represents the total average of all measurements (this number is only transmitted in Continuous Avg mode). Following this will be 1 to N four digit pachymetry measurements, represented in microns. The number of measurements transferred (N) depends upon the number of measurements for which the *Pachette 2* was programmed. The data stream is terminated with ASCII carriage return and line feed characters.
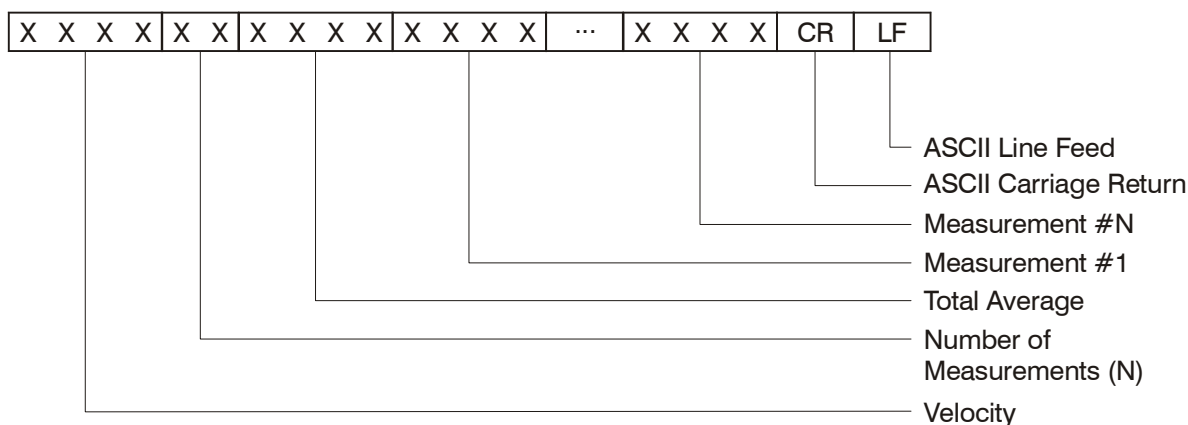

Figure XIII-A *Format of data stream sent by Pachette 2*.