KIOSK

HEARING SCREENER

Operations Manual

MedRx®

Kiosk Stand-Alone Hearing Screening Tablet

Contents

Getting to Know Your MedRx Kiosk

The MedRx Kiosk software represents a new era of lead generation for your office. This is a calibrated hearing screening device that utilizes the tablet's compact size to perform its functions. MedRx Kiosk software offers 3 types of hearing screenings with various integrations. The software is designed to be a patient driven hearing screening. The following sections of this manual will familiarize you with the MedRx Kiosk software.

This manual assumes that the system hardware, software and drivers are installed and working properly. The scope of this manual is to get you "up and running" with the MedRx Kiosk System.

Intended Use Statement:

The MedRx Kiosk software is designed for tablet use intended to generate leads for hearing clinics with an estimated hearing loss in participants. The MedRx Kiosk will provide estimated hearing thresholds for chosen frequencies. These devices should be set up by professionals educated and/or training in the field of audiometry and designed to be operated by customers.

Indication For Use Statement:

This device is a lead generation tool for hearing clinics with the ability to provide estimated hearing screenings. It is for use by professionals with the desire to market to large groups of customers and provide a service to the community.

Transducers and Accessories

Use the accessories provided with your Kiosk. Use of unapproved accessories is not recommended.
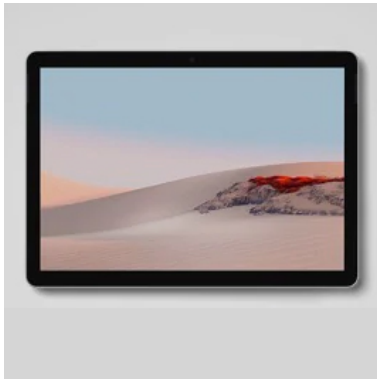
Tablet
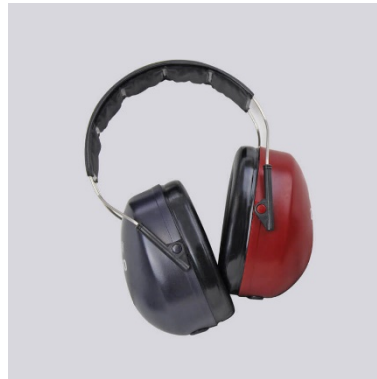
DD65 v2a Headset with c-cable

DD65 v2 Headset with single plug

USB Stick with software

Loading Calibration Files

The MedRx Kiosk is calibrated to transducer and type of tablet. This calibration procedure results in a series of files that the Kiosk software reads to keep the hardware in calibration. These files are preloaded on each tablet and supplied on a USB Stick. Contact your MedRx Technician for calibration details.

Kiosk Module & Software Overview

The MedRx Kiosk software can run stand-alone, with HearingBI.com integration or from the NOAH™ System.

Launching the MedRx Kiosk Software

Stand-alone and HearingBI

- Double click the MedRx Kiosk shortcut on your Windows Desktop.

NOAH

- Launch NOAH.
- Select a patient
- Launch MedRx Kiosk module following NOAH procedures.

Basic Software Options

Several options are available which allow the professional to customize the MedRx Kiosk Software to meet their needs.

To access the professional settings press: **Shift + F1**

Note: The default on-screen keyboard does not have the F1 key available. You will need to change the onscreen keyboard settings temporarily or attach an external keyboard.

Click the settings wheel in the top left of the onscreen keyboard to change keyboard types.

Select the below keyboard to access the F1 Key with an on screen keyboard.
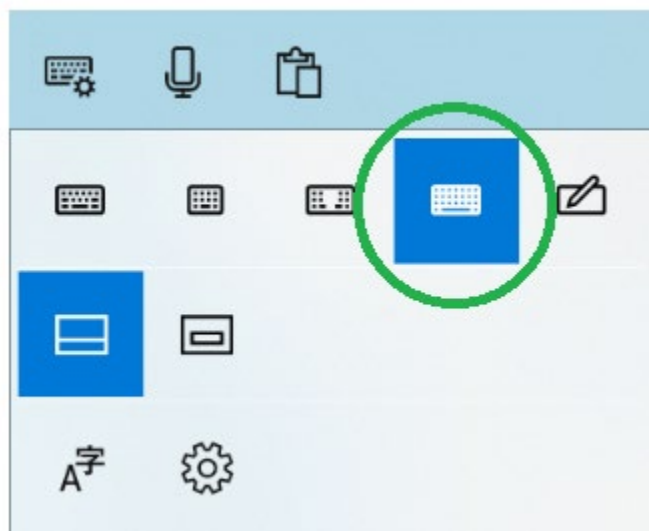
Press the Fn key on the onscreen keyboard to access the F Keys. With Fn selected, press **Shift + F1** to access the setup.

Be sure to set the keyboard back to the original after setup changes have been made.
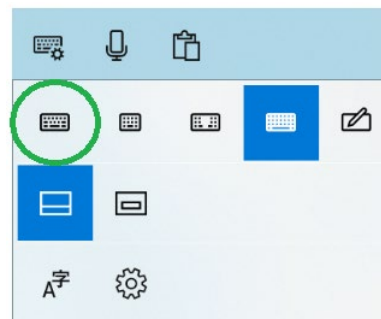
Note: The software options are password protected to prevent customers from accessing the controls. Be sure to use a strong password to protect the Kiosk.

