



# Glyconics-DS System User Manual

## 1. MANUFACTURER DETAILS



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## 2. REGULATORY INFORMATION

Glyconics-DS is a Class IIa medical device in accordance with Regulation (EU) 2017/745, as amended.

EMDN Code: Z12040115

The Glyconics-DS System is supplied by Glyconics Ltd as the manufacturer of the medical device.

The relevant parts of the following references have been used when preparing this document:

- EU Medical Devices Regulation (EU) 2017/745, as amended
- ISO 13485:2016
- ISO 20417:2021
- IEC 60601-1
- IEC 60601-1-2
- UN38.3
- IEC 62471

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This CE mark relates to the Glyconics-DS device with software combination only



Relates to the Glyconics-DS cradle

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### 3. SAFETY INSTRUCTIONS

#### 3.1. Hazard Conventions

	<b>WARNING</b>	<p>A <b>WARNING</b> note denotes a hazard. It calls attention to an operating procedure practice, or the like that, if not correctly performed or adhered to, could result in <b>damage, severe personal injury or death.</b></p> <p><b>Do not proceed</b> beyond a <b>WARNING</b> note until the indicated conditions are fully understood and met.</p>
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	<b>CAUTION</b>	<p>A <b>CAUTION</b> note denotes hazard. It calls attention to an operating procedure practice, or the like that, if not correctly performed or adhered to, could result in <b>personal injury, damage to the product or the loss of important information.</b></p> <p><b>Do not proceed</b> beyond a <b>CAUTION</b> note until the indicated conditions are fully understood and met.</p>
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	<b>NOTICE</b>	<p>A <b>NOTICE</b> note indicates important information for using the device.</p> <p>You may proceed beyond a <b>NOTICE</b> after you have reviewed the indicated information provided.</p>
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### 3.2. Symbols

The following symbols are used in this document:

	<b>Electricity Hazard</b>
	<b>Eye Hazard</b>
	<b>Fire Hazard</b>

## 4. DEVICE DESCRIPTION

### 4.1. The Glyconics-DS System

The Glyconics-DS System comprises the following components:

- The Glyconics-DS Device - a hand-size near-infrared diffuse reflectance (NIR) spectrometer
- The Glyconics-DS Cradle - an interoperable accessory device for positioning the Glyconics-DS Device

- The Glyconics mobile application (App) for display of results to the healthcare professional.

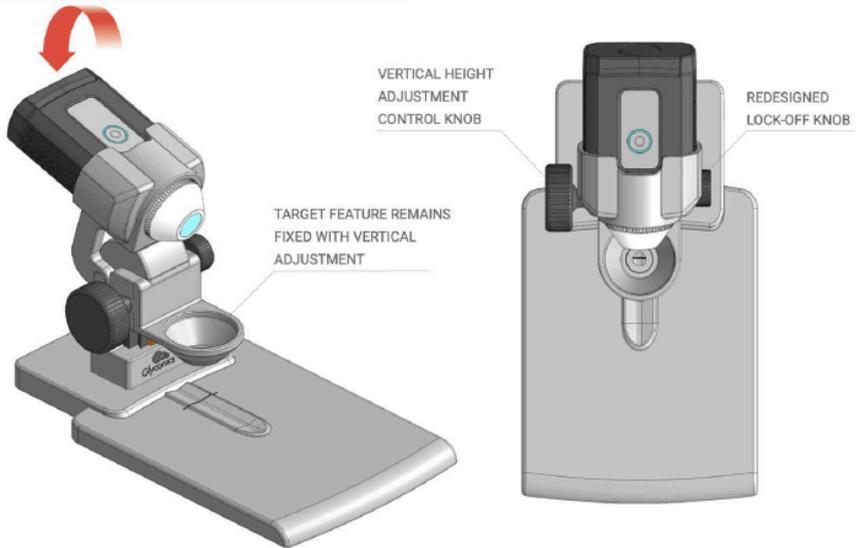
This document relates to use of the entire Glyconics-DS System, comprising all of the above components, as shown in Figure 1.

**Figure 1. The Glyconics-DS System (Device, Cradle and Mobile Application)**



A more detailed image of the Glyconics-DS Device in its Glyconics-DS Cradle is provided in Figure 2.

**Figure 2: Glyconics-DS Device and Cradle**



The Glyconics-DS Device and Glyconics-DS Cradle are initially supplied together and are provided in suitable robust, labelled packaging.

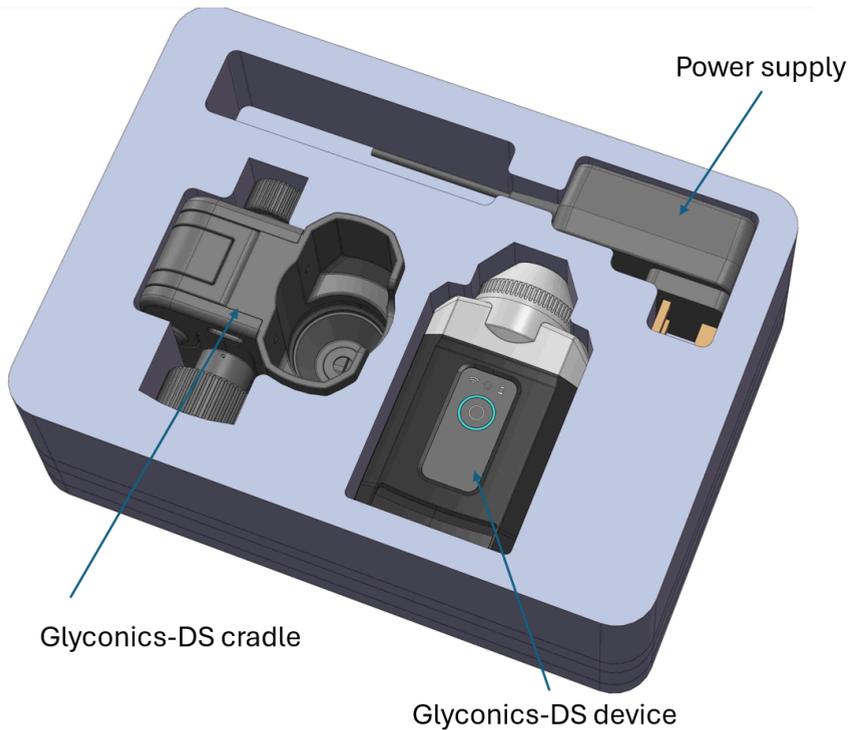
A mobile iOS device is required for use of the Glyconics Mobile App. The Glyconics Mobile App must be downloaded from the Apple App store onto any iOS device (iOS 17.1.0 or later) prior to use with the Glyconics-DS System.

A power cable (USB-PD charger) is also supplied with the Glyconics-DS System. Further details regarding accessories for use with the Glyconics-DS System are provided in Section 5.9.

#### **4.2. The Glyconics-DS Device**

The Glyconics-DS Device is a reusable, software-driven, non-invasive and non-sterile device. An image of the Glyconics-DS system is presented in Figure 3.

**Figure 3. The Glyconics-DS system**

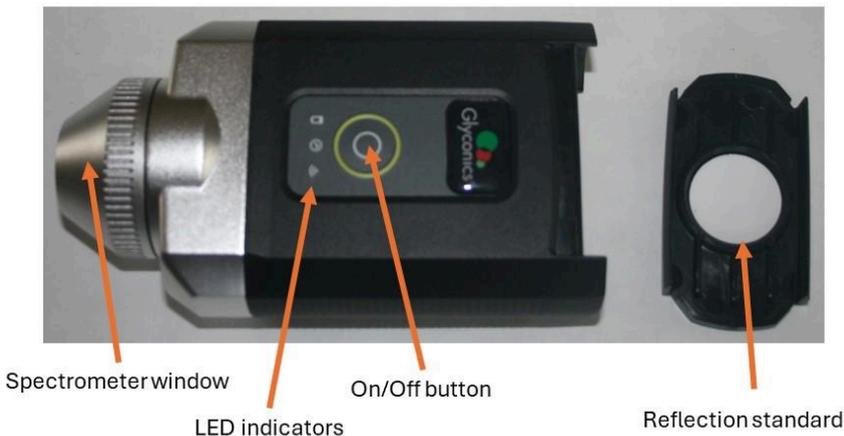


The Glyconics-DS device is hand-size and comprises a miniaturised spectrometer, a sapphire glass specimen interface with infrared collection optics, and a removable reference standard reflector. It is powered by an internal rechargeable lithium battery and uses a wireless Bluetooth connection as a primary data interface to a mobile device. The key features of the Glyconics-DS device are shown in Figure 4.

