



CURVE

INSTRUCTIONS FOR USE

**Intuitive Colorimeter Curve
August 2018 V2**

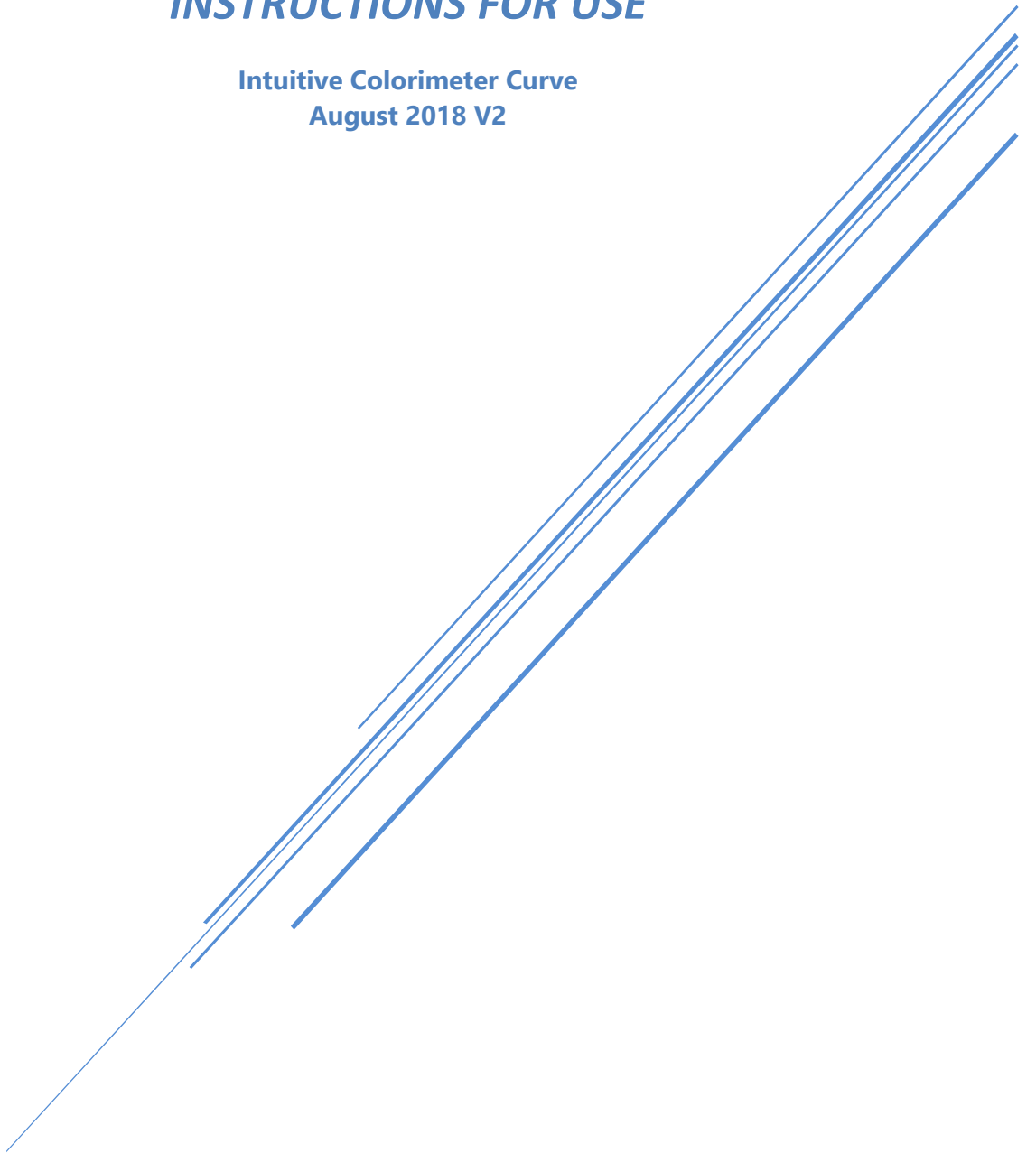


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1. Introduction

The Intuitive Colorimeter enables an ophthalmic tint to be chosen according to a patient's subjective assessment of its effects on perception and visual comfort. A particular tint can be selected rapidly and efficiently. Precision Tints can reduce visual stress and perceptual distortion.

Individuals differ with respect to the tint that they find therapeutic, and the tint needs to be precisely determined if the benefits are to be optimized.

The Colorimeter has undergone open and double-masked clinical trials. This manual describes procedures derived from 25 years' experience/research.