Kiosk Settings

The MedRx Kiosk settings are password protected. Please be sure to set a secure password during initial setup.

Note: Initial setup you can simply hit the **Login** button

You will need to enter Kiosk settings to exit the Kiosk application and view the tablet desktop.

Kiosk Settings Window

The **Settings window** is divided into the following functions:

Kiosk Preferences

① Test Settings	② Connection Settings
③ Application Settings	④ Compliance Settings
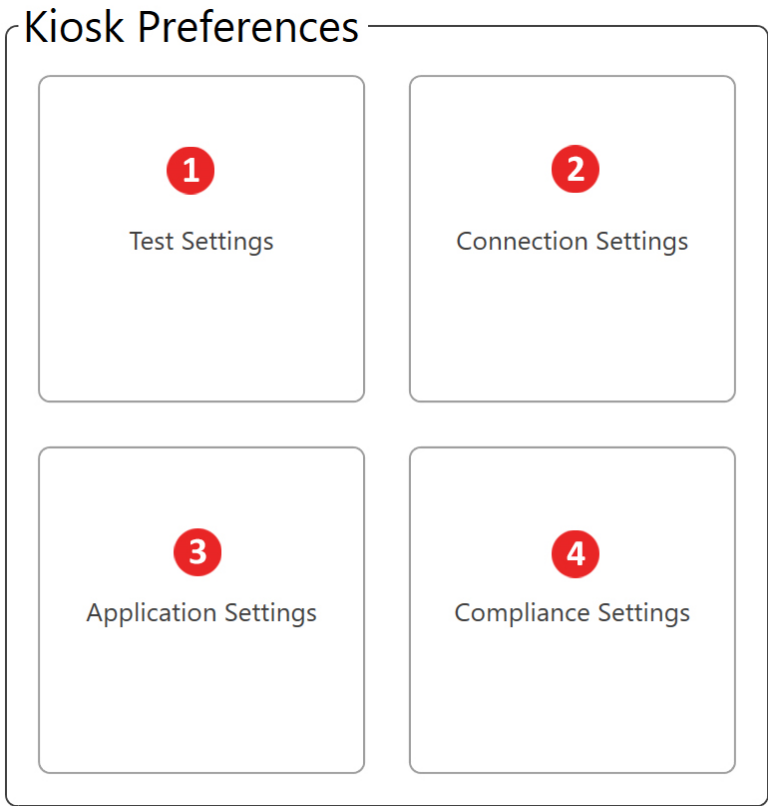
1. Test Settings
2. Connection Settings
3. Application Settings
4. Compliance Settings
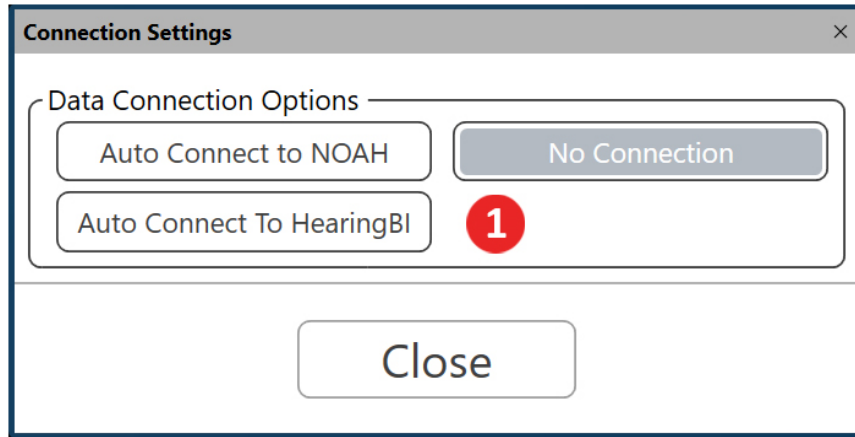
The **Test Settings** contain the following settings

Test Settings   ✕

Screening Test Type

+/- Screening   Flat Screening   Auto Screening   ①

Default Level: 50 ▼

Test Frequencies

250Hz   500Hz   750Hz   1000Hz   1500Hz
2000Hz 3000Hz 4000Hz 6000Hz   8000Hz

Randomize Frequencies   ②

Transducer   DD65v2 ▼
Pulse Type   Continuous ▼   ③
Result Calculation Highest3 ▼
Result Display Type Basic ▼