The Glyconics-DS device works by directing infrared (IR) light to the middle fingernail of the tested person, which reflects back a precise pattern of invisible light that is converted into an electrical signal producing person-specific spectra. These spectra allow identification of the person-specific glycated keratin signature. Anonymous test data is forwarded

via Bluetooth for analysis and storage in a cloud-based database, and the analysed test result is displayed via the Glyconics mobile App.

**Figure 4. The Key Features of the Glyconics-DS Device**



#### **4.3. The Glyconics-DS Cradle**

The Glyconics-DS Cradle is an accessory to the Glyconics-DS Spectrometer System. It is supplied in the Glyconics-DS System case with the Glyconics-DS Device (spectrometer).

The purpose of the Glyconics-DS Cradle is to accurately position the Glyconics-DS Device above the nail of the tested person and ensure the safe operation of the Glyconics-DS Device with no sensation of weight on the nail of the patient or the hands of the user.

The Glyconics-DS cradle holds the Glyconics-DS Device in the optimal position for data acquisition avoiding artefacts owing to the possibility of slight movement by the individual being tested. The Glyconics-DS cradle facilitates alignment between the fingernail and the spectrometer ensuring an optimal signal reflection and consistent results while providing the user with a clear view of the target area.

The Glyconics-DS Cradle is shown in Figure 5. When secured to the Glyconics-DS Device, the three subcomponents of the Glyconics-DS Cradle allow adjustment of the height of the mount with the holding cup up and down to accommodate the test fingernail. The mount can be pushed back to facilitate a better view of the target through the holding cup 10 mm aperture, as shown earlier in Figure 1.

**Figure 5. Glyconics-DS Cradle**



#### **4.4. The Glyconics Mobile Application**

The Glyconics Mobile Application (App) connects to the Glyconics-DS Device via Bluetooth connection.

A mobile iOS device is required for use of the Glyconics Mobile App. The Glyconics Mobile App must be downloaded from the Apple App store onto any iOS device (iOS 17.1.0 or later) prior to use with the Glyconics-DS device. The Glyconics Mobile App is currently not available for use with Android devices.

The Glyconics Mobile App receives the raw data from the Glyconics-DS Device, sends it onto the Cloud for analysis, and then displays the results on the mobile device (e.g. iPad) screen.

## **5. GETTING STARTED**

### **5.1. Intended Use**

The Glyconics-DS System is intended to be used by trained healthcare professionals (HCP) for screening for diabetes by assessing the absorption pattern of glycated keratin in the fingernails of individuals as an indicator of risk of diabetes.

The Glyconics-DS System is solely intended for informing the HCPs of risk of diabetes. The Glyconics-DS System is not intended to be used to diagnose diabetes or influence clinical decision-making.

The Glyconics-DS System is indicated for use in:

- Adults ( $\geq 18$  years of age) with an unknown diabetes status
- Individuals with at least one visually assessed undamaged, intact (preferably middle) fingernail.

### **5.2. Intended Users**

The Glyconics-DS System is intended for use by trained HCPs only. It is not for use by lay-persons.

Training in the use of the Glyconics-DS system is provided before its use as an online training module provided by Glyconics.

Do not use the Glyconics-DS System if you have not previously been trained in its use.

### **5.3. Contraindications**

The Glyconics-DS System is intended for external patient use only, subject to the following contraindications:

- mechanical damage or marks on the surface of the nail after removal of nail polish, or
- use of acrylic or gel nail decoration and polish, which cannot be removed.

The use of Glyconics-DS System has not been tested on patients with the following conditions:

- Individuals with any known chronic medical conditions impacting the blood-based comparative assessment methodology for glycaemia (HbA1c)
- Any structural, deviating and visually detectable deviations in the appearance of the nails potentially impacting the quality of the spectral measurement
- Use of any systemic or topical medications known to modify either the surface or structure of the nail or accuracy of blood-based assessed HbA1c value.

#### 5.4. General Warnings

	<b>WARNING</b>	<b>Risk of Fire or Electrical Shock</b>
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	 	<p>Damaging the Glyconics-DS device may cause fire or electrical shock.</p> <p>Damaging the charger may cause fire or electrical shock</p> <p>Liquids or water that get into the housing can cause damage, fire or electric shock. Never immerse the Glyconics-DS Device and its accessories completely in water or other liquids.</p> <p>Do not operate the Glyconics-DS Device if it has fallen into water, or if it is damaged in any way.</p> <p>Do not operate the Glyconics-DS Device with a damaged cord.</p> <p>Do not attempt to perform any maintenance activities other than those outlined in these instructions.</p> <p>Always switch the Glyconics-DS Device off before performing any kind of maintenance activities.</p> <p>Protect the Glyconics-DS Device and its accessories from physical damage or extreme shock.</p>
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The following warning is regarding the use of a device with a lithium-ion battery to avoid the hazards of personal injury and potent fire:



**WARNING**

Do not dismantle, open or shred the Glyconics-DS device batteries.

The battery is not replaceable by the user. Do not attempt to service or replace the battery.

Do not expose the Glyconics-DS Device or its battery to heat or fire.

Do not subject the Glyconics-DS Device or its battery to mechanical shock.

In the event of cell leaking, do not allow the liquid to come into contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical attention.

The Glyconics-DS Device needs to be charged before each use.

Do not leave the Glyconics-DS Device on prolonged charge when not in use for more than 4 hours.

After extended periods of storage, it may be necessary to charge and discharge the Glyconics-DS Device battery several times to obtain maximum performance.

Use the Glyconics-DS Device battery only in the application for which it was intended.

		Dispose of the Glyconics-DS Device properly.
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Other general warnings:

	<b>WARNING</b> 	<b>Risk of injury by epilepsy</b> The Glyconics-DS Device emits flashes of light that can increase the risk of injuries for people with epilepsy. Make sure there is sufficient room lighting to avoid that risk.
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### 5.5. General Precautions

	<b>CAUTION</b> 	<b>Risk of dazzle</b> Do not look directly into the spectrometer window when performing a measurement to avoid dazzle.
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	<b>CAUTION</b>	<b>Risk of burns</b> Never perform measurement if the Glyconics-DS device is above the maximum operating temperature.
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	<b>CAUTION</b>	Not for use in combination with a machine with moving parts.
	<b>CAUTION</b>	The battery within the Glyconics-DS Device should not be allowed to fully discharge.
	<b>CAUTION</b>	Do not use in oxygen rich environments.
	<b>CAUTION</b>	Do not use in an area with stray magnetic fields.
	<b>CAUTION</b>	Not for use by photosensitive persons.

	<b>WARNING</b>	<p>The Glyconics-DS System is a medical device for diabetes risk assessment. It contains no user-serviceable parts.</p> <p>Unauthorized modifications, including software changes, firmware updates, or physical alterations, are strictly prohibited.</p> <p>Such modifications may compromise device accuracy, pose risks to patient safety, invalidate regulatory approvals, and impact cybersecurity.</p> <p>Any suspected tampering or unauthorized access should be immediately reported to Glyconics and relevant authorities.</p>
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### 5.6. General Notices

	<b>NOTICE</b>	<p>The Glyconics-DS System is for indoor use only.</p>
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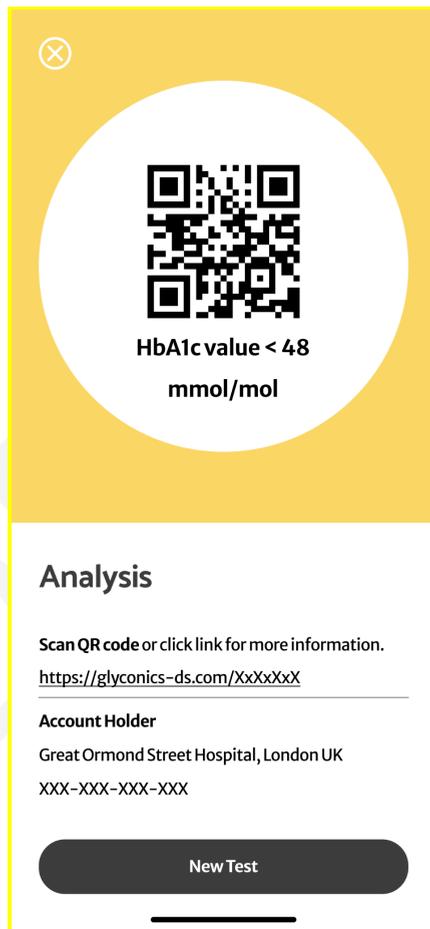
	<b>NOTICE</b>	<p>The Glyconics-DS System should not be operated in a dark environment.</p>
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### 5.7. Clinical benefits

The Glyconics-DS System provides a rapid, non-invasive, accurate and sustainable tool designed for mass-screening, for immediate assessment of

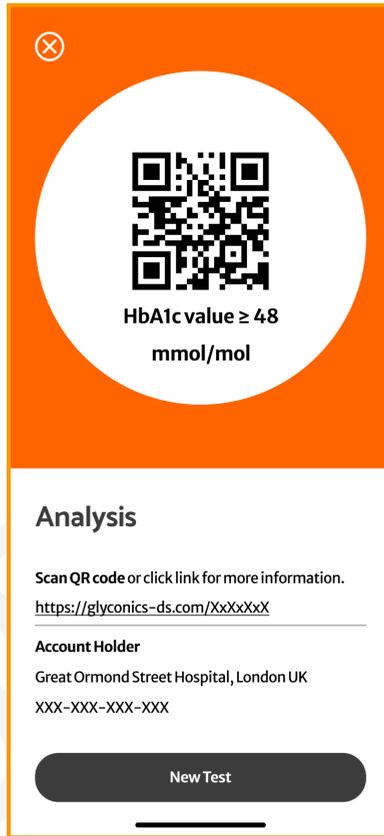
the tested individual's current diabetes risk. The clinical test outcome, the screening test result, is displayed on a mobile application as being above or below an HbA1c level of 6.5% / 48 mmol/mol, based on detection of the absorption pattern of glycated keratin in a fingernail.

