

# MPS II Manual

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# MPS II 用戶手冊

MPS II 是一個世界領先的黃斑色素密度測量

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*by Elektron Technology UK Ltd.*

# MPS II Manual

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# 1 MPS II



[www.elektron-healthcare.com](http://www.elektron-healthcare.com)

## 1.1 介？

必須按操作說明使用 MPS II / MPS 9000。請在操作前閱讀說明。

說明手冊是正確培訓使用本設備的補充。

測試結果只能由相關合格人員進行分析。確保本設備只能由相關合格人員操作是醫療機構經理和所有者的責任。

聯絡您的銷售顧問以獲得關於現場培訓的詳情。

### 1.1.1 Elektron公司提示

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#### 1.1.1.1 版本歷史

發佈	日期	變更
1.00版本	102年6月24日	V5軟體新版本
1.11版本	102年8月3日	拼寫和語法校正, 以及一些格式變更
1.2版本	102年8月30日	? 詳情模式測試添加圖像估計訊息

### 1.1.1.2 重要警告

	<p><b>警告</b></p> <p>本設備必須與接地電源連接</p>	
	<p><b>警告</b></p> <p>本設備電子元件內有危險電壓。其中沒有任何用戶可維修零件</p>	
	<p><b>警告</b></p> <p>本設備不適合在富氧環境中使用</p>	
	<p><b>警告</b></p> <p>本設備任何時間都應保持乾燥</p>	

### 1.1.1.3 手冊和設備上所用符號的解釋

手冊和設備上所用符號的定義。



警告



閱讀手冊



WEEE指令

0

電源關閉 (0)

1

電源開？ (1)



B型應用組件



危險電壓



CE標誌



USB



防護性接地



AC主電源

#### 1.1.1.4 資料庫警告

？降低因電腦硬碟故障而造成損失的可能性，強烈建議定期備份病人記錄資料庫到USB記憶體或其他可移動存儲設備，並將其帶離現場或保存在合適的安全地點。

配置嚮導 (如下圖所示 )可設置備份區間和保存位置。



默認位置？ C:\users\登錄名\，但可設置？電腦上任何位置。

將資料庫備份拷貝帶離現場或保存在合適的防火安全地點是好的實務。

MPS II軟體使用的資料庫基於PostgreSQL資料庫程式。

資料庫結構保證每位病人在資料庫中都有獨立條目 (稱？記錄)。

病人記錄包括所有聯絡訊息以及他們完成的每個測試，並附帶風險因素訊息和所有營養補充劑推薦。

資料庫內建安保機制阻止未授權者訪問其中的資訊。

每次進行黃斑測試後，結果 (如果保存)將附在病人 記錄 卡後。

#### 1.1.1.5 聲明

Microsoft、Windows、Windows 7™和Windows 8™是微軟公司註冊商標。

Elektron技術英國有限公司通過持續改進流程來減少設備加工、運輸和使用過程中對環境和社區的負面影響。



產品或包裝上的這個標誌顯示？保護環境，本產品在到達使用期限後必須依法回收，不得於家戶垃圾一同丟棄。將電氣電子垃圾交到指定回收點進行正確回收是您的責任。分類丟棄垃圾將幫助保護自然資源並確保垃圾以保護人類健康和環境的方式回收。要獲得更多關於附近授權回收點的訊息，請聯絡您的本地政府、家戶垃圾丟棄服務者或產品銷售顧問。



## 1.2 如何使用本手冊

本手冊適用 MPS II 黃斑色素檢測機。

本手冊中所有 MPS II 或 MPS 9000，均指 MPS II 獨立單元，生產商參考號？MPS 9000 或 MPS 1000。

本手冊會提到膝上型電腦或電腦，後者指個人電腦。  
具體電腦型號無關緊要，因？軟體是相同的。

如果您有一臺有觸摸板或外接滑鼠的膝上型電腦，您需要將屏幕上的滑鼠指針移動到您想選擇的按鈕/項目上，然後點擊左鍵。

軟體升級時，最新的操作說明將隨軟體一同安裝。

可從您的銷售顧問處獲得軟體更新（如果有）。

本手冊中的屏幕截圖可能來自不同版本的軟體，所以可能於您機器上安裝的軟體畫面有些許不同。

本手冊中的訊息在出版時都是正確無誤的。  
請確保 MPS II 附帶所有材料和軟體都保存在安全地點。

### 軟體使用

軟體提供視覺提示以幫助您操作軟體和執行測試。  
屏幕控制會以不同色彩顯示以幫助您識別。



如不能使用，以灰色顯示。



如可以使用，以藍色顯示。



如果是下一步需要點擊的按鈕，以綠色顯示。

## 1.3 黃斑色素介紹

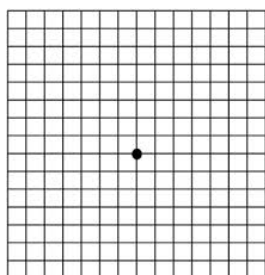
老年性黃斑部病變 (AMD) 是 50 歲以上人士導致失明最主要的原因，危險性隨年齡增長而變大。人們對這種疾病的認識、測量得病風險以及如何預防疾病的需求都在不斷增長。

隨着全球老齡化，狀況更加緊迫，預期會給健保服務帶來更大財政負擔。  
保守地說，如果每個人都能活到 100 歲，那麼我們的黃斑部都會不同程度地退化。

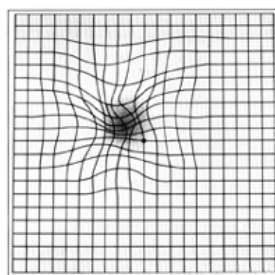
考慮到當前 AMD 無法根治，通過改進飲食、生活方式和優化黃斑色素等級（眼睛的防曬霜）來預防這種疾病變得非常重要。

黃斑部是眼睛後方視網膜上最中心和敏感的部位，黃斑色素作為抗氧化劑，保護視網膜免受藍光傷害。如果這種色素減少，那麼視網膜會變得更加脆弱，更容易逐漸退化。通過檢測低黃斑色素等級，MPS II 降低了長期失明的風險。  
患 AMD 的人視覺嚴重扭曲，很難閱讀和識別人臉。

最終狀況惡化可能導致完全失明。  
黃斑色素密度被發現與飲食和其他生活方式因素有關，包括吸菸。



正常阿姆斯勒方格表



AMD 患者阿姆斯勒方格表

經科學驗證測量黃斑色素密度的技術異色光閃爍式光度法 (HFP) 已有 30 多年的歷史。新的 MPS II 使用相同的技術，但由於 LED 照明技術進步，新設備精細化原有技術並將其置於一個更容易使用的小型機殼內。

較早期技術，MPS II 更加易於病人使用。與傳統方法中觀察者必須設置閃爍消失（或最小化）點不同，本測試包括一系列對閃爍按下按鈕的反應，使病人進行測試以及眼科職業醫師準確測定閃爍閾值和光密度變得更加容易。

訪問我們的網站以瞭解更多關於 AMD 預防、檢測和治療的最新臨床文獻和發展。

[Elektron 醫療網站](#)

## 1.4 MPS II 測試

MPS II 是用於測量病人的黃斑色素密度的電腦化設備。

目的是識別病人患上 AMD 風險。

MPS II 使用低密度光，以特定波長和校準密度，測量病人對於異色閃爍光的反應。

病人注視設備中的光刺激，被告知看到閃爍的時候按下按鈕。

目標背景亮度保持在 250cdm-2 以降低視柱細胞和短波錐細胞的感應。

MPS II 內置微處理器以控制光密度和測試程式。

？ 進行全部操作，本設備被一臺執行 Microsoft Windows 8™ 或 Windows 8™ 作業系統的電腦控制。

MPS II 使用簡單，不需要對電腦瞭解很多便可操作。

一旦安裝，您便立刻擁有對病人進行定期黃斑色素檢查的能力。

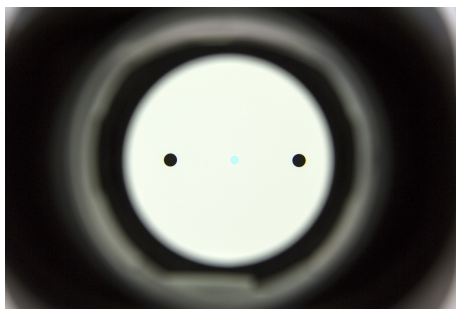
到那時，您對本設備的信心會隨？每次使用而增長。您會很快發現操作的簡單以及獲取有效和準確黃斑色素數據的容易。

軟體包含一個強大的資料庫，以存儲黃斑色素結果以及病人信息。使用這個資料庫，可生成報告來監測病人使用營養補充劑後的進度。

### 1.4.1 MPS II 目標

MPS II 目標是儀器中最重要的單元，設備中的光學元件必須保持清潔，在不使用時用防塵罩避免灰塵。

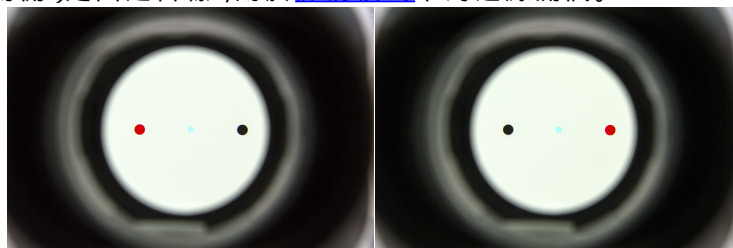
下圖顯示目鏡中的視圖 -



白色背景上有三個可見圓圈。

測試中，中心（較小）目標會發出藍綠色光，閃爍會在這裏看到。

較大的圓圈（在兩側）是固定目標，用於[詳情模式](#)下的邊緣測試。



邊緣固定目標發出紅色光。邊緣測試中，病人被指示在注視邊緣目標同時，用眼角觀察中心固定目標（在[標準模式](#)下無要求）。

病人在邊緣測試中注視正確的目標非常重要。如果兩側任何一個紅色邊緣固定目標閃爍，病人應該注視它們。如果兩側任何一個光源都沒有閃爍，病人應該直接注視中心目標。

兩種狀況下，對於中心目標閃爍的反應是相同的。

## 1.4.2 測試策略

因？黃斑色素位於視網膜中央區域，所以其他介質變化，如水晶體變黃，不會影響MP值。注意設置初始藍/綠比時應考慮病人年齡。病人年齡越大，越在右側遠離起點。

如果病人已被植入人工水晶體，眼睛可能會年輕很多，所以軟體在選擇IOL按鈕後 (病人表格)會自動設置年齡？26歲。

II首先測試病人對閃爍的敏感度。？使病人儘量進入常態，初始閃爍頻率接近30Hz。有些病人依舊在常態之外，會影響曲線形狀以及測量準確度。過高的敏感度使得曲線初始於高值(>30Hz)從而保持扁平。過低值導致曲線初始於低值(<30Hz)，從而太深(有時低於5Hz)，可能會中止執行。最適宜的敏感度發生在最低值處於20Hz和15Hz區間中。如病人因糖尿病介質變黃，誤差會更高，因？他們的介質會年長一些。

光顏色不同時，很難說它們是否有相同的密度或亮度。本設備使用？所周知的異色光閃爍式光度法(HFP)來識別兩個不同波長光的相同亮度點。

黃斑色素敏感吸收可見光譜中460nm的藍色區域，並只存在於視覺中心6度。HFP測試固定在中心，那裏的黃斑色素最多。

使用持續的白色背景，藍色和綠色光閃爍交替進行。選擇藍色光與黃斑吸收相符。

II通過以一系列不同的密度比呈現兩種光以獲得相同亮度點。閃爍頻率初始於高值，閃爍不能被察覺(目標看上去是穩定的藍綠色)，然後閃爍率以每個藍綠密度比降低至病人看到閃爍，在這時病人按下反應按鈕。