2. Intended use

The device is intended for patients who may benefit from the use of Precision Tinted Lenses to provide relief from the symptoms of Visual Stress.

The Colorimeter is used to provide an assessment of patient's requirements for precision tinted lenses to reduce discomfort and perceptual distortion.

The Curve allows for different values of hue, saturation and brightness to be explored. The patient views the reflected light within the device via a software-enabled LED array that provides exact values of hue, saturation and brightness to be controlled via a tablet. The patient reports responses to changing colour. These levels can then be transferred to the manufacture of precision tinted lenses that the patient can wear in spectacles.

3. Indications and contraindications

Indications

The use of the Intuitive Colorimeter is recommended for patients who suffer from visual symptoms arising from the following conditions:

- Visual Stress
- Dyslexia
- Migraine
- Visual distortion
- Movement of the printed text
- Patterns in the print
- Tiring easily whilst reading

Contraindications:

None known

4. Precautions

Patients should be informed that examination with the colorimeter entails a small risk of headache or nausea. Those with photosensitive epilepsy should be examined in the presence of someone who knows what steps to take in the event of a seizure. The risk of a seizure during colorimetry is, however, small.

We advise that the Curve is not used in environmental conditions outside the specified ranges, such as excessive temperatures (+10 - +40 degrees Celsius) or electromagnetic interference.

The mains connected component (power supply) is compliant with the relevant EMC directive 2014/30/EU

5. Warnings

- Do not look directly at the LED's
- Do not place hands inside the device
- **Only use the supplied power supply with part number 262 – 02 - 004**
- Do not place anything on top of the device
- Do not tilt the device. Adjust a chair or table for optimum viewing angle
- Only use the tablet for operating the device. Do not download any other apps or software to the tablet as this may risk infecting the tablet with malware or viruses. Cerium cannot be responsible for the performance of the software if any third-party software is installed on the Tablet, other than that which was pre-installed at delivery.
- Always check the colour from the device with Lenses from Cerium using the Lens Checking light.

6. Curve features:

Parts:

- Colorimeter with test material drawer

Replaceable parts

- Tablet with charger
- Power supply
- Headrest
- Viewport cover
- Trail lens frame
- Dust cover
- Auxiliary lens set
- Test plate



7. How to affix the tablet

The tablet can be operated while attached to the instrument (on the angled tablet mount) or can be removed and used remotely. (FIG 1) To remove the tablet, remove the charger cable from the tablet and lift the tablet directly upwards.

There are 2 gaskets on the back of the tablet which are then used to click back onto the instrument. These gaskets also provide an angle for table top use. (FIG 2)



FIG 1



FIG 2

8. How to insert test Material

The main viewing window on the front of the instrument reveals an inner surface on which visual material such as the test plate or text can be placed. The material can be mounted by pulling out the tray (FIG 3). Suitable visual material is included with the colorimeter, but practitioners may wish to use readable text as well, such as the patient's school book or the Wilkins Rate of Reading Test. *Please note that any material used must have a matte surface to prevent reflections of the LED lamps.*



FIG 3

9. Operation of tablet

The tablet used is a Lenovo Tab 4 10inch. The main on/off button is located on the top of the left side. Navigation through the tablet is found at the bottom of the screen - with a back, home and app button.

Other information such as Bluetooth, internet status, battery life, and time can be found in the top right corner.

Please note that all other applications have been locked on the tablet to ensure protection of the Curve software. Do not download any other apps or software to the tablet as this may risk infecting the tablet with malware or viruses. Cerium cannot be responsible for the performance of the software if any third-party software is installed on the Tablet, other than that which was pre-installed at delivery.

Please note that there is a 30-minute shut down set on the tablet.

10. How to charge the tablet

The instrument provides inbuilt charging capability. A built-in charging cable can be plugged into the tablet if mounted on the instrument. (FIG 4) Charging will be automatic if the instrument is turned on. An external charger will also be provided so wall charging can also be utilized.



FIG 4

11. Setting up the assessment

The Curve is designed to be placed on a table that can be adjusted in height. The patient sits at a comfortable viewing distance and looks into the instrument through the curved viewing aperture. A soft headrest is featured to provide comfort. (FIG 5) The examiner sits beside the patient, on the patient's right, operating the tablet.

The assessment is carried out in a dimly lit room.

The assessment is carried out under binocular viewing conditions unless there are indications that the optimal tint may differ in the two eyes and the patient is prepared to countenance wearing spectacles with differently coloured lenses.