A **negative screening test result** (no immediate risk of diabetes), HbA1c value below 6.5% / 48 mmol/mol is displayed on the mobile application as a yellow screen\*:



\*the account holder with its location is provided as an example

A screening test result indicative of elevated risk of undiagnosed diabetes, HbA1c value above 6.5% / 48 mmol/mol, is displayed on the mobile app as a dark orange screen\*:



\*the account holder with its location is provided as an example

The accuracy (specificity: proportion of people without the condition who test negative) of the System in detecting those with no immediate need for further invasive, blood-based diagnostic testing is independent of age, gender, ethnicity or presence of concomitant conditions or medications.

Table 1 displays the accuracy; high specificity and negative predictive value (NPV) for the Glyconics-DS System as tested in up to 700 individuals, with focus on the 94.7% (95%CI 92.6 - 96.9) specificity and 99% (95%CI 98.0, 100.0) NPV for testing negative in the ANODE03 study conducted in the intended use population only.

**Table 1. Clinical accuracy in delivering dichotomised outcomes against an HbA1c level of 6.5% / 48 mmol/mol.**

<b>Clinical investigation</b>	<b>Specificity (%, 95%CI)</b>	<b>NPV (%, 95%CI)</b>
ANODE01 n=100	95.2 (89.8 -100.0)	92.5 (84.3, 100)
ANODE02 n=100	98.5 (95.5 – 100.0)	65.3 (55.9, 74.7)
ANODE03 n=492	94.7 (92.6 – 96.9)	99.0 (98.0, 100.0)

### 5.8. Side Effects

No anticipated or unanticipated adverse events have been reported following use of the Glyconics-DS System in three independent clinical investigations, which included up to 700 participants both with and without Type 2 diabetes.

Any side effect experienced by the patient or the user when using this product should be reported directly to Glyconics Ltd ([safety@glyconics.com](mailto:safety@glyconics.com)).

## **5.9. Installation**

The Glyconics-DS System requires simple assembly of the Glyconics-DS Device with the Glyconics-DS Cradle and installation and downloading of the Glyconics Mobile Application onto a suitable iOS mobile device prior to use.

No additional installation is required.

Assembly of the Glyconics-DS Device with the Glyconics-DS cradle is described later in Section 6.2.

Downloading and setting up of the Glyconics Mobile App is described later in Section 6.3.

## **5.10. Purpose of the System Connection to an IT-Network**

The Glyconics-DS Software Package is designed to connect to an IT-Network in order to guarantee the use of a cloud-based application for data processing and analysis. The system connection enables the following:

**Data Transfer:** The Glyconics-DS Spectrometer Firmware gathers raw light sensor data from a person's nail, processes it, and sends this data to the Glyconics-DS Mobile Application. Through the secure SW Security Framework (SSF), this data is encrypted and transferred to the mobile app for further processing.

**Cloud Communication:** The Glyconics-DS Mobile Application serves as the communication hub, forwarding the raw, decrypted spectral data to the Glyconics-DS Cloud-Based Backend Software. The cloud backend performs advanced analysis using Glyconics' proprietary chemometric algorithm to evaluate diabetes risk.

**Data Processing and Results Display:** The cloud-based backend returns the results of the analysis (either a "high" or "low" diabetes risk factor) to the mobile application, which then displays the result on the user's device, such as an iPad.

The connection to the IT-Network is essential for enabling real-time communication between the Glyconics-DS Device and the cloud, ensuring seamless data transfer, secure processing, and timely feedback to the user.

### **5.11. Required characteristics of the IT-NETWORK**

The integration of Glyconics-DS System into an IT-NETWORK does not require an IT-NETWORK integrator due to the simplicity of its network requirements. With no network dependencies, it can be easily incorporated into existing IT environments without specialised design or configuration.

The only requirement is a stable internet connection for the device running the Glyconics Mobile app, with a download speed of at least 20 MB/s. This can be achieved through standard internet connections, either via Wi-Fi or mobile data, without needing additional IT resources.

Mobile data provides an alternative for environments where connecting to secure or restricted networks is difficult. As long as the connection meets the speed requirement, the app will function fully.

For use on secure or restricted networks, such as in hospitals, the device must be authorised to connect according to the organisation's procedures, ensuring compliance with security policies without further network configuration

### **5.12. Required configuration of the IT-NETWORK**

The configuration of the IT-NETWORK required for the solution is straightforward, primarily ensuring that the mobile device running the Glyconics Mobile app is connected to a stable network with a download speed of at least 20 MB/s. An iPad or iPhone can be connected to the internet either by joining a Wi-Fi network or by using mobile data. To connect via Wi-Fi, simply go to the device's settings, select "Wi-Fi," and choose a network from the available options, entering the password if required. For mobile data, ensure the device has a SIM card with an active data plan, then enable mobile data in the settings under "Mobile Data" to connect automatically to the cellular network. No specialised or custom network setup is necessary. In secure or restricted network environments, such as hospitals, the only requirement is that the device is authorised to connect to the network

according to the organisation's internal protocols. This ensures compliance with security measures without the need for additional network adjustments.

### **5.13. Intended Information Flow between the Glyconics-DS System, the IT-NETWORK, and Other Devices**

The Glyconics-DS Device (spectrometer) generates raw analogue optical sensor data, which is converted into digital values. This data is transmitted to the SSF framework on a smartphone or tablet via Bluetooth, employing encryption and error detection to ensure the integrity and validity of the data.

The SSF framework processes the received data, converting it into a light spectrum, following standard spectrometer practices. This results in an array of light spectrum data points, which undergo internal checks for quality. The processed data is then transmitted to the backend system over Wi-Fi or mobile communication, using encryption and error detection to maintain data security.

The backend system processes this data, applying the proprietary Glyconics-DS algorithm to calculate a medical score. This score is then sent back to the SSF framework on the mobile device, again using encrypted communication with error detection to ensure its accuracy. The SSF framework, without further processing, relays the validated medical score to the mobile application user interface (UI), where it is visually displayed without any additional manipulation.

The Glyconics-DS Mobile Application UI presents this data directly to the user. If the medical score is less than or equal to 0.5, a positive graphical screen is shown. If the score is greater than 0.5, a negative graphical screen is displayed. Throughout this process, neither the SSF framework nor the UI alters or processes the medical data beyond its transmission and visual representation, ensuring compliance with IEC 62304:2006+A11:2015 guidelines.

## 5.14. Accessories

The Glyconics-DS System shall be used only with the accessories described below.

### 5.14.1. Cleaning Accessories

The Glyconics-DS Cradle and Glyconics-DS Device must be cleaned with commercially available universal wipes in between patients.

The universal wipes are not supplied with the Glyconics-DS System and are commercially available.

The cleaning requirements of the Glyconics-DS System is described further in Section 8.

### 5.14.2. Charging Accessories

	<b>CAUTION</b>	The power cord of the USB PD charger must not be replaced by an inadequately rated cord.
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	<b>CAUTION</b>	The USB PD charger must have double insulation or reinforced insulation.
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A USB PD charger and power cord that is required for charging the Glyconics-DS Device is supplied with the Glyconics-DS System. A replacement power supply must meet the technical Specifications for the charging accessories which are provided in Section 11 and be suitable for medical application.