Close
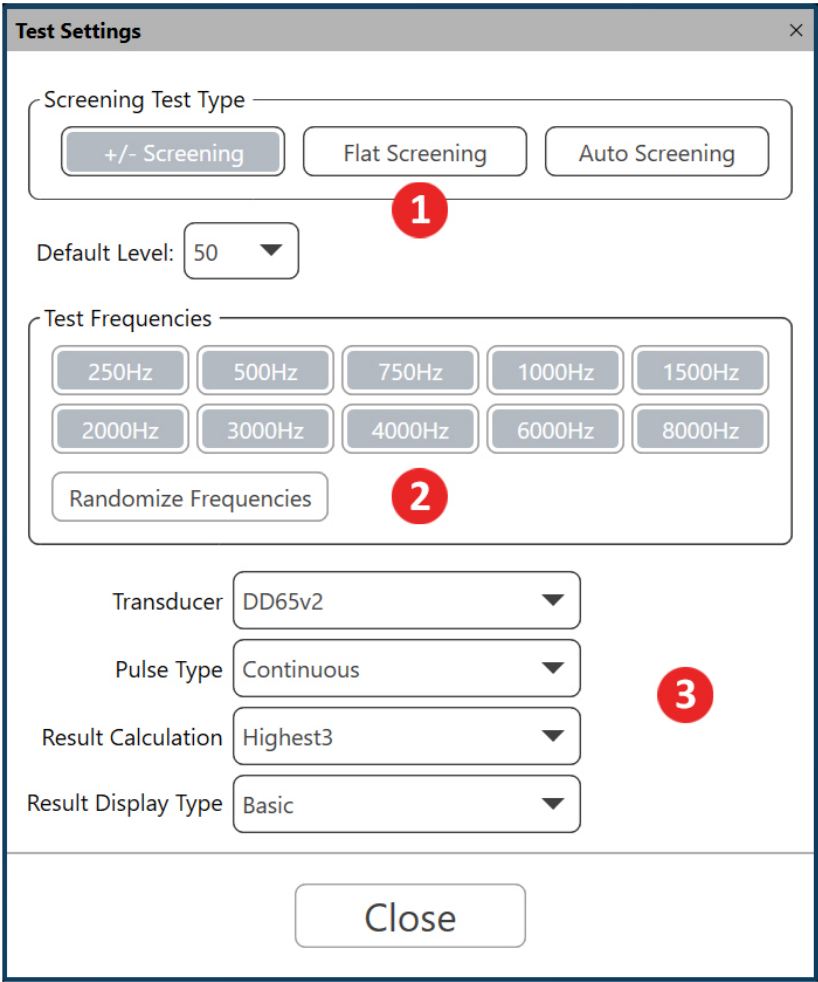
1. Test Type and Starting Level
2. Screening Frequencies
3. Test/Result Settings
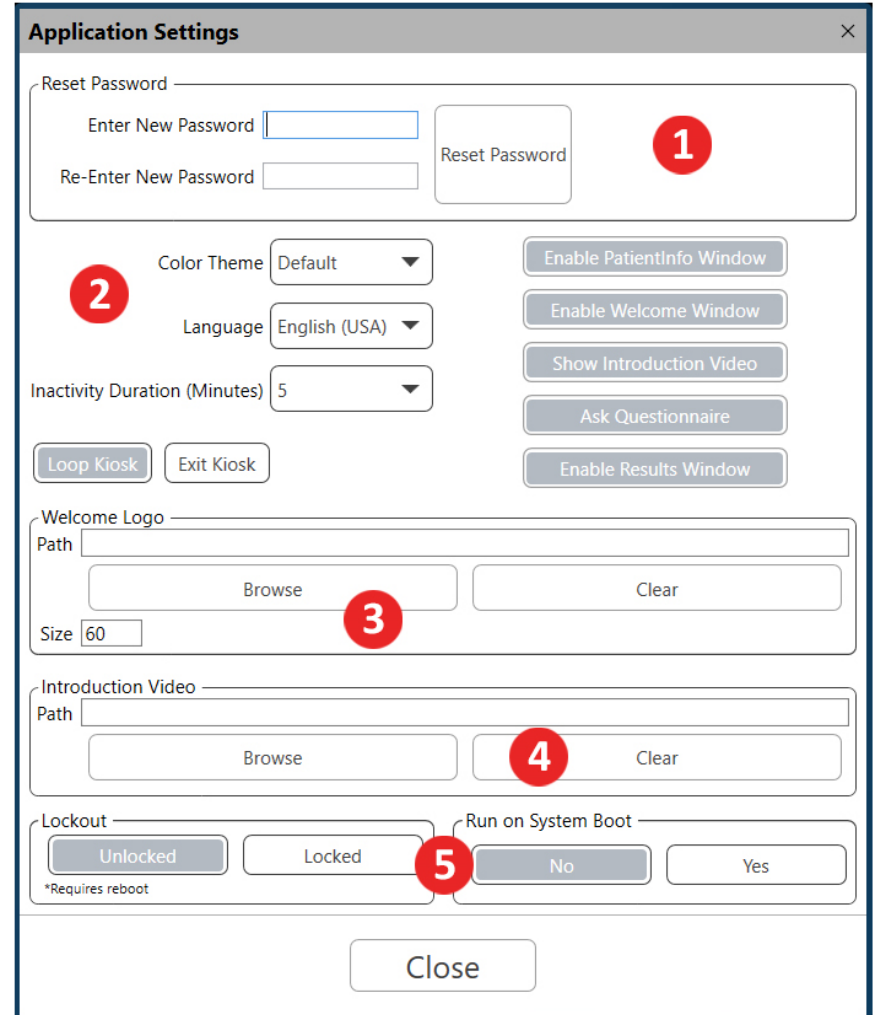
The **Connections Settings** contain the following settings

