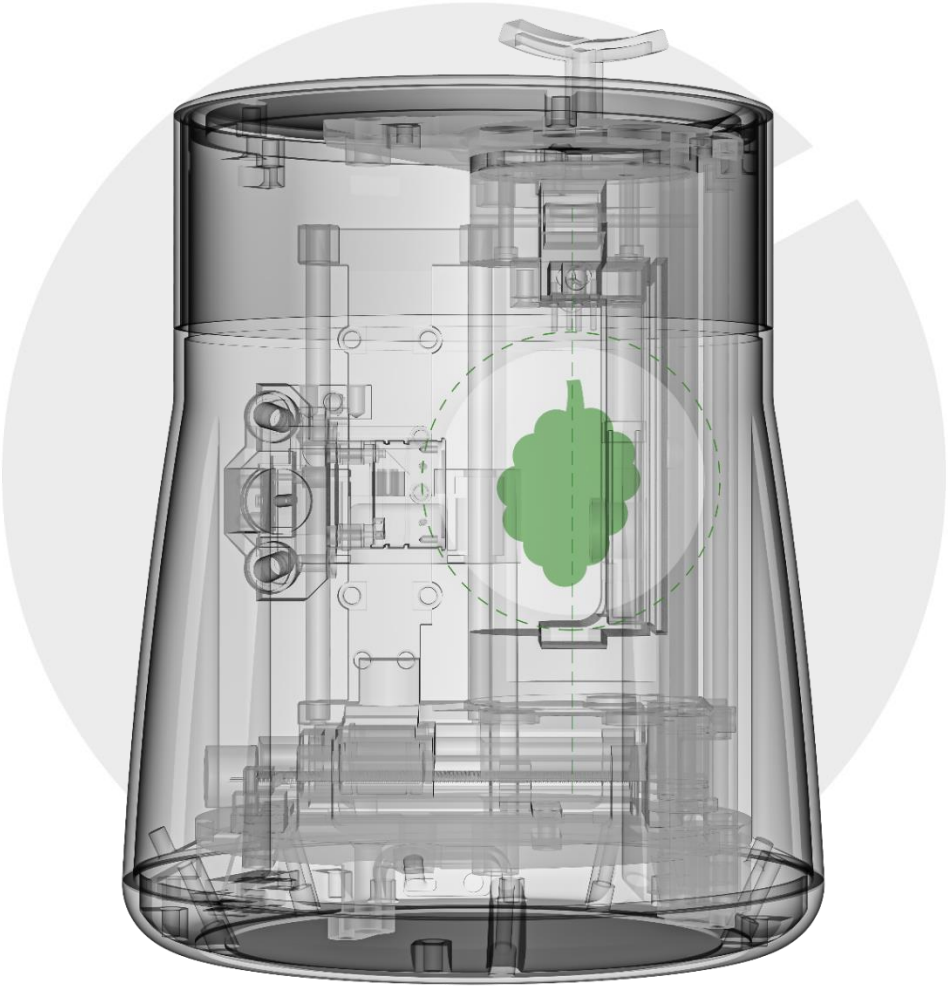
GemmaCert

GemmaCert Compliance

European / German Pharmacopeia



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1. Introduction

1.1 Scope

This document outlines European and German pharmacopeia compliance of cannabis analysis service provided by GemmaCert. GemmaCert equips its customers, including pharmacies, with cannabis analysis solution comprising GemmaCert device, GC app and access to GemmaCert backend. Figure below depicts GemmaCert cannabis analysis solution.

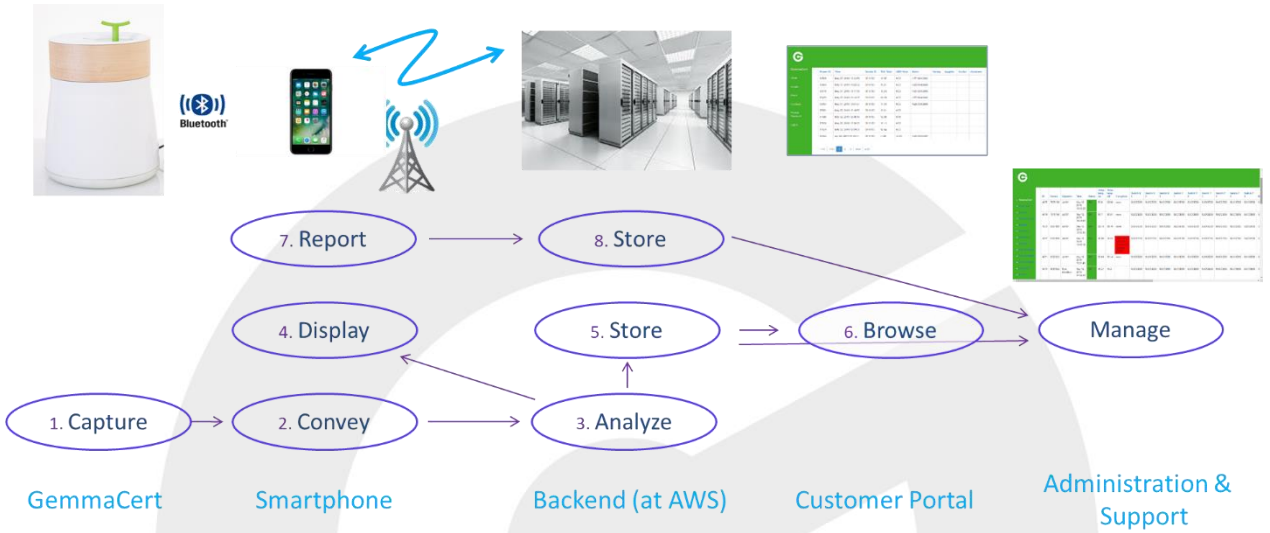


Figure 1 – GemmaCert Cannabis Analysis Solution

Solution components operate in concert and no component may provide any useful service on its own. Accordingly, their compliance cannot be verified stand alone.

GemmaCert solution is developed entirely in-house. Development comprises GemmaCert device design, manufacturing & qualification, software deployed in all components, Reference Library collection and chemometric model development & validation. Accordingly, this document need not refer to any external material or compliance references by parties outside GemmaCert.

Release 1.0 of this document addresses classification only, i.e. identification of analysed sample as cannabis or non-cannabis. Reference to quantitative analyses is provide herein as background only.

1.2 Definitions and abbreviations

Term/Acronym	Means	Comments
a.k.a.	Also known as	Alternative term; synonym
AWS	Amazon Web Services	Host GemmaCert Backend
BIT	Built In Test	Set of device self-tests conducted autonomously
CET	Central European Time	
EMC	Electro Magnetic Compatibility	
FAT	Factory Acceptance Test	Internally referred as FT (Final Testing)
FT	Final Testing	
GC	GemmaCert	
HW	Hardware	

IMCA	Israel Medical Cannabis Authority	Branch of the Health ministry serving as domestic cannabis regulator
ISRAC	Israel Laboratory Accreditation Authority	
LabUI	Laboratory User Interface	Software used by staff to record and maintain lab analyses results
LED	Light Emitting Diode	
NIR	Near Infrared	
NIRS	Near Infrared Spectroscopy	
OTS	Off The Shelf	Not developed in-house
SW	Software	
QC	Quality Control	
QM	Quality Management	

Table 1 – Abbreviations & Definitions

1.3 Applicable norms and standards

Standard ref.	Title	Relevance	Comments
Ph.Eur. 2.2.40	European Pharmacopeia, NIR Spectroscopy chapter	Guiding document	
EMEA/CHMP/CVMP/QWP/ 17760/2009 Rev2	Guideline on the use of near infrared spectroscopy by the pharmaceutical industry and the data requirements for new submissions and variations	Guiding document	
TUV	Compliance Certificate	Device safety compliance	See Appendix B
ISO/IEC 17025: 2017	General requirements for the competence of testing and calibration laboratories	Reference Library quality	GemmaCert Lab, generating the Reference Library, is ISO-certified; Accreditation Certificate No. 457 by Israel Laboratory Accreditation Authority
IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements	Compliance – Safety	GemmaCert device has passed compliance tests by accredited lab
EN 61010-1:2010	"	Compliance – Safety	"
EN 301489-1 V2.1.1 2017	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the	Compliance EMC	GemmaCert device has passed compliance tests by accredited lab

Standard ref.	Title	Relevance	Comments
	essential requirements of article 6 of Directive 2014/30/EU		
EN 301489-17 V2.2.1 2017	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility	Compliance EMC	"
EN61000-6-1-2007	Electromagnetic compatibility (EMC). Generic standards. Immunity for residential, commercial and light-industrial environments	Compliance EMC	"
EN61000-6-3-2007	Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments	Compliance EMC	"
EN61326-1	EMC Emissions/Immunity Requirement Changes for Laboratory Equipment	Compliance EMC	"
EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	Compliance Radio	"
FCC, part 15, subpart B	Equipment Authorization – RF Device	Compliance Radio	"

Table 2 – Standards & Norms

1.4 Integration in the QM system

GemmaCert QM comprises multiple components, associated with hardware, software, Reference Library quality, configuration control, change management, release procedures, service monitoring, feedback & improvements.

GemmaCert multi-technology nature precludes relying on single set comprising repository, tool & procedure to address all. Hence GemmaCert QM would be best explained first decomposing it into repositories, tools & procedures employed and then providing integrated view.

GemmaCert employs repositories listed in the table below.

Repository	Hosted by	Serves	Comments
GemmaCert Sharepoint	Microsoft	Requirement documents	
		Specification documents	
		Device production file	
		Compliance test reports	
		User Guides & Manuals	
Github	Github	GemmaCert device code	
		GemmaCert FT code	Device software executing FT
		GC App code	
		Backend code	
		Chemometry code	
GemmaCert Production domain	AWS	Device configuration	
		Device test results	
		Device calibration	
		Device dependent attributes	
		Operator dependent attributes	Access to applications, analyses controls & thresholds
		Users' raw spectra	
		Users' analyses results	
		Users' comments	Free text fields describing samples
		Chemometric Models	Outlier & Estimation models
GemmaCert Reference domain	AWS	Reference Library spectra	
		Reference Library HPLC results	
		Reference Library sample data	Batch and individual sample descriptions: supplier, variety etc.
SalesForce support	AWS	Users' service tickets	Both user-entered and automatically generated tickets

Table 3 – GemmaCert Repositories

Access to all repositories listed in table above is credentials controlled. GemmaCert does not maintain any in-house repository and no item remains stored at developers' computers or any local storage.

Tools engaged for Quality Management include OTS tools and in-house developed proprietary ones. Table below lists QM tools engaged.

Tool	Source	Serves	Comments
GIT	OTS	Software version control	
GemmaCert device FT	In-house	Device quality control	
Host PC FT	In-house		Host PC runs Final Testing procedure and records results interfacing the Backend
Backend FT	In-house		Analyzes various measurements to identify pass/fail, conducts calibration and records all results
LabUI	In-house	Reference Library quality	
GCA web service	In-house		
Outlier & Estimation	In-house		
Barcode reader	OTS		
Model Administration	In-house	Model quality	
Batch Estimation	In-house		Regression tests following model, parameter or threshold changes
GCA web service	In-house	User service quality monitoring & anomaly detection	
Automated Alert	In-house		Accessed through GCA web service
SalesForce	OTS		Ticket management

Table 4 – GemmaCert Quality Management Tools

GemmaCert maintain several procedures to assure product & service qualities. These comprise:

1. Hardware amendment procedure
2. Model amendment procedure
3. Parameter/threshold amendment procedure
4. Software release procedure

Hardware amendment procedure

Hardware amendment procedure addresses both GemmaCert device and its accessories. The procedure is triggered on either:

- hardware design fault or non-compliance detection
- need for new functionality

GemmaCert device hardware is stable and no design faults have been detected between Q2/2019 and Q2/2020. However, amendment had to applied to meet EMC compliance tests listed above. Any amendment modifies Hardware Version, which is recorded in Production database at FT. Hardware Version is a 3-part field structured as A.B.C. Most recent Hardware Version at the time of compiling release 1.02 of this document was 1.2.

GemmaCert device features modular design, where various analysed material forms are accommodated by replaceable accessories, rather than device design changes. Consequently, need for new functionality

is answered through accessory development. Most recent accessory developed at the time of compiling release 1.0 of this document was Extract accessory.

Hardware amendment procedure follows the steps:

1. Launch decision approved by CEO & CTO
2. Potentially few iterations:
    a. Prototyping
    b. Lab tests
    c. Performance tests (in the event of new functionality involves series of sample analyses)
3. FT verification
4. Review & Production decision approved by CEO & CTO
5. Retrofit decision by CEO & CTO (need devices in stock or received for servicing be retrofitted to the amendment)

Model amendment procedure

Model amendment procedure addresses both replacement of deployed models and creation of new models, e.g. first version of previously non-existent Extract models. The procedure is triggered on either:

- Detection of missing Reference Library coverage
- Need & potential for performance improvement through algorithm modifications
- New functionality, e.g. Extract analysis

The latter trigger is initiated by Marketing, while the two former ones by Customer Support. The procedure comprises:

1. Launch decision approved by CEO & CTO
2. Reference Library sample collection specification by CTO
3. Sample sourcing by Lab Manager / ISO Manager
4. Sample analyses into Reference Library
5. Model Generation & Validation
6. Model Regression tests (Batch Estimations)
7. Lab tests (actual analyses, as performed by users)
8. Review & Production decision approved by CTO
9. Deployment in Production domain

Parameter/threshold amendment procedure

GemmaCert strives to minimize the need for chemometric model replacement. To this end spectra analysis is extensively parametrized, e.g. spectra validity thresholds and number of valid spectra required to produce analysis results are configurable and may be configured per customer, if so desired. Despite the ease to amend parameters & thresholds, any such amendment is considered no less critical than model amendment. Consequently, it is controlled by Parameter/threshold amendment procedure. The procedure is triggered by Customer Support upon identification of potential performance improvement for some users at least. Customer Support is equipped with extensive re-estimate means, which allow repeated analyses of user spectra under configurable parameter settings.

- Detection of missing Reference Library coverage
- Need & potential for performance improvement through algorithm modifications

- New functionality, e.g. Extract analysis

The latter trigger is initiated by Marketing, while the two former ones by Customer Support. The procedure comprises:

1. What-if analyses by Customer Support & CTO
2. Regression tests (Batch Estimations)
3. Lab tests (actual analyses, as performed by users)
4. Review & Production decision approved by CTO
5. Deployment in Production domain

Software release procedure

GemmaCert device software and GC App software updates engage users. Depending on internet connection quality at customer premises, device software update may last several minutes. Therefore, GemmaCert strives to minimize number of these software updates.

Customer Portal and Backend software updates are entirely transparent to users, apart from very short service outage on Backend software update. Backend software updates are routinely done between 7:30 & 8:00 CET on Sundays, thus minimizing the number of users potentially experiencing any outage. Backend extensively serves service monitoring needs. Therefore, most of its updates do not reflect any functionality change experienced by users. Rather, the updates equip GemmaCert staff with better insights into service quality.

Software update periodicity derives from considerations above:

Software Product	Mandatory update (months)	Optional update (months)	Comments
GemmaCert Device	6	3	
GC App	6	2	
Backend	2	NA	No optionality – applies to all users at once
Customer Portal	3	NA	No optionality – applies to all users at once

Table 5 – Software Updates Periodicity

Customer Portal software release procedure comprises:

1. Change specification & review by Marketing, Software & CTO
2. Implementation & test by developer/s (in Test domain, entirely decoupled from Production)
3. Review & Production decision approved by CTO
4. Deployment in Production domain (no selectivity here – deployment affects all)

Backend software release procedure comprises:

1. Change specification & review by Software & CTO
2. Implementation & test by developer/s (in Test domain, entirely decoupled from Production)
3. Lab tests (actual analyses, as performed by users, in Test domain)
4. Review & Production decision approved by CTO
5. Deployment in Production domain (no selectivity here – deployment affects all)

GemmaCert

GC App software release procedure comprises:

1. Change specification & review by Marketing, Software, Customer Support & CTO
2. Implementation & test by developer/s (in Test domain, entirely decoupled from Production)
3. Lab tests (actual analyses, as performed by users, in Test domain)
4. Review & Production decision approved by CTO
5. Applicability decision by Software, Customer Support & CTO:
    a. Mandatory vs. optional update
    b. Identify updated customers (avoid bothering users not in need of the new functionality)
6. Deployment in Production domain (update database indicating applicable version per customer)

GemmaCert device software release procedure comprises:

1. Change specification & review by Software, Customer Support & CTO
2. Implementation & test by developer/s (in Test domain, entirely decoupled from Production)
3. Lab tests (actual analyses, as performed by users, in Test domain)
4. Review & Production decision approved by CTO
5. Applicability decision by Software, Customer Support & CTO:
    a. Is update mandatory
    b. Which users shall update (avoid bothering users not in need of the new functionality)
6. Deployment in Production domain (update database indicating applicable version per device)

1.5 Valid device, document and software versions

Valid versions at the time of compiling release 1.0 of this document are listed in table below. Note that more than one version may be valid for any configuration-controlled item.