## 6. SETTING UP THE GLYCONICS-DS SYSTEM FOR THE FIRST TIME

	<b>WARNING</b>	Do not use the Glyconics-DS System unless you have received the appropriate training.
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	<p style="text-align: center;"><b>NOTICE</b></p>	<p>There must be a stable internet connection &gt; 20 MB/s download speed at all times when using the Glyconics Mobile App or the Glyconics-DS Device. This may be provided by either your local WiFi or mobile systems.</p> <p>Connection to IT-NETWORKS could result in previously unidentified RISKS TO PATIENTS, OPERATORS, or third parties</p> <p>It is the responsibility of the organisation using the system to identify, analyse, evaluate, and control these potential risks. This includes implementing appropriate security measures and monitoring the network to mitigate any potential hazards.</p> <p>Changes to the IT-NETWORK could introduce new risks that require further analysis. These changes may affect the overall functionality or safety of the system, making it essential to reassess risks whenever modifications are made to the network infrastructure.</p> <p>Changes that may introduce new risks include:</p> <ul style="list-style-type: none"><li>- Modifications to the network configuration, such as adjustments to security protocols or bandwidth settings.</li></ul>
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- The connection of additional devices or systems to the network.
- The disconnection of items or devices previously part of the network.
- Equipment update and upgrade

Each of these changes should be evaluated to ensure continued safety and reliability of the network

### **Technical Specifications of the Network Connection**

For optimal performance, the device running the Glyconics Mobile app (iPad or iPhone) must be connected to a network that meets the following technical specifications:

#### **1. Network Speed:**

The network must provide a stable internet connection with a minimum download speed of 20 MB/s. This requirement applies whether the device is connected via Wi-Fi or mobile data.

#### **2. Mobile Data Connection:**

		<p>In the case of mobile data, the device should be connected to a network that supports 4G LTE or 5G to meet the minimum download speed requirements. A data plan that ensures sufficient bandwidth for the application’s operations should be in place.</p> <p>3. Security Specifications:</p> <p>For secure or restricted networks, such as those used in healthcare environments, the device must be authorised to connect to the network in accordance with the organisation’s security protocols. This may involve device authentication, MAC address filtering, or certificate-based access.</p>
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	<b>NOTICE</b>	When not in use, the Glyconics-DS System should be stored in the protective case provided.
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	<b>NOTICE</b>	Do not use the Glyconics-DS system near a window when being used for assessments.
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## 6.1. Charging the Glyconics-DS Device

	<b>WARNING</b>	The Glyconics-DS Device must be charged indoors only.
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	<b>WARNING</b>	Do not use the Glyconics-DS System whilst the Glyconics-DS Device is being charged
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	<b>WARNING</b>	Do not charge the Glyconics-DS Device in an enclosed environment.
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	<b>CAUTION</b>	<b>Risk of Electric Shock</b>
	For charging via USB, only use certified USB PD chargers for your country. Glyconics recommends a USB PD charger must support 15 V, 2A output.	

Before the Glyconics-DS System can be used (at first use), the Glyconics-DS Device must have been charged for at least 1 hour.

The battery level is displayed on the Glyconics Mobile App after it is connected to the Glyconics-DS Device (via Bluetooth).

Charging of the Glyconics-DS device must be performed indoors, and at non-condensing temperatures of between 0°C and 30°C (32 °F – 86 °F).

The Glyconics-DS device is charged via the USB-C charging port on the rear of the device, according to the following steps:

1. Remove the baseplate with the reflectance standard to expose the USB-C port (Figure 6).

**Figure 6. Removing the Glyconics-DS Device Baseplate with the reflectance standard**



2. Connect the charger to the Glyconics-DS Device using the USB-C port (Figure 7).

**Figure 7. Connecting the charger to the USB-C Port of the Glyconics-DS Device**



3. Connect the power cable to the charger.
4. Plug in the charger and turn the plug on.
5. Leave the Glyconics-DS device to charge for least one (1) hour
6. Disconnect the charged Glyconics-DS device before use.

## 6.2. System Assembly

	<b>CAUTION</b>	Pitch point: Fingers may become trapped in the Glyconics-DS Cradle joint. Ensure fingers are not near the bezel in the cradle.
---	----------------	--

	<b>CAUTION</b>	Do not unscrew the head screw of the Glyconics-DS Device as this may damage the sensor.
---	----------------	---

To assemble the Glyconics-DS System, first position the Glyconics-DS Device in the Glyconics-DS Cradle as shown in Figure 8.

**Figure 8. Positioning the Glyconics-DS Device in the Glyconics-DS Cradle**



Push the Glyconics-DS Device into the Glyconics-DS Cradle.

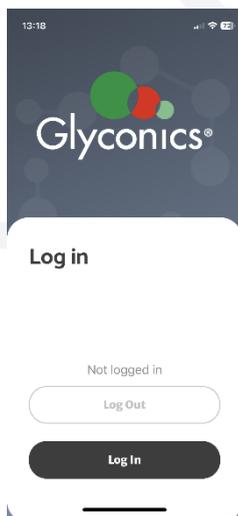
Next, proceed with setting up your user account in the Glyconics Mobile App for the first time, as described in Section 6.3 below.

### 6.3. Setting up a User Account

Before you can use the Glyconics-DS System you must first download the Glyconics Mobile App from the Apple App Store onto an iOS device (e.g., iPad). Note the Glyconics Mobile App is not yet compatible with Android devices.

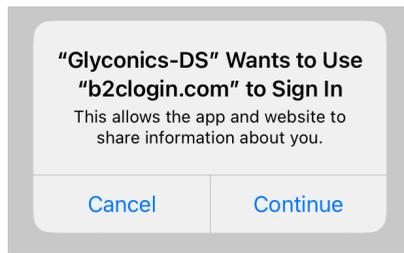
Then proceed with the steps below:

1. Open the Glyconics Mobile App on the iOS device. The login screen will be displayed.



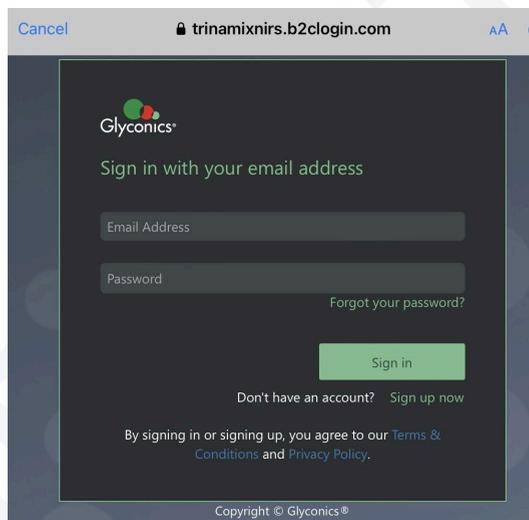
2. Press <Log In>

You will see the following message on the screen:



3. Press <Continue>

The following sign-in screen will appear:



4. Select <Sign up now>

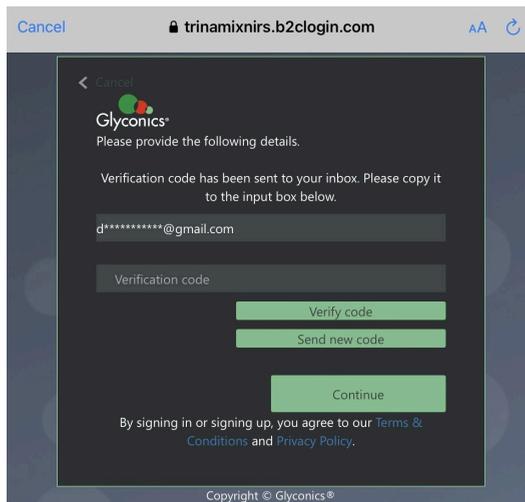
The following screen will appear:

The image shows a registration form for Glyconics. At the top left, there is a back arrow and the word "Cancel". The Glyconics logo is centered at the top, followed by the text "Please provide the following details." Below this, there are several input fields: "Email Address", "New Password", "Confirm New Password", "Given Name", and "Surname". A green button labeled "Send verification code" is positioned below the "Email Address" field. At the bottom right, there is a green button labeled "Create". At the very bottom, a line of text reads "By signing in or signing up, you agree to our [Terms &](#)".

Enter the e-mail address that you are going to use for the account.

Then select <Send verification code>

You will receive a verification code. Enter the code into the box on the screen.

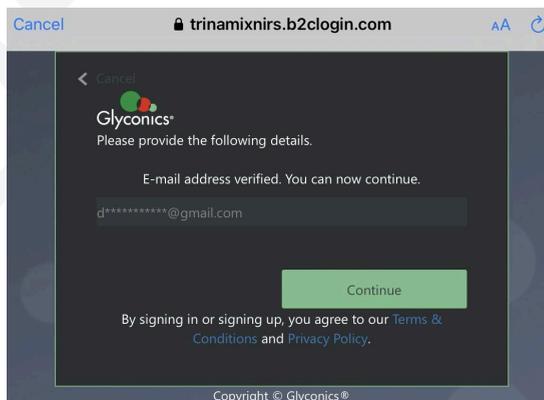


5. Select <Continue>

This will then allow you to enter a strong password, along with your given name and your surname.

6. Select <Create>

You will then receive a second verification code as confirmation that your account has been safely set-up.



