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一、适用范围、规格型号、配套试纸、检测方法和原理

1.1 适用范围

本产品与配套血糖试条配合使用，用于全血血样中葡萄糖测试，可用于医疗机构血糖测试、糖尿病患者或其他人群进行自我血糖监测。本产品只用于血糖水平的监测，不适用于糖尿病的最终诊断。

1.2 规格型号

真睿TRUE METRIX GO

1.3 配套试纸

TRUE METRIX血糖试纸（如需购买血糖试纸，请联系三诺或其授权经销商取得）

1.4 检测方法和原理

血糖试纸的反应区固定有特殊化学物质，血样中的葡萄糖与之接触后发生化学反应产生微电流，血糖仪检测微电流并转换成血糖浓度结果显示出来。血糖值显示为血浆血糖值。

二、仪器主要结构及其各配件组成结构和示意图

2.1 主要结构组成

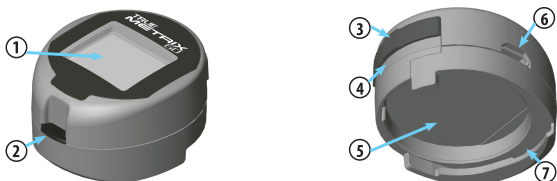
主机：血糖仪由电路板、按键、液晶显示屏、外壳组成。

配件：采血笔（经医疗器械备案的合格产品）、电池、拓展坞（选配）、数据线（选配）。

注：拓展坞（选配）仅适用于真睿TRUE METRIX、真睿TRUE METRIX AIR，数据线（选配）仅适用于真睿TRUE METRIX GO。

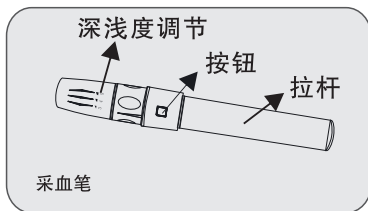
2.2 血糖仪及各配件组成示意图

2.2.1 真睿TRUE METRIX GO示意图



①屏幕 ②试纸插口 ③设置键 ④电池盖 ⑤标签 ⑥Micro-USB接口
(用于连接数据线后与PC进行数据传输, 数据线为选配件) ⑦ 瓶盖锁槽

2.2.2 采血笔示意图



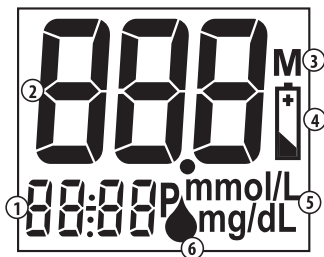
采血笔的使用方法请见采血笔使用说明书

注意：

血糖仪只能与“配套试纸”中注明的血糖试纸配合使用，请勿与其他公司产品或本公司其他型号产品混用。

三、显示说明

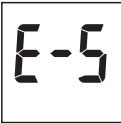
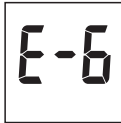
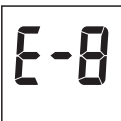

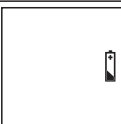
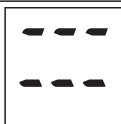

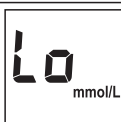
全屏显示各符号说明：



- ① 时间，日期，质控符号，平均值符号（7天，14天，30天）
- ② 测试结果
- ③ 测试值为储存结果符号
- ④ 电池符号
- ⑤ 单位符号
- ⑥ 滴血符号


	等待加样		测试中
	血糖测试结果 (示例)		质控液测试结果 (示例)

	设置年		设置日期
	设置时间		7天平均值
	14天平均值		30天平均值
	血糖查询结果 (示例)		无效的血细胞 压积
	超过仪器测试 温度范围		未检测出样本 或加样错误
	使用过的试纸		仪器错误

	试纸错误		测试中移除试纸 或测试中连接迷 你USB接口
	仪器错误		仪器错误
	电池电量低		屏幕损坏
	测试结果高于 33.3mmol/L		测试结果低于 1.1mmol/L