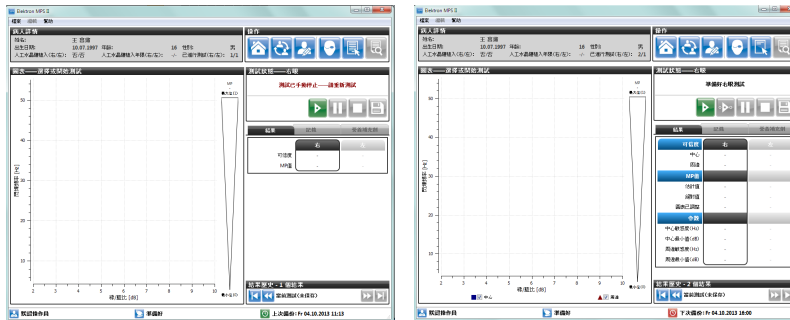
這個過程以不同的密度重複，以獲得圖像。曲線的最低值對應藍綠目標的相同亮度點。軟體以這個最低值和病人年齡計算MP值。

### 1.4.3 標準測試

MPS II軟體最新版本應用版本4中的標準模式算法。

由本儀器發明人之一開發，算法解讀篩選結果的有效性。

軟體前期版本依賴操作員主觀判斷決定結果有效性。新算法透過自動解讀結果，解除了操作員的這個責任。當然依舊保留詳情測試界面，以進行糖尿病測試、臨床研究和教學，但很多人會發現標準模式適用於大多數案例的簡單性。兩種模式以一個簡單的按鈕切換 (顯示如下) -



標準模式包含詳情模式控制的子集。

黃斑指數從病人年齡和中心測試 (不需要邊緣測試) 計算得出。

算法透過病人對測試的反應，分析圖像形狀和測試結果。有三種可能結果，清楚顯示以下圖像 (接受，慎重和拒絕) - 檢視 [附件 3 - 置信區間](#)。

在大多數個案中，結果會被接受。在一些例子中，結果不被接受 (程式會確保這些結果不能以有效值保存)。標準模式算法產生較低但可接受的結果時，最終決定由操作員作出。

#### 1.4.4 詳情測試模式

[標準模式](#)不適合的病人，如糖尿病病人，可適用詳情模式。

本測試進行兩項測量。第一項測量中，病人直視目標刺激（用黃斑中心區域），和標準測試一樣，目標發出的光穿過它們的黃斑色素。

在測試的第二階段，病人注視刺激光兩側8度的邊緣（這樣他們以黃斑色素不存在的區域接受刺激）。

病人像先前一樣對閃爍刺激進行反應。測試結束後，中心和邊緣結果被用來確定病人的黃斑色素密度。

方法是計算被中心和邊緣區域吸收的藍光比。  
密度越高，藍光吸收越多。

### 1.4.5 術語解釋

取決於您運行的是哪一個測試MPS II軟件可提供三種可能的結果。

標準測試會給出年齡估計。

詳細模式測試會給出一？年齡估計，一個絕對結果和操作員控制下的調整後的圖形結果。  
這三個術語解釋如下：

#### MP-估值

這意味著已經使用患者的年齡估計部分的測試。病人的MP水平已經從他們的中心測試及估計周邊測試結果中計算出來。它不是一個絕對測量。

#### MP-絕對

這是一個完整的測量，兩個部分都是由患者進行的測試，是一？完整的測量，沒有估計。對於那些不能使用他們的年齡來估計周邊測試結果的眼疾患者或糖尿病病人這個測試是必要的（特別是糖尿病患者有不同的年齡相關結果）。

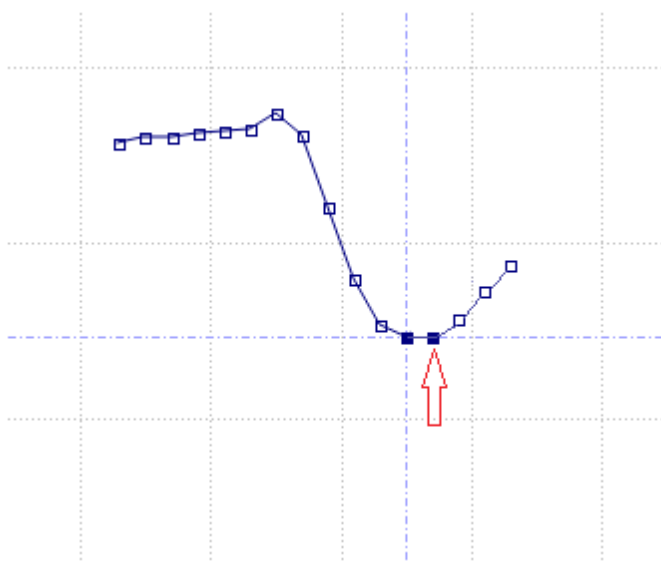
要計算絕對測量我們需要做一個中心測試（病人直接注視目標點）然後再做一個周邊測試（病人注視固定的紅點）。通過比較這兩個結果，我們可以找出病人的MP水平。

#### MP-圖形調整

這是通過移動圖形上的最低點來改變詳細測試結果的絕對值。

例如，如果病人的中心試驗曲線看起來像下面的圖片，該軟件將選擇右手點為最小值（箭頭所示），但你可以看到，在Y軸上有兩個點的位置完全相同。操作員可以移動到另一點，看它對MP水平結果有什麼影響。（在本例中，這個變化將是最小的）。

這個新的MP值與計算結果被一起記錄在數據庫中作為調整值因為操作者已經改變了該軟件最初計算結果。





## 2 安裝

MPS II被設計使用標準USB線 (已提供)與膝上型電腦或個人電腦連接。

不推薦擴展已提供的連接線，因為個人/膝上型電腦與MPS II的通訊可能因此變得不可靠。

連接說明請查看快速上手指南或[附件 1](#)。

軟體安裝說明請查看快速上手指南或[附件 2](#)。

完整軟體合約詳情請查看[附件 8](#)中的使用者授權合約 (EULA)。

(本合約與安裝軟體時同意的合約相同。)

**注意在安裝MPS II軟體和驅動程式之前請不要將USB線插入您的電腦。**

軟體安裝完成執行後，會在屏幕下方顯示設備連接狀態、當前操作員名字 (本例中為AC)，以及下次預訂備份日期。



可將MPS II置於任何穩定平面或電子桌上。

避免設備搖晃或傾倒，並確保設備後方通風。

確保設備的任何部分不會超過MPS II放置平面邊緣過多。

確保設備前面留足夠的空間給病人舒服得坐下。

MPS II內置電源。電源通用，不需要依不同電壓而調整。但需要確認使用正確的保險絲 (見[附件 1](#)或設備背部的標籤)。

病人反應按鈕與設備背部相連，必須保證病人可以拿到。設備開關在背部面板。

### 3 測試模式最好實務

兩種測試中，不管是標準還是詳情模式，告知病人會發生什麼從而正確進行測試非常重要。

下面是優化測試的一些貼士和技巧。

- 將全光圈 (或降低光圈) 測試鏡片置於機器最前方讀數？Rx的插槽。如果沒有，使用病人的眼鏡 (近SV，漸進鏡，雙光眼鏡) 或隱形眼鏡 (遠距Rx鏡片、多焦鏡片或單視矯正近距鏡片)，但不要使用有色眼鏡。

- 用眼罩擋住沒有進行測試的眼睛。在中介或暗視光操作。測試右眼，然後左眼，只進行中心測試 (如標準模式)，然後保存結果。

- 告知病人測試需要集中精神，但需要鼓勵他們正常眨眼。當看到中心點閃爍，手指要像“上了弦的箭”，速度是關鍵。

- 在正式測試前有簡短的熟悉性測試以檢查他們對於閃爍的反應。  
這個測試設置初始藍/綠比，在圖像上以方塊顯示。測試大約30秒。  
只有在反應非常不一致的狀況下，才會出現錯誤訊息“範圍過大”以及“重新開始”。  
結束後，中心點會暫時變黑。病人必須繼續注視 (不要讓病人的頭移開)，因？正式測試會在屏幕亮起後立刻進行。  
閃爍的中心光可能會有些漂白和/或殘影。告訴病人這是因？他一直注視的結果，就好像“注視太陽”。

- 注視屏幕，如果發現病人按下按鈕過快，或者在反應之間沒有集中精神，中止測試並提示病人有關測試說明，或者重新開始測試，或過後重複測試。強調持續的交流任何時候都不過。用如“你做的很好”，“尋找閃爍”和“快完成了”等話語鼓勵病人，因？沉默會使病人懷疑他們是否準確進行測試。

取決於MP，一般來說這個測試需要大約60秒完成。HFP測試的可重複性已有研究，成績修正被用來降低標準偏差 (SD)。但是在只有中心測試的標準模式下，重複測試中的任何“噪聲”都已最小化，所以不同測試的可比性很大。

- 只有在同時存在其他病理 (糖尿病黃斑部病變、AMD) 的狀況下進行中心和邊緣測試 (如詳情模式)。

首先進行中心測試。然後告知病人他們必須注視邊緣目標上方 (右眼注視左側目標，反之亦然)，然後用他們的餘光觀察中心藍色閃爍目標。他們可能想注視中心目標，但您必須告知他們抗拒誘惑。

如果他們直視中心閃爍目標，那麼結果無效，因？他們做的只是又一次中心測試。進行到一半，中止測試，告知他們需要注視紅色目標下方。同樣地，他們只有在看到閃爍後才能按下按鈕。

這會避免閃爍目標因？托私勒現象而消失。按下按鈕後眨眼也可以達到相同效果。

## 4 選擇病人

開？程式等待主菜單屏幕出現 -



您有兩個選擇 :-



測試新病人

如果病人從未進行過測試，您需要在資料庫中[創建新病人](#)。



測試/檢視已有病人

如果您以前對該病人進行過測試，那麼點擊[測試已有病人](#)按鈕從資料庫中選擇他的記錄。

## 4.1 創建新病人

如果病人從未使用本設備進行過測試，那麼他們不會出現在資料庫中。  
選擇測試新病人按鈕。



測試新病人

病人條目屏幕會顯示。  
必須錄入的項目以紅色高亮顯示。

The screenshot shows the 'Elektron MPS II' software window. The main title bar is 'Elektron MPS II'. Below it, there's a menu bar with '檔案', '編輯', and '幫助'. The main content area is titled '添加新病人' (Add New Patient) and has a subtitle '輸入個人資料並選擇測試圖案以進入檢測畫面'. There are four tabs: '個人資料' (Personal Information), '風險因素' (Risk Factors), '記錄' (Records), and '營養補充劑' (Nutritional Supplements). The '個人資料' tab is active. It contains several sections: '名字和出生日期' (Name and Date of Birth) with fields for '稱呼' (Title), '名' (Name), '姓' (Surname), '出生日期' (Date of Birth), and '性別' (Gender). The '出生日期' field is highlighted in red. Below this is '病史詳情' (Medical History Details) with fields for '人工水晶體' (Artificial Intraocular Lens) and '糖尿病' (Diabetes). The '糖尿病' field is highlighted in red. At the bottom is '聯絡資訊詳情' (Contact Information Details) with fields for '國家' (Country), '省' (Province), '地址' (Address), '電話' (Phone), and '電子郵件' (Email). The '電話' field is highlighted in red. The status bar at the bottom shows 'Default Operator', '準備好' (Ready), and '下次備份: Fr 04.10.2013 16:00'.