Connection Settings ✕

Data Connection Options

| Auto Connect to NOAH | No Connection |

Auto Connect To HearingBI **1**

Close

1. Data Connection Types

The **Application Settings** contain the following settings

Application Settings ✕

Reset Password

Enter New Password [   ]

Re-Enter New Password [   ]   Reset Password   **1**

2 Color Theme [Default ▼]   Enable PatientInfo Window

Language [English (USA) ▼]   Enable Welcome Window

Show Introduction Video

Inactivity Duration (Minutes) [5 ▼]   Ask Questionnaire

Loop Kiosk   Exit Kiosk   Enable Results Window

Welcome Logo
Path [   ]

Browse   **3**   Clear

Size [60]

Introduction Video
Path [   ]

Browse   **4**   Clear

Lockout   Run on System Boot

Unlocked   Locked   **5**   No   Yes

*Requires reboot

Close

1. Change Passwords   4. Introduction Video
2. Enable Windows   5. Service Settings
3. Main Screen Logo

The **Compliance Settings** contain the following settings

Compliance Settings ✕

1 GDPR Required [Yes] [No]

Marketing Setup

Email Required ? [Yes] [No]

2 Phone Required ? [Yes] [No]

Marketing Consent Required ? [Yes] [No] **3**

Privacy Policy Document Path [   ]

4 [Browse] [Clear]

[Close]

1. GDPR Selection   3. Marketing Consent
2. Required Fields   4. Privacy Policy Path

Test Types

There are 3 types of hearing screenings available. Each type will change how the customers hearing results are obtained. You may also set the level at which the test begins.

Test ─────────────────────────────

[+/- Screening] [Flat Screening] [Auto Screening]

AutoTest Start Level: [30 ▼]

The +/- Screening

Testing Right Ear ◀

Adjust the volume level UP (+) or DOWN (−)
to get to the lowest level you can hear.

−────────────○────+ ☑
              NEXT

Select NEXT when your ready for the next tone.

+/- Screening will provide a slider for the customer to adjust for hearing threshold. This test will result in an audiogram. Customers can use the slide bar or click the + and − button to change the level being presented.

The Default Level will be the level at which the first tone is presented.

The Flat Screening

Testing Right Ear

Do you hear the tone?

Yes	No

Flat screening is designed for a very quick hearing screening without level changes. Each frequency will be presented at the Flat Screening Level with a Yes or No response only. The results will be either a No Response or Threshold at the level chosen.

The Auto Screening

Testing Right Ear

Press the button when you hear a tone

Press

Auto screening is a threshold seeking hearing screening. The test will begin at the start level and increase in 5 dB steps until the button has been pressed 2 times. The threshold will be the average between the two button pushes. The end result will be a threshold audiogram.

Screening Frequencies

Test Frequencies

250Hz	500Hz	750Hz	1000Hz	1500Hz
2000Hz	3000Hz	4000Hz	6000Hz	8000Hz

Randomize Frequencies

Screening Frequencies will determine which frequencies are presented to the customer. All traditional audiometric frequencies are available as options. We recommend choosing 4 frequencies with a high frequency bias. This will help eliminate false positive screenings or screenings with hearing loss that upon further investigation have normal hearing.

You can also choose to randomize the presentation order of the frequencies selected. This will change the order of selected frequencies presented to each ear and will change between each customer.

Test/Result Settings

Transducer | DD65v2 ▼

Pulse Type | Pulse ▼

Result Calculation | Highest3 ▼

Result Display Type | Basic ▼

Transducer Selection

The default transducer for the MedRx Kiosk is the DD65v2 with a 3.5mm plug. This is a noise isolating headphone with consistent frequency response. This headphone also does not require special accessories to connect to the tablet.

The transducer must have a calibration file installed on the software to provide accurate hearing estimates.

Pulse Type

Choose from **Pulse Tones** or **Continuous Tones** for presentation during the hearing screening.

Result Calculation

There are four result calculation options. The result calculation is used for the Basic Result Display and Hearing Loss indicator within HearingBI.

Highest – Uses the single highest threshold to determine hearing loss

Highest3 – Averages the three highest thresholds to determine hearing loss

PTA – Uses the traditional Pure Tone Average (500, 1000 and 2000 Hz) to determine hearing loss

HFA – Uses the High Frequency Average (1000, 2000 and 4000 Hz) to determine hearing loss

Result Display Type

Result Display Type determines what the customer will see at the end of the hearing screening.

Note: Enable Results Window must be selected in the Enabled Windows section **(see Application Settings on page 9)**

Basic: This will show a right and left ear in different colors: Green for Normal, Orange for Moderate, Red – refer customer to hearing professional.

Advanced: Advanced results will display an audiogram view of the screening results

Data Connections

Data Connection Options

Auto Connect to NOAH | No Connection

Auto Connect To HearingBI

Data connections will determine how the hearing screening data is processed.

Auto Connect to Noah

This feature will launch Noah before MedRx Kiosk will open. You will need to select a patient to start testing.