You must then e-mail [info@glyconics.com](mailto:info@glyconics.com) to verify that you have passed the online training module test and have a verified e-mail address for the Glyconics Mobile App. Glyconics will inform you per e-mail when your account has been verified and is ready to use. You are ready to use the Glyconics-DS System when you have received this confirmation.

## 7. USING THE GLYCONICS-DS SYSTEM

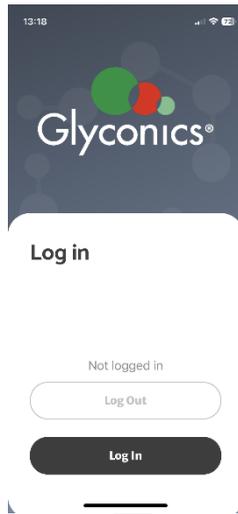
	<b>NOTICE</b>	Do not proceed with this step until you have set up the Glyconics-DS System according to the instructions in Section 6 above.
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Instructions for using the Glyconics-DS System are provided in the step-by-step guide below.

Before proceeding with using the Glyconics-DS System, you must ensure that the Glyconics-DS device and Glyconics-DS Cradle are securely assembled, and your user account is set up in the Glyconics Mobile App. If you have not performed any of these actions then please go back to Section 6 and follow the instructions accordingly.

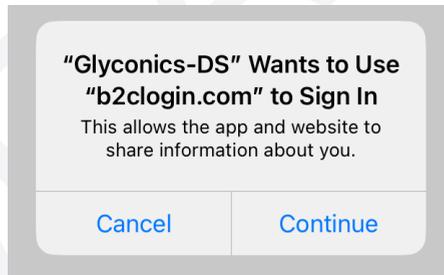
### 7.1. Connecting the Glyconics-DS Device to the Glyconics Mobile App

1. Open the Glyconics Mobile App on the mobile device.



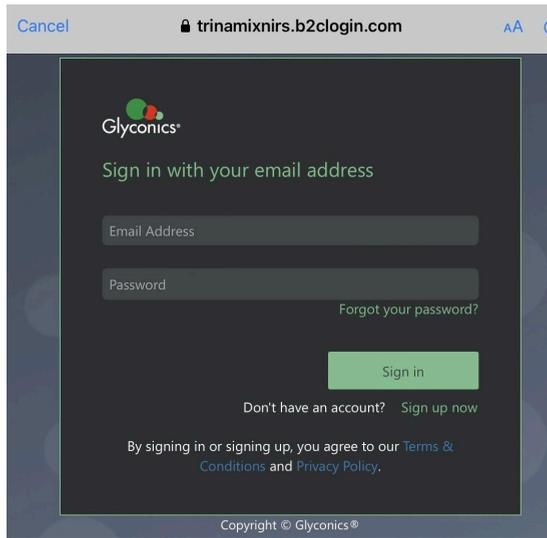
2. Press <Log In>

The following screen will appear:



3. Press <Continue>

The following screen will appear:



Log into the Glyconics Mobile App using your account username and password.

Select <Sign in>

The password and account will be verified by the system.

You may have to check your registered e-mail address for a verification code. If the application requests a code follow the on screen instructions. You will not be able to access the Glyconics Mobile App without this verification.

4. Once you have successfully logged in, the following screen will appear:



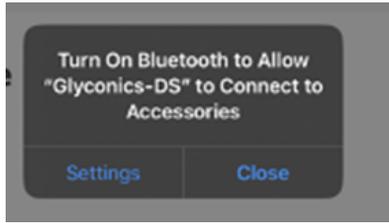
The appearance of this screen confirms that the WiFi has worked and your password has been checked by the online password verification.

Initially the Glyconics Mobile App will not be connected to a Glyconics-DS Device. Follow the steps below to connect them.

5. Return to the Glyconics Mobile App and select <Connect> on the screen

By selecting connect, the Glyconics Mobile App will attempt to connect to the Glyconics-DS Device via Bluetooth. Ensure that the mobile device and the Glyconics-DS Device are within 8 metres of each other for optimal connection.

If Bluetooth is switched off on your mobile device then you will see the following message on the screen:



Select <Settings> to turn on Bluetooth mode on your mobile device.

If Bluetooth is already turned on on the mobile device, proceed to Step 6.

6. Turn on the Glyconics-DS Device using the On/Off button, as shown in Figure 4 earlier.

The following screen will appear on the Glyconics Mobile App:



7. Select the respective Glyconics-DS Device and press <Confirm>.

The following screen will appear on the App:



Note: If the Glyconics Mobile App is not connecting to the chosen Glyconics-DS Device then contact Glyconics Customer Support (see Section 17 Troubleshooting And Customer Support).

When the Glyconics Mobile App and the Glyconics-DS Device successfully connect then the Glyconics Mobile App will confirm the chosen Glyconics-DS Device information, including the serial number. The serial number is located on the label at the rear of the Glyconics-DS device.

You are now ready to proceed with calibrating the Glyconics-DS System, as described in Section 7.2.

## 7.2. Calibrating the Glyconics-DS System

	<b>NOTICE</b>	Calibration will be automatically initiated every 2 hours or after 100 tests have been performed or when you have logged out of the Glyconics mobile application.
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	<b>NOTICE</b>	The Glyconics-DS System must have been charged for at least 1 hour before it can be used each time.
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	<b>NOTICE</b>	There must be a stable internet connection > 20 MB/s download speed at all times when using the Glyconics Mobile App or the Glyconics-DS Device. This may be provided by either your local WiFi or mobile systems.
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	<b>NOTICE</b>	Only perform Stage 2 of the calibration process using the spectrometer lid. Use of another object will result in rejection of the calibration
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The Glyconics-DS System must be calibrated according to the following steps before each first use and every hour. a.

Calibration must be performed in two stages:

1. Using no sample

2. Using the reflectance standard of the Glyconics-DS Device as the sample.

Follow the step-by-step guide below to perform the calibrations. The Glyconics Mobile App will also guide you through the process.

### **Calibration Stage 1: Using no sample**

1. Log into the Glyconics Mobile App and connect to the Glyconics-DS Device as described in Section 7.1 above.
2. Check that the window of the Glyconics-DS Device is not dirty or damaged. If the window appears dirty then clean it using an IPA wipe. If the window is damaged then contact Glyconics customer support (see Section 17 Troubleshooting And Customer Support). When you are confident that the window is not clean or damaged, proceed to Step 3.
3. On the Glyconics Mobile App Information screen (Section 7.1, Step 7), press <New Test>.

If this is the first test after logging into the Glyconics Mobile App, or if the Glyconics-DS Device has not been used for 2 hours or more, then the following screen will be displayed:



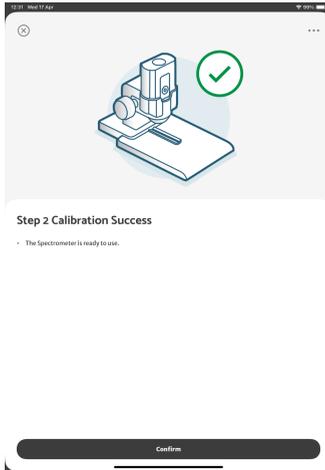
Ensure the Glyconics-DS Device is pointing down, and is at least 2 cm from the Glyconics-DS Cradle baseplate.

4. Press <Calibrate> on the Glyconics Mobile App screen.

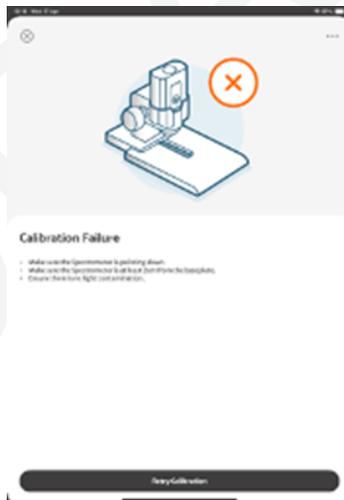
The halogen lamps on the Glyconics-DS Device will now flash.

The result of the calibration will be displayed on the App screen.

If the calibration is successful then the following screen will appear:



If, for any reason, the calibration failed, then the following error screen is reported:



Repeat from step 3.

## Calibration Stage 2: Using the Glyconics-DS Device lid as the sample

Perform this stage immediately after completing stage 1 of the calibration process.

1. Ensure the Glyconics-DS Device is still powered on. If not, then turn the Device on using the On/Off button as shown earlier in figure 4. Section 7.1.
2. Remove the reflection standard from the top of the Glyconics-DS Device. Ensure the lid is not damaged and is dry. If the lid is missing then do not proceed and instead contact Glyconics Customer Support (see Section 17 Troubleshooting And Customer Support)..