您必須至少填寫病人的姓、名、出生日期和性別以建立新記錄。  
選擇稱呼同樣會設置性別，例如選擇先生會設置性別？男。

您可以從截圖中看到年齡顯示無效。這是因？病人年齡小於1歲。

其他字段可以？空，如果需要可以以後填寫。

錄入所有必需的病人詳情後，測試按鈕會以綠色高亮顯示。



此時您也可以點擊風險因素選項卡錄入病人的其他相關風險因素。

從而給您機會與新病人討論風險因素。

其他選項卡包括記錄和營養補充劑。記錄讓您錄入詳情如病人使用的屈光矯正 (如他們是否佩戴眼鏡), 但一般可以在測試後填寫。

按下綠色測試按鈕創建記錄  然後直接進入測試屏幕, 或者

按下首頁按鈕以放棄所有已作變更並回到首頁。  
(您會被問及是否想放棄記錄)



也可以保存變更而不對病人進行測試。



## 4.2 選擇已有病人

如果在資料庫中有病人以往測試，選擇測試已有病人按鈕。

資料庫列表按姓氏字母順序顯示所有病人。



測試/檢視已有病人

在搜索框內鍵入名字以查找特定病人 - 當您開始在搜索框鍵入姓氏的時候，程式會自動清理以顯示匹配記錄。

The screenshot shows the Elektron MPS II software interface. The top section, '已選病人' (Selected Patient), displays details for a patient named 王 喜蒲 (Wang Xipu), including address, age, birth date, and gender. Below this is the '搜索病人' (Search Patient) section, which contains a search table. The table has columns for name, gender, birth date, test status, patient ID, and address. The table lists several patients, with 王 喜蒲 (Wang Xipu) highlighted. The bottom status bar shows '默認操作員' (Default Operator), '準備好' (Ready), and '上次備份: Fr 04.10.2013 11:13' (Last backup: Fr 04.10.2013 11:13).

名	性	出生日期	測試(右/左)	病人ID	地址
草	少雨	13.10.1988	1/1		610022 四川 成都 5号楼原 售楼中心
王	喜蒲	10.07.1997	1/1	43543...	610023 四川 成都 太平 13-15 园路
石	富	05.07.2004	1/1	67867...	60034 四川 成都 大石路 青白江
廚師	根	04.08.2005	1/1	66767...	639089 四川 成都 金牛路 郫縣
張	永恆	08.05.1954	1/1	67676	四川 成都 173号 溫江

找到病人後，點擊姓名以選擇。  
然後您可以：



測試病人



在資料庫編輯這位病人的詳情



檢視這位病人以往測試結果



或者如果發現資料庫中沒有該病人,您可以點擊添加新病人按鈕 (而不需要回到主菜單重新開始) 添加病人到資料庫。



或者取消回並到主菜單

## 5 標準測試模式

標準測試模式只進行中心測試 (透過病人的黃斑色素) 並用年齡估計他們的邊緣測試結果。

中心測試結果和透過年齡估計的邊緣測試結果會被用來生成MPOD值。

本測試可以可靠且可重複的適用大部分人, 只要他們沒有過往病理 (糖尿病黃斑部病變、AMD)。

在這些狀況下需要進行[詳情模式測試](#)。

測試詳情[如下](#)

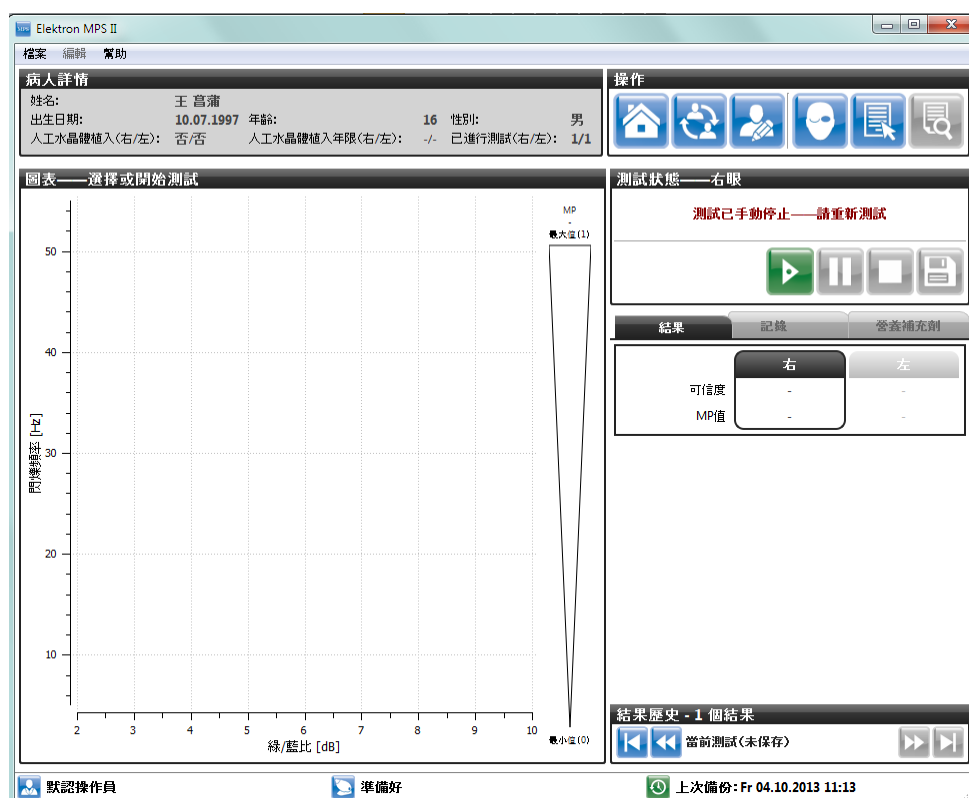


## 5.1 標準測試 – 總結

- 開？程式 (通常從桌面圖標)
- 選擇[新病人](#) - 錄入信息到病人表格  
或者[已有病人](#) - 在資料庫中找到他們
- 點擊測試圖標
- 默認首先進行右眼測試, 擋住病人的另一隻眼
- [告知病人](#)會發生什麼以及如何進行測試
- 開始測試
- 在測試中給病人以反饋
- 測試結束後確認軟體已接受該眼測試結果
- 擋住病人已測試過的一隻眼, 按下換眼按鈕測試另一隻眼
- 兩眼測試後, 與病人審查結果

## 5.2 標準測試 – 序列

測試屏幕顯示如下，默認選擇右眼。  
測試屏幕用來記錄新數據以及檢視先前記錄。



如果您希望首先測試左眼，點擊換眼按鈕。



確認病人舒服地坐下並用眼罩遮住沒有測試的一隻眼。

將反應按鈕交給他們，讓他們注視儀器內，調整角度以便在注視目鏡時舒服地按下按鈕。

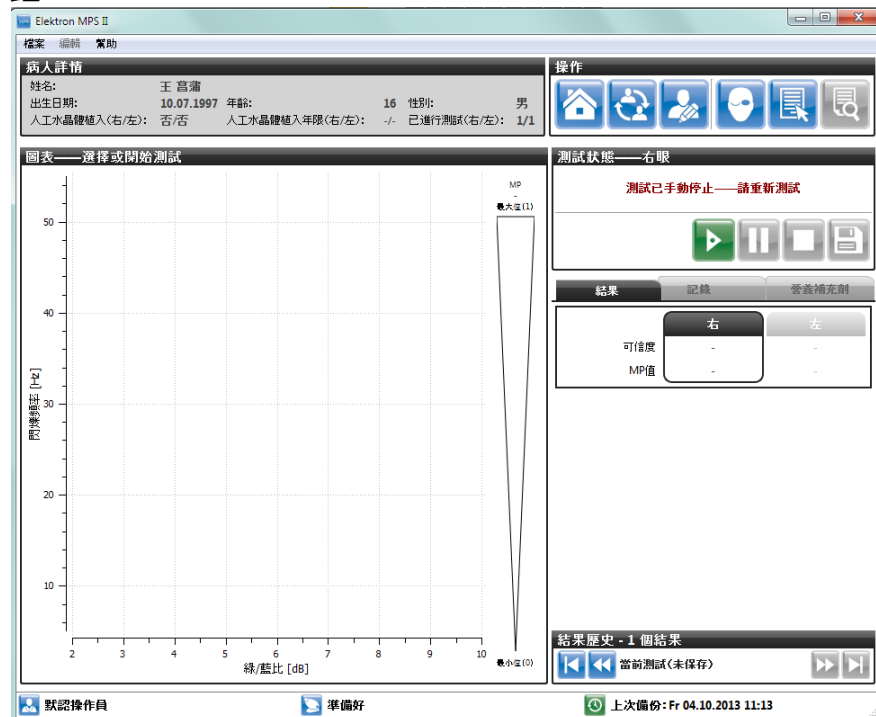
以下是給病人的說明 -

請在目鏡中尋找三個目標圓圈。  
注視中心圓圈 (只注意光線，不需要其他)。  
中心目標會亮起藍-綠光，然後開始閃爍。  
當您看到目標開始閃爍後按下並釋放按鈕。  
建議按下按鈕後眨眼。  
測試會從新設定並重複五、六次。  
中心目標會暗下來，變換成略微不同的顏色，保持注視。  
同樣地，目標會開始閃爍，像先前一樣按下並釋放反應按鈕。  
測試大概需要一到兩分鐘的時間。

屏幕顯示軟體已準備好進行右眼測試。

軟體會以綠色高亮顯示指導您該按下哪些按鈕。

如下屏幕截圖顯示我們已經準備開始測試因？開始測試按鈕是屏幕上唯一的綠色按鈕



在病人準備好後按下開始測試按鈕。

測試的第一階段檢查病人對閃爍的反應並在屏幕上記錄。

本階段記錄一組五個結果。

注意如果初始分佈太高，可能會有五個以上的結果。如果病人反應過快或過慢，測試不會繼續。

如果病人閃爍閾值可以接受，測試階段會進行。

這時中心目標暗下並重新設置？略微不同的顏色。

重要的是病人不會認？測試已完成而停止注視目標。

屏幕圖像隨？測試進行從左至右以藍色方塊標記病人反應。

注意第一個中心測試點不會使用或顯示在圖像中。圖像會從第二個點開始。

最適合的曲線會依這些點畫出。

注意：您可以在測試中透過測試狀態框中的控制中止並重新開始測試或完全停止測試。



重新開始、中止和停止

測試進行中，給病人反饋和鼓勵。

完美狀況下，病人測試結果可以生成一條有清晰最小值定義的下行曲線。  
標準模式分析這條曲線的形狀並測試結果。  
測試結果由曲線最小值和依病人年齡作出的邊緣估計值計算得出。

測試完成後可告知病人放鬆。

軟體會分析測試，置信度在屏幕上會以不同色彩顯示。

三個不同的結果是

接受



慎重



拒絕



接受顯示數據已被接受，軟體可以確定最低值。

慎重顯示軟體可以確定最低值，但對數據的清晰度不夠滿意 – 建議重新測試。


拒絕顯示數據無法生成結果，必須重新測試。


(更多詳情見附件3 [置信區間](#))

結果會顯示在屏幕右側的結果框。



如果需要測試另一隻眼 (我們建議初次檢查時測試)，那麼按下換眼按鈕，用眼罩遮住已測試過的眼並？另一隻眼測試設定設備。

測試完成後，保存按鈕會可用。 

這時，按下保存按鈕保存數據 (只測試過一隻眼) 或按下換眼按鈕測試另一隻眼。 

也可以從新測試當前測試中的一隻眼。 

按下生成報告按鈕可以生成PDF格式的病人測試結果以列印。 

您會被提示保存檔案，然後會以您默認的PDF檢視器顯示。

兩眼測試後如果選擇保存，那麼兩個結果會同時保存，不需要分別保存它們。如果只測試一隻眼，結果可以分別保存。

如果沒有保存便按下首頁 ，編輯病人  人或切換病人按鈕， 您會被提示尚未保存並問及是否希望保存或放棄測試。

注意一旦保存，結果便不可刪除。



### 5.3 病人說明

請在目鏡中尋找三個目標圓圈。  
注視中心圓圈 (只注意光線, 不需要其他)。  
中心目標會亮起藍-綠光, 然後開始閃爍。  
當您看到目標開始閃爍後按下並釋放按鈕。  
建議按下按鈕後眨眼。  
測試會從新設定並重複五、六次。  
中心目標會暗下來, 變換成略微不同的顏色, 保持注視。  
同樣地, 目標會開始閃爍, 像先前一樣按下並釋放反應按鈕。  
測試大概需要一到兩分鐘的時間。

## 6 詳情測試模式

病人已有病理如糖尿病黃斑部病變狀況下適用詳情模式, 可在進行中心測試 (透過病人的黃斑色素) 後進行邊緣測試。邊緣測試中病人注視黃斑色素區以外的一點, 並從 眼角 觀察閃爍目標。