In Kiosk Enabled Windows section **(see Application Settings on page 9)** the Patient Information Window and Questionnaire Window are not available. It is also not suggested to Loop Kiosk and instead Exit at the end of the hearing screening.

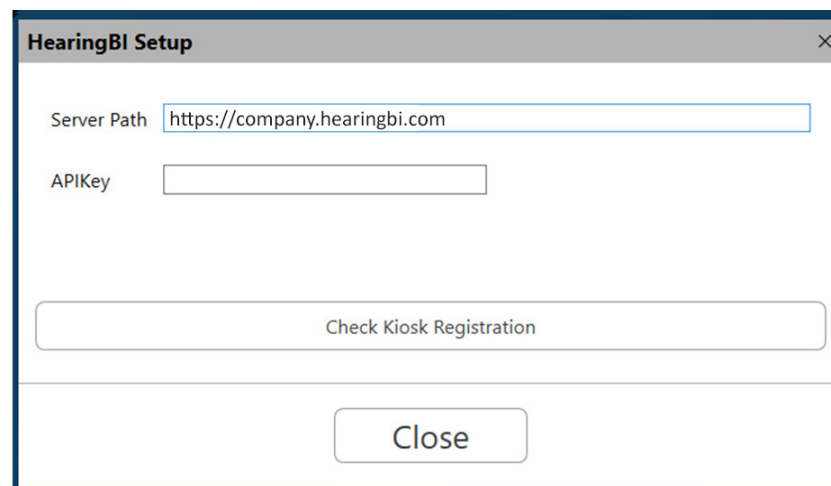To view results, you will need to open Noah to view the audiogram results.

Auto Connect to HearingBI

This feature will send all results to the HearingBi.com databases. You must have a HearingBI account to enable this feature. MedRx Kiosk is designed to be a looping unattended customer facing screening tool with HearingBI connected.

In Kiosk Enabled Windows section **(see Application Settings on page 9)** the Patient Information Window is required for HearingBI use. The Questionnaire Window is an optional window available for HearingBI connections. The questions asked are available to view in the HearingBI interface.

An internet connection is required to transfer results into HearingBI. Kiosk has a fallback offline mode when connected to HearingBI. Tests will be stored on the Kiosk until a wireless connection is restored. When internet connection is restored, Kiosk will transmit the offline stored results on initial bootup of the software and/or on the completion of the next hearing test.

HearingBI Connection Parameters

To connect to HearingBI you must have your company specific server path or URL and an API Key. Your MedRx representative will provide your company specific server path. API keys are generated inside of HearingBI in the Administration and Settings area.

Example Server Path: https://company.hearingbi.com

Where "Company" will be your specific URL name. You must enter exactly as listed above without any trailing information in the URL.

A single API key can be used for any number of kiosks. The number of kiosks registered to an API key can be viewed inside of HearingBI.
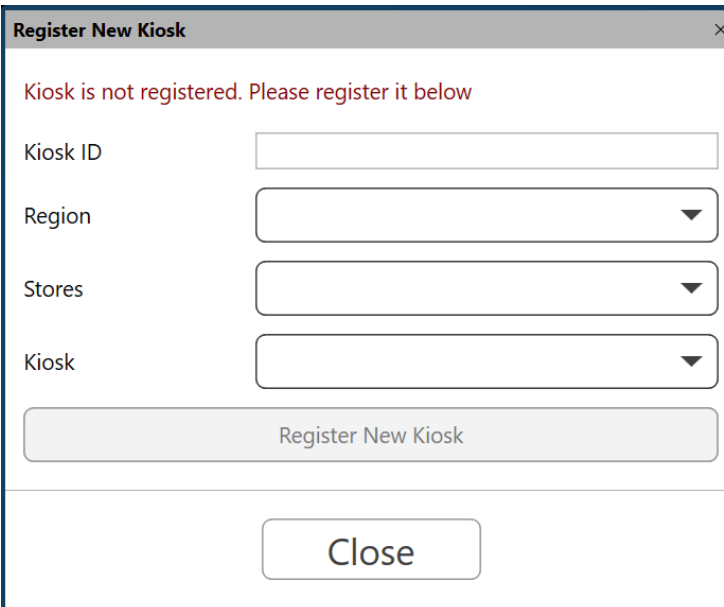
Note: Deleting an API key in HearingBI will revoke access to any tablet using the API to send results.

Registering a Kiosk

In order to register a Kiosk, you must first create your system in HearingBI. A Region, Store and Kiosk must all be created in order to register a Kiosk.

HearingBI is organized so that a Region can have multiple Stores and Stores can have multiple Kiosks. If you have purchased multiple Kiosks, they can be assigned to a single store or each Kiosk can be assigned to separate stores. The **Kiosk emails sent to customers will contain the assigned stores information** including store name, store address, phone number and email address. Be sure your system is set up to reflect your desired outcomes.

After successful connection to HearingBI, you will need to choose the Kiosk to activate from HearingBI. Kiosk will prompt you to select from Region, Stores and Open Kiosks. A Kiosk must be available (unregistered) in HearingBI and assigned to selected Store/Region to appear in Kiosk registration.