Place the lid flat under the spectrometer window, ensuring the Glyconics-DS Device is pointing down, as shown in the diagram below:



3. Press <Calibrate> on the Glyconics Mobile App

The halogen lamps on the Glyconics-DS Device will flash. If the calibration is successful then the following screen will appear:



If calibration fails then repeat Stages 1 and 2 of the process. If problems persist then contact the Glyconics Customer Support (see Section 17 Troubleshooting And Customer Support)..

4. Press <Confirm> on the Glyconics Mobile App to proceed. The App then returns to the home page and you are ready to perform the testing according to Section 7.3 below.
5. Place the lid onto the top of the Glyconics-DS Device after calibration.

### **7.3. Performing a Test**

When calibration is complete, the following screen will be displayed on the Glyconics Mobile App indicating that the Glyconics-DS System is ready to be used. The App screen includes an indication of the battery charge. If the battery level is below 10% do not proceed and instead charge the battery

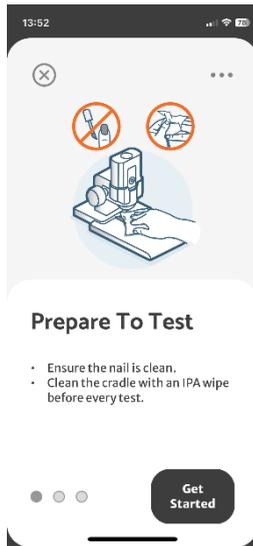


according to Section 6.1.

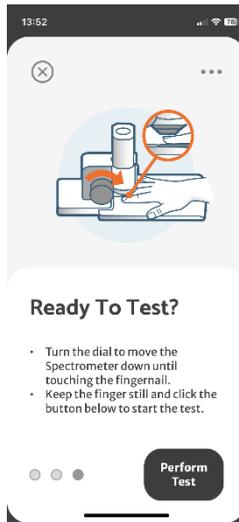
Testing of an individual patient should then be performed according to the following steps:

1. Clean the baseplate and the lens of the Glyconics-DS Device with a commercially available universal wipe. Do not use IPA or hydrogen peroxide wipes
2. Instruct the individual to clean and dry their hands according to Section 8.1.
3. Ensure the Glyconics-DS Device is switched on the Glyconics-DS System is not placed near a window.
4. Press <New Test> on the Glyconics Mobile App screen.

The following screen will then be displayed:



5. Instruct the individual to place their hand into the Glyconics-DS System.
6. Press <Get Started> on the Glyconics Mobile App. The following screen will be displayed:

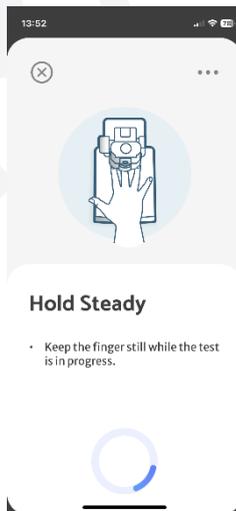


7. Push back the Glyconics-DS Cradle mount to allow a better visualisation of the target aperture, as shown in the picture below:



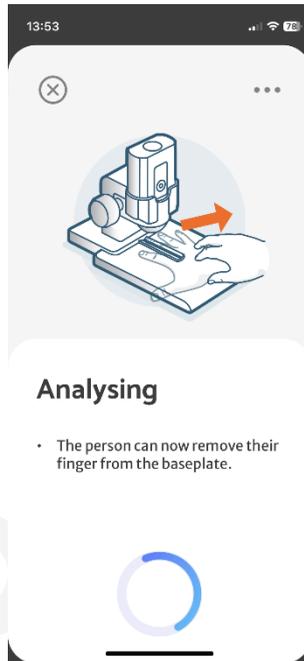
8. Ask the individual to place their hand palm-down on the Glyconics-DS Cradle positioning the middle finger along the groove.
9. Check and adjust the finger if necessary to align the middle of the fingernail beneath the window of the Glyconics-DS Device using the aperture and markings for guidance.
10. Ensure the individual's hand and arm are comfortable to minimise movement of the finger during the readings.
11. Lower the Glyconics-DS Device using the rack and pinion stage until light contact is made with the fingernail.
12. Once the nail positioning is completed, move the Glyconics-DS device into the down position. Instruct the individual to keep their finger as still as possible, and not to remove their finger or hand until testing is complete.
13. Press <Perform Test> on the Glyconics Mobile App display.

The following message advising the patient to keep their finger steady will display on the App.



The test takes between 10 and 15 seconds. Do not move the Glyconics-DS Cradle during testing. There will be three scans in total. The scan status will be indicated on the Glyconics Mobile App.

14. When the tests are complete the App will display the following message:



The person may remove their finger from the Glyconics-DS System while the data is being analysed.

They must be offered hand sanitizer after the measurement has been completed.

The data is then sent via the mobile device to the Cloud for analysis and a result is returned to the mobile device within a few seconds.

If a result is not received, first check the Glyconics-DS System Troubleshooting section if results are still not returned then contact Glyconics Customer Support.

15. When the testing is complete, the Glyconics-DS Device and Glyconics-DS Cradle must be cleaned (see Section 8) for the next individual (see Section 7.2 if requirements for re-calibration are met) or turned off and stored in its original case. Also log out of the Glyconics Mobile App when all testing is complete for a particular day.

If there are any problems with the testing process then refer to table 2 within section 17 ‘Troubleshooting And Customer Support’. If not resolved, contact Glyconics Customer Support (see Section 17 Troubleshooting And Customer Support).

## 8. CLEANING REQUIREMENTS

### 8.1. Patient (Fingernail)

To avoid cross contamination between tested individuals, a strict cleaning/washing sequence must be adhered to.

Individuals must wash their hands using a sanitizing soap or solution. They must then thoroughly rinse their hands to remove any traces of the chemicals. They should then dry their hands completely, removing all water.

Before the test, the targeted fingernail must be cleaned using an IPA wipe and then dried.

The tested individual must be offered hand sanitizer after the measurement has been completed.

### 8.2. Glyconics-DS System

	<b>CAUTION</b>	Do not use acetone for cleaning as this could damage the paint on the Glyconics-DS cradle.
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	<p><b>CAUTION</b></p>	<p>Do not use IPA or hydrogen peroxide wipes for cleaning the Glyconics-DS Cradle</p>
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The Glyconics-DS Cradle and Glyconics-DS Device must be cleaned with commercially available universal wipes in between each patient test.

The universal wipes are not supplied with the Glyconics-DS System and are commercially available.

Cleaning of the Glyconics-DS System using the above method is not expected to compromise compliance of the System with the applicable Regulations.

## 9. GLYCONICS-DS DEVICE STATUS LEDS

The Glyconics-DS Device incorporates several LEDs that serve as indicators for the device.

### 9.1. Connection Indicator



green blinking, 1x/1 s

connected via Bluetooth®

### 9.2. Measurement Indicator

green blinking, 4x/1 s

measurement ongoing

green flashing, 3x/1 s	wait for next measurement
green duration, 2 s	measurement successful

### 9.3. Battery Indicator

green flashing, 1x/2 s	charging (USB PD charger connected)
green blinking, 1x/1 s	battery level < 30 %
green	battery level high
off	device off, no USB PD charger connected

### 9.4. Special (error) Indications (all three LEDs)

	green running light, 1x/1 s	device in firmware update mode. current firmware valid
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## 10. TECHNICAL SPECIFICATIONS

### 10.1. Environmental Conditions

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**Operating temperature**                      0 °C - 30 °C / 32 °F - 86 °F  
(non-condensing) for operation

0 °C - 30 °C / 32 °F - 86 °F  
(non-condensing) for charging

---

**Storage temperature**                      -20 °C - 60 °C / -4 °F - 140 °F  
(non-condensing)

---

**Relative Air humidity**                      20 % - 80 % (operation)

20 % - 90 % (storage).

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**Maximum Height above sea level**      2000 m for operation

---

**Wet location**                                  USB PD charger: No. Dry location  
use only

---

**Enclosure**                                      Type 3 Enclosure (UL50E)

---

**Type of use**                                    indoor (operation)

indoor (charging)

---

**Ventilation requirements**                None. Allow the Glyconics-DS  
Device housing to emit heat.

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## 10.2. Physical Specifications

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**Dimensions (device)** approx. 152 x 84 x 52 mm

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**Weight (device)** 560 grams

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**Dimensions (cradle)** approx. 295 x 175 x 140 (at highest point) mm

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**Weight (cradle)** 1860 grams

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## 10.3. Spectroscopic Specifications

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**Spectral range** ~ 1450 - 2450 nm

---

**Speed: time to result** 10 seconds

---

## 10.4. Electrical Specifications

---

**Power Input (for charging)** USB PD with 15 VDC\*  
via USB Type C connector

---

**Wireless connection** wireless low energy  
via integrated antenna

---

**Fuses** no exchangeable fuse

---

## 10.5. Battery Specifications

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<b>Type</b>	rechargeable lithium ion battery
<b>Model</b>	Friwo FB3S1P18650-26
<b>Nominal voltage</b>	11.1 V
<b>Nominal capacity</b>	2600 mAh
<b>Charging current</b>	1300 mA
<b>Transport classification</b>	UN class: 9 UN number: 3480, lithium ion battery energy of battery: < 100Wh

---

## 10.6. RF Module Specifications

The Glyconics-DS Device contains the following radio frequency (RF) module:

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<b>Type</b>	Würth Proteus-I AMB2621 / 2608011024000
<b>Frequency range</b>	2.44 GHz
<b>Max. output power</b>	Typ. -2 dBm, max. 0 dBm

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## 10.7. Lamp Module

The Glyconics-DS Device uses a changeable lamp module, containing six (6) lamps and the associated reflectors.