Item	Version	Release date	Comments
GemmaCert Device HW	1.0		
GemmaCert Device HW	1.1		
GemmaCert Device HW	1.1.1		
GemmaCert Device HW	1.2		Amendments for EMC compliance
GemmaCert Device SW	1.1.38		No longer operative. Installed at devices not in use. Mandatory update upon first operation.
GemmaCert Device SW	1.1.38.4		
GemmaCert Device SW	2.2.0	28/10/2019	
GemmaCert Device SW	2.2.03	24/03/2020	
GemmaCert Device SW	3.0.15	2/08/2020	Update from previous versions mandatory
GemmaCert Device SW	3.0.17	19/08/2020	Supports GemmaCert-Lite device. Update for deployed devices not mandatory.
GC App	2.1.0	28/10/2019	
GC App	2.1.1	29/01/2020	
GC App	2.1.2	22/04/2020	
GC App	2.1.7	16/08/2020	Mandatory update for operation
Backend	2.1.2	7/10/2020	Updates transparent to customers
LabUI	2.9	21/01/2020	Updates affect development only
Model	29.2.1.1	4/10/2020	Updates transparent to customers
German Pharmacopeia Compliance	1.02	12/10/2020	This document
GemmaCert Quick Reference Guide	1.10	21/3/2020	Also included as Appendix in this document

Table 6 – Valid Versions

1.6 Scope of validation

Scope of validation evolves incrementally through releases of this document:

- Releases 1.x – Flower and Ground matter identification as cannabis / non-cannabis
- Releases 2.x – Flower, Ground matter and Extract analyses for THC & CBD contents
- Releases 3.x – Flower and Ground matter analyses for Moisture content and for Mold presence

In all releases above validation shall demonstrate results accuracy irrespective of device used.

1.7 Limits of NIR technology

Cannabis analysis based on NIR technology faces triple challenge:

- Plant material exhibits overlapping spectra of various molecules
- High water absorbance in NIR bands
- Cannabis flower non-homogeneity

The two former challenges are non-specific to cannabis. Unlike synthetic samples, such as various polymers or pure materials, plant matter comprises multitude of different molecules. In high concentrations each of these molecules could have a very distinct spectrum. In blend they produce a rather non-descript waveform, void of evident peaks.

Water content in plant matter varies substantially. Water absorbance bands, if included in analysed spectra, may result in spectra variability, unrelated to analyses target, eventually resulting in false correlations between spectra and target molecule content.

The latter, non-homogeneity, is specific to cannabis flower analysis. Cannabis non-homogeneity expresses in both physical & chemical properties.

Physical non-homogeneity refers to analyzed flowers featuring varying sizes and irregular shapes. These challenge NIR analysis because its results are very sensitive to distance. Furthermore, varying sizes may result in sensor examining area, where there is no sample.

Chemical non-homogeneity refers to uneven active ingredient distribution across analyzed flower. Uneven active ingredient distribution manifests both visibly and through chemical analysis. First figure below depicts trichome density of a cannabis flower; significant because over 90% of cannabis active ingredients are contained in trichomes. Left to right the figure shows raw close-up photo, trichome map identified by dedicated image analysis algorithm and trichome density map styled as a thermal image.

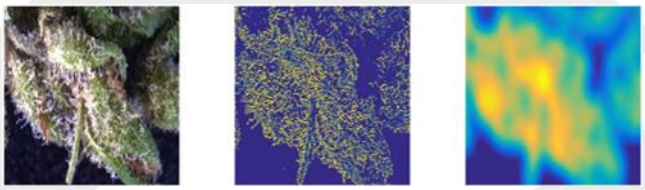


Figure 2 – Cannabis Flower Trichome Density Example

Next two figures depict CBD & THC contents in various parts of the same cannabis flower, accomplished by cutting every flower into a few pieces and analyzing each piece by applicable chemical analysis means (HPLC).

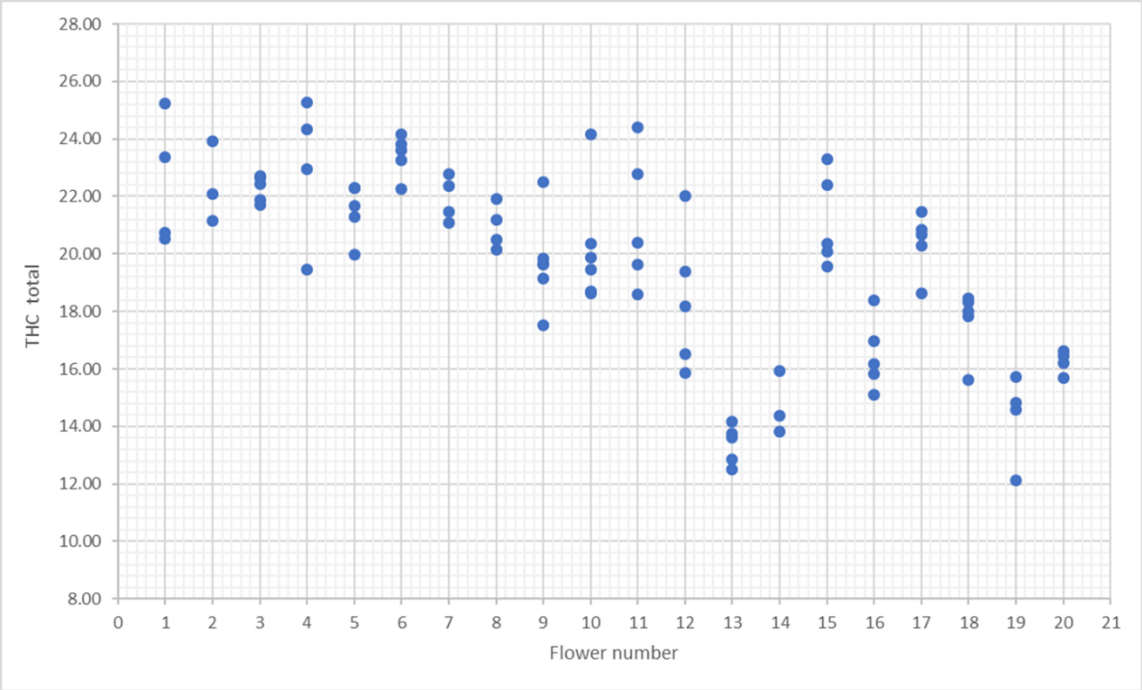


Figure 3 – THC Contents in Flower Piecewise Analyses

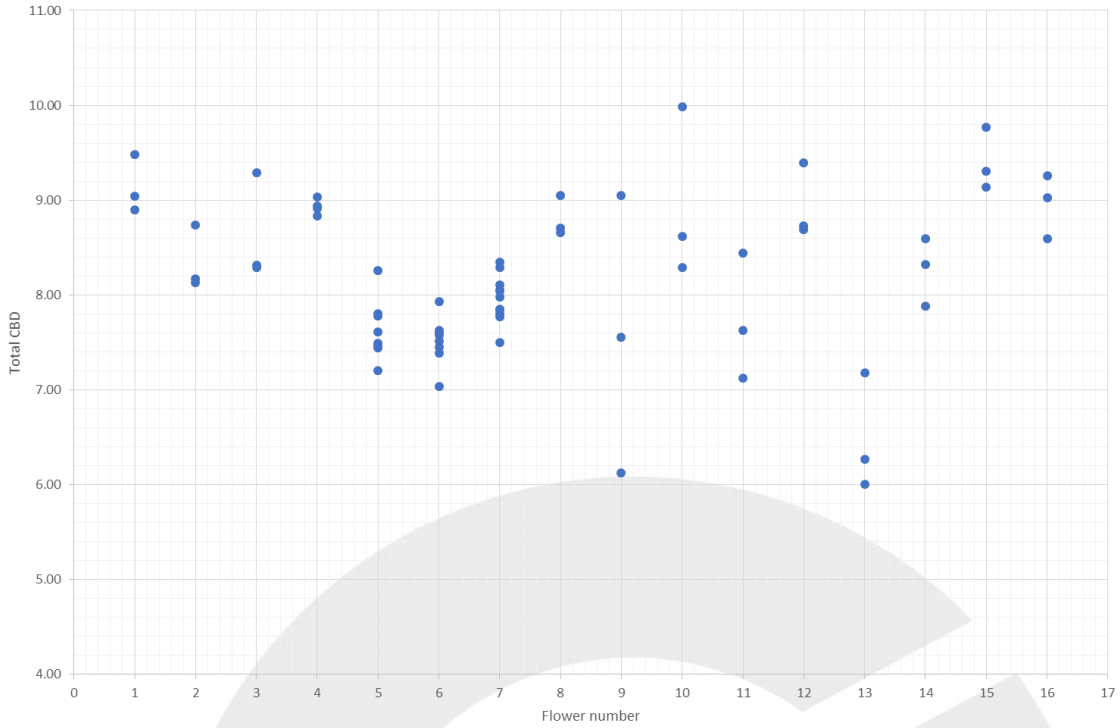


Figure 4 – CBD Contents in Flower Piecewise Analyses

In addition to the above, NIR analysis of cannabis faces challenges common to any Optical analysis of plant material:

1. Examined samples tend to be sticky, potentially polluting sensor lens. Cannabis buds are particularly sticky, as large fraction of flower volume and weight are trichomes, composed mostly of resin.
2. Examined samples produce fallout, potentially polluting sensor lens and clogging equipment internals over time. Cannabis flowers produce plenty of fallout because they are dried to very low level of moisture to avoid molding and extend shelf life. Drying makes the flower lose elasticity and weakens its structure.

GemmaCert addresses these challenges employing combination of visible image analysis and motion mechanics. Visible image analysis allows detection of analyzed flower shape. Motion mechanics allow positioning spectrometer at desired locations and distances from the analyzed flower and measuring spectra at any number of locations desired.

GemmaCert avoids results confusion by varying water contents by excluding water absorbance peak band from analysis at the time of compiling release 1.02 of this document. This is a temporary exclusion, as GemmaCert has moisture content measurement on its roadmap, upon implementation of which moisture effects will be fully accounted for.

2. Validation documentation

Customers instruction detailed in this chapter outlines validation procedure conducted to verify sample classification as cannabis or non-cannabis functions as expected and delivers valid results. Instructions detailed herein are stated as list of required actions, under the assumption that user is familiar with device and smartphone app operation. Operation quick reference is enclosed in Appendix A or this document.

2.1 Procedural instructions

Table below lists user actions and expected results validating correct functioning.

#	User Action	Expected Result
1	Login into GC App with wrong password	Login fails – verifies no fake possible
2	Login into GC App with correct password	Login succeeds
3	Connect Device to power and wait 2 minutes	White light at device top blinks
4	Connect GC App to the Device	Blue light at device top stable
5	Read "About"	Product versions displayed as detailed in "Valid Versions" above
6	Analyse Flower without placing any sample in device	GC App advises to verify sample placement
7	Analyse Ground without placing any sample in device	GC App advises to verify sample placement
8	Analyse 8 non-cannabis samples as Flower	GC App advises to verify correct sample
9	Analyse 8 intact cannabis flowers as Flower	GC App confirms cannabis
10	Analyse 8 non-cannabis samples as Ground	GC App advises to verify correct sample
11	Analyse 8 intact cannabis flowers as Ground	GC App confirms cannabis

Table 7 – Validation Procedure

2.2 Sample acceptance and rejection

Rejected samples are samples for which analysis has produced no results. GC app displays and actionable user guidance to amend the situation if possible.

Analysed sample may be rejected for a variety of reasons, including sample identification as non-cannabis - "outlier" in professional terms. Spectra, measured in course of analysis, are first validated as spectra. Spectra may be found invalid for variety of results:

- device experienced shock or vibration during measurement
- sample has not been placed correctly
- measured signal too weak, e.g. due to sample sparsity

Only valid spectra proceed to comparison to GemmaCert cannabis reference database for identification. Finally, if number of remaining non-rejected spectra is above threshold, they are analysed to produce cannabinoid content. Figure below depicts the flow.

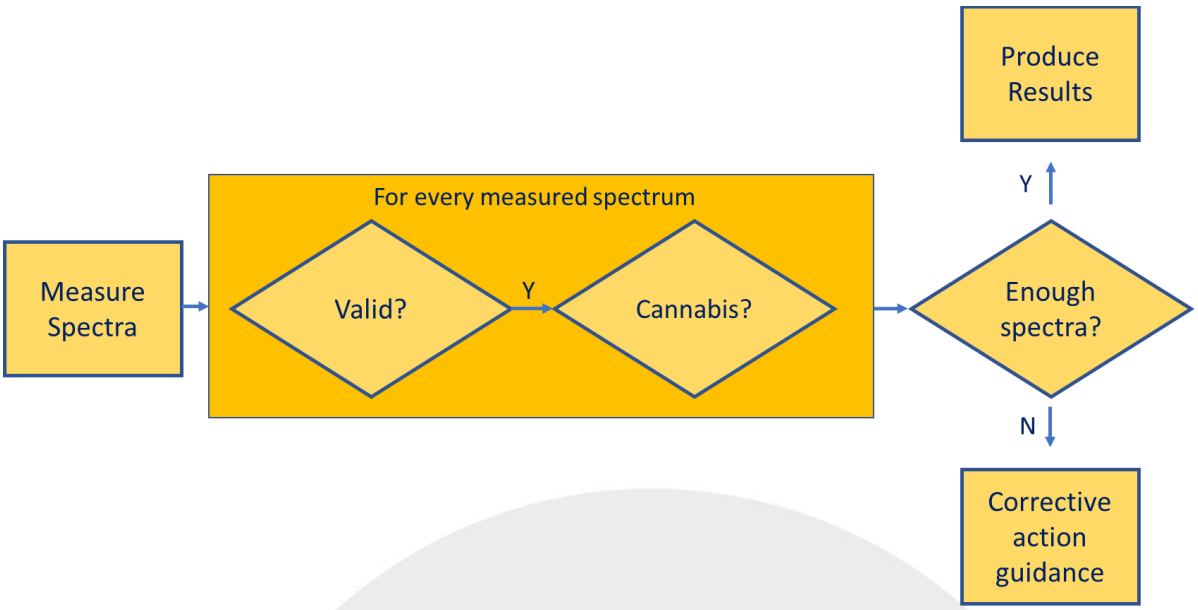


Figure 5 – Sample Spectra Acceptance and Rejection

Therefore, **non-cannabis samples may be rejected as invalid spectra**, prior to comparison to cannabis database.

2.3 Substance table

Plants, widely available at spice shops, are difficult to place within the device due to dried leaf tendency to fall apart. With some effort analysis of dried sage, basil, thyme, parsley and tobacco leaves can be attempted. User is advised to avoid thin samples such as a single sage or tobacco leaf, as these do not pose identification challenge. Several leaves may be stacked together to produce a useful sample. Dried flowers of sage, basil and lavender are suitable alternatives.

GemmaCert uses plants, which can be conveniently pierced on the flower pin without falling apart. Common hop (Homulus Lupulus) is of particular interest, being member of the Cannabaceae family along with Cannabis makes it ideal to examine potential confusion.

Table below proposes substances to be used for validation. These include cannabis samples to be identified as such and non-cannabis samples to be rejected as non-cannabis.

#	Category	Samples
1	Positive	Dried intact cannabis flowers
2	Negative	Dried Algerian tea, Anise, Butterfly pea, Cactus flower, Chrysanthemus, Dianthus spp, Helichrysum arenarium, Common hop, Indian rose, Lavender, Mayweed, Moroccan rose, Punica granatum, Red clover, Tagete erecta, Tanacetum and other flowers

Table 8 – Validation Samples

User may select other substances of non-cannabis plant matter. Note that all substances must be dried to avoid device soilage.

GemmaCert has validated cannabis identification through analyses of cannabis and plants which may cause erroneous results, listed above. Table below details validation outcome.

Samples	Analysis outcome	
	Accepted	Rejected
Cannabis	100%	0% ("false negative")
Non-cannabis	1% ("false positive")	99%

Table 9 – Outlier Detection Performance

Occurrence of 1% false positive attributed to a single plant – dried Lavender flowers. The high figure of 1% is result of Lavender analysis repeated multiple times to identify a solution. While 95% of Lavender analyses resulted in rejection, some have not been rejected and produced erroneous results.