四、使用操作

4.1 安装电池

 电池不可充电。数据线仅用于仪器连接电脑传输数据，请不要使用该数据线连接任何充电设备进行充电。如果处理不当电池存在爆炸风险。请勿将电池投入火中。请勿拆卸电池或重复充电。请勿随意丢弃，请遵循当地法规要求处理废旧电池。



本仪器由1颗3V的CR2032锂电池(不可充电)供电。屏幕显示电池电量低时请更换电池。

1. 握住试纸瓶，逆时针旋转1/4从试纸瓶上取下仪器。
2. 拉出仪器背后的电池盖。
3. 取出电池盖中的电池。
4. 使新电池正面朝上，装入新电池。将电池盖装入仪器。

5. 按设置键开机。如果仪器不能正常开机，打开电池盖检查电池是否正负端装反。装上电池盖并重复步骤5。如果仪器仍然不能正常开机，请拨打客服电话。

4.2 仪器设置

注：没有安装在试纸瓶盖上仪器也能正常工作。

<p>安装仪器：</p> <ol style="list-style-type: none">1. 将试纸瓶盖面向左边。2. 使试纸插口面向自己，将仪器底部安装在试纸瓶盖上。3. 握住试纸瓶，顺时针旋转1/4。如果安装正确，试纸插口与试纸瓶盖应在一条垂直线上。	
<p>取下仪器：</p> <ol style="list-style-type: none">1. 握住试纸瓶，逆时针旋转1/4。2. 从试纸瓶上取下仪器。	