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<b>Lamp type</b>	incandescent lamp. 3V, 440 mA
<b>Model</b>	MGG 1332-00
<b>Modulation</b>	max. 16 Hz
<b>Class</b>	Exempt (IEC 62471)

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## 10.8. Material Specifications (Glyconics-DS Device)

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<b>Window (specimen interface)</b>	sapphire glass
<b>Spectrometer head</b>	anodized aluminum
<b>Spectrometer body and reference standard</b>	PC GF20, UL94 V-0, UL746C f-1 rated
<b>Foil</b>	cover film: PET

---

## 11. ACCESSORIES SUPPLIED WITH THE GLYCONICS-DS SYSTEM

A USB-C PD Charger, power cord and cable with the following specifications are supplied for use for charging the Glyconics-DS Device.

Item	Type	Input	Output
USB-C PD charger		100 – 240 V ~ 50 – 60 Hz	DC. / 15 V 2A

The power supply should be compliant with ECI 60601-1.

## 12. PACKAGING, STORAGE AND TRANSPORT

### 12.1 Warnings, Precautions and Notices

	<b>WARNING</b>	<b>Fire hazard and Risk of Injury:</b>
		The Glyconics-DS device must be switched off during transport or shipping. Use the original shipping box to store, transport or ship the unit. Protect the transport box from impact by placing it in a carton.

	<p><b>WARNING</b></p>	<p><b>Fire hazard and Risk of Injury:</b></p>
		<p>The Glyconics-DS device contains a lithium-ion battery. Such batteries are dangerous goods for transport. Comply with all local and international transport regulations when shipping or transporting the unit or batteries. These regulations include e.g. Section II of PI966, ADR/RID, IATA, DOT, IMDG.</p>

	<p><b>NOTICE</b></p>	<p>For storing the device for a long time: Store all components in a dry, clean, and dust-free, low-humidity environment that is as dry as possible. Charge the battery to greater than 80% of the maximum capacity</p>
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## 12.2 Battery Transport Classification

- FRIWO Battery type: FB3S1P18650-26
- UN Class 9
- UN number UN3480, Lithium Ion Battery
- UN number UN3481, Lithium batteries packed with equipment
- Energy of battery <100 Wh
- The respective caution label should be placed on bulk packaging .

## 12.3 Storage

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**Storage temperature**

-20 °C - 60 °C / -4 °F - 140 °F  
(non-condensing)

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**Relative Air humidity**

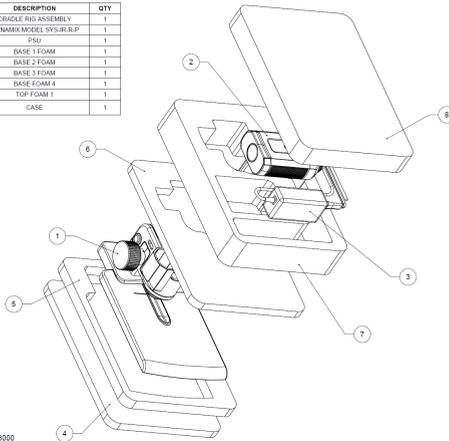
20 % - 90 % (storage).

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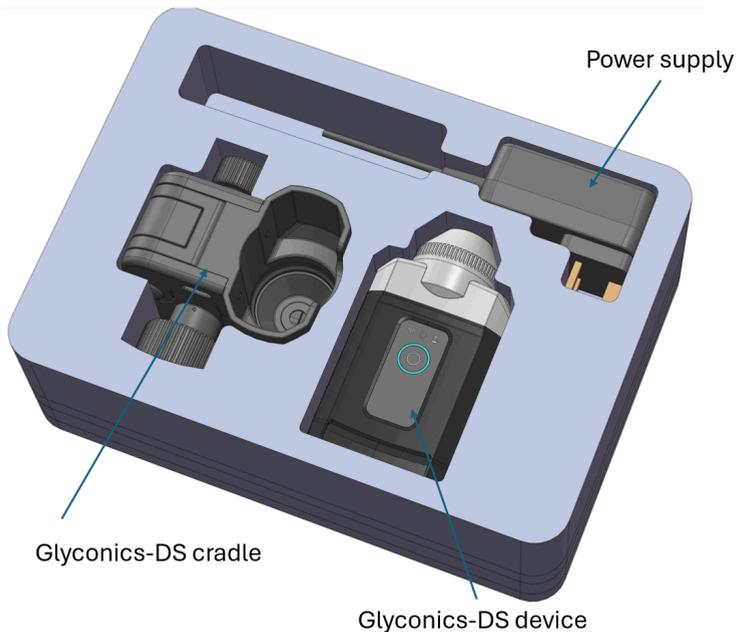
## 12.4 Assembly of storage box for Glyconics-DS system

The Glyconics-DS system fits into a flight box with form inserts. When shipping the Glyconics-DS system ensures the form inserts are placed in the correct order shown in the figure below.

ITEM	PART NUMBER	DESCRIPTION	QTY
1	0-CRA-GA-100	CRADLE RIG ASSEMBLY	1
2	NIR SPECTROMETER	TRINAMAX MODEL SYS-IR-R/P	1
3	0-CRA-F01	PSU	1
4	3000 BASE 1	BASE 1 FOAM	1
5	3000 BASE 2	BASE 2 FOAM	1
6	3000 BASE 3	BASE 3 FOAM	1
7	3000 BASE 4	BASE 4 FOAM	1
8	3000 TOP 1	TOP FOAM 1	1
9	B & W OUTDOOR CASE TYPE 3000	CASE	1



The components of Glyconics-DS are installed in the order flight box in the order shown in the figure above. The completed layout is shown below.



## 12.5 Assembly and disassembly of Glyconics-DS system

### 12.5.1 Assembly

- (1) Remove the top layer of foam inserts from within the flight box. To reveal the Glyconics-DS Device and power supply.
- (2) Remove the power supply and Glyconics-DS device. Place on a flat stable surface.
- (3) Remove the next two layers of foam inserts.
- (4) Keep all foam layers for future use.
- (5) Remove Glyconics-DS cradle from the flight box. Place on a flat stable surface.
- (6) Place the flight box and foam inserts in a safe place for future use.
- (7) Place the Glyconics-DS device into the Glyconics-DS cradle with the Glyconics logo facing outwards until there's a click.

(8) The Glyconics-DS system is ready to use.

### 12.5.2 Disassembly

(9) To disassemble first remove the Glyconics-DS device from the Glyconics-DS cradle. Place on a flat stable surface.

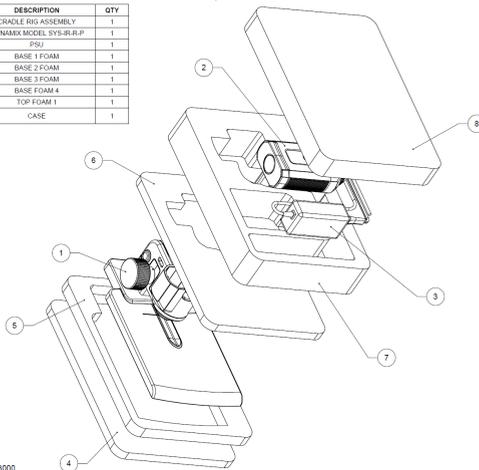
(10) Locate the flight box and inserts.

(11) Place the foam inserts (4 and 5) into the flight box. Place the Glyconics-DS cradle into the box.

(12) Place the foam inserts (6 and 7) into the flight box. The power supply and Glyconics-DS device are now placed into the flight box.

(13) Place foam insert (8) into the flight box. Close the lid of the flight box. The flight box is ready for shipping or storage.