It appears that oils composition in Lavender resembles that of Cannabis, or at least their respective effects in measured spectra resemble. GemmaCert continues work to resolve this Lavender challenge.

3. Structure of the reference library

3.1 Origin of the data for the reference library

Reference library creation and continuous maintenance comprises procurement of cannabis flowers from growers, measurement of their spectra by several GemmaCert devices, sample preparation towards HPLC analysis, HPLC analysis and finally association of measured spectra with HPLC analysis results, serving as spectra chemometric labels.

Reference library creation and maintenance is conducted mostly at GemmaCert in-house ISO-certified analytical lab. However, full coverage of the various cannabis varieties, cultivation process effects, drying procedures and other variability causes do not allow relying on cannabis flower supply in GemmaCert home market alone. Full coverage database mandates inclusion of samples cultivates and processed abroad.

Complete ban on cannabis delivery across most national borders, as well as state borders within USA, precludes transport of cannabis to GemmaCert in-house lab. Consequently, GemmaCert occasionally conducts library collection sessions abroad, in Europe and in USA. These sessions are conducted at qualified labs, equipped with up to date HPLC equipment and other essential tools. Spectra measurement on these sessions is conducted by GemmaCert staff, dispatched for that purpose. HPLC analyses are conducted by the host lab staff, following HPLC protocol review by GemmaCert ISO manager and GemmaCert Lab manager.

To date GemmaCert has conducted HPLC analyses of over 8000 samples. About 80% of these have been analysed at in-house lab and the remainder at labs in Europe and USA.

3.2 Scope and selection of data for the reference library

GemmaCert has established initial versions of its reference library by random procurement of samples from domestic authorized growers. To this end GemmaCert was granted a permanent procurement license by IMCA (Israel Medical Cannabis Authority), branch of the Health ministry serving as domestic cannabis regulator.

Following said initial version establishment GemmaCert commenced continuous monitoring of the cannabis market to identify potential gaps in its reference library. Gaps are identified by monitoring publicly available data sources, engaging with selected customers and automated monitoring of customer analyses which turn outside chemometric models, deployed at that time (a.k.a. "model outliers"). Upon identifying and verifying a reference library gap GemmaCert designs and conducts a gap-closing session, either at home or abroad.

Reference library contents at the time of compiling release 1.0 of this document are depicted as Total THC vs. Total CBD chart below.

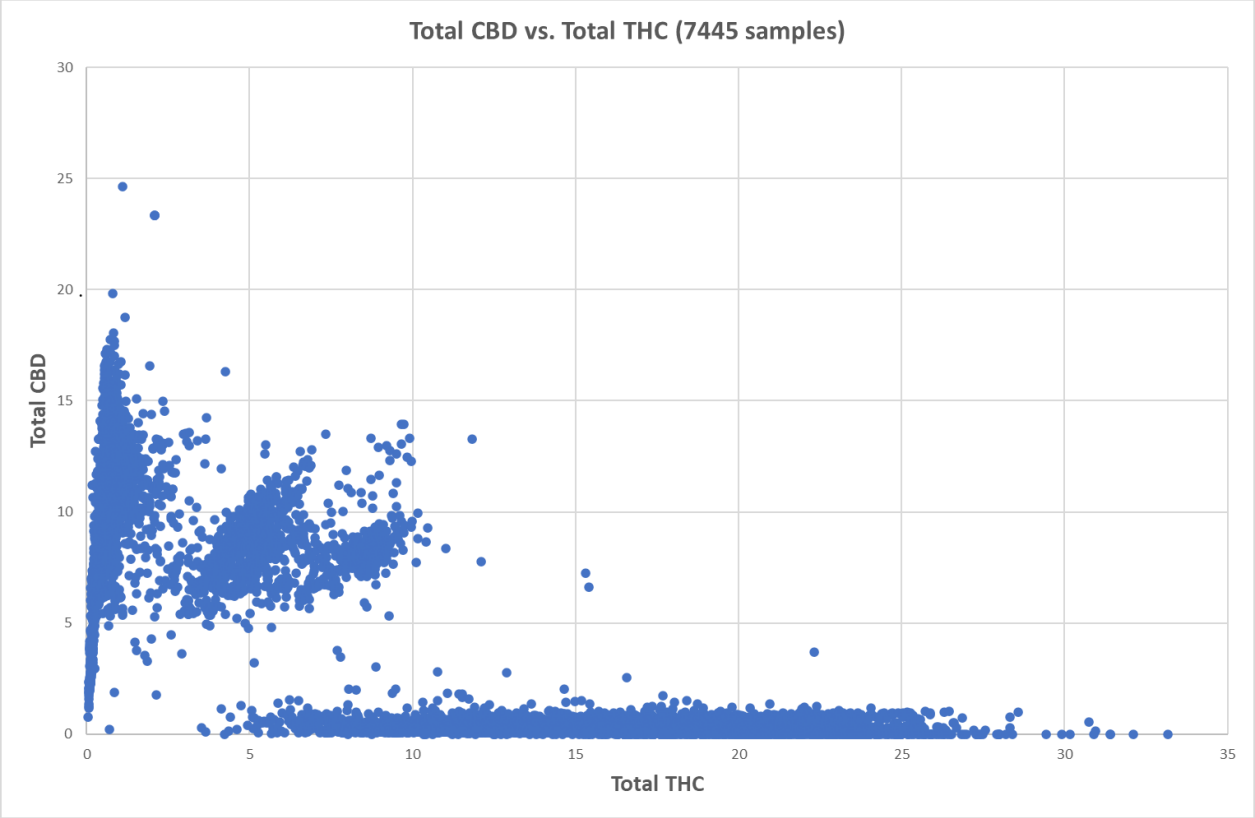


Figure 6 – GemmaCert Reference Library Composition

Evidently, not all THC-CBD combinations exist. Some of the white portions in the chart above could attribute to inherent plant nature; e.g. despite some claims on THC contents over 30% GemmaCert has found no such evidence apart from some rare examples; this is further confirmed by experienced growers' claim that THC plus CBD content may never exceed 30%. However, any such rules of thumb may break through conventional or GMO breeding.

Much of the white portions in the chart above likely attribute to lack of market interest in such compositions. Such portions could be populated at no notice, due to market interest developing at some, possibly remote, market. GemmaCert becomes aware of such appearances through customers' analyses resulting in model outliers.

In addition to monitoring appearance of previously unencountered composition, GemmaCert also monitors coverage density. To this end GemmaCert has specified 9 cannabis composition categories and has partitioned every category into narrow contents slices. GemmaCert strives to populate every such slice with 80 samples at least.

Spectra of every sample is measured both as an intact flower and as ground matter. Hence in effect number of reference library records is double the number of HPLC analyses.

3.3 Mathematical pre-treatment of spectra

Spectra in reference library do not automatically qualify for chemometric model generation. Rather, certain filters are applied to remove corrupted or otherwise illegal spectra. Spectra may turn invalid for various reasons, attributing to human error, environmental conditions or sample nature. Some examples below:

- No sample inserted into device – human error
- Sample placed inaccurately – human error
- Vibration – environmental conditions
- Shock – usually human error, but could attribute to environment as well
- Very sparse sample – sample nature, particularly characteristic of hemp

Invalid spectra are excluded from chemometric model generation applying a series of filters to Reference, Dark and Reflectance spectra:

- Reference spectra filters
    - Minimum signal level
    - Noise
    - Shape (peak analysis)
- Dark spectra filters
    - Noise
    - Shape (peak analysis)
- Reflectance spectra filters
    - Minimum signal level

Spectra found invalid are excluded from chemometric model generation, yet they are neither deleted nor marked invalid. These spectra remain in reference library, as exclusion criteria may change over time due to accumulated experience and/or pre-processing improvements which allow to recover earlier unusable spectra.

Reference, Dark and Reflectance spectra serve inputs to Absorbance calculation. Absorbance is calculated per standard industry formula and then homogenized applying proprietary cross-device calibration. Cross-device calibration brings spectra measured by various devices to a common base, such that inherent differences between sensors embedded in various devices no longer show in spectra. The process relies on spectral characteristics of devices acquired by dedicated calibration conducted at FAT (a.k.a. “Final Testing”).

Absorbance spectra are not yet suitable for chemometric model generation. Suitability of Absorbance spectra are examined applying following filters:

- Noise
- Shape (peak analysis)

The rationale of applying filters also to Absorbance is the possibility of Reflectance and Reference being valid, while their ratio is not.

Figure below depicts spectra processing sequences. Sequence outlined in text above is depicted by the figure segment named “Model flow”.

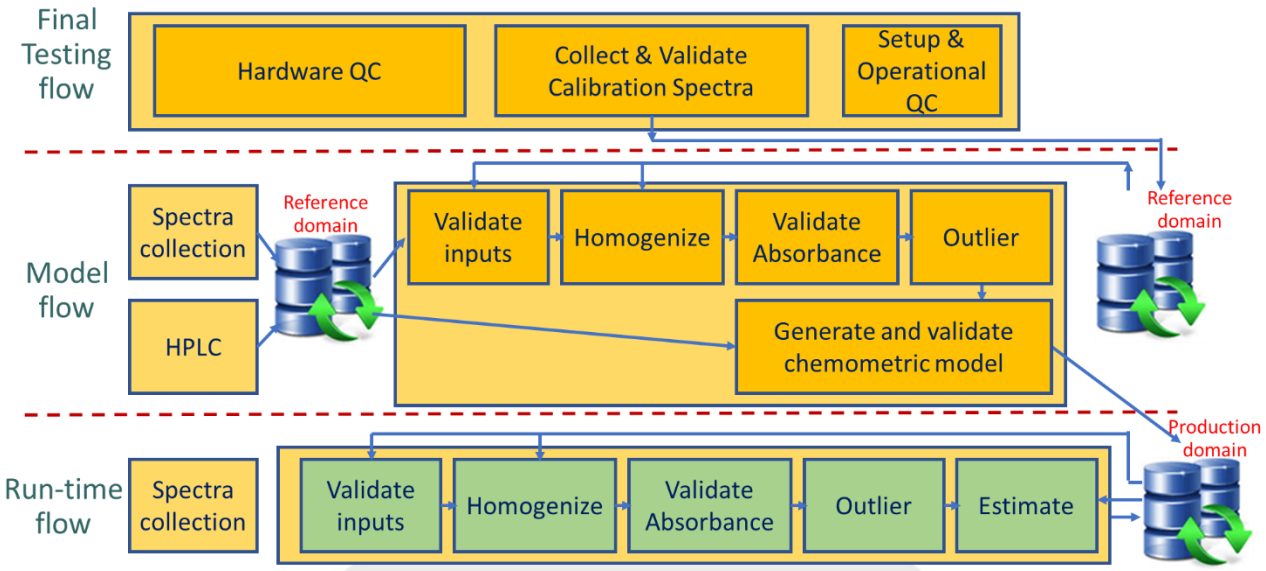


Figure 7 – Spectra Processing Flows

The device is lightweight, therefore prone to spectra corruption due to environmental conditions or user even slightly moving the device during operation. GemmaCert perceives such occurrences unavoidable and attempts compensating for these by statistical means. Accordingly, multiple sample spectra are measured during analysis. These spectra are measured at various sample locations, which also helps coping with sample non-homogeneity.

Reference library measurements comprise 24 spectra per sample. Thanks to stable environment and skilled team, measurements conducted at GemmaCert in-house lab mostly produce all 24 spectra valid. This may not necessarily be the case when reference library is measured at other locations. This is the rationale for extensive spectra validation as outlined above.

Minimum number of valid spectra is mandated to provide analysis results to customers. No such mandate is applied to reference library measurements; any number of valid spectra per sample are utilized to generate chemometric models.

3.4 Creation of the reference library

3.4.1 Software used

Reference library comprises sample spectra measured by multiple GemmaCert devices and sample compositions produced by HPLC analyses. Accordingly, reference library production relies on software components operating the device and recording its measurements, identical to the software serving operation by customers, and LabUI software used to record and retrieve HPLC results.

Figure below depicts reference library spectra collection. Software products used are listed in smaller font underneath every component name.

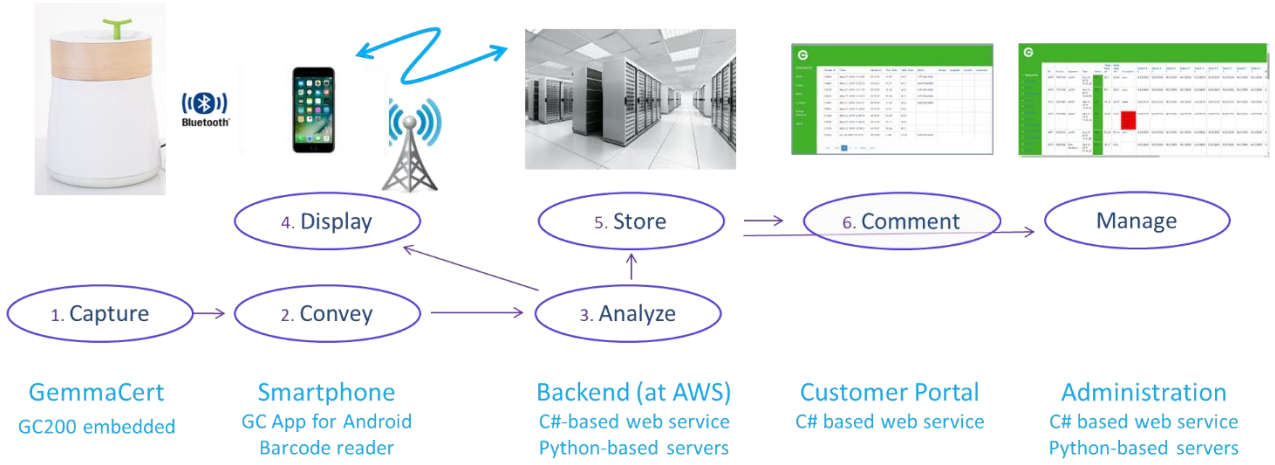


Figure 8 – Reference Library Spectra Collection

All software products listed in figure above, apart from Barcode reader, are proprietary, developed and maintained entirely in-house. They are identical to software products serving customers. The sole difference is referring to Reference domain, while customers are served by Production domain. Reference domain is strictly isolated from Production domain for security and data integrity purposes, as depicted in figure below. No information is conveyed between the two domains and chemometric models, generated & validated within Reference domain, are published at Production domain manually by Administrator. Lower part of the figure outlines LabUI software position in reference library flow.

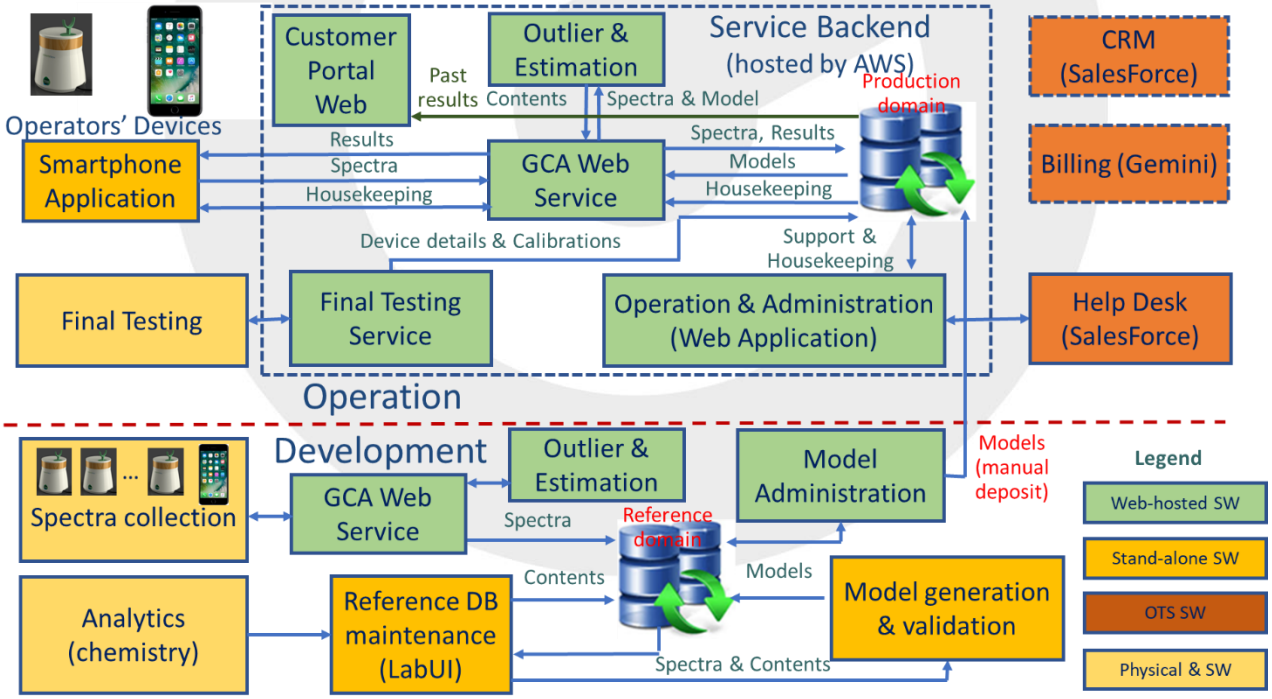


Figure 9 – GemmaCert Software Products

Model may be yet unavailable or not adequately covering analyzed samples during Reference Library collection. Therefore Outlier & Estimation function presence in Reference Library collection may appear out of place. The purpose is equipping GemmaCert staff engaged in Reference Library collection with immediate feedback on just measured spectra quality. Such feedback helps the staff take immediate corrective action, such as more accurate placement of the sample or attending some environmental disturbance.