Register New Kiosk ✕

Kiosk is not registered. Please register it below

Kiosk ID [   ]

Region [▼]

Stores [▼]

Kiosk [▼]

[Register New Kiosk]

[Close]

You will be prompted of a successful registration when completed.

Kiosk is registered

Deactivate a Kiosk from HearingBI

Kiosks must be unregistered from the HearingBI portal. If you need to change the Kiosk registration, first enter HearingBI, navigate the Kiosk section and click deactivate.

Now you will be able to register your Kiosk as a different name with a different parent store and region, if desired.

No Connection

This feature is designed to allow customers to demo the product in looping fashion without storing results.
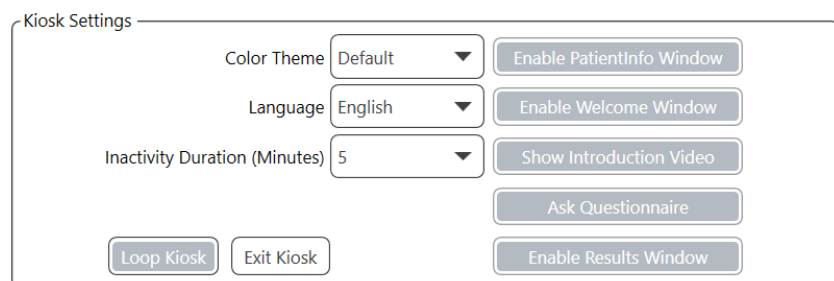
Hearing Screening results are not recoverable in this state.

Reset Password

This references the password used to access the MedRx Kiosk Setup and Exit abilities. We recommend using a secure password as this is the defense between the tablet and malicious individuals.

Enable Windows

The MedRx Kiosk software has the ability enable or disable select windows that the customer will see.

Patient Window – Patient Demographic Window which will contain Privacy Statement for customers. This window is **required** with HearingBI connection. Do not use this window with Noah connection.

Welcome Window – The Welcome Window is the opening window which welcomes the customer to begin the hearing screening. This is required in order to use Custom Logos Images.

Introduction Video – The Introduction Video lets you choose which video file to play. An Introduction video file must be present for the video to play.

Ask Questionnaire – The Questionnaire Window will display the list of questions present in HearingBI. Questionnaire information is only stored with a connection to HearingBI.

Enable Results Window – This will provide hearing screening results in either Basic or Advanced to the customer at the end of the screening.

Color Theme – This will change the color of the Kiosk Settings

Language – This will determine which language the Kiosk presents to the customers. This will also determine the **validations** used in the Patient Information Window. Be sure this is updated to your country to validate information appropriately.

Inactivity Duration – Amount of time in minutes before the Kiosk resets back to the Welcome Window. Setting to "0" means the Kiosk will never reset.

Loop Kiosk/Exit Kiosk – This determines what will occur at the end of the Kiosk screening. HearingBI is designed for the looping interface.

Welcome Logo

In Kiosk, you have the ability to load custom welcome logos.

The Welcome Logo will place an image in the Welcome Window.

Introduction Video

In Kiosk, you have the ability to load custom introduction videos.

Introduction video path will play during the Introduction Video window. Be sure your introduction video is of the same type of test being given to the patient. MedRx has a premade +/- Intro video and Auto Test Intro video that comes saved on the tablet and USB stick.

Note: Be sure you have selected the video that matches your test type.

Service

The service button at the bottom of the Kiosk is designed to change settings on the tablet. This is used when in customer facing or looping mode.

Lockout – This feature will disable standard windows functions (edge swipes, Ctrl + Alt + Del, etc.). This is highly recommended as it will prevent the Kiosk from being misused and deter malicious intent.

Run on System Boot – Will start the Kiosk on initial boot. This is important if the tablet reboots undesirably. It will ensure the Kiosk software is automatically started and screenings can resume.

GDPR Selection

The GDPR field is designed to change the text to be GDPR appropriate. This should be used in EU countries which must comply with GDPR.

Required Fields

The required fields will mandate that a user complete the field in the Kiosk demographic input.

Marketing Consent

The Marketing Consent is designed around GDPR and the requirement to have the customer agree to marketing. GDPR has additional requirements around customer consent and ease of language to verify the customer understands the contact that may occur from using the MedRx Kiosk.

Countries which must comply with GDPR should require the additional marketing consent. The marketing consent will add the email and telephone agreement to the customer interface.

☐ I accept and consent the privacy policy

☐ I agree to be contacted by email and telephone

Privacy Policy

The privacy policy path allows customers to display a custom privacy policy to their customers. Simply select the PDF document to display to the customer and it will link in the customer interface.

EMC Precautions

The MedRx Kiosk needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information.

List of all cables and maximum lengths of cables, transducers and accessories:

Transducer / Accessories	Maximum Cable length
USB Cable	3 meters
All Headsets	2 meters

⚠ Warnings!

- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the MedRx Kiosk as replacement parts for internal components, may result in increased emissions or decreased immunity of the MedRx Kiosk.
- The MedRx Kiosk should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the MedRx Kiosk should be observed to verify normal operation in the configuration in which it will be used.
- The MedRx Kiosk may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The MedRx Kiosk does not have life supporting function.
- Portable and mobile RF communications equipment can affect the MedRx Kiosk.