中心和邊緣測試結果用來生成MPOD值。

該測試可靠並可重複的適用大部分人, 但是很多病人在進行邊緣測試前需要練習。

如果病人沒有其他已有病理 (糖尿病黃斑部病變、AMD), 那麼可適用[標準測試](#)。

詳情[如下](#)

## 6.1 詳細的測試 -總結

- 開？程式 (通常從桌面圖標)
- 選擇[新病人](#) - 錄入信息到病人表格  
或者[已有病人](#) - 在資料庫中找到他們
- 點擊測試圖標
- 默認首先進行右眼測試 ,擋住病人的另一隻眼
- [告知病人](#)會發生什麼以及如何進行測試
- 開始測試
- 審查結果 ,然後進行邊緣測試
- 審查邊緣測試結果 ,擋住病人已測試過的一隻眼 ,測試另一隻眼
- 兩眼測試後 ,與病人審查結果

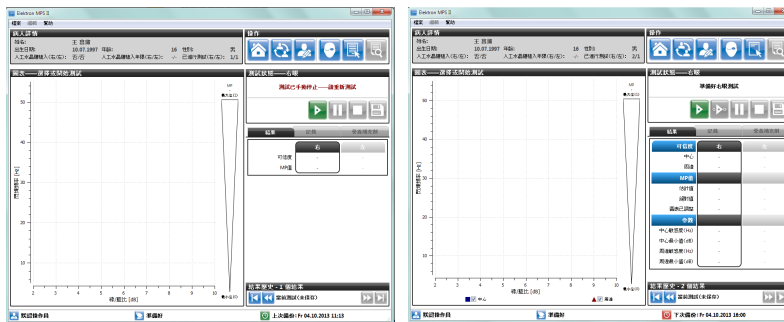
## 6.2 詳情測試 - 序列

如何選擇病人請見標準模式章節([標準測試](#))

按下測試病人按鈕進入測試屏幕。



按下切換到詳情模式按鈕從標準模式 (左) 變更到詳情模式 (右)。



顯示測試屏幕，默認選擇右眼。

測試屏幕用來記錄新數據和檢視以往記錄。

按下換眼按鈕換左眼



確認病人舒服地坐下並用眼罩遮住沒有測試的一隻眼。

以下是給病人的說明 -

*請在目標中尋找三個目標圓圈。*

*注視中心圓圈 (只注意光線, 不需要其他)。*

*中心目標會亮起藍-綠光, 然後開始閃爍。*

*當您看到目標開始閃爍後按下並釋放按鈕。*

*建議按下按鈕後眨眼。*

*測試會從新設定並重複五、六次。*


*中心目標會暗下來, 變換成略微不同的顏色, 保持注視。*

*同樣地, 目標會開始閃爍, 像先前一樣按下並釋放反應按鈕。*

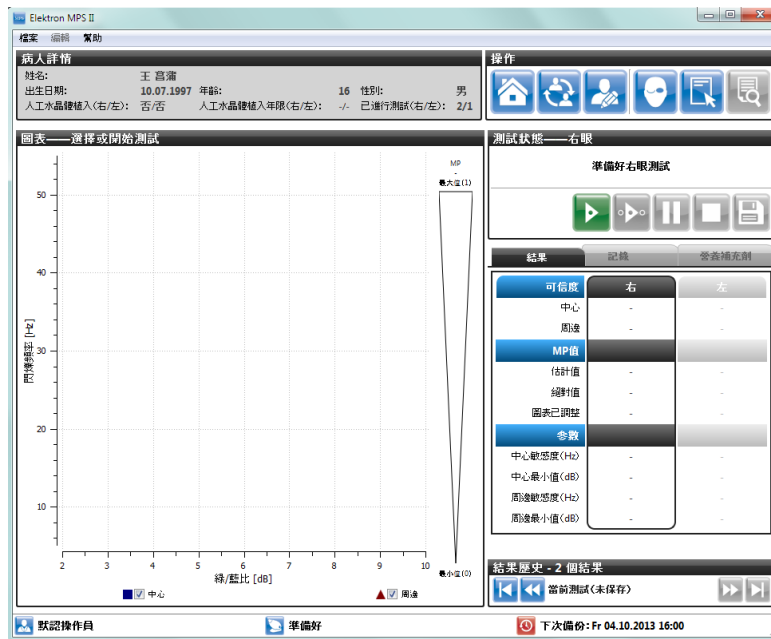
*測試大概需要一到兩分鐘的時間。*

屏幕顯示軟體已準備好進行右眼測試。

軟體會以綠色高亮顯示指導您該按下哪些按鈕。

如下屏幕截圖顯示我們已經準備開始測試因？開始測試按鈕  是屏幕上唯一的綠色按鈕





如果病人首次使用儀器，最好給他們一些練習。(進行測試但不保存結果  
當病人準備好後按下開始測試按鈕。

測試的第一階段檢查病人對閃爍的反應並在屏幕上記錄。

本階段記錄一組五個結果。

注意如果初始分佈太高，可能會有五個以上的結果。如果病人反應過快或過慢，測試不會繼續。

如果病人閃爍閾值可以接受，測試階段會進行。

這時中心目標暗下並重新設置？略微不同的顏色。

重要的是病人不會認？測試已完成而停止注視目標。

屏幕圖像隨？測試進行從左至右以藍色方塊標記病人反應。

注意第一個中心測試點不會使用或顯示在圖像中。圖像會從第二個點開始。

‘最適合’的曲線會依這些點畫出。

注意：您可以在測試中透過測試狀態框中的控制中止並重新開始測試或完全停止測試。



重新開始、中止和停止

測試進行中，給病人反饋和鼓勵。

完美狀況下，病人測試結果可以生成一條有清晰最小值定義的下行曲線。

中心測試結束後，病人可坐好。軟體會顯示中心測試的置信區間。

軟體會分析測試，置信度在屏幕上會以不同色彩顯示。

三個不同的結果是



接受顯示數據已被接受，軟體可以確定最低值。

慎重顯示軟體可以確定最低值，但對數據的清晰度不夠滿意 – 建議重新測試。

拒絕顯示數據無法生成結果，必須重新測試。

可以重新進行中心或邊緣部分測試，放棄？該部分測試收集的數據，但保留另一部分。

例如，如果中心測試結果可以接受，但邊緣測試結果建議慎重，那麼可以在保留中心測試數據的狀況下，只重新進行邊緣測試。

(更多詳情見附件3 [置信區間](#))

如下結果顯示中心測試結果可以接受，MPOD估計值0.44基於中心測試結果。

結果	記錄	參考補充劑
可信度	右	左
中心	接受	-
周邊	-	-
MP值		
估計值	0.48	-
絕對值	-	-
圖表已調整	-	-
步驟		
中心敏感度 (Hz)	41.60	-
中心最小值 (dB)	6.50	-
周邊敏感度 (Hz)	-	-
周邊最小值 (dB)	-	-

中心測試完成後，邊緣測試按鈕會激活 (以綠色顯示)。



進行邊緣測試時給病人新的說明。

## 第二部分

**請重新注視目鏡。**

注視中心圓圈兩側亮起的紅色圓圈 (只注意光線，不需要其他)。

中心目標會像先前一樣亮起藍-綠光，然後開始閃爍。

對中心目標閃爍按下並釋放按鈕的反應，但不要直視它。

建議按下按鈕後眨眼。

測試會從新設定並重複五、六次。

中心目標會暗下來，變換成略微不同的顏色，保持注視兩側紅色目標。

同樣地，中心目標會開始閃爍，像先前一樣按下並釋放反應按鈕。

測試大概需要一到兩分鐘的時間

當病人準備好後按下邊緣測試按鈕。

病人反應會在中心測試圖像上以紅色三角顯示。

與中心測試相同，主測試開始前會有閃爍閾值測試。


測試狀態框內訊息告知您目前進行測試階段。




邊緣測試完成後，置信區間會顯示在MPOD值邊。  
邊緣和中心測試結果整合生成MPOD絕對值並在估計值下顯示。

可信度	右	左
中心	接受	-
周邊	接受	-
MPOD值		
估計值	0.52	-
絕對值	0.46	-
圖表已調整	-	-
參數		
中心敏感度(Hz)	45.90	-
中心最小值(dB)	6.50	-
周邊敏感度(Hz)	41.70	-
周邊最小值(dB)	4.60	-

如果需要測試另一隻眼 (我們建議初次檢查時測試),那麼按下換眼按鈕,用眼罩遮住已測試過的眼並?另一隻眼測試設定設備。

測試完成後,保存按鈕會可用。 

這時,按下保存按鈕保存數據 (只測試過一隻眼)或按下換眼按鈕測試另一隻眼。 

也可以從新測試當前測試中的一隻眼。 

兩眼測試後如果選擇保存,那麼兩個結果會同時保存,不需要分別保存它們。如果只測試一隻眼,結果可以分別保存。

如果沒有保存便按下首頁 , 編輯病  人或切換病人按鈕,  您會被提示尚未保存並問及是否希望保存或放棄測試。

注意一旦保存,結果便不可刪除。

## 6.3 邊緣測試病人說明

### 第二部分

請重新注視目鏡。

注視中心圓圈兩側亮起的紅色圓圈 (只注意光線, 不需要其他)。

中心目標會像先前一樣亮起藍-綠光, 然後開始閃爍。

對中心目標閃爍按下並釋放按鈕的反應, 但不要直視它。

建議按下按鈕後眨眼。

測試會從新設定並重複五、六次。

中心目標會暗下來, 變換成略微不同的顏色, 保持注視兩側紅色目標。

同樣地, 中心目標會開始閃爍, 像先前一樣按下並釋放反應按鈕。

測試大概需要一到兩分鐘的時間

## 6.4 圖像估計

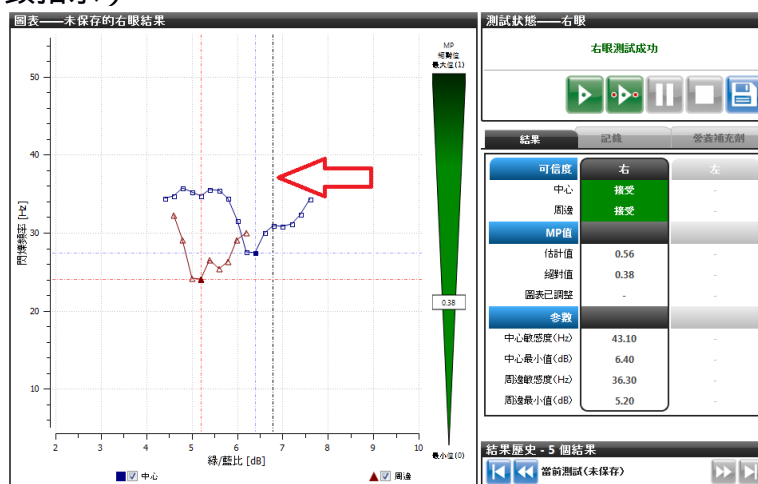
有時可能需要調整軟體選擇的最低值 - 例如圖像底部的兩點有完全相同的等級。

軟體接受完全不同最低值的可能性很低, 因? 它一定會在超過一個最低值的狀況下建議慎重。

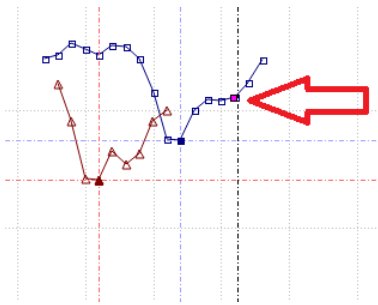
有兩點最低值的狀況下, 軟體會選擇第二點, 您可以選擇另一個以考察區別。

要改變圖像光標位置, 您必須已經完成一個完整的中心和邊緣測試。

這樣可以移動滑鼠光標到圖像曲線, 您會看到曲線上有一條垂直線隨光標移動。(箭頭指示)