3.4.2 Software functionality

Table below lists software products engaged in Reference Library collection and maintenance and details their respective functionalities.

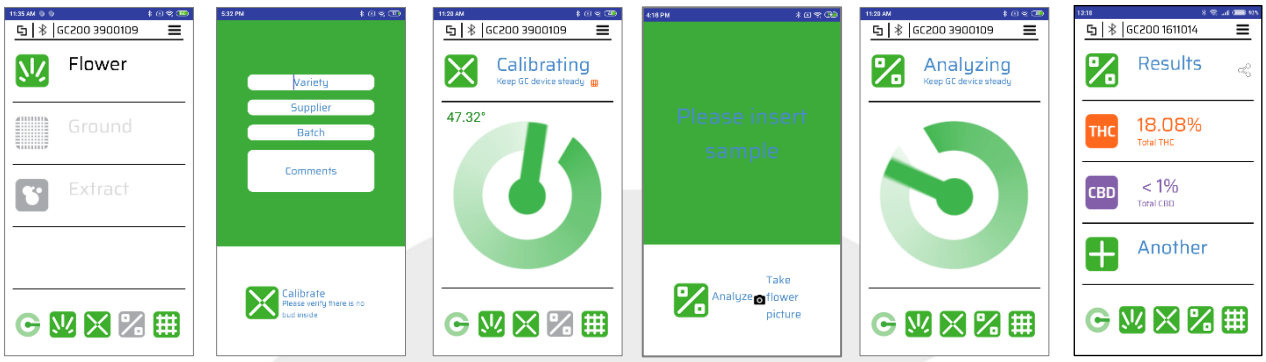
Software Product	Deployed at	Functionality	Comments
GC200	GemmaCert device	Monitor device hardware Measure spectra as specified by Mode attributes received anew from GC App for every sampling session Deliver measured spectra to GC App upon measurement completion	Identical to software deployed at customers' devices Doesn't process the spectra in any way
GC App	Smartphone	User interface for device operation Convey communications between GemmaCert device and GCA Web Service	Identical to software deployed at customers' devices Doesn't process the spectra in any way
Barcode reader	Smartphone	Read barcodes identifying samples	OTS software
GCA Web Service	AWS	Maintain REST API versus GC App Retrieve Mode attributes from database and convey these to GC App Receive and record in database device self-test results & exceptions Receive and record in database measured spectra Pass measured spectra to Outlier & Estimation and receive spectra analysis results Convey spectra analysis results to GC App with appropriate instructions	Outlier & Estimation produces spectra quality metrics, which are meaningless to human eye. GCA Web Service translates the metrics to actionable user instructions in words.
Outlier & Estimation	AWS	Conduct all spectra validity analyses, as outlined above Conduct estimation of sample active ingredients	Estimation is not essential for Reference Library collection. It is employed as means to alert staff they could be collecting other than planned.
Customer Portal Web	AWS	Add or modify free text describing measured samples	Optional. Free text describing samples, e.g. variety, is entered at GC App. Customer Portal is used only to amend.
LabUI	Lab PC	Feed HPLC results into database. Normalize HPLC results to account for input matter weight. LOD correction.	Part of ISO-certified GemmaCert Lab
Model Administration	AWS	Review measured sample details and spectra validity metrics Generate spectra plots	Provide performance insights based on model metrics

Table 10 – Software Products Engaged in Reference Library

GemmaCert device is not equipped with any operation controls, apart from "P" button on top cover which allows placing device in dormant state. It has no display, apart from two-color LED indications of activity under the "P" button. The device is operated exclusively though GC App and its operation attributes are configured exclusively through Model Administration.

Some of GC App and Model Administration screens are visualized below for clarity sake.

Figure below depicts GC App screens displayed through single sample measurement, left to right



Select sample mode | Optional – type in sample description | Calibration in process | Optional – take sample photo | Analysis in process | Results

Figure 10 – GC App Screens Through Spectra Measurement

GCA Web Service allows spectra exploration immediately following its measurement. Primary display used is Results screen, as in figure below.

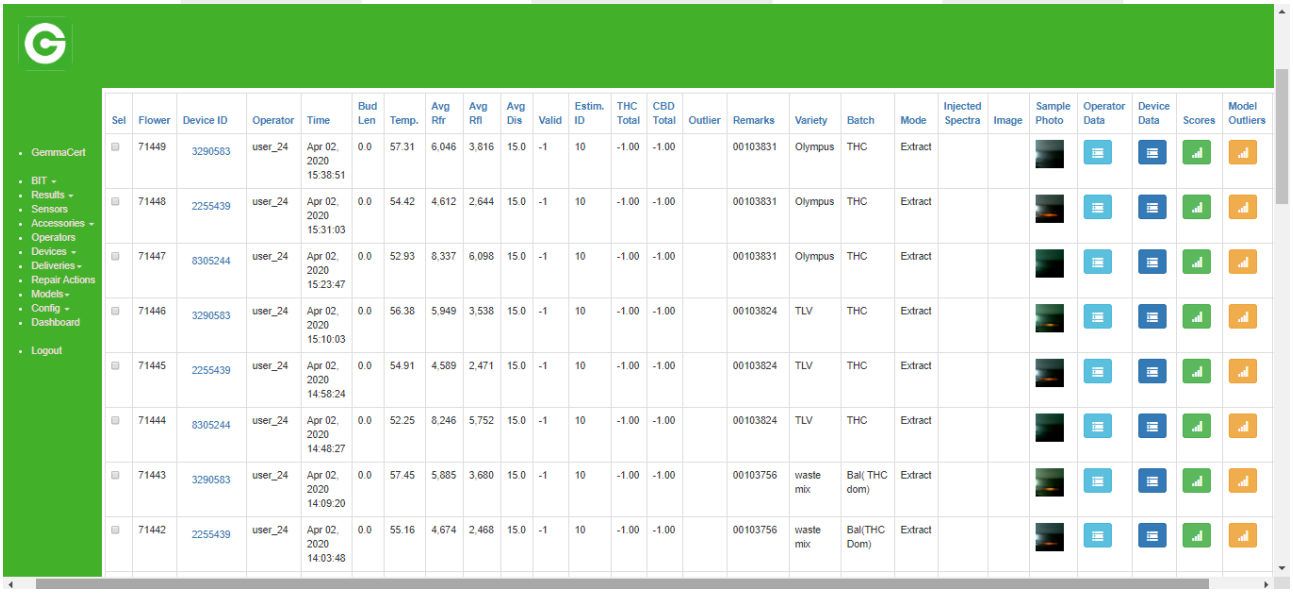


Figure 11 – GCA Web Results Screen, Model not yet available

Figure above depicts Reference Library collection for Extract. At the onset of Extract analyses there are no applicable chemometric models. Consequently, spectra are not analyzed for validity (indicated by "-1" in "Valid" column) and no results are produced (indicated by "-1" in THC and CBD columns).

"Remarks" column shows sample barcode, which identifies every sample uniquely through the entire Reference Library collection process, from sample ingestion into the database to HPLC analyses

completion. “Remarks” values are fed by barcode reader software installed at the smartphone operating the GC App. “Variety” and “Batch” fields are typed manually at GC App.

In absence of validated chemometric models, spectra validity is examined by visual inspection. To this end staff can select any set of samples and generate visualizations of all spectra components, including Reference, Reflectance and Absorbance. Figure below depicts Extract absorbance spectra.

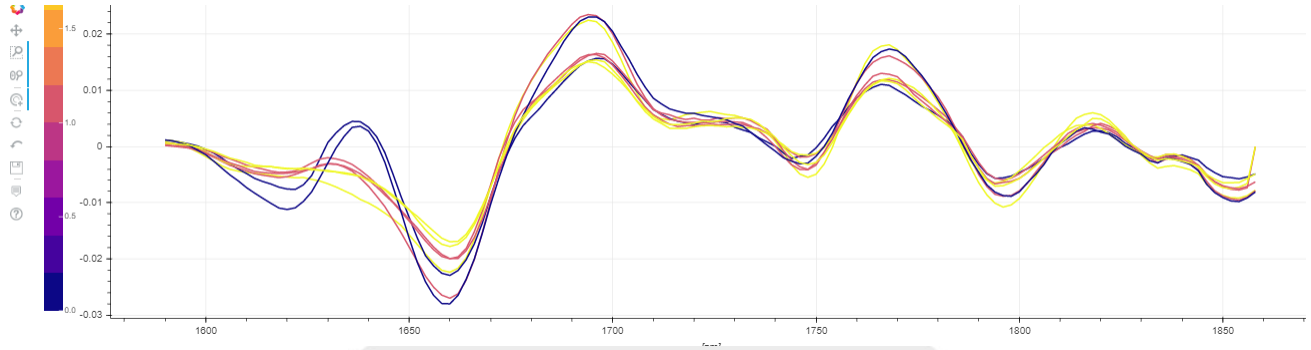


Figure 12 – Extract Absorbance Spectra

In presence of validated chemometric models, staff is alerted on invalid spectra immediately through the GC App. Alert thresholds are configurable, e.g. 20 out of 24 measured spectra. Nevertheless, staff is instructed to refer to GCA Web to verify correctness and completeness. Figure below depicts Reference Library spectra collection in presence of validated chemometric models.

Figure 13 – GCA Web Results Screen, Model available

One of the samples in figure above has produced no valid spectra. On such events staff examines the cause of spectra invalidity, using the “Scores” function to display spectra metrics versus thresholds. Figure below depicts spectra scores, showing noise above threshold for this sample.

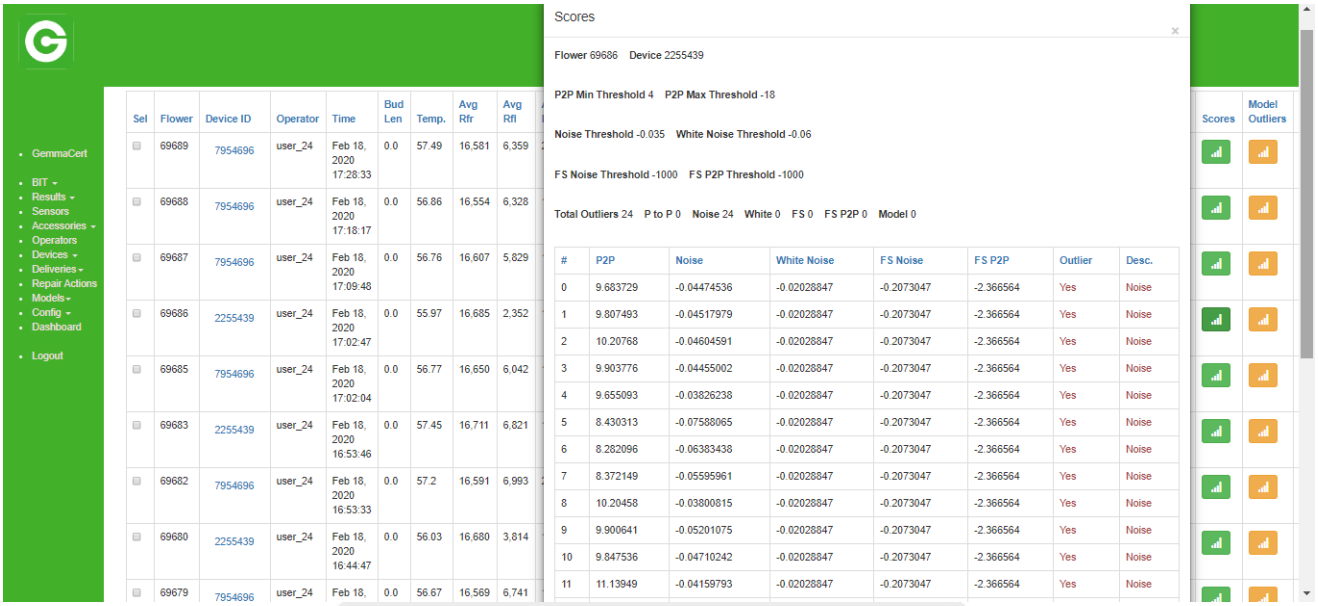


Figure 14 – Invalid Spectra Score for Cause Identification

Staff may drill-down deeper to get a visual impression of how acute signal noise was. Figure below depicts the invalid spectra. The broken curves indicate noisy spectra.

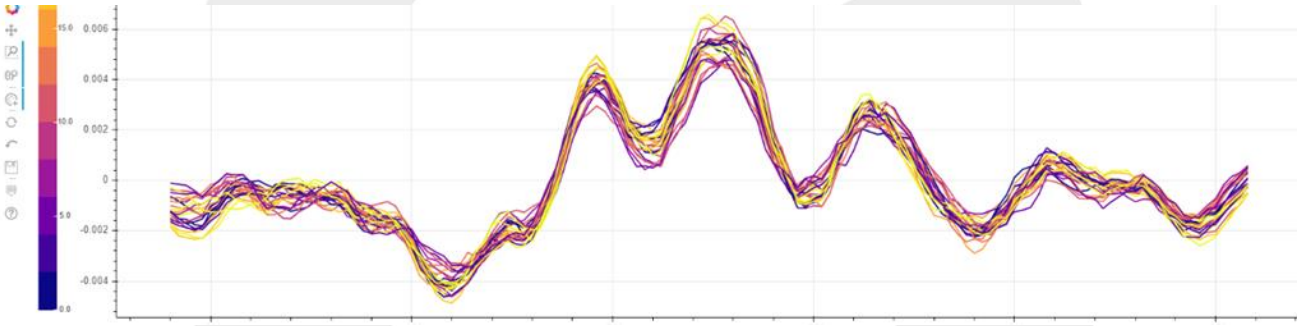


Figure 15 – Noisy Spectra Example

Reviewing Reference Library spectra through GCA Web Service staff may decide to add comments or complete some missing description, e.g. sample varieties. Customer Portal web application allows editing the free text fields and record deletion, e.g. when barcode is found corrupted. Figure below depicts Customer Portal interface.

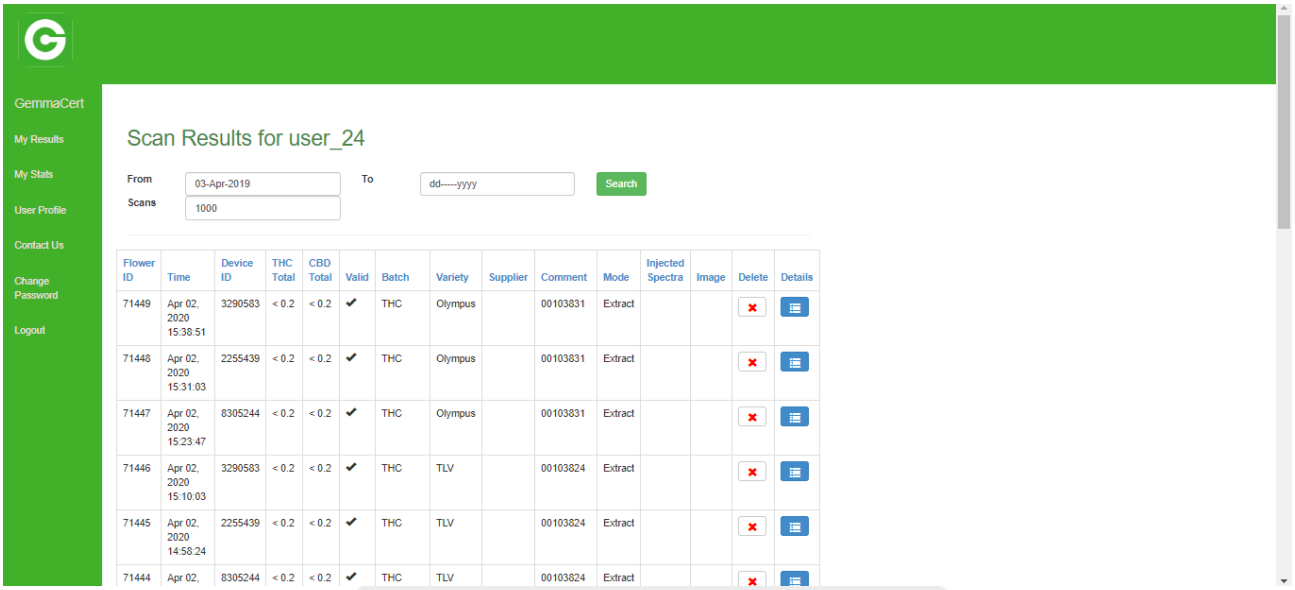


Figure 16 – Customer Portal

This concludes review of software engaged in spectra measurement in Reference Library collection. The analytical part, which provides HPLC results serving as chemometric model label data, is conducted exclusively using LabUI software, described below.