The power supply is connected at the back of the instrument, via a power lead and an easy on/off switch is located just above. **NOTE:** The Colorimeter should only be connected to the electricity supply via the transformer lead supplied with the instrument.

Before using the Colorimeter, patients should undergo a full optometric examination. The optometrist should look for any binocular vision or accommodative problems. If any clinically significant anomalies are detected, they should be treated, before considering tinted lenses.



FIG 5

12. Setting up the software

The software communicates with the Curve via Bluetooth. You must ensure that Bluetooth is active in your tablet. Drag the top bar down on your tablet and click on the Bluetooth icon – active connectivity will be shown in the top right corner of the screen.

You must then pair your instrument with your curve software. Under "available devices" you will see your colorimeter listed, by the relevant serial number. Click on this and you will connect. (FIG 6)

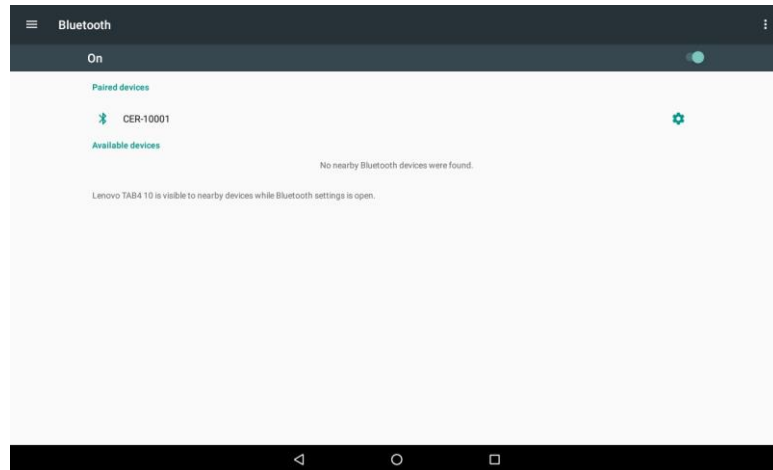


FIG 6

13. Operating the software

First, you need to create a Curve account. You will be asked to enter a username and password as well as your practice details. You will be able to enter 2 email addresses so that information can be sent separately. (FIG 7)

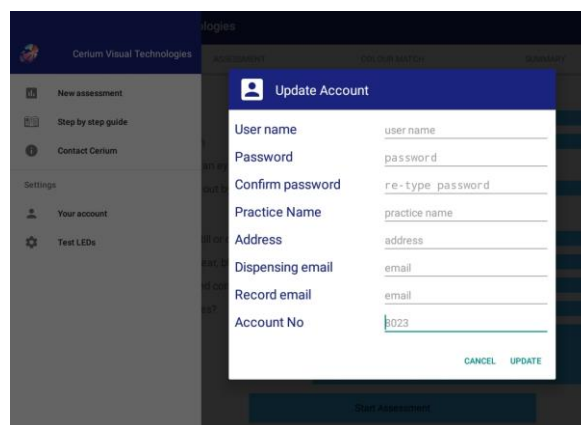



FIG 7

Details of your account can be found on the side menu bar by clicking the  icon. Your account details can also be updated here. (FIG 8)

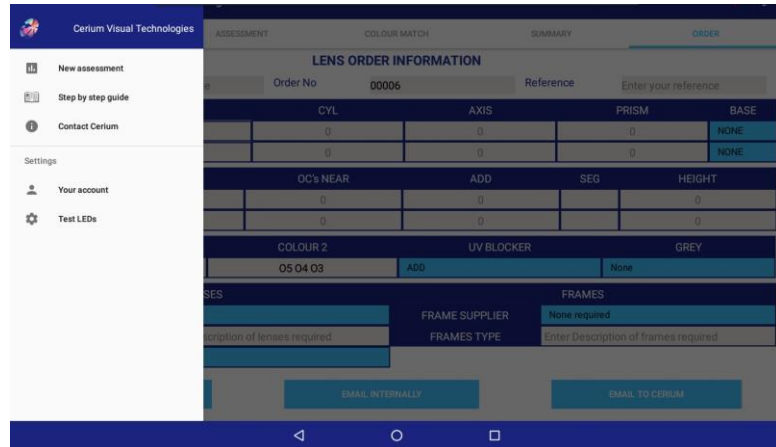


FIG 8

To start an assessment, click on New Assessment on the side menu bar.

History and Symptoms

Enter the patient name.