ITEM	PART NUMBER	DESCRIPTION	QTY
1	G-CRA-GA-100	CRADLE RIG ASSEMBLY	1
2	NR SPECTROMETER	THORLAB MODEL SYS-RU-1P	1
3	G-CRA-PSU	PSU	1
4	3000 BASE 1	BASE 1 FOAM	1
5	3000 BASE 2	BASE 2 FOAM	1
6	3000 BASE 3	BASE 3 FOAM	1
7	3000 BASE 4	BASE 4 FOAM	1
8	3000 TOP 1	TOP FOAM 1	1
9	R & W OUTDOOR CASE TYPE 3000	CASE	1



FOAM INNERS TO FIT:  
B & W OUTDOOR CASE TYPE 3000

## 13. HAZARDOUS MATERIALS

The Glyconics-DS Device or Glyconics-DS Cradle does not include potentially poisonous, injurious or hazardous substances that can be liberated under normal operating conditions.

## **14. DISPOSAL**

Thank you for taking the responsible step of disposing of the Glyconics-DS Device electrical equipment in accordance with EU regulations. Proper disposal ensures the protection of the environment and human health. Below are guidelines to assist you in complying with EU rules during the disposal process:

**Check Local Regulations:** Familiarize yourself with local regulations and guidelines specific to your EU member state regarding the disposal of electronic waste. Different regions may have specific instructions or designated collection points for electronic waste.

**Proper Disposal Method:** Do not dispose of the Glyconics-DS Device or battery in regular household waste bins. Improper disposal can harm the environment and is against EU regulations. Follow designated disposal procedures to prevent pollution and contamination.

**Certified Recycling Facilities:** Choose recycling facilities that are certified and compliant with EU standards for electronic waste management, such as the Waste Electrical and Electronic Equipment (WEEE) Directive. Look for certifications such as WEEE compliance or e-Stewards certification to ensure responsible handling of electronic waste.

By following these guidelines, you contribute to the proper disposal and recycling of the Glyconics-DS Device and battery in compliance with EU rules, minimizing environmental impact and supporting sustainable waste management practices. Thank you for your commitment to environmental stewardship and compliance with EU regulations.

## **15. MAINTENANCE**

The Glyconics-DS Device (spectrometer) must be charged at least once every 6 months to at least 80% to maintain good battery life.

There are no other maintenance requirements for the Glyconics-DS Device or Glyconics-DS Cradle.

The lifetime of the Glyconics-DS Device is 7 (seven) years or 15,400 readings from the date of manufacture of each Glyconics-DS device due to the lifetime expectation of the components within each Glyconics-DS Device.

The Glyconics-DS Device must be charged once every 6-months to at least 80% to maintain good battery life.

Neither the Glyconics-DS Cradle or the Glyconics Mobile App have a defined lifetime as long as they are used and stored in accordance with the instructions provided within.

## 16. REPORTING OF ANY SIDE EFFECTS OR SERIOUS INCIDENTS

All side effects relating to the use of the Glyconics-DS System should be reported to Glyconics Limited ([safety@glyconics.com](mailto:safety@glyconics.com)).

If, in relation to the use of the Glyconics-DS System, a death or a serious deterioration of health of a patient, user, or other person has occurred, this should be reported to Glyconics Limited ([safety@glyconics.com](mailto:safety@glyconics.com)) and the competent authority of your country. When in doubt, always report.

For a list of competent authorities, refer to the following link: [Vigilance Contact Points](#)<sup>1</sup>

## 17. LABELLING SYMBOLS AND DEFINITIONS

	Consult instructions for use
	Temperature limit

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<sup>1</sup> URL:

[https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts\\_en#other-contact-points](https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en#other-contact-points)

	Manufacturer
	Date of manufacture
	CE Mark
	Type B applied part
	Authorised Representative in the European Community/European Union
	Use-by date
	Serial number
	Humidity limitation
	<p>This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EU in the European Union, and per Regulations 2013 (No. 3113) in the UK is required.</p> <p>Contact the manufacturer for details.</p>

## 18. ELECTROMAGNETIC COMPATIBILITY

The Sensor needs special precautions regarding EMC and needs to be installed and put

into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect the Glyconcis-DS system.

Use of accessories, transducers and cables other than those specified or provided by Glyconcis Limited could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The Glyconcis-DS system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Glyconcis-DS system should be observed to verify normal operation in the configuration in which it will be used.

	<b>Warning</b>	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other other equipment should be observed to verify that they are operating normally.
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	<b>Warning</b>	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.
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	<p><b>Warning</b></p>	<p>Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment or system, including specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p>
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	<p><b>Warning</b></p>	<p>This equipment has been tested for radiated RF immunity only at selected frequencies , and use of emitter at other frequencies could result in improper operation.</p>
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### **18.1 Guidance and manufacturer’s declaration – electromagnetic emissions**

The Glyconics-DS system is intended for use in the electromagnetic environment specified below. The customer or the user of the Glyconics-DS system should ensure that it is used in such an environment.

Emissions test: RF emissions; CISPR 11

Compliance: Group 1

Electromagnetic environment – guidance: The Glyconics-DS system 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.

Emissions test: RF emissions; CISPR 11

Compliance: Class B

Electromagnetic environment – guidance: The intended use environment is a both a professional healthcare facility environment, and non-clinical environment such as football grounds or conferences.

The table below lists the immunity test levels at specific test frequency for the effects of some wireless communications equipment. The frequencies and services listed in the table are representative examples in healthcare and in various locations where the Glyconics-DS system may be used.

Test frequency (MHz)	Band (MHz)	Service	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	Terrestrial Trunked Radio 400 (TETRA 400)	To be updated post-60601-1-2 testing	0.3	To be updated post-60601-1-2 testing
450	430-470	General Mobile Radio Service GMRS 460, Family Radio Service FRS 460	To be updated post-60601-1-2 testing	0.3	To be updated post-60601-1-2 testing
710	704 – 787	long-term evolution LT Band 13,17	To be updated post-60601-1-2 testing	0.3	To be updated post-60601-1-2 testing
747					
780					
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	To be updated post-60601-1-2 testing	0.3	To be updated post-60601-1-2 testing
870					
930					

1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	To be updated post-60601-1- 2 testing	0.3	To be updated post-60601-1-2 testing
1845					
1970					
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	To be updated post-60601-1- 2 testing	0.3	To be updated post-60601-1-2 testing
5240	5100-5800	WLAN 802.11	To be updated post-60601-1- 2 testing	0.3	To be updated post-60601-1-2 testing
5500					
5785					

The Glyconics-DS system is intended for use in the electromagnetic environment specified below. The customer or the user of the Glyconics-DS system should assure that it is used in such an environment.

**Immunity test: Electrostatic discharge (ESD); IEC 61000-4-2**

**IEC 60601 test level:** ± 8 kV contact; ± 2 kV, 4 kV, 8 kV, 15 kV air

**Compliance level:** ± 8 kV contact; ± 2 kV, 4 kV, 8 kV, 15 kV air

Electromagnetic environment – guidance: Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

**Immunity test: Power frequency (50/60 Hz); magnetic field; IEC 61000-4-8**

**IEC 60601 test level:** 30 A/m 50 Hz or 60 Hz

**Compliance level:** 30 A/m 50 Hz or 60 Hz

Electromagnetic environment – guidance: Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

## 19. TROUBLESHOOTING AND CUSTOMER SUPPORT

Replacement spare parts for the Glyconics-DS System can be obtained from Glyconics Customer Support. The following spare parts are available:

**Table 1: Glyconics-DS System Replacement Parts**

Item Name	Component Code
Calibration reference standard	1000033000

Glyconics Customer Support contact details:

Email: [info@glyconics.com](mailto:info@glyconics.com)

Phone: +44 (0)1256 644431

Troubleshooting solutions are presented in Table 2.

If the Glyconics-DS System still cannot be operated after completing the recommended troubleshooting activities then please contact Glyconics Customer Support.

**Table 2. Glyconics-DS System Troubleshooting**

Problem	Possible Cause	Troubleshooting
<b>Mobile App</b>		
Email verification fails	Invalid or incorrect email address	Repeat the email verification.
Test result is not returned to the iOS device.	The iOS device may not be properly connected to the system, or there may be interruptions in the wireless, Bluetooth, or internet connection.	Check the network settings and confirm that the iOS device has active and stable internet access.  Verify that the iOS device

		meets the minimum hardware and software requirements specified for use with the system
The App has timed out	Assessment has taken too long	Logout from the app and restart the testing. Calibration will be required.
<b>Glyconics-DS Device</b>		
Spectrometer lid is missing	The lid has not been placed at the top of the device after calibration	Get in contact with customer service to request a replacement of the lid.
System parts (e.g. charger) are missing	Incorrect order	Get in contact with customer service to request a replacement part.
Bluetooth cannot be enabled	Non-functional bluetooth module	Get in contact with customer service to request a replacement Glyconics-DS Device.
<b>Glyconics-DS Cradle</b>		
Cradle does not move up or down	Physical obstructions or debris might be preventing movement.	Verify no obstructions are present. If the problem persists, get in contact with customer service to request a replacement Glyconics-DS Cradle.