Guidance and manufacturer's declaration – electromagnetic emissions

The MedRx Kiosk is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx Kiosk should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The MedRx Kiosk uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The MedRx Kiosk is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The MedRx Kiosk is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx Kiosk should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact discharge +/- 8 kV air discharge	+/- 6 kV contact discharge +/- 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The MedRx Kiosk is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx Kiosk should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MedRx Kiosk requires continued operation during power mains interruptions, it is recommended that the MedRx Kiosk be powered from an uninterruptible power supply or a battery

Guidance and manufacturer's declaration – electromagnetic immunity			
The MedRx Kiosk is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx Kiosk should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MedRx Kiosk, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	$d = 1{,}17 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}17 \times \sqrt{P}$ 80 to 800 MHz $d = 2{,}33 \times \sqrt{P}$ 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency ranges applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MedRx Kiosk is used exceeds the applicable RF compliance level above, the MedRx Kiosk should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MedRx Kiosk. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between			
Portable and mobile RF communications equipment and the MedRx Kiosk			
The MedRx Kiosk is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MedRx Kiosk can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MedRx Kiosk as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter meters		
W	150 kHz to 80 MHz $d = 1{,}17 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1{,}17 \times \sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}33 \times \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1   At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

NOTE 2   These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Safety

- Regarding electrical safety, this device is designed to be used only by professionals in the hearing healthcare industry.

- It is Class II Medical Electrical (ME) equipment that is part of an ME system. ▣

  This device provides Type B protection ☖ (Type B equipment, Type B applied part)
- This device is not protected from ingress of water. Power is supplied by an un-grounded mains power cable to a medical grade power supply and also supplied by the USB cable connected to a computer. The USB computer power must be able to supply at least 500mA at the standard USB voltage.
- Power is supplied by the USB cable connected to a computer.
- This device is to be operated on non-conductive surfaces only.
- The computer used with this device should conform to the requirements of IEC 60601-1.
- A MULTIPLE PORTABLE SOCKET-OUTLET or extension cord shall not be connected to the system.
- The power supply cable should always be accessible in order to disconnect it from the supply mains.
- Do not connect items that are not specified as part of the system.
- The use environment should be between 15°C and 35°C ⌀35C , humidity within 30% to 90% ⌀90% and an atmospheric pressure range from 80 kPa to 104 kPa.
- Storage temperature range at least from -20°C to +70°C and humidity level from 10% to 90%.
- All components with patient contact are made of bio-compatible materials.

- This device does not produce any adverse physiological effects.
- Install the device as directed by this manual to achieve optimal use. Clean accessories per the cleaning instructions prior to use. No Sterilization is required for components of this device. However, new foam inserts are needed for each patient where applicable and cleaning of the device and accessories should follow the procedure outlined below.
- The device is not intended to be operated in an environment with anesthetics, oxygen or NO. It is not an AP or APG device. This ME System is not intended for use with flammable anesthetics.
- This device uses Type B application parts temporarily placed on the patient during testing. They are nonconductive and can be immediately withdrawn from the patient at any time.
- The device is intended for continuous operation.
- The computer and the device or accessories may be located in the patient environment if required.
- Contact the local MedRx distributor for safe and proper disposal of this equipment. Proper disposal may require that it be sent to collection facilities for recovery and recycling.
- All repairs should be sent to MedRx for evaluation and / or repair. However, necessary diagrams and repair instruction will upon request be provided to authorized repair personnel.
- There are no known contraindications for the use of this equipment.
- The Instructions for Use (the Installation and Software Training manuals) are supplied as an electronic copy on a USB flash drive. Paper copies of the manuals may be also requested from the company, and will be sent within one business day of the request.
- Refer to the Training manual and Help files for test options and descriptions.

Symbols that may be used

| SN or SN | Type B applied part. | Manufacturer | EC REP | Built-in microphone: | Transport and storage |
| Indicates that the device serial number will follow | Type B applied part. (Type B equipment) | Manufacturer (MedRx) | Authorized Representative in Europe | Built-in microphone: Room monitor. | Transport and storage humidity range. |

| Special Disposal Required | Read the instruction manuals for safe usage of the device (operating instructions) | CE 0123 | Class II Equipment | Keep dry | Transport and storage temperature range. |
| | | The TUV CE-mark indicates that MedRx meets the requirements of Annex II of the MDD 93/42/EEC. | | | |

.

Recommended Procedures for Cleaning and Disinfecting

1. A tablet screen protector should be used prior to sanitizing the touchscreen. Tablets without screen protectors may have touchscreens damaged by use of 70% Isopropyl Alcohol or any other disinfectant.

2. It is recommended that 70% Isopropyl Alcohol should be applied to a soft clean cloth or tissue, not directly on the component to be cleaned. The cloth should never be wet, just damp.

   Do not let 70% Isopropyl Alcohol or water enter the tablet microphone sound inlet.