Obtain a description of perceptual distortions and/or visual discomfort. Ask the patient to look at the text on the test plate in the colorimeter. Make sure the patient is at a comfortable viewing distance. Ask the patient to report any perceptual distortions by asking the guided questions and note responses. You also have the option of adding other free notes. (FIG 9)

All information entered here is populated into an electronic record form.

Note: The patient must have had an eye examination in the last 12 months – this box must be ticked to proceed with the examination.

Click *Start Assessment* to begin.

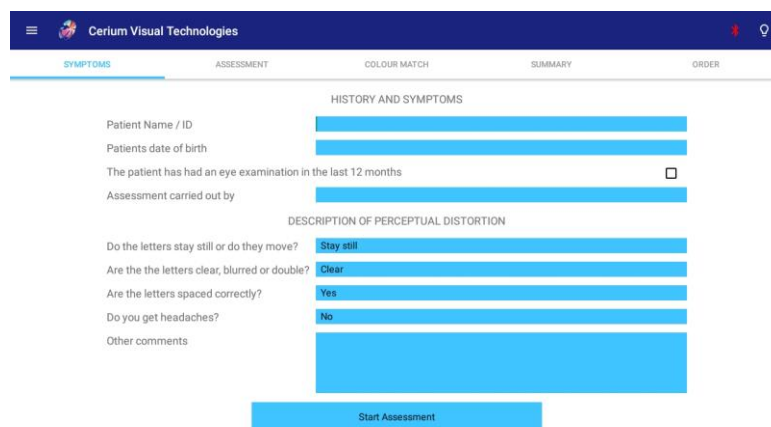


FIG 9

Assessment

Shortlist Hues

Touch a sector of the hue wheel and a colour will gradually appear. (FIG 10) Ask the patient whether their symptoms are better or worse than they were under white light. Press the appropriate 'smiley' to record their response, and then return to white by touching the center of the wheel. Compare each of the colours with white. Twelve different hues are presented in succession.

Note: The saturation is set to a default of 30 but can be altered to 20 or 40 if required.

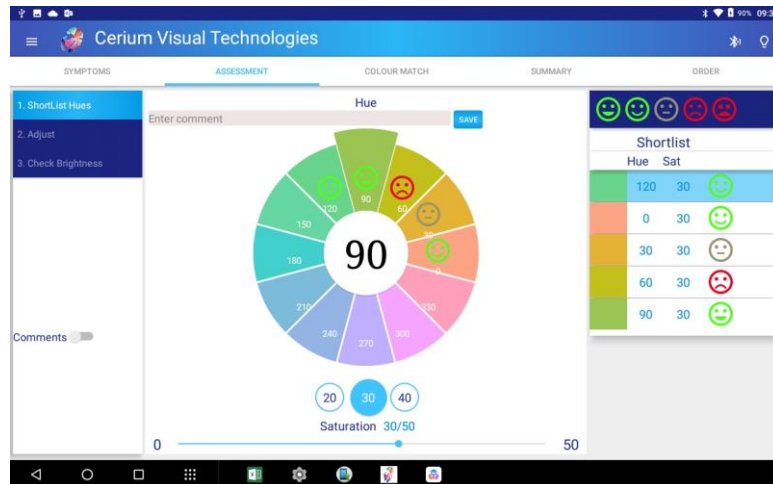


FIG 10

Note: A response "Smiley" can only be designated when the colour reaches full saturation

Note: You will not be able to offer another colour until the saturation slider returns to zero and white light is shown.

Comments can be added to each of the 12 sectors. To view the comments, click on the *Comments* switch (FIG 11)

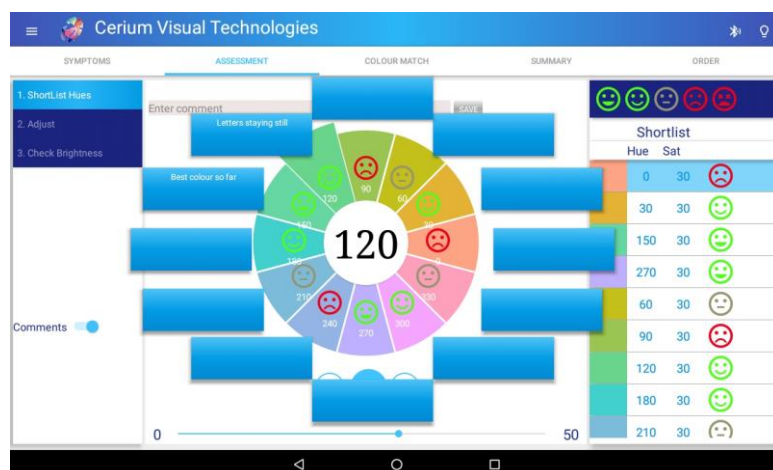


FIG 11

1. Adjust

Adjust saturation

Obtain the optimal saturation of each of the beneficial hues by sliding the saturation bar. Compare these optimised settings, two at a time, and select the best. (FIG12)