LabUI is an in-house developed software which creates records of all the experimental data produced by the company, both within its in-house lab and elsewhere. LabUI links between laboratory work and GemmaCert data base. Figure below depicts LabUI use in conjunction with laboratory analyses process.

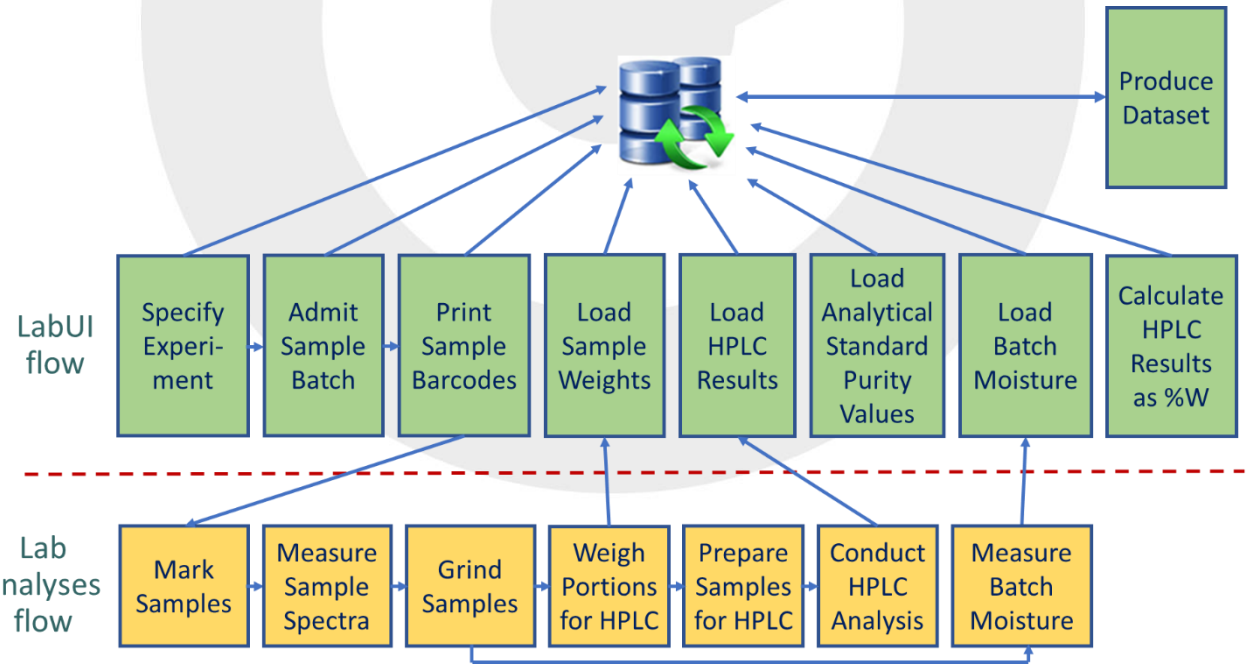


Figure 17 – LabUI and Lab Analyses Flows

Two concepts worth explaining here are Experiment and Dataset. Experiment is the granularity of Reference Library collection. Experiment may comprise from few to few hundreds of samples, depending on objectives. Dataset is the granularity of chemometric model inputs. Experiment may result in one or more Datasets, e.g. intact flower and ground matter are most often analyzed in one experiment, producing two distinct datasets – flower & ground.

Flow depicted in figure above commences with specifying Experiment. Experiment specification comprises sample types & counts, devices & tools used, procedural instructions and objectives. Figure below depicts Experiment specification screen of LabUI.

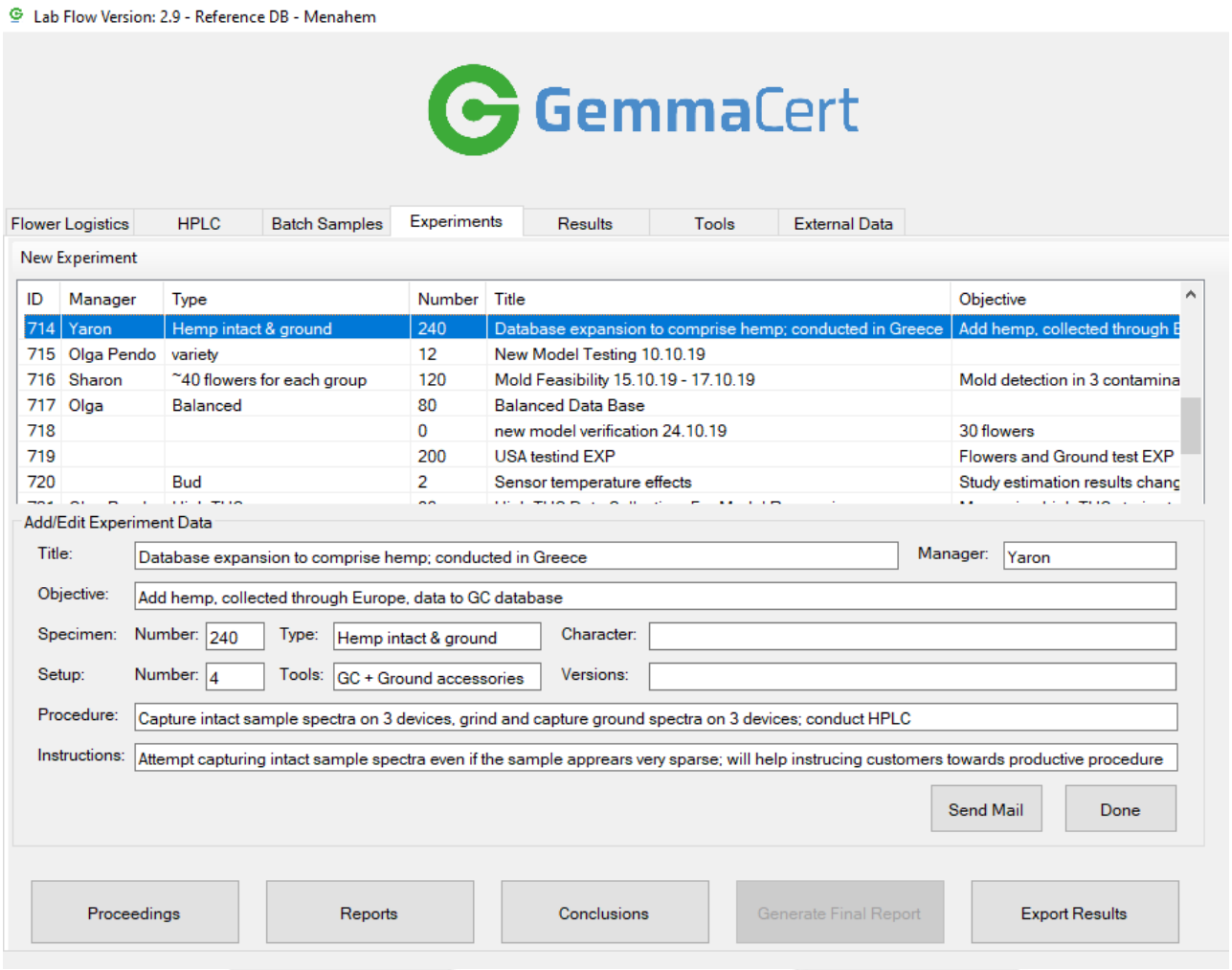


Figure 18 – Experiment Specification in LabUI

The process then proceeds to admit samples. Sample admission is done in Batches. Batch is associated with supplier and variety or any other desired characteristic. Batch is always associated with an Experiment. Batch specification allows selection of supplier and variety already in database or creation of new ones. Figure below depicts batch creation in Lab UI.

Generating & printing barcodes is the next step. Barcode numbers uniquely identify samples and serve associating measured spectra with HPLC results.

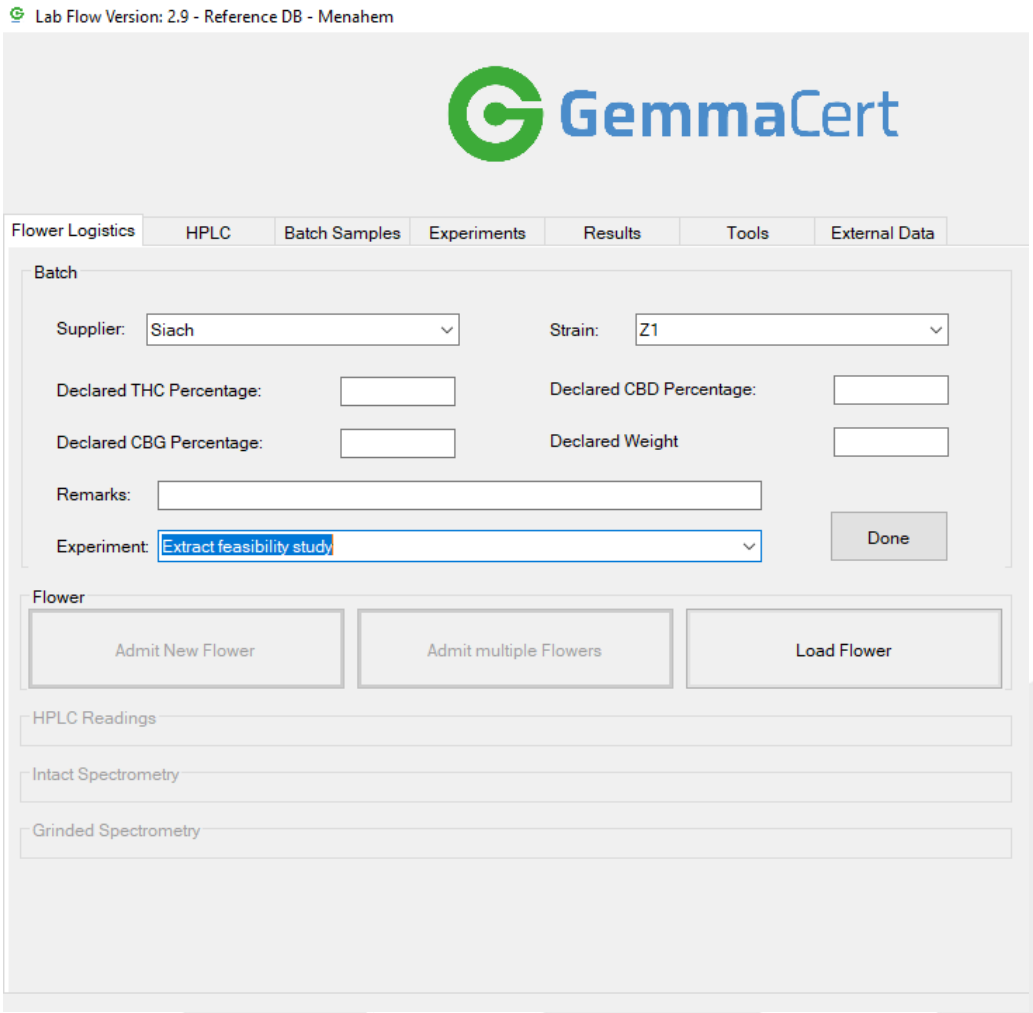


Figure 19 – Batch Creation in LabUI

Various LabUI screens serve loading analyses results, as these become available:

1. Sample weights
2. HPLC raw data file (components amount [ng])
3. Analytical standards purity values
4. Moisture content per batch

When all above are available, LabUI calculates HPLC results as weight percentages.
Following that Reference Library records, generated in the Experiment, are available for chemometric model generation. These records are exported into requested Dataset/s per configurable export criteria.
Figure below depicts Reference Library export in Dataset by LabUI.

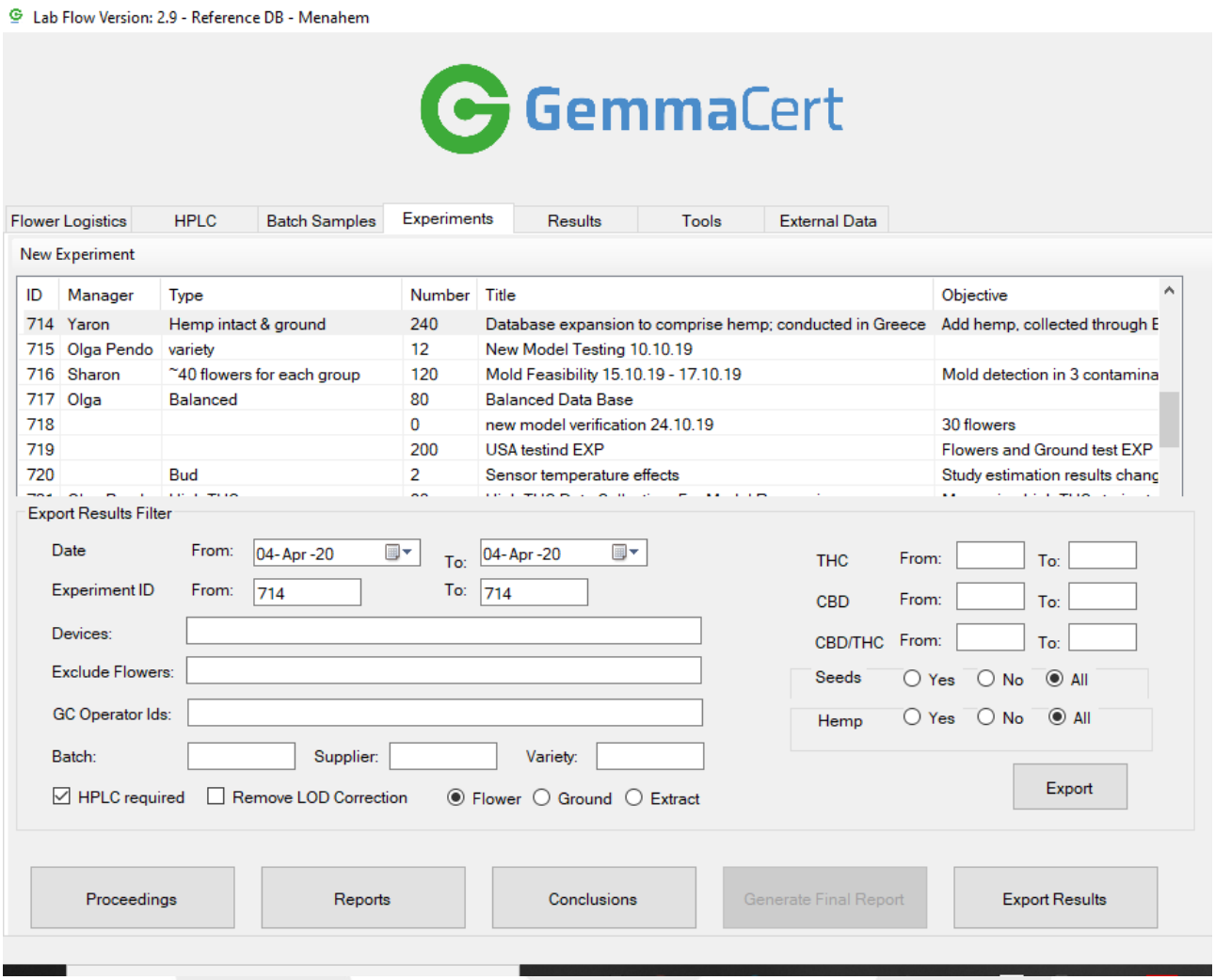


Figure 20 – Reference Library Records Export into Dataset by LabUI

This concludes review of software employed to create and maintain Reference Library.

4. Spectrometers and accessories used

GemmaCert solution for cannabis active ingredient analyses relies on a single device model, named "GemmaCert" as well. GemmaCert is a compact table-top / counter-top device, designed for indoors operation in moderate environmental conditions. Figure below depicts the device with its power supply.

Figure 21 – GemmaCert Device with Power Supply

GemmaCert is equipped with 3 optional accessories, depicted in figure below:

- Reflector + Flower Pin – serves analysis of intact flowers
- Ground accessory – serves analysis of ground matter
- Extract accessory – serves analysis of extract, enclosed in plastic blister

GemmaCert device characteristics, as detailed in device datasheet, below.