如果左擊, 您會看到中心曲線 (藍色) 上出現粉色點 (箭頭指示)。這意味? 新選擇的最低點。



在邊緣曲線 (紅色) 上進行同樣操作, 不過這次左擊時按住SHIFT按鈕。  
一個粉色三角會出現在新的最低點。(黃色箭頭指示)

圖像估計讀書會顯示在表格中, 滑動條上的值會改變。(紅色箭頭指示)



您可以在圖像上移動並點擊多次, 每次圖像估計值都會變更。

## 6.5 測試報告

軟體可生成不同種類的報告。

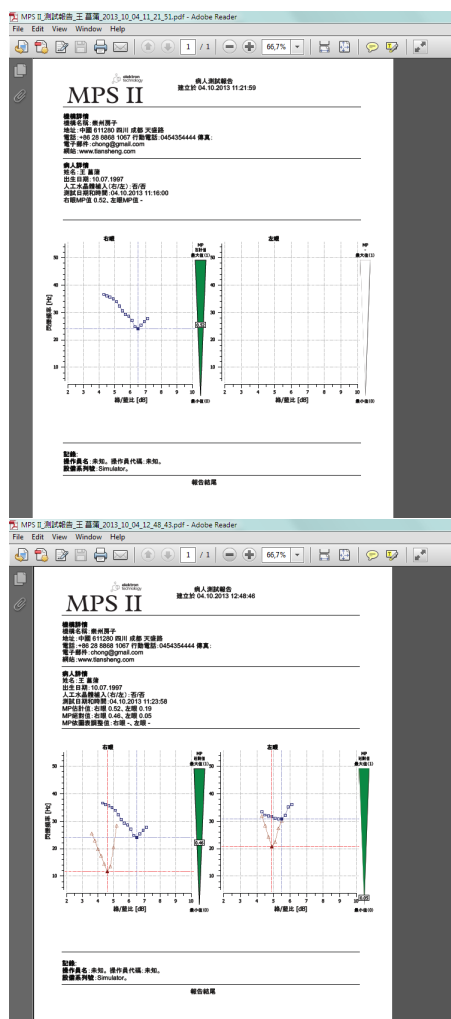
分別？

1. 測試完成報告 – 顯示剛剛進行的測試結果
2. 病人時間軸報告 – 顯示病人已有結果詳情
3. 醫療機構報告 – 顯示特定時間範圍內的所有測試結果。這份報告也可以由單獨的操作員生成。

### 1. 測試完成報告

測試完成後在測試屏幕按下報告按鈕後生成

典型的報告如下 -



會顯示病人詳情，同時顯示醫療機構詳情、圖像和記錄的雙眼MPOD值。

測試報告生成？PDF檔案，在電腦默認PDF檢視器顯示之前，您會被提示保存。然後您可以檢視、編輯、列印或保存到其他位置。

您的PDF檢視器的標準控制都可用。  
(更多資訊請見您的PDF檢視器幫助檔案。)

雙眼結果 (如果一同測試) 在同一頁面輸出。

## 2. 病人時間軸報告



在主菜單按下檢視報告按鈕訪問。

報告以圖像和表格格式顯示病人在特定時間範圍內的所有測試。

時間範圍默認？從當天開始前一年。

點擊病人時間軸標籤，然後從下拉列表中選擇病人。

機構檢測紀錄	病人檢測紀錄
選擇病人 王 慕 蕭 [出生日期:1997/7/10] 太平 13-15	

報告顯示如下。



您可以透過變更時間範圍框內的開始或結束日期來變更時間範圍。  
會顯示日曆。

**日期範圍**

開始日期: 2012/10/4

完成日期:

2012/10/4

十月 2012

週日	週一	週二	週三	週四	週五	週六
30	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31	1	2	3
4	5	6	7	8	9	10

您可以透過點擊月份邊上的小三角並從下拉列表中選擇需要的月份來變更月份。  
您也可以透過點擊框上方的左右箭頭來修改月份。

可以選擇報告的開始和結束日期。



按下保存並檢視報告按鈕保存報告？PDF。

您會被提示保存檔案，然後會在您默認的PDF檢視器中顯示。

### 3. 醫療機構時間軸報告



在主菜單按下檢視報告按鈕訪問報告。

顯示特定時間範圍內所有操作員的所有測試。

默認時間範圍？當天開始前一年。

與病人時間軸相同，可以透過點擊日期變更開始和結束日期。

報告也可以只顯示特定操作員的結果。

測試編號	測試日期	測試時間	操作員	右眼MPD對焦	右眼MPD調節	右眼MPD調節	右眼中心可視度	右眼周邊可視度	左眼MPD對焦	左眼MPD調節	左眼MPD調節	左眼中心可視度	左眼周邊可視度
1	04.10.2013	11:23:58	2	0.52	-	-	接受	-	-	-	-	-	-
2	04.10.2013	12:50:46	2	0.52	0.46	-	接受	接受	0.19	0.05	-	接受	接受
3	04.10.2013	12:58:14	1	0.48	-	-	接受	-	-	-	-	-	-
4	04.10.2013	12:58:49	1	0.12	-	-	接受	-	-	-	-	-	-
5	04.10.2013	13:17:46	1	0.51	-	-	接受	-	-	-	-	-	-
6	01.10.2013	09:16:53	1	0.53	0.48	-	接受	接受	0.36	0.26	-	注意	接受
7	04.10.2012	09:22:57	2	-	-	-	拒絕	拒絕	0.57	0.58	-	注意	注意
8	02.06.2013	09:28:40	3	0.44	0.41	-	注意	注意	-	-	-	拒絕	拒絕
9	04.01.2013	09:32:55	4	0.30	-	-	注意	拒絕	0.49	0.24	-	接受	注意



點擊保存並檢視報告按鈕以保存報告？PDF

您會被提示保存檔案，然後會在您默認的PDF檢視器中顯示。



## 7 檢視以往記錄數據

有兩種方法可以檢視病人結果歷史。

1. 測試開始或結束時，記錄歷史 (如下圖) 會顯示在測試屏幕右下角，或者
2. 不需要進行測試，可直接透過主菜單。

從主菜單，像通常一樣在測試/檢視已有病人屏幕選擇病人



測試/檢視已有病人

選擇病人並點擊檢視病人結果按鈕



您會進入測試屏幕但同時顯示他們最近的測試結果。

使用屏幕底部結果歷史的控制按鈕可以檢視病人以往記錄。

下面的例子顯示病人在資料庫中有 2 則以往記錄。用換眼按鈕查看另一隻眼的圖像結果。



四個按鈕備用來切換記錄 -

按鈕的意義解釋如下。



移動到第一則病人記錄並顯示數據



移動到上一則病人記錄並顯示數據



移動到下一則病人記錄並顯示數據 (以灰色顯示因？我們在最後一則記錄)



移動到最後一則病人記錄 - 這將是我們尚未完成的一則記錄

最後一個按鈕用來移動到新病人記錄，準備好記錄數據。

注意屏幕必須在新病人記錄以記錄數據 (上面最後兩個按鈕會以灰色顯示)。同時注意記錄計數反應到訪數量，不管進行單眼或是雙眼測試。

## 8 配置嚮導

配置嚮導在全新安裝後首次使用軟體時自動執行。

它會指導軟體安裝者更改軟體語言、添加用戶以及設置備份策略。

也可以點擊主菜單 (首頁) 配置鏈接在任何時間執行。



第一個屏幕允許您更改顯示語言。

注意：語言變更會立即生效，所以如果您不能閱讀某種語言，不要點擊下一步，因為您可能不能回到上一頁。



第二個屏幕允許您檢視、選擇和添加新操作員。  
注意：您不能刪除操作員。您只能設置他們？未激活。



第三個屏幕允許您錄入病人詳情  
這些詳情會出現在病人的[測試報告](#)拷貝。



最後一個屏幕允許您設置資料庫檔案自動備份策略。  
您可以選擇在特定區間或每次軟體退出時備份。

備份位置可以是本地或網路上 (如果連接網路) 的任何資料夾。

## 9 附件 1.MPS II 安裝

MPS9000 / MPS II 必須按操作說明使用。請在操作前閱讀說明。

### 1 位置

II 操作所在房間電氣安裝必須符合當地電氣法令。設備必須遠離液體以及可燃液體和氣體。

### 2 供電電源

供電電源要求 15VA, 100 至 240V 交流電。IEC 許可的電纜必須使用截斷面至少  $0.75\text{mm}^2$  的導體 (已提供的電源線符合此標準)。

### 3 電源連接

拔出電源輸入連接下方的小抽屜, 從上方讀取保險絲等級, 以檢查 MPS II 已針對電源電壓使用合適等級的保險絲。設備背部面板的規格欄標明正確的等級。使用電纜連接 MPS II 背部的電源輸入連接與牆上的電源接口。

### 4 週邊

如果設備放置於電氣桌上, 桌子需要以合適的接地電源線與主電源連接, MPS II 應與桌面上的電源連接。

### 5 安全

確保電線不會出現在地面, 不會被利器割傷。只使用與 EN60950 兼容的膝上型電腦、個人電腦、列印機和顯示器。

### 6 EMC

II 與 EMC 歐洲指令 2004/108/EC 相符, 但它不會釋放輻射。如果干擾其他設備, 將其遠離其他設備或改變放置角度。不要在設備附近使用發射機或行動電話。本設備與 EMC 關於醫療設備的 EN60601-1-1 (B 類) 要求相符, 但不應該將其放置在敏感設備或強電磁場附近。

### 7 環境溫度和溼度

設備只能在溫度  $10$  至  $35$  攝氏度、溼度  $30\%$  至  $80\%$  (不結露) 以及氣壓  $700$  至  $1060$  mbar 的環境中使用。

保存和運輸只能在溫度  $-20$  至  $50$  攝氏度、溼度  $10\%$  至  $80\%$  (不結露) 以及氣壓  $500$  至  $1060$  mbar 的環境中進行。

### 8 電氣連接

下圖顯示設備背部面板連接。



在MPS II上使用正確的保險絲很重要，因？損害可能發生。  
等級在輸入槽下顯示。  
設備必須接地。

## 9 膝上型或個人電腦

連接膝上型/個人電腦電源線到合適的電源。

用USB數據線 (已提供) 連接MPS II後方的USB接口以及電腦上的空間USB接口。

USB線“長方形”一端連接電腦上的USB接口，另一端（方形端）連接MPS II背部的USB接口。

## 10 附件 2.軟體安裝

MPS II與電腦連接前需要加載軟體和驅動。

提供以下說明 -

[安裝到新電腦，或](#)  
[升級已有軟體](#)

點擊以上鏈接以選擇章節...