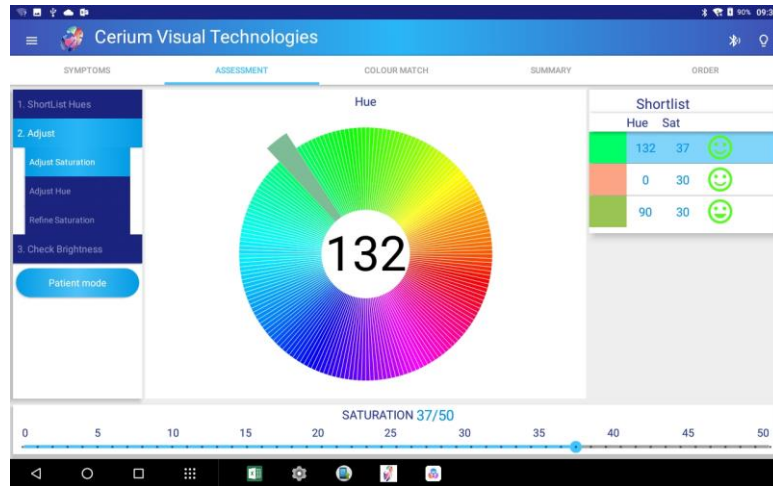


FIG 12

You can select "Patient mode" and encourage the patient to adjust the strength of colour for themselves by holding the tablet in both hands and using the thumb of the left hand to decrease saturation and the thumb of the right hand to increase it. (FIG 13)

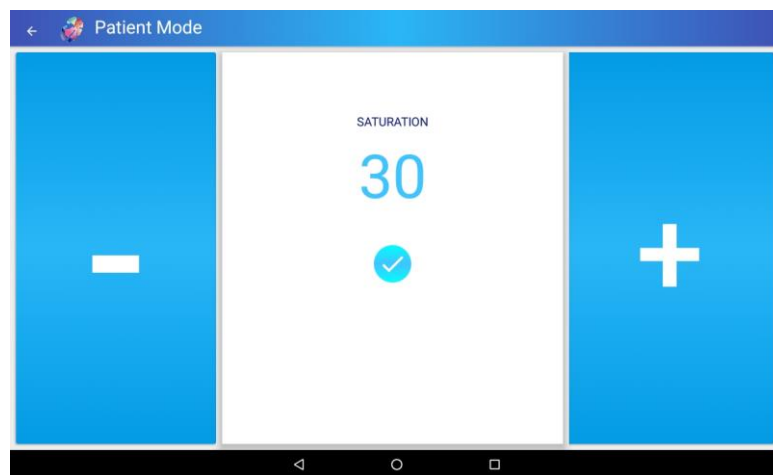


FIG 13

Adjust Hue

Having selected the best combination of hue and saturation, the best hue is adjusted by small amounts. By default, the program offers hues 20 degrees each side of the original selection, but this can be reduced by changing the step size. There are therefore three alternatives, the original hue, a hue above the original and a hue below the original, all with the original saturation. Choose which of these three alternatives the patient prefers. Compare them two at a time as before. Click the blue tick for the preferred option (FIG 14)

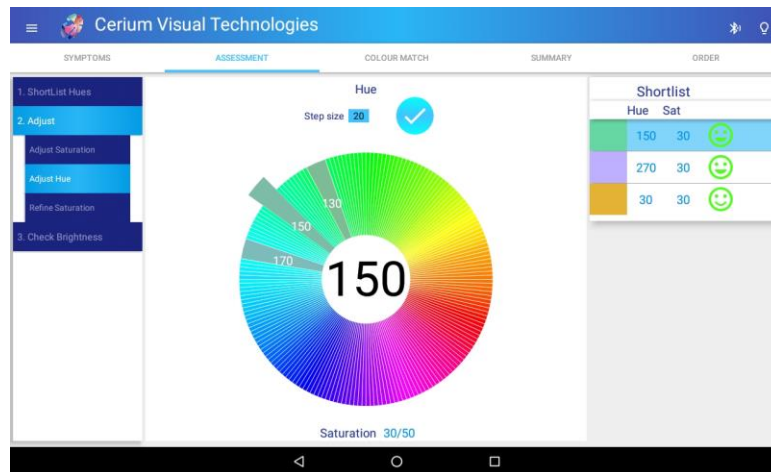


FIG 14

Refine saturation

If the patient selects a new hue, then readjust saturation at the revised hue. Repeat the steps, adjusting hue and saturation alternately, until you and your patient are satisfied that the setting is the best that can be obtained. (FIG 15)