Power:

- *6vdc 3A, by 110/220 AC/DC*
- *No battery*

Storage temp.: *-10°c to +45°c (14°F - 95°F)*

Operating temp.: *+10°c to +35°c (50°F - 113°F)*

Dimensions:

- *Height 224mm*
- *Diameter top 144mm*
- *Diameter bottom 166mm*

Weight: *1958gr.*

GemmaCert device is entirely safe, compliance with applicable safety standards and national norms validated by certified lab (see reference in Applicable Norms and Standards).

GemmaCert integrates technologies:

- *NIR Spectroscopy*
- *Image Analysis*
- *Motion mechanics*

Data Analytics, another key technology in GemmaCert solution, is confined to GemmaCert Backend, deployed in the cloud. There are no Data Analytics components within the device.

NIR Spectroscopy is implemented embedding a spectrometer with integrated illumination. Spectrometer operates in 1550nm-1950nm range. Spectrometer operation is assisted by integrated references:

- Calibration Reference (a.k.a. “White”)
- Embedded Reference (polymer with distinct, temperature independent, spectra fingerprint)

Image Analysis identifies sample shape to allow optimal spectrometer positions versus the analysed sample. Image Analysis also assists malfunction and user mistake detection, e.g. selection of Flower mode while Ground Accessory is inside. Image Analysis is implemented with a camera and two sets of illumination LEDs.

Motion mechanics serve placing spectrometer at desired locations and distances from the analysed sample. Motion mechanics comprise a 3-dimension motion system operating orthogonal X, Y & Z axes.

5. Validation of the measuring system

5.1 Spectroscopic accuracy of the devices

Spectroscopic accuracy of the embedded spectrometer listed in table below.

Attribute	Values	Relevance
Wavelength range	1550 – 1950 nm	
Wavelength resolution	15 – 21 nm	
Wavelength points	0.1 nm, up to 512 sampling points in total	In practice 2 nm intervals used, constituting 201 sampling points
Wavelength switching time	1 msec	Little impact on measurement duration; most of the duration due to Averaging
SNR	> 7500	
Wavelength temperature response	< 0.1 nm / °C	

However, overall device accuracy is not determined by the attributes listed in table above alone. The reason is accuracy dependency on two factors:

- Sensor temperature
- Sensor placement versus measured object

The accuracy impact of sensor temperature is contained by measuring spectra in temperature range 47°C to 57°C. To this end device software monitors sensor temperature continuously and applies warm-up or cool-down procedures as needed. Software blocks spectra measurement during warm-up and cool-down. This mechanism limits spectrum variability to < 1 nm, which is immaterial sampling spectra at 2 nm intervals.

The accuracy impact of sensor placement is contained by controlling sensor distance to measured object through visible image analysis. Visible image analysis allows maintaining consistent performance of a device, despite potential changes due to wear, and consistent performance between devices, despite potential assembly tolerances.

5.2 Spectroscopic examination as part of the FAT

GemmaCert conducts an automated FAT (a.k.a. FT – Final Testing). FAT comprises 3 parts:

1. Hardware Quality Control, described elsewhere in this document
2. Calibration spectra collection and validation
3. Delivery Readiness:
    a. Setup – install Production software & test it operates
    b. Cross-device Calibration – calculate spectra conversion to a common base

GemmaCert device is not marked as "available" unless all 3 parts above conclude in success. The entire FAT sequence is depicted in figure below.

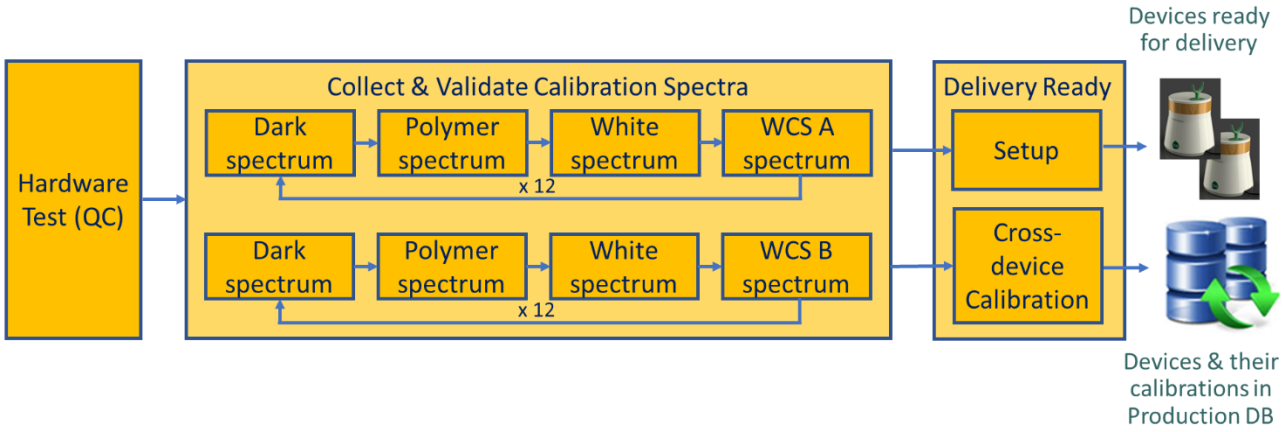


Figure 22 – FAT Sequence

Measuring and analysing WCS (Wavelength Calibration Standard) spectra serves dual purpose:

- Input for Cross-device Calibration
- Spectra accuracy & stability

Figure below depicts WCS assemblies.

Figure 23 – WCS Assemblies

WCS spectra are processed as any sample spectra would – calculation of Absorbance using Reflectance, Dark & White spectra. This is repeated 12 times for each of the WCS samples analysed, presently two samples referred here as "WCS A" and "WCS B". The rationale of repetition is verifying stability, accounting also for sensor temperature changes. This results in Absorbance spectra per WCS, similar to the depicted in figure below.

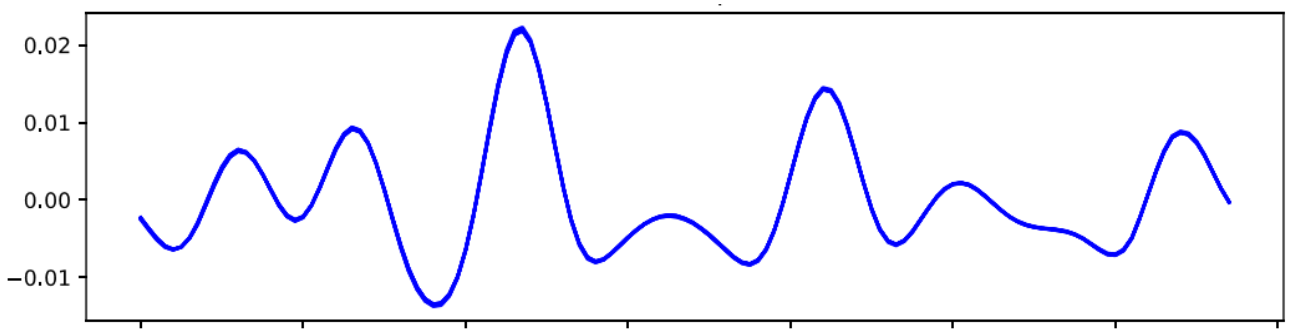


Figure 24 – WCS Absorbance Spectra

The thick curve attributes to not absolutely prefect overlap of the 12 spectra plotted. Overlap imperfection is calculated and serves criterion for rejection. At the time of compiling release 1.02 of this document a single sensor out of hundreds analysed has been found faulty through this spectra consistency test.

WCS spectra found consistent proceed to Cross-device Calibration. Cross-device Calibration calculates a per-device Absorbance conversion function to reference device Absorbance. Cross-device Calibration calculation may also result in rejection. This occurs if calculated conversion factors exceed thresholds.

In summary, WCS may result in FAT failure due to either of:

- WCS A spectra inconsistency
- WCS B spectra inconsistency
- Cross-device Calibration factors exceeding thresholds

FAT measures & records also Polymer spectra. Unlike WCS, Polymer is embedded within GemmaCert device and serves monitoring spectra changes over time, rather than any matching between various device spectra. Embedded Polymer spectra measured during FAT are recorded in database and used subsequently to compare Polymer spectra measured during device operation by users. Polymer spectra example is depicted in figure below.

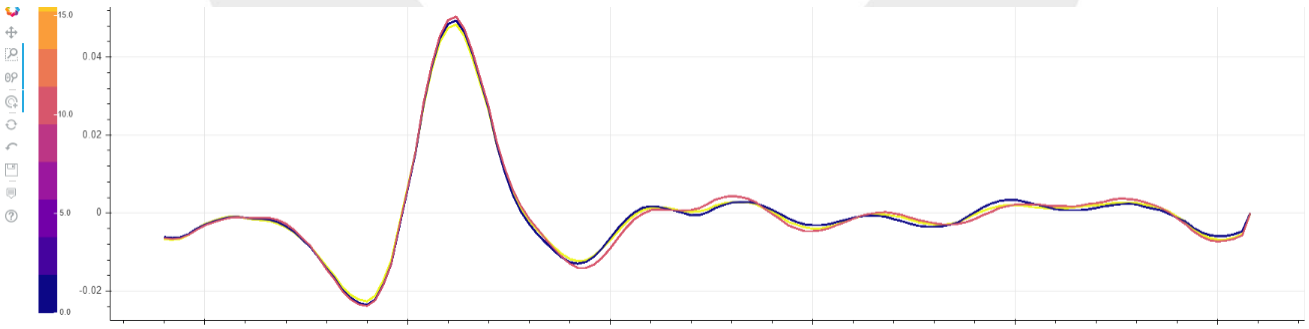


Figure 25 – Embedded Polymer Spectra

Embedded Polymer spectra would not be adequate for Cross-device calibration. They are adequate to identify changes over time, e.g. due to sensor aging. Change is identified when Polymer spectra of a device differ by more than 2 nm, the wavelength sampling step.

5.3 Referencing / white balance

GemmaCert device contains an embedded White reference implemented by a 20x20 mm piece of a Zenith sheet. Device measures White spectrum anew with every single analysis and maintains an expiration period, whence White spectrum expires after a configurable time period. At the time of

compiling release 1.02 of this document White expires in 4 minutes. Following that user is instructed to calibrate again.

White reference is replaceable by user. Automated Alert mechanism notifies GemmaCert Support on White inadequacy, as well as other malfunctions, triggering White replacement. Figure below depicts embedded White.

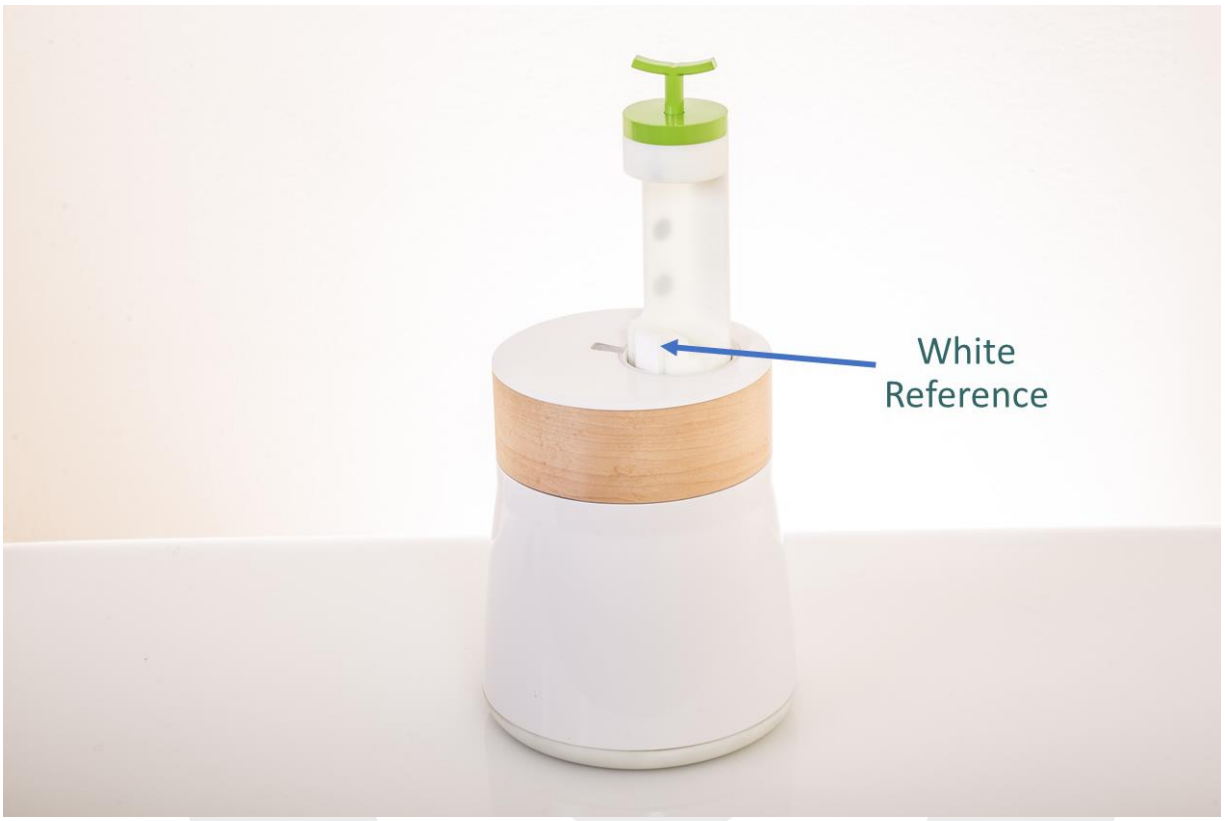


Figure 26 – Embedded White Reference

5.4 Daily device testing

GemmaCert users need not initiate any daily device testing. The device performs BIT (Built In Test) automatically on every power on. BIT lasts about 1 minute and verifies hardware functionality. User is immediately alerted on malfunction and advised on course of action. Automated ticket is generated for GemmaCert Support staff.

Alerts to GemmaCert Support staff may also be triggered by user analyses when these repeatedly fail to produce valid Reference, Embedded Polymer or sample Absorbance spectra. Alert mandates repeated failure because occasional failures may occur due to unstable environment.

5.5 Periodic device inspection with certified standards

GemmaCert device does not require periodic inspection with standards. Device health is continuously monitored as described above.

By the time of compiling this document all instances of repeatedly invalid spectra have attributed to motion mechanics, rather than to sensor. Many of these are resolved by remote service. The rest are sent to GemmaCert for service. Device service always concludes with FAT, thus spectra measurement accuracy is validated and Cross-device Calibration is repeated.

5.6 Ensuring device comparability

GemmaCert device comparability is established through Cross-device Calibration, outlined in paragraphs above. GemmaCert has selected an extensively tested device, operating since long at GemmaCert lab, as the reference device. Cross-device Calibration produces spectra conversion procedure and set of factors, which convert any newly measured spectrum by any other device to match the spectrum of the said reference device. In fact, the reference device is no longer necessary and may be decommissioned or otherwise cease to exist. The only inputs needed are WCS spectra measured by the reference device.

Cross-device Calibration warrants match between converted WCS spectra of various devices. Figures below depict WCS spectra of reference device in red and calibrated device in blue before and after calibration.