3. To ensure that cross contamination does not occur, use a clean cloth or sealed Alcohol swabs for each device to be cleaned.

4. Wipe the surfaces of the customer headset and headphone pads with the 70% Isopropyl Alcohol.

5. Let all components that have been cleaned, thoroughly dry before use.

Technical Information

The MedRx Kiosk is an active, diagnostic Class IIa medical device according to the EU medical directive 93/42/EEC.

Safety Standards:
IEC 60645-1
IEC 60601-1-2
IEC 60601-1

Performance Standards:
IEC 60645-1
ANSI S3.6:2010

Physical
Display: No
Dimensions: W x D X H: 19.1 x 9.3 x 13.4 cm/ 7.5 x 3.6 x 5.3 inch (excluding connections)
Weight: 389g / 0.86 lbs

Power Supply
Mains power: 15V, 0.5A
Warm-up Time: None at room temperature

Environmental
Operating Temp: +15°C to +35°C / + 59°F to +95°F
Operating humidity: 30 % to 90 % RH (non-condensing)
Operating atmospheric pressure: 700 hPa to 1060 hPa
Transport: storage temperature:
-20°C to +70°C / -4°F to +94°F
Transport and storage humidity:
10 % to 90 % RH (non-condensing)
Transport and storage atmospheric pressure:
500 hPa to 1060 hPa

Equipment Classification
Type of protection against electric shock:
Powered via SELV Class II mains adapter
Degree of protection against electric shock**:**
Type B applied part
Degree of protection against ingress of water:
Not protected
Mode of operation: Continuous operation
Equipment mobility: Portable

Transducer
Outputs: USB A or USB C
Transducer types and ref level:
 DD65v2a: ISO 389-1 Table 3
Static headband tension: Headphones: 10+/-0.5 N
Sound attenuation characteristics: ISO8253-1, Table 3

Test Signals
Frequencies**:** AC: 125Hz, 250Hz, 500Hz, 1kHz, 1.5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz
Frequency accuracy: < 1 %
Distortion: < 2 %
Output level Range: AC: -10dbHL to 120 dBHL max
Level step size**:** 5 dB or 1 dB
Tone present: Continuous

Maximum Hearing Levels Provided by Each Frequency:

FREQUENCY [HZ]	AIR CONDUCTION [DB HL]
125	85
250	105
500	115
750	115
1000	120
1500	120
2000	120
3000	120
4000	120
6000	105
8000	100

FREQ [HZ]	125	250	500	1000	2000	4000	8000
ATTENUATION [DB]	8.3	15.5	26.1	32.4	43.6	43.8	45.6

Routine Checks and Subjective Tests

The user of the instrument should perform a subjective instrument check once a week. The purpose of routine checks is to ensure, as far as possible, that the equipment is working properly, that its calibration has not noticeably altered and that its attachments, leads and accessories are free from any defect that might adversely affect the test result.

Check that audiometer output is approximately correct on air conduction by sweeping through at a hearing level of, for example, 10 dB or 15 dB and listening for "just audible" tones. This test shall be performed at all appropriate frequencies and for both earphones.

Check at high level (e.g. hearing levels of 60 dB on air conduction) on all appropriate functions (and on both earphones) at all frequencies used; listen for proper functioning, absence of distortion, freedom from interrupter clicks, etc.

Listen at low levels for any sign of noise or hum, for unwanted sounds (break-through arising when a signal is introduced in another channel) or for any change in tone quality as masking is introduced. Keep a record of the results.

Limited Warranty

MedRx, Inc warrants this product to be free from defects in material and workmanship for one year from the time of purchase. If this system fails to perform as specified during this period, the purchaser is responsible for calling MedRx at (888) 392-1234 or (727) 584-9600. The company's representative will advise the owner to either return specific components or the entire system to:

> MedRx, Inc.
> 1200 Starkey Road #105
> Largo, FL 33771 USA

MedRx will repair or replace any defective devices, fully test the system and/or components and ship the system promptly back to the owner. There is no cost for the repair or return shipping, provided the system is one year old or less and has not been misused, abused or damaged. Such damage includes, but is not limited to, dropping, exposure to excessive heat greater than 100ºF and water/liquid damage.

Repair or replacement of the system as provided under this warranty is the sole and exclusive remedy of the purchaser. MedRx shall not be liable for any consequential or incidental damages or for breach of any express or implied warranty. Except to the extent of applicable law, any implied warranty, merchantability or fitness of this product is limited to the duration of this warranty.

MedRx will, at its discretion, service and repair out of warranty products at the purchaser's request, charging for parts and labor as necessary.

The limited warranty is deemed void if software or hardware is installed on this product which is not pre-approved by MedRx, Inc. Approved software includes NOAH™ and HIMSA approved hearing aid manufacturer programming modules for fitting hearing aids.

MedRx, Inc. is not responsible for problems resulting from installation of unapproved software or hardware. In the event of unapproved software or hardware installed on the system causing a conflict, MedRx will service the product for a fee to be determined at the time of service.

Any extension of this warranty past the initial one-year warranty is subject to the following (where applicable).

1. A $300 deductible per repair.
2. Extended warranty does not include cables, connectors or peripherals.