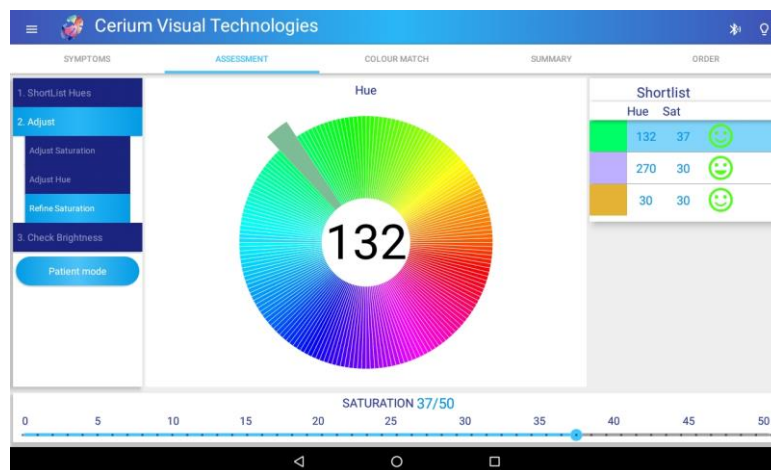


FIG 15

2. Check Brightness

Luminance is halved (by pressing the lower of the two buttons). See whether the reduction in brightness improves comfort and clarity. If it does, then go back to the previous step and increase the saturation slightly. Sometimes when the saturation is slightly increased the patient is equally tolerant of the bright and dark settings, which is desirable. (FIG 16)

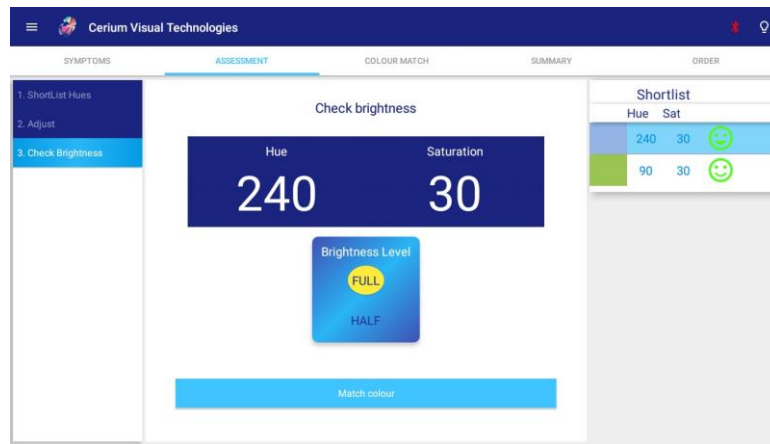


FIG 16

Colour Match

The Hue and Saturation chosen by the patient is automatically populated over to the match colour screen.

The nearest combination of trial lenses that matches the chosen hue and saturation is calculated – these are shown in your lens table, which is a graphical image of your auxiliary lens set. (FIG 17)

Other information is also shown here:

- Transmission of chosen lenses
- UV requirement
- Traffic light advice
- Alternative lenses for differing lighting conditions

NOTE: This page is locked as default, but you can unlock if you wish to adjust the HUE/SATURATION values or the lens combination by clicking the unlock button. There is also the option to revert to the original combination at any time by clicking RESET button.