设置时间 / 日期

仪器出厂时已经预设默认的时间和日期。第一次使用仪器之前或更换电池之后，请检查时间日期，如有必要，请按以下步骤更新时间日期：

1. 关机状态下按住设置键直到出现全屏显示并且屏幕开始闪烁。松开设置键。仪器进入设置模式。

2. 时间显示且小时开始闪烁。按动设置键调整小时。

3. 调整至正确小时后，数字闪烁9次，然后跳至分钟设置。

4. 重复步骤2~4设置分钟，月，日，年。

如果在设置过程中，仪器关机，请按照步骤1开始重新操作。

每次按下设置键仅增加1位数字。一旦数字达到最大限值，屏幕回到最小数字。按下设置键调整数字，当数字调整完成后松开设置键。

当发生以下动作时，仪器自动开机：

- 试纸插入试纸口；
- 按下设置键

当发生以下动作时，仪器自动关机：

- 移除试纸；
- 按下设置键 3 秒钟；
- 2 分钟之内没有任何动作

4.3 测试

根据采血笔说明书安装好采血笔及采血针。

1. 检查血糖试纸瓶上的失效日期和开瓶日期。如已超过失效日期或开瓶日期后4个月（以先到期的为准），请放弃使用，并使用新的血糖试纸进行测试。

2. 使用前，将血糖仪与血糖试纸置于室温环境10分钟。

3. 使用温水和肥皂清洗采血部位，并风干。

4. 从试纸瓶中取出1根试纸，立即盖紧瓶盖。取出试纸后应立即使用。

5. 将血糖试纸插入血糖仪上的试纸插口，血糖仪开机。

6. 等待滴血符号显示。在测试完成之前保持试纸插入仪器的状态。在试纸插入仪器之前请勿在试纸上滴加血样。

7. 使用采血笔采血。在向试纸加样前使血样形成血滴。为了促进血滴形成，可放低手指并轻轻按摩。

8. 保持血糖试纸插入血糖仪的状态，使血糖试纸加样端边缘接触血样，血样被吸入试纸。

9. 当血糖仪发出短促的“哔”提示音且屏幕显示3条横线时，将试纸从血样中移开。

10. 血糖仪显示测试结果，记录测试结果。

11. 移除试纸和采血针丢弃至指定容器内。仪器关机。测试结果自动储存。

使用过的试纸和采血针请按照医用废弃物处理。

注：

-如果试纸在空气中暴露时间过长，仪器显示错误提示。移除并丢弃该试纸，使用新的试纸重新测试。

-请勿在试纸加样区之外滴加血样。

-在测试结果显示之前移除试纸，仪器显示错误提示。该测试结果不储存于仪器-内。使用新的试纸重新测试。请勿在测试结果显示之前移除试纸。

-静脉血请由专门的医护人员进行血样采集。

与实验室测试结果对比

当该仪器与实验室测试结果对比时，使用仪器测试必须在实验室测试30分钟之内完成。

4.4 结果查询

查询平均值 (7天, 14天, 30天)

1. 仪器关机状态下，短按并松开设置键。
2. 屏幕依次显示7天平均值，14天平均值，30天平均值。如果2分钟内没有任何操作，仪器自动关机。如果没有平均值，仪器显示3条横线。

查询测试结果

本仪器可储存500个血糖测试结果。当第501个血糖测试结果被存入，最早储存的血糖测试结果会被自动覆盖。

1. 在仪器显示平均值界面状态下，再次按下并松开设置键。
2. 屏幕显示最近的血糖测试值及储存结果符号。血糖测试结果与储存结果符号、时间、日期一同显示。
3. 再次按下并松开设置键浏览测试结果。

注：仪器仅储存1个质控液测试结果。质控液测试结果与质控液符号一同显示。

五、检查系统

日常质控作为血糖测试系统运行状态的检测手段，有以下两种质控测试方法让您了解您的测试系统是否正常工作及使用者测试步骤是否正确。定期进行系统检查，可以确保仪器提供准确的检测结果。

5.1 自动自测：

注：自动自测不能代替质控液测试。

1. 插入试纸。
2. 仪器出现全屏显示。检查全屏显示是否有缺漏部分。
3. 滴血符号闪烁。仪器准备开始测试。

如果显示错误提示，请勿使用仪器进行测试，并查看故障章节。

5.2 质控液测试：

5.2.1 何时需要进行质控液测试

- 第一次使用仪器时；
- 检验您的测量步骤是否正确时；
- 使用一瓶新血糖试纸时；
- 长期未使用血糖试纸进行测试时；
- 测试结果异常时；
- 血糖试纸存放环境温湿度超出正常储存条件时；
- 您想检测仪器或血糖试纸是否正常工作时；
- 怀疑仪器损坏时（如仪器跌落、压碎、受潮时）；

重要信息：该产品共有3个浓度的配套质控液，请使用至少2个浓度的质控液来测试系统是否正常工作。

⚠ 试纸瓶贴上的质控范围并非建议血糖值，仅用于质控液测试结果参考。请勿服用质控液。

5.2.2 质控检查步骤

仅使用TRUE METRIX质控液进行质控测试。

1.检查血糖质控液瓶和血糖试纸瓶上的失效日期。如质控液已超过失效日期或开瓶日期后3个月（以先到的日期为准），请放弃使用，并使用新的血糖质控液进行测试。如试纸已超过失效日期或开瓶日期后4个月（以先到的日期为准），请放弃使用，并使用新的试纸进行测试。

2.使用前，将血糖仪、血糖试纸与血糖质控液置于室温环境10分钟。如果是首次打开血糖质控液瓶，请在瓶标签上注明开瓶日期。

3.洗手并风干。

4.轻轻倒转血糖质控液瓶几分钟。请勿摇晃。从瓶中取出血糖试纸，立即盖好瓶盖。取出试纸后应立即使用。

5.将血糖试纸插入血糖仪，启动血糖仪。在测试完成之前保持试纸插入仪器的状态。在试纸插入仪器之前请勿在试纸上滴加质控液。

6.打开质控液瓶盖，挤出一滴血糖质控液到一小块未用过的铝箔或清洁的塑料薄膜上，丢弃。

7.使血糖试纸的加样端接触血糖质控液滴。血糖试纸吸入血糖质控液。

8.当血糖仪开始测试，将血糖试纸从血糖质控液滴移开。

9.测试完成后，测试结果与质控液符号一同在屏幕上显示。

10.当血糖仪显示出结果，将其与血糖试纸瓶标签上的质控范围进行对照。如果质控液测试结果在质控范围内，该仪器可用于测试血样。如果质控液测试结果不在质控范围内，使用新的试纸再次进行质控液测试。如果质控液测试结果仍然不在质控范围内，请勿使用该仪器及试纸进行测试。请致电售后服务机构。