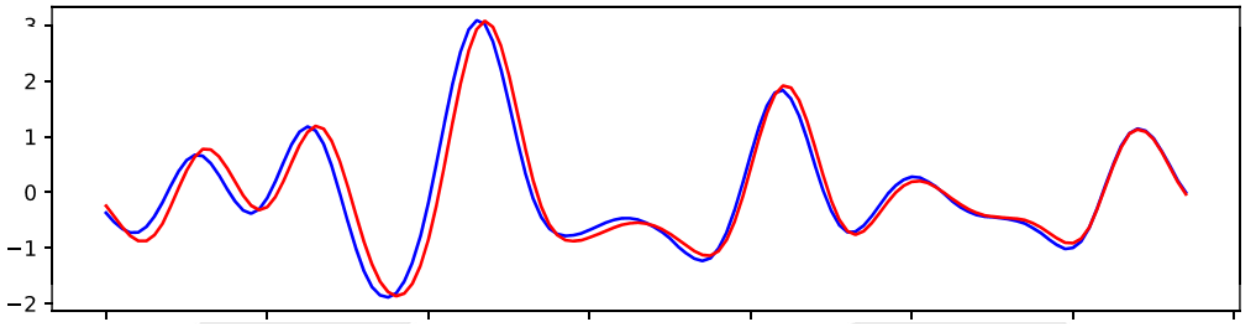


Figure 27 – Reference & Calibrated Device Spectra Before Calibration

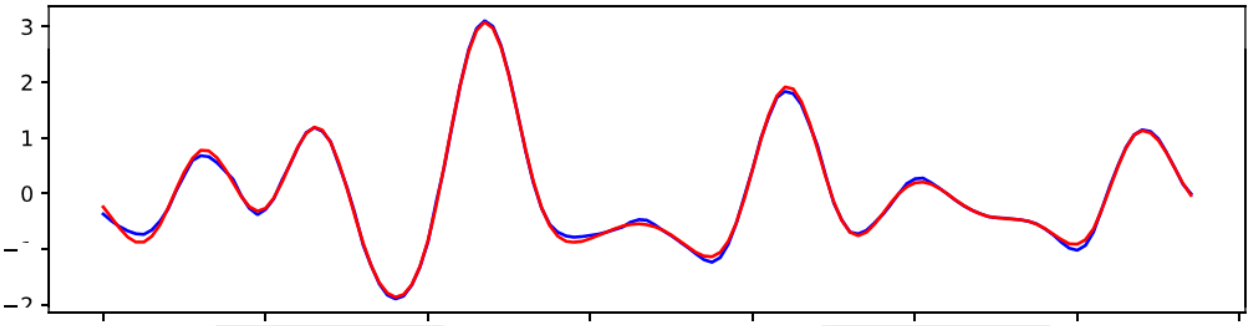


Figure 28 – Reference & Calibrated Device Spectra After Calibration

Cross-device Calibration alone is not adequate to warrant device comparability. Its' capability to match analysed sample spectra is limited by the fact that sample spectra features and WCS spectra features do not necessarily coincide along the wavelength axis. Spectral features of WCS stem from oxide molecular bonds while those of analysed samples stem from organic molecular bonds.

Theoretically, WCS could have been replaced with calibration references comprising molecules of interest. Such methods are employed for grain analyses, where grain is packed into vacuum-sealed glass containers and used to cross-calibrate between devices. Unfortunately, similar method could hardly be applied to cannabis due to difficulty to produce calibration samples which do not change over time.

GemmaCert complements Cross-device Calibration with Reference Library spectra collection by multiple GemmaCert devices. This allows GemmaCert machine learning algorithms to learn and account for potential differences between individual devices.

5.7 Verifying measurement results do not depend on device employed

GemmaCert routinely uses multiple devices at its lab, both for Reference Library collection and for Regression. Verifying accurate identification of cannabis / non-cannabis is accomplished by 12 positive and 12 negative analyses with 8 distinct devices.

5.8 Device fault isolation

GemmaCert device performs BIT on every power-on and reports BIT results to the Backend. Along with BIT results it reports any exceptions that could have occurred during operation. Exceptions are not necessarily device faults, e.g. operation attributes could have been corrupted in communications along the route between Backend and device. BIT results are accessible to Support staff through Web service BIT Results display, depicted below.

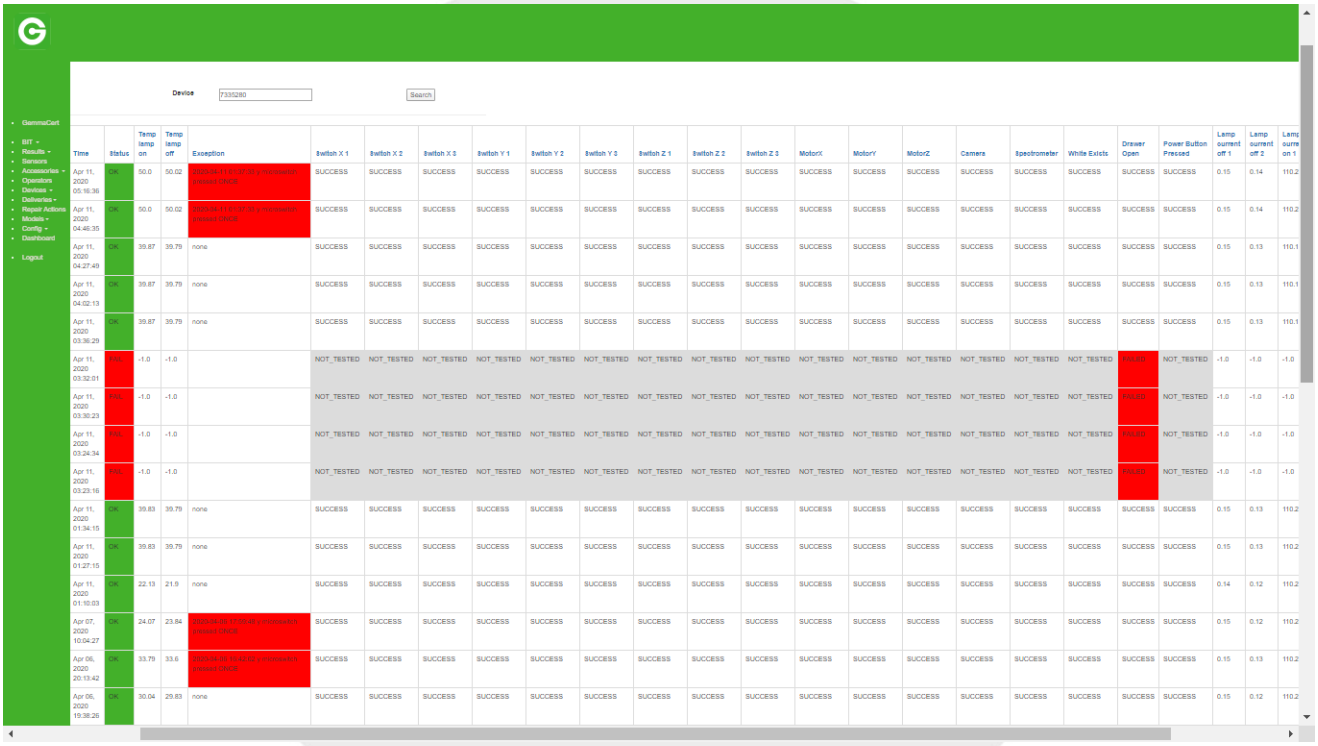


Figure 29 - BIT Results Display

Users are notified on BIT failure and advised through their GC App to contact support. Users can contact support through either GC App, Customer Portal or email to support@gemmacert.com, per their preference.

Irrespective of whether user contacts support or not, support is alerted on device faults by the automated Alerts mechanism, which produces report per figure below (operator identity erased for customer privacy).

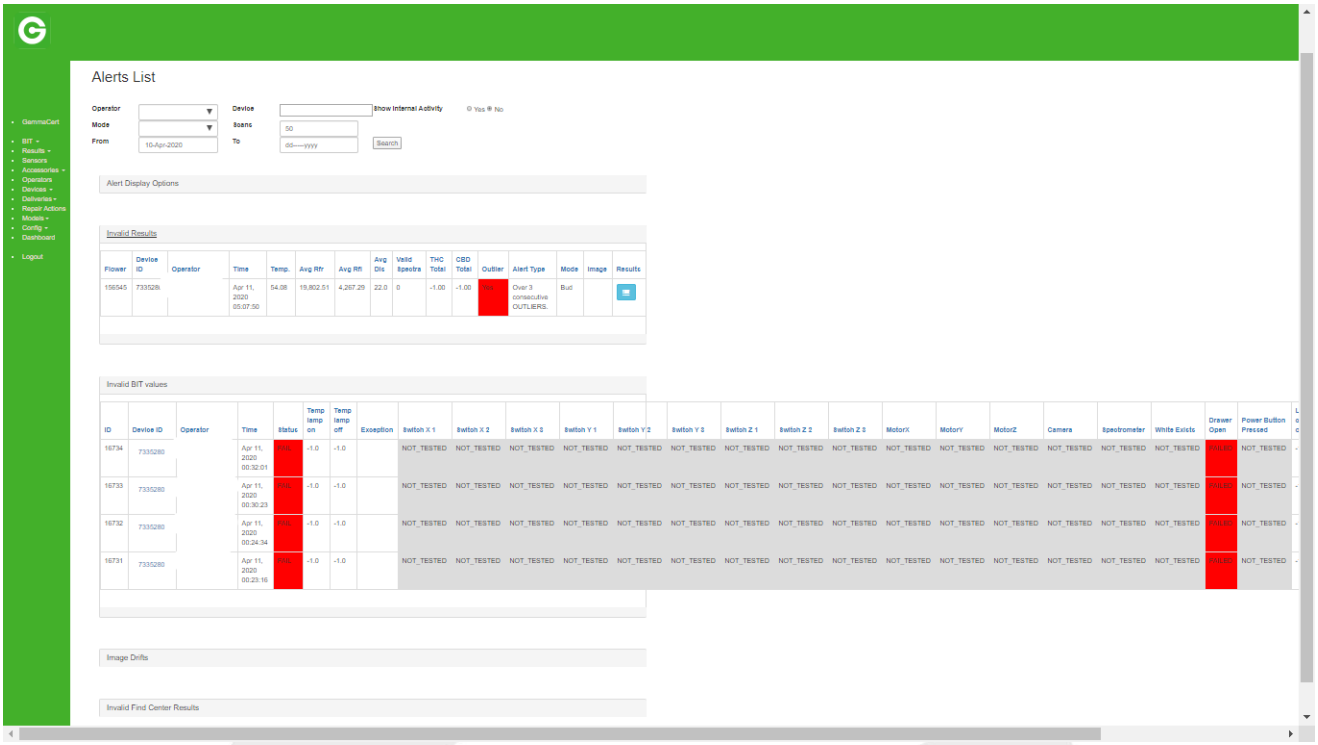


Figure 30 – Alerts Report Example

Some device fault instances may be resolved by user instruction, e.g. device not performing BIT because the sample container (a.k.a. "drawer") has been pulled out when powering the device on. Other fault instances mandate support attending the device.

At the time of compiling release 1.02 of this document support attends faulty device with user assistance. Support requests user to connect device to a PC with a USB cable and open a Remote Control session for remote access. Once connected and open, support can test all device subsystems and monitor device internals through embedded camera. GemmaCert device software supports multiple fault isolation commands: movement of any axis by any number of steps, cyclic movement, camera snapshot etc.

Requiring user assistance in fault isolation procedure could be perceived as not adequately user-friendly. GemmaCert will amend that by developing remote access into the device through the smartphone used with GC App. User will be involved at a minimum, only confirming consent to avoid any privacy violation.

6. Procedure

6.1 Sample preparation

GemmaCert analyses three types of samples:

- Flower (a.k.a. "bud")
- Ground matter
- Extract

Flower analysis requires no sample preparation. Flower is placed as is on the flower pin and inserted into the device. Consequently, flower remains unchanged through the analysis.

Ground matter analysis requires grinding unless the material has been received already ground. Grinding with a manual grinder is recommended. Grinding should achieve grain size of 0.5mm for best performance. Use of electrical grinders is not recommended, as these will break trichomes and distribute their sticky contents around. Centrifugal force will then spread trichome contents on grinder walls, effectively reducing concentrations detected by analysis.

Extract analysis requires filling extract into plastic blister supplied by GemmaCert, using a metal spatula. Blister must be full and air bubbles must be avoided. Extract viscosity varies. Some extracts are difficult to spread. To ease filling the blister such extracts may be heated prior to filling. Some extracts are closer to liquid than to paste. Such extract can be placed in refrigerator to turn them more viscous.

6.2 Measurement

Measurement workflow is identical to the workflow of spectra measurement for Reference Library, as described in "Software Functionality" above.

6.3 Analysis Process

Analysis commences with sample photo and spectra measurement by GemmaCert device. Device conveys sample photos and all measured spectra to GC App. GC App appends optional text fields describing the sample, as entered by the user, and optional photo taken with the smartphone, and forwards to Backend. None of the optional data items participate in analysis; they are there to assist users' operations accessing analyses results through Customer Portal.

Backend conducts spectra analysis as depicted in figure below.

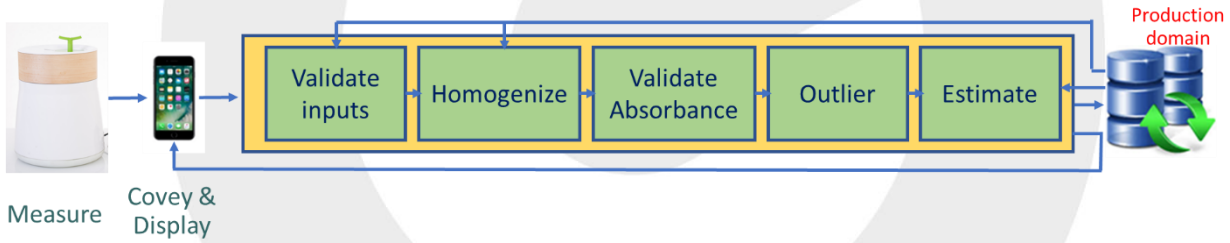


Figure 31 – User Analyses Sequence

Backend analysis of user-measured spectra begins with spectra validation, applying filters below to Reference, Dark and Reflectance spectra:

- Reference spectra filters
  - Minimum signal level
  - Noise
  - Shape (peak analysis)
- Dark spectra filters
  - Noise
  - Shape (peak analysis)
- Reflectance spectra filters
  - Minimum signal level

Reference, Dark and Reflectance spectra serve inputs to Absorbance calculation. Absorbance is calculated per standard industry formula and then homogenized applying proprietary cross-device calibration, as described in "Assuring Device Comparability" above.

Absorbance spectra are not yet suitable for chemometric model generation. Suitability of Absorbance spectra are examined applying following filters:

- Noise
- Shape (peak analysis)
- Outlier

The rationale of applying filters also to Absorbance is the possibility of Reflectance and Reference being valid, while their ratio is not.

Outlier detection (a.k.a. "Model Outlier") is implemented applying a chemometric outlier model to every Absorbance spectrum. Outlier model implements "novelty" technique, i.e. identifies whether Absorbance spectrum is within the multi-dimensional space encompassing validated fraction of the Reference Library. Outlier is therefore the means to identify whether a sample is cannabis or not.

Outlier rejection boundaries are configurable and can be tuned per application, balancing between false positive and false negative, where "false positive" refers to non-cannabis identified as cannabis and "false negative" refers to cannabis identified as non-cannabis. Outlier rejection boundaries are configured by specifying percentage of valid Absorbance spectra produced from Reference Library that would be identified as outliers.

Number of Absorbance spectra, which passed all filters above, must equal or be greater than configurable valid spectra threshold to allow estimation. This last filter avoids estimating results based on very small number of spectra, not necessarily representative of the sample. This filter is applied to Flower and Ground analysis. The filter is not applied to Extract, as extract is adequately homogeneous to disregard the possibility of non-representative spectra.

At the time of compiling release 1.0 of this document estimation provides two numerical results

- Total THC %
- Total CBD %

Both percentages above are calculated in total sample weight and represent active ingredient content when sample is consumed, i.e. fully decarboxylated.

7. Data storage

7.1 Users' spectra & results

Users' analyses data are stored AWS, under Production domain. The storage includes:

- Raw spectra as measured: Dark, Reference, Polymer & Reflectance
- Calculated data: Absorbance spectra and spectra validation scores
- Attributes with which analyses have been conducted
- Analyses results as provided to users, along with any text fields describing analyzed samples entered by users

Users can browse through their analyses results and conduct statistical analyses per batch using Customer Portal. Customer portal also allows producing and printing a sample label and exporting analyses results into Excel. Figure below depicts Customer Portal Results screen.