膝上型或個人電腦必須運行Windows 7™或Windows 8™作業系統。

電腦必須達到或超過以下規格：

1GHz或更快的32(x86)或64(x64)位處理器

1GB記憶體 (32位 )或2GB記憶體 (64位 )

2GB可用硬碟空間 (32位 )或3GB(64位 )

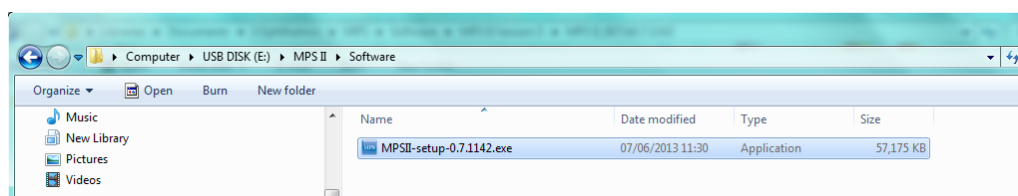
至少一個未使用的USB端口。

附加要求以使用某些特性：

Adobe PDF reader XI

## 10.1 安裝到新電腦

- 1 將已提供的MPS II USB閃存驅動器插入電腦上的USB端口。
- 2 如果提示操作,選擇開?資料夾以檢視檔案。
- 3 開?軟體資料夾,應與下圖顯示類似。



MPS II Vx.xx檔案名會不同,取決於軟體版本號。

- 4 雙擊MPSII-setup-5.xx.xx.exe程式開始安裝
- 5 取決於電腦的UAC (使用者帳號控制) 設置,您可能會看到Windows安保訊息 – 回答是
- 6 語言選擇對話方塊會出現,選擇您的語言並點擊OK
- 7 點擊下一步
- 8 閱讀並接受授權合約並點擊下一步
- 9 選擇目標資料夾 (建議保持默認) 然後點擊下一步
- 10 選擇開始菜單資料夾 (建議保持默認) 然後點擊下一步
- 11 選擇創建桌面圖表並點擊下一步
- 12 點擊安裝以開始安裝。需要幾分鐘完成安裝。
- 13 完成後點擊完成按鈕。
- 14 現在可透過桌面圖表執行軟體。
- 15 配置嚮導會在首次執行。詳情見[配置嚮導](#) 章節。



## 10.2 升級已有安裝

建議升級已有安裝前備份現有資料庫。

按照上一章節[安裝到新電腦](#)說明操作

軟體升級不同的地方是病人資料庫不會被覆寫 ,而會被導入新軟體後立即可用。

### 10.3 設置程式

可從桌面圖標或Windows程式菜單 (從開始按鈕開?) 執行。  
雙擊桌面圖標開始 -



**重要提示 - 請閱讀**

安裝後首次執行軟體, [配置嚮導](#) 會執行。配置嚮導只會在首次執行軟體時執行。

主菜單顯示後, 您可以操作軟體。



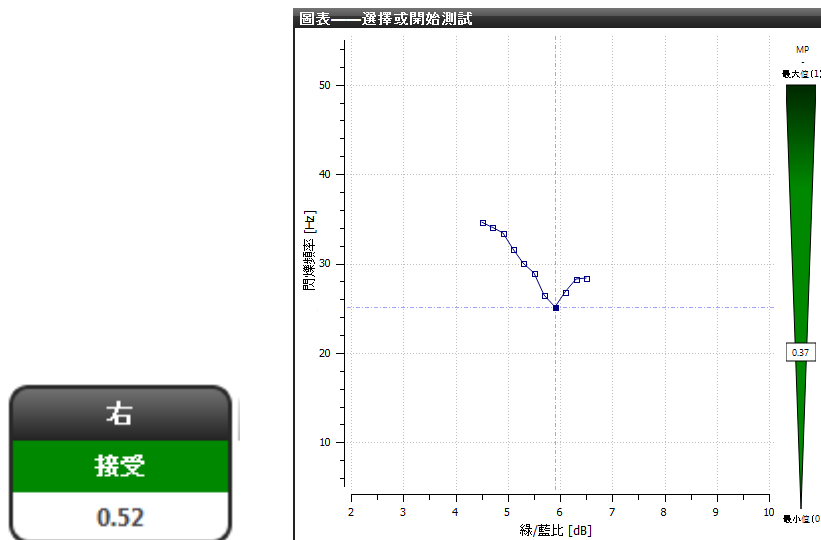
## 11 附件 3.置信區間

結果有三種 ,如下圖顯示 -

### 接受

結果已被分析。分析結果可接受。

範例如下。數據在可接受的閃爍率下顯示可區分的最低值 ,所以數據的置信區間沒有問題。您可以看到結果以綠色顯示 ,並且MPOD垂直指示也以綠色顯示。

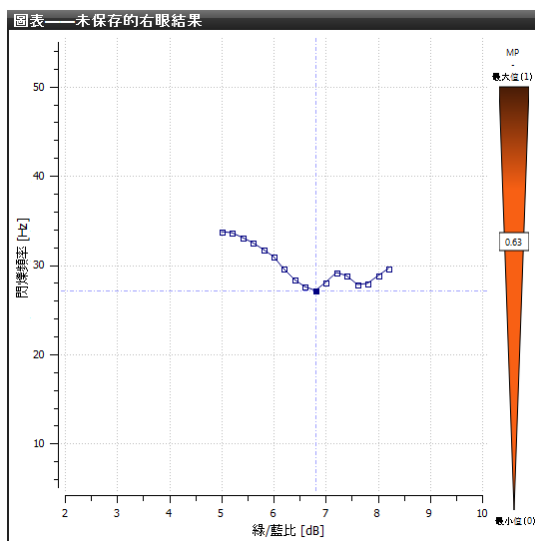


### 慎重接受

結果已被分析 ,但分析建議慎重。圖像需要詳查。

範例如下。數據顯示較差的最低值 (在可接受的閃爍率下) ,所以需要慎重。

同樣地 ,您可以看到結果和指示均以橘黃色顯示。



如果建議慎重，請檢查 -

輕微噪聲數據  
扁平圖像

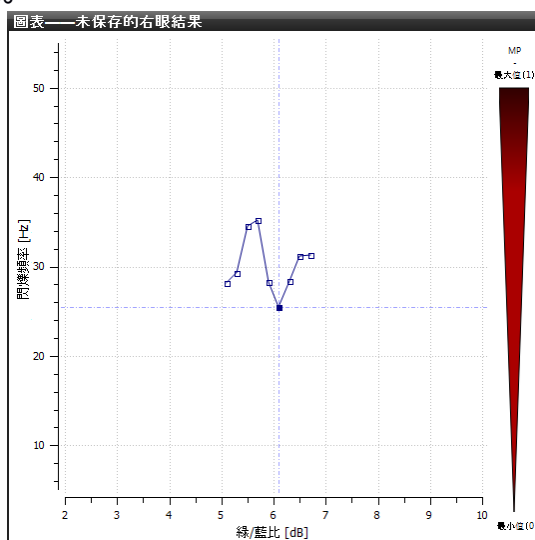
建議病人頻繁眨眼 - 如在每次按下按鈕後  
建議病人看到閃爍後立刻按下按鈕

拒絕

結果已被分析，分析拒絕結果。必須從新測試。

範例如下。數據顯示一個明確定義的最低值，但在之前有不尋常的波動。

拒絕在此以紅色顯示。



如果拒絕，請檢查 -

IOL可能性

最低值與初始值相同

結果讀數？0

數據噪聲過多

與病人確認IOL或色彩或錄入年齡

與病人確認IOL或色彩或錄入年齡

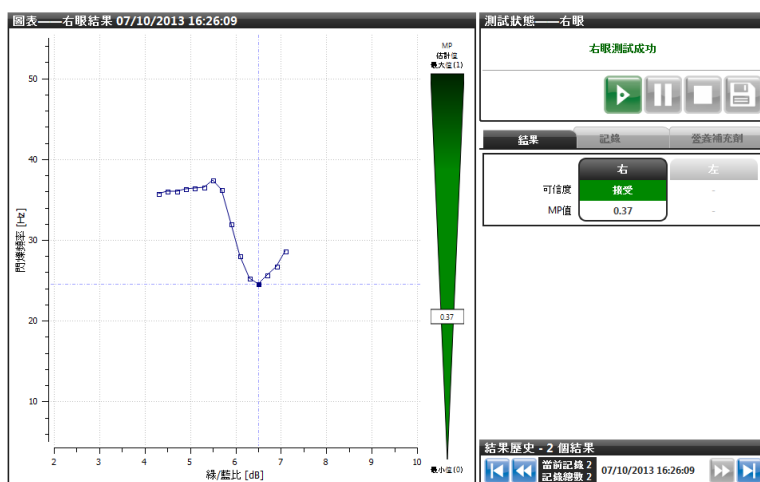
與病人確認IOL或色彩或錄入年齡

建議病人頻繁眨眼 - 如在每次按下按鈕後

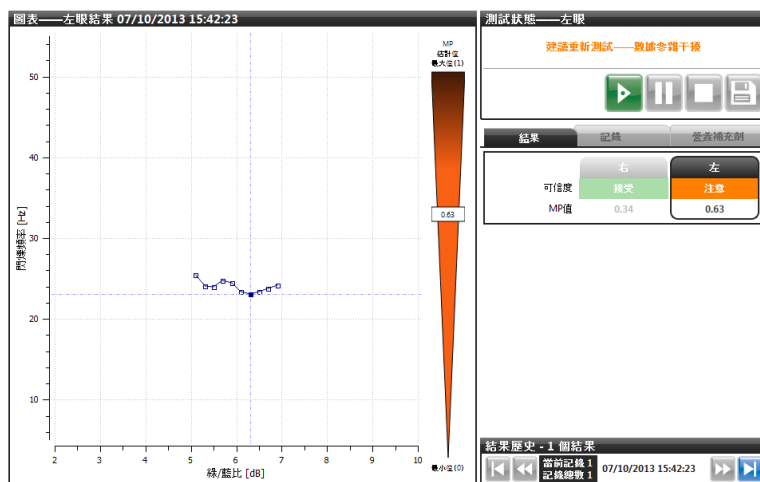
數據點過少	建議病人頻繁眨眼 – 如在每次按下按鈕後
最低值與最終值相同	建議病人頻繁眨眼 – 如在每次按下按鈕後
閃爍過高	建議病人等待直到看到閃爍

## 12 附件 4.範例數據

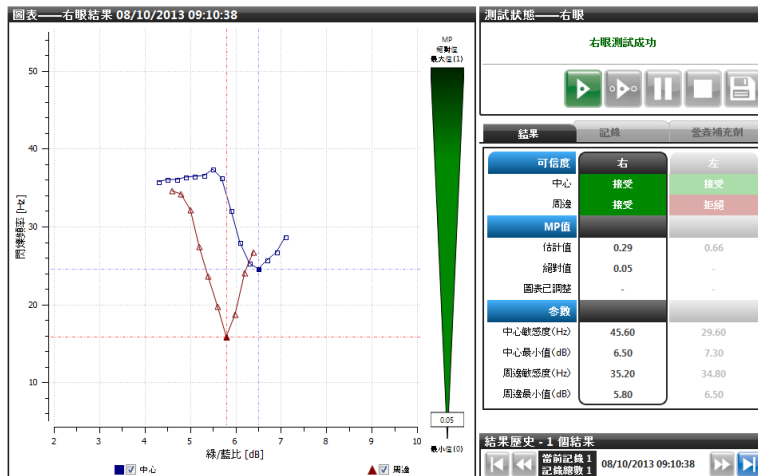
以下截圖顯示一些樣品數據，是不同置信區間的例子。接受，慎重



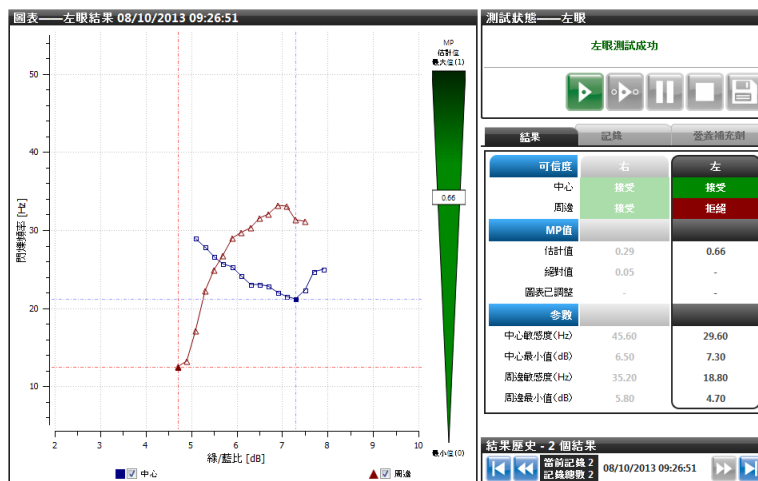
標準模式下的結果。可接受的數據在圖像下以綠色區域顯示。



本例？軟體因噪聲數據而建議重新測試。



本例？詳情模式下接受數據屏幕。您可以看到中心和邊緣測試都已被接受。



本例？詳情模式拒絕。

中心測試數據被接受，但邊緣測試數據因與預期結果不符而被拒絕。

您可以看到本例中軟體提供了基於中心讀數的MPOD結果估計值而不是絕對值，因為邊緣數據被拒絕。

## 13 附件 5.技術規格

### 1 類型

測量黃斑色素密度的電腦化設備

測量長度 :17cm 背景亮度 :250cdm-2

### 2 刺激

光譜輸出 ? 470nm和 530nm的 LEDs

極限視角 :1度 (中心) ,3度 (邊緣) 亮度 :100 – 1000cdm-2

### 3 注視目標

散射型紅色 LEDs ,光譜輸出 625 - 675nm

### 4 輸入 / 輸出

USB 1.1 B型接口 (? 外部控制)