11.结果显示后，将血糖试纸从血糖仪移除并按照医用废弃物处理。仪器自动关机。重新盖紧血糖质控液瓶。

六、保存和保养

1. 血糖仪保存应避免灰尘，液体，防止剧烈振荡和碰撞。

2. 如仪器表面粘有异物，需要马上进行清洁。保持仪器关机且无试纸插入状态，使用棉签或干净无毛布沾75%的酒精或中性清洁剂进行擦拭。擦拭完成后让仪器自然风干。

3. 如长时间不使用仪器，使用棉签或干净无毛布沾75%的酒精或中性清洁剂进行擦拭。擦拭完成后让仪器自然风干，卸下电池后再保存。

4. 请勿在测试中清洁仪器。

5. 切勿让污垢、尘埃、血渍或液体经插口或缝隙进入仪器内。

七、保修

只有本公司或本公司的代理机构才能检查或提供任何零部件。

在正常使用情况下，如产品出现故障，本公司承诺十年包换。请认真填写保修卡，并将需要返回的部分，返回本公司。

如仪器故障需返回本公司，请将仪器用布或棉签蘸取少量的75%酒精擦拭清洁后再寄回本公司。

八、使用注意事项

1. 请按照厂商规定的方法使用本仪器，否则会对仪器造成损害或造成不准确的测试结果。

2. 本产品仅用于体外检测指尖毛细血样本。

3. 请勿在木糖吸收实验后进行测试。

4. 本仪器的测试结果只能作为血糖监测用，不能作为糖尿病诊断的依据。参考治疗医生和糖尿病专家的意见，不能仅根据检测的结果而违背他们的指导。当您使用本仪器得出同症状不相符的测试结果后，应立刻到医院检查。

5. 不适用于重症患者或新生儿。

6. 测试期间，仪器可能会与血液接触。因此使用过的仪器有携带感染物的风险。当本仪器在医疗场所使用时，医护人员请遵循你单位对卫生设备相应的感染控制步骤，如戴手套或其他个人防护。

九、故障

1. 试纸插入后，不能开启仪器


原因	解决方法
试纸插入时正反颠倒或上下颠倒	移除试纸。重新正确插入试纸。
试纸未完全插入	移除试纸。重新正确插入试纸。
试纸故障	使用新试纸进行测试。

原因	解决方法
电池电力不足	更换新电池
电池安装不正确	重新安装电池，使+电极端面朝上
仪器故障	请与客服联系

2. 加入样本后，仪器不能开始测试

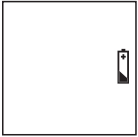
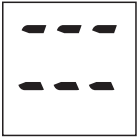


原因	解决方法
样本量不足	换用新试纸，吸入足够的样本量，重新测试
插入试纸后2分钟后加样	使用新试纸进行测试。在插入试纸后2分钟内滴加血样。
试纸故障	使用新试纸进行测试。如果仍然无法开始测试，请与客服联系。
仪器故障	请与客服联系

3. 错误提示

屏幕显示	原因	解决方法
	无效的血细胞压积	使用新试纸对指尖毛细血管血样进行测试。如果仍然显示错误提示，请与客服联系。

屏幕显示	原因	解决方法
	<p>超过仪器测试温度范围</p>	<p>将仪器和试纸在5°C-40°C环境下平衡10分钟直至达到测试温度范围。</p>
	<p>未检测出样本或加样错误</p>	<p>使用新试纸按照说明书重新进行测试。</p>
	<p>使用过的试纸，试纸暴露在空气中时间过长</p>	<p>使用新试纸进行测试。如果仍然显示错误提示，请与客服联系。</p>
	<p>仪器错误</p>	<p>请与客服联系</p>