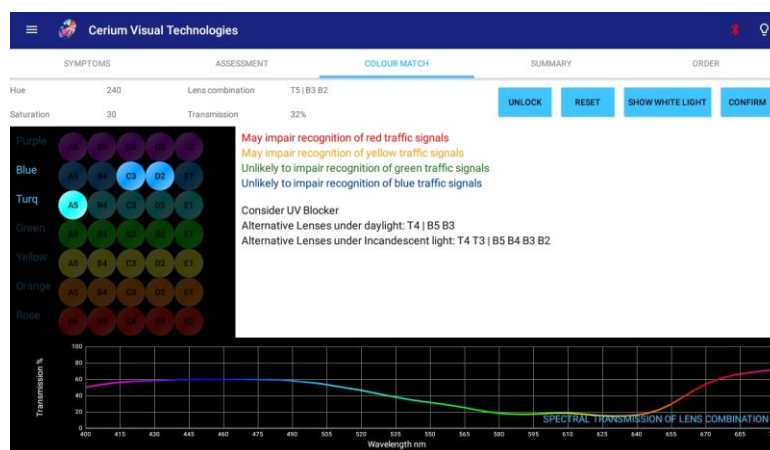


FIG 17

Mount the trial lens in the frame and offer them to the patient to wear. Select “Show white light” and ask the patient whether the text is “as clear as it was just now” (i.e. without the lenses when the coloured light was on). If it is not, adjust the lenses. Hold them over the circular white port (FIG 18), turn on the coloured light again and compare the colour of the two ports, adjusting the combination of trial lenses as necessary to obtain a match. The matching should be done in a dim room. Please see further details on page 20.

The tinting procedure uses dyes identical to those used for the trial lenses and the spectral transmission of the spectacle lenses is therefore guaranteed. Other dyes will not provide the same spectral transmission.



FIG 18

Click confirm to proceed

Summary

All information gathered through the assessment will be populated into a summary page. This can then be printed or emailed as a record of the assessment. (FIG 19). Click confirm to proceed to Order.

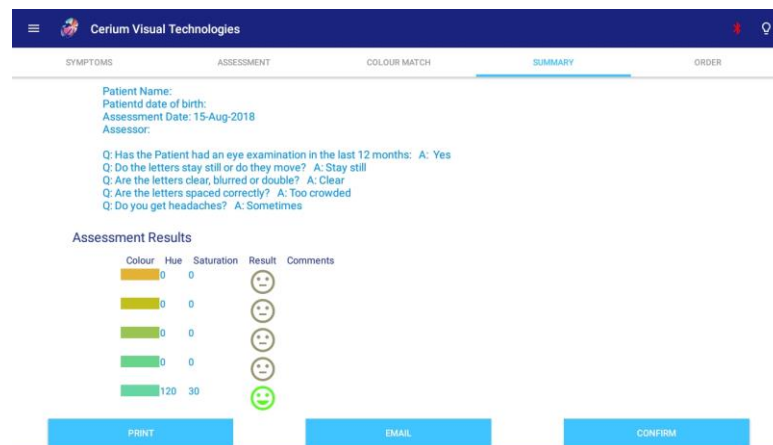


FIG 19

Order

Your practice details, patient name and colour codes will be automatically populated over to the order page. You are then able to fill in all other relevant sections. (FIG 20)

Orders can then be sent directly to Cerium, by Clicking “Email to Cerium”

OR

The form can be emailed to an internal practice email address (entered on registration) and then sent to Cerium later.

OR

The order can be printed and sent to Cerium as a hard copy.

Cerium Visual Technologies						
SYMPTOMS		ASSESSMENT		COLOUR MATCH		
SUMMARY		ORDER				
LENS ORDER INFORMATION						
Patient Name / ID		Order No		Reference		
Enter patient name		00009		Enter your reference		
		SPH	CYL	AXIS	PRISM	BASE
RIGHT		0	0	0	0	NONE
LEFT		0	0	0	0	NONE
		OC's DIST	OC's NEAR	ADD	SEG	HEIGHT
RIGHT		0	0	0		0
LEFT		0	0	0		0
		COLOUR 1	COLOUR 2	UV BLOCKER	GREY	
		B4	P6 P5 P4 P3	ADD	None	
		LENSES		FRAMES		
LENS SUPPLIER	Cerium		FRAME SUPPLIER	None required		
LENS TYPE	Enter Description of lenses required		FRAMES TYPE	Enter Description of frames required		
Uncut Lens Dia	60					
PRINT		EMAIL INTERNALLY		EMAIL TO CERUM		

FIG 20

NOTE: The software has a built-in shut down time of 10 minutes. Click on the screen and the software will re appear. This will not affect the assessment.

14. Cleaning and maintenance

Regular cleaning of the headrest between patients with an alcohol wipe is advised.

The device itself can be cleaned with mild detergents and alcohol wipes.

Please contact Cerium Visual Technologies for any maintenance or servicing.

15. Accessories and spares

- Tablet
- Headrest
- Viewport cover
- Trial lens frame
- Dustcover
- Auxiliary lens set
- Test plate

16. Troubleshooting

- Colour not showing:
 - LED, s can be tested by clicking on the Test LED option on the side bar and tapping each of the individual colour strips. (FIG 21) If any colour does not show, please contact Cerium Visual Technologies.