電源輸入接口 (IEC320)

病人反應按鈕

### 5 電氣規格

電源輸入電壓 :100-240 Vac ,通用輸入

保險絲 : 2 off 20mm x 5mm IEC 60127-2 高爆容

保險絲等級 : 240Vac T0.5AH250V, 110VAC T1AH250V

頻率 50/60 Hz

耗電量 : 15 VA

電源輸入接口 : IEC 320接口

### 6 尺寸

300 x 230 x 300 - 350 (可變) (L x D x H) mm

### 7 重量

4.5 kg

### 8 分類

第一類電源

B型應用組件。持續操作

設備不適合在可燃物與空氣、氧氣或笑氣混合時使用。

### 9 環境

溫度

操作 . . . . . 10° - 35°C (41° - 95°F)

保存 . . . . . -20° - 50°C (-4° - 122°F)

相對溼度

操作 . . . . . 30% - 80% (不結露)

保存 . . . . . 10% - 90% (不結露)

最大震動

操作 . . . . . 0.9 GRMS 隨機震動通過空氣作用於產品

保存 . . . . . 1.3 GRMS 隨機震動通過卡車作用於產品

最大衝擊

操作 . . . . . 1.52 m/sec (60 inches/sec) (脈波寬度小於等於 2 ms)

保存 . . . . . 2.03 m/sec (80 inches/sec) (脈波寬度小於等於 2 ms)

高度

操作 . . . . . 0 - 3048 m (0 to 10,000 ft)

保存 . . . . . 0 - 12,192 m (0 to 40,000 ft)

### 10 週邊和可拆卸零件

MPS II提供以下週邊和可拆卸零件：

USB記憶體包含安裝軟體

電源線 (隨國家不同)



防塵罩

病人反應按鈕 (PRB)

不同電壓使用的可更換保險絲

**11 可選項目**

電子桌 (無桌面)

可放置列印機的定製桌面

V型桌面

噴印機

**12 備用零件列表**

眼罩

操作手冊

防塵罩

可更換電源線

病人反應按鈕

可更換保險絲

**13 EC一致性聲明**

以設計目的使用,本設備符合醫療設備指令 93/42/EEC (已修正)要求的一類醫療設備標準。對本設備的任何改進都可能影響設備與相關指令和標準的一致性。

## 14 附件 6 維護和保固

[定期檢查](#)

[維護](#)

[清潔](#)

[防護性維護](#)

[可替換零件](#)

[備用鏡片](#)

[維修和重新校準](#)

[保固](#)

### 14.1 定期檢查

使用前檢查設備和電源線。

如有任何損壞，在合格人員檢查前不應使用設備。

要特別關注設備背部的電源線和病人反應按鈕線。

### 14.2 維護

任何維護或清潔前，請確認電源線已從電源接口拔掉從而隔離設備與電源。也可通過拔掉可拆卸電源線將設備和電源隔離。

### 14.3 清潔

設備置於一個可按需要清潔的機殼中。清潔需要在設備與電源隔離的狀況下進行。

機殼

機殼可用濕布清潔。不要使用擦洗劑。不要讓液體進入 MPS II。

鏡片

鏡片可用任何鏡片清潔布或滅菌抹布清潔。不要使用擦洗劑。

目標屏幕

目標屏幕有時可能滯留灰塵，取決於使用環境。小型灰塵可在移除目鏡後（看下一段）向位於鏡片兩邊的兩個孔中的任何一個吹入空氣從而“吹淨”。請使用專用空氣，如氣霧罐。

目鏡

目鏡可能會傳播污染或感染給他人。

可移除目鏡清潔/消毒。目鏡可更換。

因可能接觸目鏡，有些病人可能有過敏反應。

選取的是一種被稱作 Evoprene 的熱塑性彈性體材料，而不是天然橡膠。

要移除目鏡，可從兩側輕輕向內擠壓，並從設備拔出（見下面）。

目鏡和可能與病人接觸的臨接區必須保持清潔，濕布清潔後用防腐劑擦淨。



## 14.4 預防性維護

推薦每六個月檢視並更換電源線,如絕緣層損壞等。

與之連接的電腦應該按製造商說明維護。  
包括硬體和軟體維護。

作業系統應該保持更新,包括任何補丁和軟體升級。

MPS II用戶軟體應該保持更新,包括任何補丁和升級。  
這些升級可從生產商和銷售顧問網站上獲得。

## 14.5 可更換零件

MPS II中沒有用戶可維修的零件。以下備用零件可從供應商初獲得 -

項目	零件碼
----	-----

防塵罩	SUN9303
USB A-B線	WIR5121
目鏡	MPS9000-328
軟體光碟	SUN5900*
T0.5AH250 HBC保險絲	FUS1226
T1AH250V HBC保險絲	FUS1227
手冊	MAN2000

主電源線 (隨國家而不同)      指定國家已獲得零件碼

\* 軟體零件碼隨新版本而變化。聯絡您的供應商已獲得最新零件碼。

## 14.6 備用鏡片

以下可用於 MPS II -

MF OPT7001	Lens +1D 1.502 Index
MF OPT7002	Lens +2D 1.502 Index
MF OPT7003	Lens +3D 1.502 Index
MF OPT7004	Lens +4D 1.502 Index

## 14.7 維修和重新校準

MPS II中沒有用戶可維修的零件，除了外部可更換項目 (保險絲)。

本設備只能由相關合格人員維修。

生產商會在收到申請後酌情提供電路圖、組件列表、描述、校準說明或其他訊息，幫助維修人員修復 MPS II 中生產商認？可以由維修人員修復的相關零件。

### 校準

推薦每年對設備進行校準以確保精確度在可接受範圍。

請聯絡您的供應商以獲得相關訊息。

出現故障時請聯絡您的供應商。

## 14.8 保固

安裝後24個月中，如發現任何在我們合理可控範圍內的材料或製造瑕疵，我們會承擔修復瑕疵的費用，條件是發現瑕疵後儘快通知並且立刻將設備發回給我們，產品運輸費用已支付、在原包裝中且安全圖章未損壞。

請注意Elektron技術保留任何時候在未通知的狀況下更改硬體或軟體規格的權利。

## 15 附件 7 -問題解決

本章處理 MPS II與電腦連接時產生的所有問題和錯誤訊息。這些問題多數狀況下都有簡單的解決方案。

如軟體？動時連接狀態訊息沒有顯示準備好，則 MPS II沒有與電腦通訊 -



如顯示沒有連接，請嘗試 -

- 檢查 MPS II已接電源
- 檢查 MPS II和膝上型/個人電腦間的USB線在兩端都已接好

如任何連線鬆動，您都必須等待軟體檢測 MPS II設備。

如上述步驟都不能解決問題，請嘗試拔掉USB線，重新？動 MPS II並連接USB線。

關於資料庫的錯誤訊息很多。請記錄下來以便服務提供者幫助您解決問題。

在安全地點保存資料庫備份以減少因硬碟/電腦故障而造成的數據損失是好的實務。

資料庫出錯時，可恢復最後一次備份以將數據損失降到最低。

## 16 Appendix 8 - Software License Agreement

**IMPORTANT NOTICE: PLEASE READ CAREFULLY BEFORE INSTALLING THE SOFTWARE**

*This licence agreement (Licence) is a legal agreement between you (Licensee or you) and ELEKTRON TECHNOLOGY UK LIMITED (English company number 04949934) of Broers Building, JJ Thomson Avenue, Cambridge CB3 0FA (Licensor, us or we).*

*The following terms are used in this Licence:*

- *The MPS II computer software and the data supplied with the software, any Maintenance Release and the associated media (Software);*
- *Software that corrects faults, add functionality or otherwise amends or upgrades the Software which we may supply to you from time to time (Maintenance Release);*
- *printed materials and online or electronic documentation we supply to you in connection with the Software (Documentation);*
- *the Macular Pigment Screener portable device provided by the Licensor (MPS Device), and PC refers to a personal computer.*

*We may also make available to you open-source software (as defined by the Open Source Initiative (<http://opensource.org>) or the Free Software Foundation (<http://www.fsf.org>) (Open-Source Software) when we supply you with the Software. Use of Open-Source Software is subject to the relevant third party licence terms, and such Open-Source Software remains the property of the relevant licensors. We licence use of the Software and Documentation to you on the basis of and subject to the terms of this Licence. We do not sell the Software or Documentation to you. Except in respect of any elements licensed from third parties, we remain the owner of the Software and Documentation at all times.*

**OPERATING SYSTEM REQUIREMENTS: THIS SOFTWARE REQUIRES A PERSONAL COMPUTER WITH WINDOWS 7™ or WINDOWS 8™ OPERATING SYSTEMS.**

**IMPORTANT NOTICE TO ALL USERS:**

- **BY INSTALLING, COPYING OR OTHERWISE USING THE SOFTWARE OR CLICKING ON THE "ACCEPT" BUTTON BELOW YOU AGREE TO THE TERMS OF THIS LICENCE WHICH WILL BIND YOU AND YOUR EMPLOYEES.**
- **IF YOU DO NOT AGREE TO THE TERMS OF THIS LICENCE, WE WILL NOT LICENSE THE SOFTWARE AND DOCUMENTATION TO YOU AND YOU MUST DISCONTINUE THE INSTALLATION PROCESS NOW BY CLICKING ON THE "CANCEL" BUTTON BELOW THE DISPLAYED LICENCE AGREEMENT. IN THIS CASE YOU MUST RETURN ANY MEDIA ON WHICH THE SOFTWARE IS STORED AND ALL ACCOMPANYING DOCUMENTATION TO THE LICENSOR.**

*You should print a copy of this Licence for future reference.*

### **1. GRANT AND SCOPE OF LICENCE**

**1.1** *In consideration of you agreeing to abide by the terms of this Licence, the Licensor hereby grants to you a non-exclusive, non-transferable licence to use the Software and the Documentation and any Maintenance Release which we make available to you on and subject to the terms of this Licence.*

**1.2** *You may:*

**(a)** *install and use the Software for your personal purposes (if you are a consumer) or your internal business purposes (if you are a business):*

**(i)** *only on one PC; and*

**(ii)** *only in conjunction with the MPS Device together with which the Software was provided to you;*

**(b)** *make up to one copy of the Software for back-up purposes only, provided you comply with the provisions in condition 2(f);*

**(c)** *use any Documentation in support of the use permitted under condition 1.2.*

**1.3** *Unless agreed otherwise by the Licensor in writing, the Software may not be used or*

*installed on more than one PC, and may not be used to process data captured by, or to communicate with, more than one MPS Device (and that MPS Device must, unless agreed otherwise by the Licensor in writing, be the one together with which the Software was provided to you).*

## **2. RESTRICTIONS**

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- (b) not to rent, lease, sub-license, loan, translate, merge, adapt, vary or modify the Software or Documentation;*
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  - (iii) is not used to create any software which is substantially similar to the Software;*
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- (f) to keep all copies of the Software secure and to maintain accurate and up-to-date records of the number and locations of all copies of the Software;*
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- (h) to include our copyright notice on all entire and partial copies of the Software in any form;*
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**3.2** *You acknowledge that you have no right to have access to the Software in source code form or in unlocked coding or with comments.*

## **4. LIMITED WARRANTY**

**4.1** *We warrant that:*

- (a) the media on which the Software is stored and distributed is (at the time it is supplied) free from defects in design, material and workmanship under normal use;*
- (b) the Software will, when properly used and on an operating system for which it was designed, perform substantially in accordance with the functions described in the Documentation; and*
- (c) that the Documentation correctly describes the operation of the Software in all material respects,*

*for a period of 90 days from the date of installation of the Software (Warranty Period). If a defect in the media occurs during the Warranty Period, we will replace it free of charge if you return it to the Licensor with (so far as you are able) a documented example of such defect or error.*

**4.2** *If, within the Warranty Period, you notify us in writing of any defect or fault in the Software as a result of which it fails to perform substantially in accordance with the Documentation, we will, at our sole option, either repair or replace the Software, provided that you make available all the information that may be necessary to help us to remedy the defect or fault, including sufficient*

information to enable us to recreate the defect or fault.