屏幕显示	原因	解决方法
	试纸错误	使用新试纸进行测试。如果仍然显示错误提示，请与客服联系
	测试中移除试纸或测试中连接迷你USB接口	拔掉USB线。使用新试纸进行测试。确认试纸移除前仪器显示测试结果。如果仍然显示错误提示，请与客服联系
	仪器错误	请与客服联系
	仪器错误	请与客服联系

屏幕显示	原因	解决方法
	<p>电池电量低</p>	<p>更换新电池</p>
	<p>屏幕损坏</p>	<p>请勿使用该仪器进行测试。请与客服联系</p>
	<p>测试结果高于 33.3mmol/L</p>	<p>使用新试纸进行测试。如果测试结果仍然显示Hi，请马上联系您的健康顾问或医生。</p>
	<p>测试结果低于 1.1mmol/L</p>	<p>使用新试纸进行测试。如果测试结果仍然显示Lo，请马上联系您的健康顾问或医生。</p>

十、血糖测试系统测量性能

此血糖测试系统准确度、测量重复性标准参考国家标准 GB/T19634-2005《体外诊断检验系统自测用血糖监测系统通用技术条件》和国际标准 ISO 15197 : 2013《In vitro diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus》。

系统的准确度要求：≥95%的测试结果的偏差应符合表1的要求；
系统的测量重复性要求：测试结果应符合表2的要求。

表1:准确度要求

测试范围	允许偏差
1.1mmol/L ~ 5.55mmol/L (20mg/dL ~ 100mg/dL)	不超过±0.83mmol/L (±15mg/dL)
5.55mmol/L ~ 33.3mmol/L (100mg/dL ~ 600mg/dL)	不超过±15%

表2：测量重复性要求

测试范围	精密度
1.1mmol/L ~ 5.55mmol/L (20mg/dL ~ 100mg/dL)	SD < 0.34mmol/L (6 mg/dL)
5.55mmol/L ~ 33.3mmol/L (100mg/dL ~ 600mg/dL)	CV < 6%

十一、产品性能参数

测试范围：1.1mmol/L-33.3 mmol/L

用量：约0.5 μ L

检测样本：新鲜指尖毛细血全血、质控液

血糖测试时间：4~7秒

结果显示：血浆血糖值

测试原理：电化学

电源：1个3V锂电池#CR2032（不可充电），最大额定电流：
10mA

电池寿命：约1000次测试或1年

生产日期：见标签

使用期限：10年（按每天监测7次血糖的使用频率确定）

本产品使用期限是按照每天监测7次血糖的使用频率确定的，在使用过程中，用户应当按照产品说明书的要求对产品进行维护、保养。在维护、保养后，经确认仍能保持基本安全性和有效性的产品，可以正常使用。

软件发布版本：V01

记忆容量：500个血糖测试值

尺寸：40mm \times 36mm \times 22mm

测试环境：

湿度：10~80%RH(不结露)

温度：5 $^{\circ}$ C~40 $^{\circ}$ C

血细胞压积：20~70%

储运条件：10~93%RH(不结露)，-20 $^{\circ}$ C~55 $^{\circ}$ C

海拔：最高可至3108米

十二、配件清单

采血笔：1支，经医疗器械备案的合格产品，具体使用及更换方法见采血笔说明书。

电池：1个3V锂电池#CR2032（不可充电），其安装、更换及注意事项内容详见本说明书“4.1安装电池”内容。

数据线（选配）

十三、符号的解释

 体外诊断医疗器械	 参考使用说明
 序列编号	 避免日晒
 避免雨淋	 电子电气产品有害物质限制使用标志
 易碎，小心轻放	 生产企业
 注意，参考随附文件	 生物危害