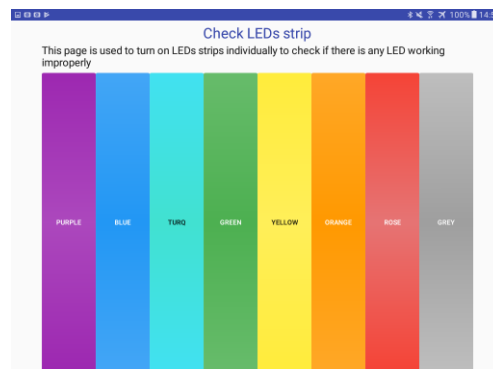







FIG 21

- Bluetooth not finding software
 - You will find a Bluetooth icon in the top right corner – in the top blue banner
 - If this is green, then you have connection
 - If this turns red when you try and action a command, then your Bluetooth connection has been lost. This is usually because the instrument is getting no power.
 - Make sure your instrument is turned on and power is getting to it (the white lens checking light will be illuminated)
 - To re - pair, click on the Bluetooth icon and a blue screen will appear. You then need to click on the relevant available device, which will be listed as your serial number (found on the back on your instrument)
 - If you continue to have problems, please contact Cerium Visual Technologies

17. Technical specifications

Model name	Intuitive Colorimeter™ Mk4
Trade name	Curve
Dimensions	Height: 523mm / 20.6 in Width: 332mm / 12.7 in (inc. tablet) 320mm / 12.6 in (ex. tablet) Depth: 536mm / 21.1 in
Requirements	Adjustable table/chair
Weight	10kgs
Light supply	LED - 4500K
Colour (Base trim only)	Royal blue Magenta Teal
Tablet	Android with 7.1 OS (minimum)
External Power supply	EMC directive 2014/30/EU
External power supply input	100-240V at 50/60HZ
Power consumption	Max: 60W

18. Symbols

Symbol	Explanation
	Conforms with the Medical Device Directive, MDD 93/42/EEC
	Manufacturer
	Part number
	Serial Number
	Consult instructions for use

19. Patent information

Patent publication number WO2017/072496

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20. Further colour match information

It is possible to match any colorimeter setting with a stack of trial lenses so that the colour appearance is closely similar, allowing for differences in brightness. This can be done using lenses from only two dyes, and the dyes are always neighbours in the circle of colours shown in (FIG 22)

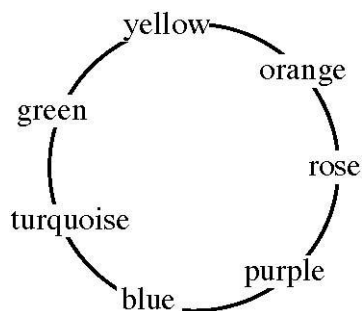


FIG 22

A yellowy green, for example, is produced by a combination of yellow and green trial lenses, and a red with a combination of rose and orange lenses. There are five pairs of lenses of each colour. The pairs are labelled by letter, starting with A for the least saturated. The deposition of dye doubles from one pair to the next; for example Trial lens B has twice as much dye as Trial lens A and half as much as trial lens C. This means that the saturation of colour can be increased by very small steps by combining the lenses, placing one lens on top of another. Table 1 shows all the possible combinations of lenses A-E in order of increasing dye deposition.

Step	Combination	Step	Combination
0	No lens	16	E
1	A	17	A+E
2	B	18	B+E
3	A+B	19	A+B+E
4	C	20	C+E
5	A+C	21	A+C+E
6	B+C	22	B+C+E
7	A+B+C	23	A+B+C+E
8	D	24	D+E
9	A+D	25	A+D+E
10	B+D	26	B+D+E
11	A+B+D	27	A+B+D+E
12	C+D	28	C+D+E
13	A+C+D	29	A+C+D+E
14	B+C+D	30	B+C+D+E
15	A+B+C+D	31	A+B+C+D+E

Table 1. Steps of increasing dye deposition achieved with combinations of trial lenses.

There are 32 steps for each colour (numbered 0-31 in Table 1), one for each combination of trial lenses. Table 1.

The tinting procedure uses dyes identical to those used for the trial lenses and the spectral transmission of the spectacle lenses is therefore guaranteed. Other dyes will not provide the same spectral transmission.



21. Contact information

For queries regarding this product, maintenance, spare parts and information contact:

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www.ceriumvistech.com



CURVE