4.3 The warranty does not apply:

- (a) if the defect or fault in the Software results from you having amended the Software;
- (b) if the defect or fault in the Software results from you having used the Software in contravention of the terms of this Licence.

4.4 We are not obligated to provide any Maintenance Releases. Unless agreed otherwise by us in writing, we have no obligation to support the Software on more than one PC, or in respect of more than one MPS Device.

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- (c) loss of anticipated savings;
- (d) loss or corruption of data or information;
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- (f) any special, indirect or consequential loss or damage, even if we were aware of the circumstances in which any such loss or damage could arise at the time we supplied the Software to you.

5.4 Other than the losses set out in condition 5.3 and in condition 5.5 (for which we are not liable), our maximum aggregate liability under or in connection with this Licence whether in contract, tort (including negligence) or otherwise, shall in all circumstances be limited to GBP1,500. This maximum cap does not apply to condition 5.6.

5.5 You agree that in entering into this Licence, either you did not rely on any representations (whether written or oral) of any kind or of any person other than those expressly set out in this Licence or (if you did rely on any representations, whether written or oral, not expressly set out in this Licence) that you shall have no remedy in respect of such representations and (in either case) we shall have no liability in any circumstances otherwise than in accordance with the express terms of this Licence.

5.6 Nothing in this Licence shall limit or exclude our liability for:

- (a) death or personal injury resulting from our negligence;
- (b) fraud or fraudulent misrepresentation;
- (c) any other liability that cannot be excluded or limited by English law.

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5.8 All references to "we" or "us" in this condition 5 shall, for the purposes of this condition 5 and condition 9.6 only, be treated as including all employees, subcontractors and suppliers of us, all of whom shall have the benefit of the exclusions and limitations of liability set out in this condition 5, in accordance with condition 9.6.

## 6. TERMINATION

6.1 Without prejudice to our other rights and remedies, we may terminate this Licence immediately by written notice to you if you commit a material or persistent breach of this Licence



which you fail to remedy (if remediable) within 14 days after the service of written notice requiring you to do so.

6.2 Upon termination for any reason:

- (a) all rights granted to you under this Licence shall cease;
- (b) you must cease all activities authorised by this Licence; and
- (c) you must immediately delete or remove the Software from all computer equipment in your possession and immediately destroy or return to us (at our option) all copies of the Software then in your possession, custody or control and, in the case of destruction, certify to us that you have done so.

6.3 Any provision in this Licence which expressly or by implication is intended to come into or continue in force on or after termination of this Licence shall remain in full force and effect.

## 7. NOTICES

7.1 Any notice required to be given under this Licence shall be in writing. If you are sending notice, it shall be delivered personally, or sent by pre-paid first-class post or recorded delivered or by commercial courier or by email to martinreeves@elektron-technology.com. If we are giving notice, we may do so by posting it on our website at www.elektron-technology.com or, if we have your contact details, we may either post it (in a manner set out above) or we may email you. If you are posting notice to us, please send it for the attention of the Company Secretary, Elektron Technology PLC at Broers Building, 21 JJ Thomson Avenue, Cambridge CB3 0FA.

7.2 Any notice shall be deemed to have been duly received:

- (a) if delivered personally, when left at the address and for the contact referred to in condition 7.1, or for the contact at the address referred to by you in any communication you send to us;
- (b) if sent by pre-paid first-class post or recorded delivery, at 9,00am on the third working day after posting (if posted from within the UK) or on the seventh working day after posting (if posted from outside of the UK);
- (c) if delivered by commercial courier, on the date and at the time that the courier's delivery receipt is signed;
- (d) if posted on our website, 12 hours after it is uploaded; or
- (e) if sent by email, 24 hours after it is sent.

## 8. EVENTS OUTSIDE OUR CONTROL

8.1 We will not be liable or responsible for any failure to perform, or delay in performance of, any of our obligations under this Licence that is caused by an Event Outside Our Control. An Event Outside Our Control is defined below in condition 8.2.

8.2 An Event Outside Our Control means any act or event beyond our reasonable control, including without limitation failure of public or private telecommunications networks or electricity supply.

8.3 If an Event Outside Our Control takes place that affects the performance of our obligations under this Licence:

- (a) our obligations under this Licence will be suspended and the time for performance of our obligations will be extended for the duration of the Event Outside Our Control; and
- (b) we will use our reasonable endeavours to find a solution by which our obligations under this Licence may be performed despite the Event Outside Our Control.

## 9. OTHER IMPORTANT TERMS

9.1 We may transfer our rights and obligations under this Licence to another organisation, but this will not affect your rights or our obligations under this Licence.

9.2 You may only transfer your rights or your obligations under this Licence to another person if we agree in writing.

9.3 We may require you to, and you agree to, permit us (and/or our contractors and agents) to inspect and have access to any premises (and to the computer equipment located there) at or on which the Software is being kept or used, and have access to any records kept in connection with this Licence, for the purposes of ensuring that you are complying with the terms of this Licence, provided that we provide reasonable advance notice to you of such inspections, which must take place at reasonable times.

9.4 This Licence and any document expressly referred to in it constitute the entire agreement between you and us and supersede all prior agreements, arrangements and understandings between you and us. You acknowledge that you have not relied on any statement, promise or representation made or given by or on behalf of the us which is not set out in this Licence or any document

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9.5 *If we fail to insist that you perform any of your obligations under this Licence, or if we do not enforce our rights against you, or if we delay in doing so, that will not mean that we have waived our rights against you and will not mean that you do not have to comply with those obligations. If we do waive a default by you, we will only do so in writing, and that will not mean that we will automatically waive any later default by you.*

9.6 *It is agreed that it is intended to confer a benefit on us and the third parties referred to in conditions 5.8 and 9.3 by making the exclusions and limitation of liability available to them in accordance with this Licence, provided that the rights of such third parties under this licence shall only be enforceable by us on their behalf. We owe no duty to them to enforce such rights and we may conduct or compromise any relevant proceedings as we see fit.*

9.7 *Except as provided in condition 9.6, a person who is not a party to this Licence shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Licence, but this does not affect any right or remedy of a third party which exists, or is available, apart from that Act.*

9.8 *Each of the conditions of this Licence operates separately. If any court or competent authority decides that any of them are unlawful, invalid or unenforceable, the remaining conditions will remain in full force and effect. If any invalid, unenforceable or illegal provision of this Licence would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.*

9.9 *No variation of this Licence shall be effective unless it is in writing and signed by us.*

9.10 *This Licence, its subject matter and its formation (and any non-contractual disputes or claims) are governed by and construed in accordance with English law. We both agree to the exclusive jurisdiction of the courts of England and Wales.*

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Version 2.1, February 1999

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*The precise terms and conditions for copying, distribution and modification follow. Pay close attention to the difference between a "work based on the library" and a "work that uses the library". The former contains code derived from the library, whereas the latter must be combined with the library in order to run.*

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*c) You must cause the whole of the work to be licensed at no charge to all third parties under the terms of this License.*

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*(For example, a function in a library to compute square roots has a purpose that is entirely well-defined independent of the application. Therefore, Subsection 2d requires that any application-supplied function or table used by this function must be optional: if the application does not supply it, the square root function must still compute square roots.)*

*These requirements apply to the modified work as a whole. If identifiable sections of that work are not derived from the Library, and can be reasonably considered independent and separate works in themselves, then this License, and its terms, do not apply to those sections when you distribute them as separate works. But when you distribute the same sections as part of a whole which is a work based on the Library, the distribution of the whole must be on the terms of this License, whose permissions for other licensees extend to the entire whole, and thus to each and every part regardless of who wrote it.*

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*In addition, mere aggregation of another work not based on the Library with the Library (or with a work based on the Library) on a volume of a storage or distribution medium does not bring the other work under the scope of this License.*

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This option is useful when you wish to copy part of the code of the Library into a program that is not a library.

4. You may copy and distribute the Library (or a portion or derivative of it, under Section 2) in object code or executable form under the terms of Sections 1 and 2 above provided that you accompany it with the complete corresponding machine-readable source code, which must be distributed under the terms of Sections 1 and 2 above on a medium customarily used for software interchange.

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However, linking a "work that uses the Library" with the Library creates an executable that is a derivative of the Library (because it contains portions of the Library), rather than a "work that uses the library". The executable is therefore covered by this License. Section 6 states terms for distribution of such executables.

When a "work that uses the Library" uses material from a header file that is part of the Library, the object code for the work may be a derivative work of the Library even though the source code is not. Whether this is true is especially significant if the work can be linked without the Library, or if the work is itself a library. The threshold for this to be true is not precisely defined by law.

If such an object file uses only numerical parameters, data structure layouts and accessors, and small macros and small inline functions (ten lines or less in length), then the use of the object file is unrestricted, regardless of whether it is legally a derivative work. (Executables containing this object code plus portions of the Library will still fall under Section 6.)

Otherwise, if the work is a derivative of the Library, you may distribute the object code for the work under the terms of Section 6. Any executables containing that work also fall under Section 6, whether or not they are linked directly with the Library itself.

6. As an exception to the Sections above, you may also combine or link a "work that uses the Library" with the Library to produce a work containing portions of the Library, and distribute that work under terms of your choice, provided that the terms permit modification of the work for the customer's own use and reverse engineering for debugging such modifications.

You must give prominent notice with each copy of the work that the Library is used in it and that the Library and its use are covered by this License. You must supply a copy of this License. If the work during execution displays copyright notices, you must include the copyright notice for the Library among them, as well as a reference directing the user to the copy of this License. Also, you must do one of these things:

a) Accompany the work with the complete corresponding machine-readable source code for the Library including whatever changes were used in the work (which must be distributed under Sections

1 and 2 above); and, if the work is an executable linked with the Library, with the complete machine-readable "work that uses the Library", as object code and/or source code, so that the user can modify the Library and then relink to produce a modified executable containing the modified Library. (It is understood that the user who changes the contents of definitions files in the Library will not necessarily be able to recompile the application to use the modified definitions.)

b) Use a suitable shared library mechanism for linking with the Library. A suitable mechanism is one that (1) uses at run time a copy of the library already present on the user's computer system, rather than copying library functions into the executable, and (2) will operate properly with a modified version of the library, if the user installs one, as long as the modified version is interface-compatible with the version that the work was made with.

c) Accompany the work with a written offer, valid for at least three years, to give the same user the materials specified in Subsection 6a, above, for a charge no more than the cost of performing this distribution.

d) If distribution of the work is made by offering access to copy from a designated place, offer equivalent access to copy the above specified materials from the same place.

e) Verify that the user has already received a copy of these materials or that you have already sent this user a copy.

For an executable, the required form of the "work that uses the Library" must include any data and utility programs needed for reproducing the executable from it. However, as a special exception, the materials to be distributed need not include anything that is normally distributed (in either source or binary form) with the major components (compiler, kernel, and so on) of the operating system on which the executable runs, unless that component itself accompanies the executable.

It may happen that this requirement contradicts the license restrictions of other proprietary libraries that do not normally accompany the operating system. Such a contradiction means you cannot use both them and the Library together in an executable that you distribute.

7. You may place library facilities that are a work based on the Library side-by-side in a single library together with other library facilities not covered by this License, and distribute such a combined library, provided that the separate distribution of the work based on the Library and of the other library facilities is otherwise permitted, and provided that you do these two things:

a) Accompany the combined library with a copy of the same work based on the Library, uncombined with any other library facilities. This must be distributed under the terms of the Sections above.

b) Give prominent notice with the combined library of the fact that part of it is a work based on the Library, and explaining where to find the accompanying uncombined form of the same work.

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