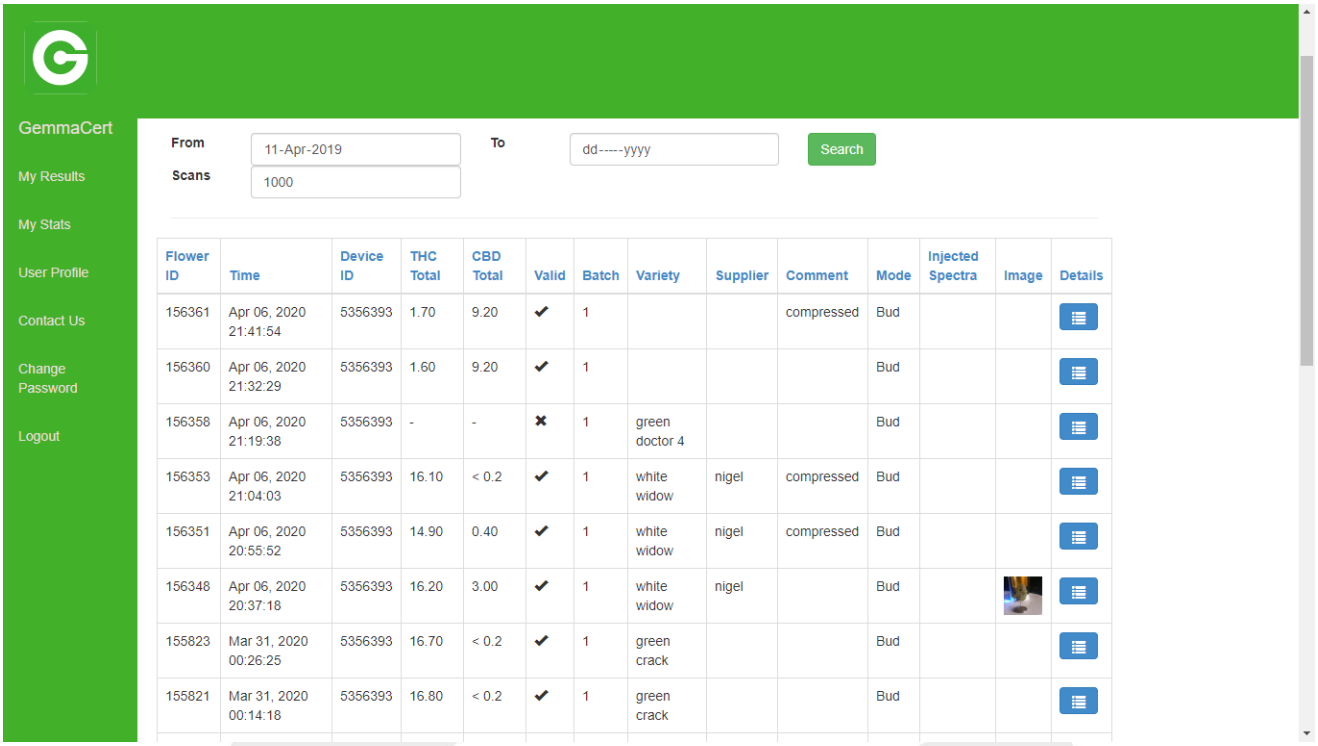


Figure 32 – Customer Portal Results Screen

User analyses data are stored by default for 1 year. Other storage periods can be configured, as required.

GemmaCert Support staff & CTO have access to user analyses data for customer support purposes.

7.2 Reference Library

Reference Library is stored at AWS under Reference domain. Reference Library comprises:

- Raw spectra as measured: Dark, Reference, Polymer & Reflectance
- Raw sample analytical: weights, moisture, HPLC outputs
- HPLC calibration data
- Calculated active ingredient contents
- Batch attributes
- Experiment attributes

Reference Library records are maintained indefinitely. Invalid records are rejected during chemometric model generation, yet not deleted.

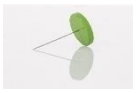
8. Appendix A – Quick Reference

GemmaCert Quick Reference Guide

1. Remove package contents and place them on a dry, stable surface. Contents comprise **body, base, reflector**, **flower pin** and **power supply**.

Package contents

Body



Base

Reflector **Flower pin**

2. Plug the round **power supply cable** into **socket** located under the body.
3. Note **Device ID** on sticker under the **base**. You will need this number for pairing (See ***Pairing GCA app with GemmaCert***).
4. Set **body** on top of **base**. Rotate **body** till tight fit.
5. Lift **sample container** by gently pulling the green handle upward.

Note: Do not use excessive force, **sample container** is not meant be to be detached from the body. When pulled-up, the container is held in place by strong magnets.

6. Slide **reflector** into **sample container**.

7. Insert **flower pin** into **sample container**.

Note: Reflector and flower pin are held in place by magnets adequate for operation, yet not for transportation. Remove them when transporting the device.

8. Drive **sample container** inwards gently pushing down the green handle.

Note: To avoid damaging the sample container do not let it fall freely.

9. Plug power supply cable into electrical outlet. The **white indicator light** on the **P button** is lit in 50 seconds and starts blinking in about 2 minutes. Blinking white indicates device ready to use (Refer to ***Getting to know your device*** below).

Getting to know your device

Before analyzing cannabis, you must initialize the device. The **P** button, located on top of the device's body, contains **blue** and **white** indicator lights which play an important role in the initialization process.

Familiarize yourself with device status indicator lights:

Light	Indicates
White steady	**Initialization in process.** 50 seconds after powering the device the P button is lit and stays lit for about 1 minute. When initialization self-test succeeds the white light starts blinking indicating readiness to pair.
White blinking 1/sec	**Ready for pairing.**
White blinking 3/sec	**Self-test failed**. Contact **GemmaCert** support (see ***Contacting GemmaCert support***), then proceed to ***Logging in to the GCA app***.
Blue steady	**Pairing complete.** Device is in **steady state.**
White & blue 1/sec alternating blinks	Calibration or analysis **in process**. Once completed returns to **Blue steady** light.

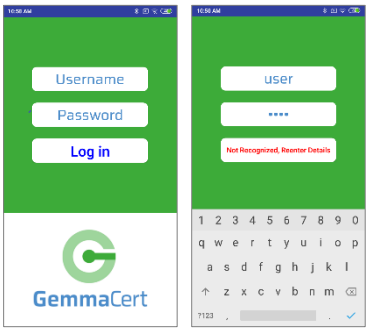
Turning the device on and off

Turn your GemmaCert on by plugging its power supply into electrical outlet. Please be advised the GemmaCert does not contain a battery. Unplugging the power supply will result in immediate shutdown.

Properly turning off your GemmaCert when not in use will prolong its life. Ensure you follow shutdown instruction for your device after use to avoid any data loss or corruption. Device shutdown is initiated by either holding the 'P' button for three consecutive seconds or pressing 'Shut down' on the drop-down menu accessed through hamburger button ☰ on the top right corner. You may safely unplug once the above steps are successfully completed.

Logging into the GCA app on your smartphone

Note: Presently Android only; iPhone app is coming soon.



1. Ensure your smartphone has Internet connection.
2. Search "GemmaCert" at GooglePlay, download and install. Browse link below if not found.
3. Open the **GCA app**. The **Login screen** is displayed.
4. Enter username and password which you received by email following your order. Upon successful login and connection with GemmaCert cloud server, the Menu screen is displayed.
5. "Not Recognized" indicates login failure. Contact Support if login fails.

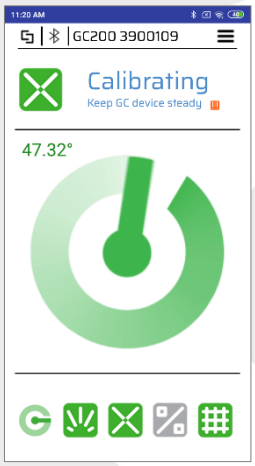
Note: Link to GCA app https://play.google.com/store/apps/details?id=com.gca.team.gcapp

Getting to know the GCA app screen

Status pane

Function in progress

Function shortcuts



Function shortcuts

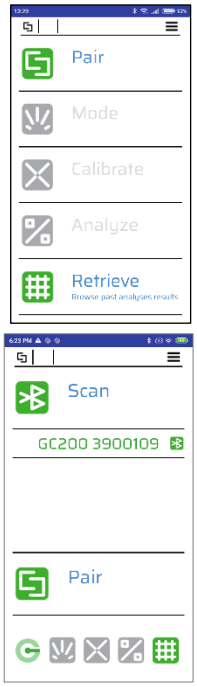
- **Home**
- **Mode** – select flower, oil or ground matter
- **Calibrate**
- **Analyze**
- **Retrieve** – display past analyses results

Pairing GCA app with GemmaCert

1. Press Pair on the GCA app Menu screen. The Pairing screen is displayed with a list of available devices.

   Note: When pairing for the first time the list is empty.

2. Select your device, scrolling as needed. You can identify your device by the **device ID** printed on stickers under the device body & base.
   Or
   If your **device ID** is not displayed on the screen, press **Scan** to detect available devices, then select your device.
3. Press **Pair**.
4. When pairing is completed:
   a. **P button** light turns to **steady blue.**



b. **Status pane** at the top of the screen displays the paired device.
c. **Mode** becomes enabled on the **Menu screen**.

Note: If pairing is not completed within 90 seconds, verify that **Bluetooth®** is enabled on your smartphone, and try again. If pairing is still not achieved, contact support (See ***Contacting GemmaCert support***).

Device software update

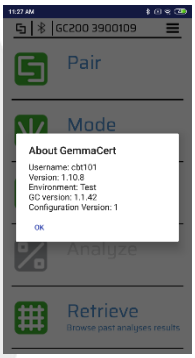
Device software up-to-date is verified on every pairing with GCA. Prompt to update is displayed upon detecting an outdated version. Three update necessity levels are indicated by distinct icons:

- Info - minor changes; update at your convenience
- Substantial - potentially affecting results accuracy, yet not mandatory
- Required - presently installed device software is no longer operable

1. Press "Yes" to confirm. Updating screen is displayed for about 30 seconds. Then device restarts; Device ID disappears from the Status pane

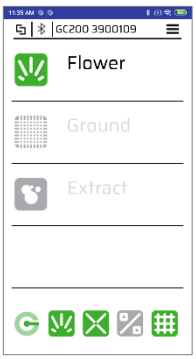
Note: Don't turn off the smartphone or the device and don't close the app, until the operation is complete.

2. Pop-up indicating update completion appears in up to 5 minutes. Device is functional and paired with the smartphone. Contact support if update fails.
3. Version info is available for your reference selecting "About" at the pull-down menu behind the top-right 3-bars icon.



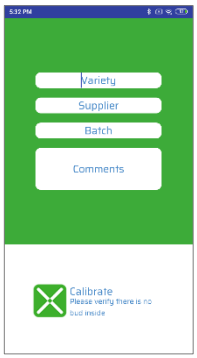
Analyzing cannabis samples

1. Press **Mode** at the **Menu screen** for **Mode selection**.
2. Press **Flower**. The **Calibrate** function on the **Menu screen** is enabled.



Note: Mode does not need to be selected before each analysis. Once selected, it applies to all subsequent analyses.

3. Press **Calibrate** at the **Menu screen**. The **Calibrate screen** is displayed, enabling you to enter optional information about:
   - Variety (Strain)
   - Supplier
   - Batch
   - Comments (Harvest date, drying protocol, etc.)



4. **Verify no flower within the device!**
5. Press **Calibrate** at screen bottom to start analysis. The white and blue lights start blinking, alternating at a rate of 1 blink per second. Calibration lasts about 1 minute. When complete, the GCA app displays Menu screen with Results key enabled, and the P button light turns to steady blue, indicating the device's Steady state.

Note: Calibration initiated shortly after powering the device comprises a warm-up period, up to 20 minutes. Temperature display indicates warm-up state; calibration commences upon reaching 47°C.

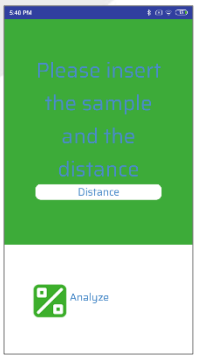
Note: Be fast - Analysis must commence within 1 minute of Calibration completion.

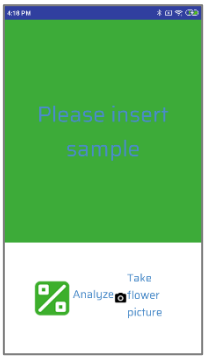
6. Pull sample container out.

Note: Do not use excessive force. The container is held in place by strong magnets and is not meant be to be detached from the body.

Note: Analyze **dried flowers only** in **room temperature only**.

7. Stick flower pin into the flower and insert the pin into sample holder or alternatively stick flower onto the flower pin while it is within sample holder; whichever way you're comfortable with.
8. Adjust flower position aligning middle of flower height with red dot close to reflector top.
9. Distance selection is displayed until software upgrade. Entering Distance is mandatory when displayed. Refer to "Distance Guidance" for details.
10. Optionally take a snapshot of the flower for your further reference at Customer Portal, by pressing the camera icon.
11. Drive sample container inwards gently using the green handle.

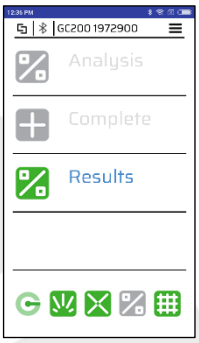


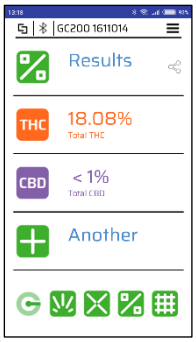


Note: To avoid damaging the sample container do not let it fall freely.

12. Press **Analyze** at screen bottom to start analysis. The white and blue lights start blinking, alternating at a rate of 1 blink per second. Analysis lasts about 2 minutes. When complete, the GCA app screen displays the Results key, and the P button light turns to steady blue, indicating device Steady state.
13. **Results** button at the display indicates analysis completion. You must retrieve the analyzed flower to view the results.
14. Pull sample container out and remove the flower.

Note: Do not apply excessive force to pull the container.

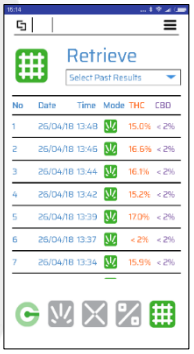




15. Press **Results** to display the sample active ingredient content. Press **Another** to start a new analysis.

Note: Remove the body from the base periodically to empty accumulated debris.

Browsing past analyses results



Browse your analyses results using either the GCA app or GC Customer Portal.

Using the GCA app press Retrieve to browse through previous analyses results. Retrieve is available also when not paired with a device.

Customer Portal allows more convenient browsing and exporting the results into Excel.

Link to Customer Portal https://prod.gemmacert.com/CustomerPortal

Contacting GemmaCert support

Use any of the means below to contact the GemmaCert support team:

- Select **Feedback** under the hamburger button at the top right corner
- Select **Feedback** at Customer Portal menu
- Email: support@gemmacert.com

Each of the means opens a support ticket is opened, enabling you to report a problem.

Safety notes

- Your **GemmaCert** is entirely safe and requires no special safety precautions other than carefully plugging the power supply cable into the electrical outlet.
- **GemmaCert** is designed for indoors use only. Cultivation greenhouses, drying rooms and processing sheds qualify as indoors in this context.
- **GemmaCert** is powered by a 6V DC, completely harmless upon contact. The device must be powered by the original power supply. Powering by non-certified power supply may have adverse safety effects.
- **GemmaCert** communicates using **Bluetooth®,** and emits no electromagnetic radiation other than the **Bluetooth®** signal.
- **GemmaCert** contains visible and near-infrared lights at intensities far below those of illumination products. These lights are encased in the device and visible only if the casing is broken or removed. Even then they are entirely safe and do not cause any damage to eyesight.
- **GemmaCert** ambient temperature ranges are:
    - Storage: -10°c to +45°c (14°F - 95°F)
    - Operating: +10°c to +35°c (50°F - 113°F)

  Note that operating at high ambient temperature the device will occasionally cool-down. The app will display a "cooling down" indication and analyses won't be available for cool-down duration.

Warnings

- Your **GemmaCert** contains delicate components. Be sure to place it on a stable, flat surface and avoid moving it abruptly. Avoid placing on vibrating surfaces; e.g. in proximity of air-condition, compressor etc.
- Do not get the device wet. For instructions on how to clean the sample holder refer to the **GC User's Guide**.
- Analyze dry flower buds only. DO NOT use GemmaCert to analyze wet flowers / live tissue.
- **GemmaCert** is powered by a standard 6V DC power adaptor equipped with a round plug. The **GemmaCert** consumes more power than a typical smartphone, and, therefore, you must use the power supply received with it. Powering with an unsuitable power supply will affect performance and could damage the device. GemmaCert may not be powered through its USB socket.
- **Flower pin** comprises a sharp needle. Please be careful when attending.
- Clean your GemmaCert thoroughly prior to international travel: Remove any trim from sample holder with a gentle paintbrush. Then empty and wipe the base.

9. Appendix B – TUV Certificate

Certificate

TÜVRheinland®

Certificate no. CU 72202850 01

License Holder:
GemmaCert LTD
6 Hamasger
Raanana
Israel

Manufacturing Plant:
GemmaCert LTD
6 Hamasger
Raanana
Israel

Test report no.: USA-SK 32083035 001 **Client Reference:** Menahem Kaplan

Tested to: UL 61010-1:2012 R4.16
CAN/CSA-C22.2 NO. 61010-1-12 + GI1 + GI2 (R2017) + A1

Certified Product: Dried Plant Matter and Extract Analyzer **License Fee - Units**

Model Desigation: GemmaCert 7

Rated Voltage: DC 6V
Rated Current: 3A
Protection Class: III

7

Appendix: 1, 1-2

Licensed Test mark:

TÜVRheinland
C US

Date of Issue (day/mo/yr)
01/10/2020

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel (203) 426-0888 Fax (203) 426-4009