十四、电磁兼容性声明

本仪器符合EMC标准GB/T 18268.1-2010及GB/T 18268.26-2010的发射和抗扰度要求。

注意：

（1）在干燥的环境中，尤其是存在人造材料（人造织物，地毯等）的干燥环境中使用本设备时，可能会引起损坏性的静电放电，导致产生错误的结论。

（2）便携式和移动式射频通信设备可能影响本仪器的性能。

(3) 禁止在强辐射源（例如非屏蔽的射频源）旁使用本设备，否则可能会干扰设备正常工作。

(4) 用户有责任确保设备的电磁兼容环境，使设备能正常工作。建议在设备使用之前评估电磁环境。

14.1 指南和制造商的声明-电磁发射

指南和制造商的声明—电磁发射		
本仪器预期使用在下列规定的电磁环境下，购买者或使用者应该保证它在这种电磁环境下使用。		
发射试验	符合性	电磁环境-指南
辐射发射GB4824	满足1组B类设备限值	本仪器仅为其内部功能而使用射频能量。因此，它的射频发射很低，并且对附近的电子设备产生干扰的可能性很小。

14.2 指南和制造商的声明-电磁抗扰度

指南和制造商的声明—电磁抗扰度

本仪器预期使用在下列规定的电磁环境下，购买者或使用者应该保证它在这种电磁环境下使用。

抗扰度试验	试验电平	符合电平	电磁环境-指南
静电放电 (ESD) GB/T 17626.2	空气放电： $\pm 2\text{kV}$ ； $\pm 4\text{kV}$ ； $\pm 8\text{kV}$ 接触放电： $\pm 2\text{kV}$ ； $\pm 4\text{kV}$	空气放电： $\pm 2\text{kV}$ ； $\pm 4\text{kV}$ ； $\pm 8\text{kV}$ 接触放电： $\pm 2\text{kV}$ ； $\pm 4\text{kV}$	地面应该是木质、混凝土或瓷砖，如果地面用合成材料覆盖，相对湿度应该至少30%。
额定工频磁场 GB/T 17626.8	3A/m，50Hz	3A/m，50Hz	工频磁场应具有在商业或医院环境中典型场所的工频磁场水平特性。

14.3 指南和制造商的声明-电磁抗扰度

指南和制造商的声明—电磁发射			
本仪器预期使用在下列规定的电磁环境下，购买者或使用者应该保证它在这种电磁环境下使用。			
抗扰度试验	试验电平	符合电平	电磁环境 - 指南
辐射电磁场 GB/T17626.3	3 V/m 80MHz ~ 2.0 GHz	3 V/m 80MHz ~ 2.0 GHz	<p>便携式和移动式射频通信设备不应比推荐的隔离距离更靠近血糖仪的任何部分使用。该距离由与发射机频率相应的公式计算。</p> <p>推荐的隔离距离</p> $d = 1.2 \cdot \sqrt{P} \quad 80\text{MHz} \sim 800\text{MHz}$ $d = 2.3 \cdot \sqrt{P} \quad 800\text{MHz} \sim 2.0\text{GHz}$ <p>式中：</p> <p>P—根据发射机制造商提供的发射机最大额定输出功率，单位为瓦特(W)；</p> <p>d—推荐的隔离距离，以米(m)为单位。</p> <p>固定式射频发射机的场强通过对电磁场所的勘测a来确定，在每个频率范围b都应比符合电平低。</p> <p>在标记下列符号的设备附近可能出现干扰 </p>
<p>注1：在 80MHz 和 800MHz频率点上, 采用较高频段的公式。</p> <p>注2：这些指南可能不适合所有的情况，电磁传播受建筑物、物体及人体的吸收和反射的影响。</p>			
<p>a.固定式发射机，诸如：无线（蜂窝/无绳）电话和地面移动式无线电台的基站、业余无线电、调幅和调频无线电广播以及电视广播等，其场强在理论上都不能准确预知。为评定固定式射频发射机的电磁环境，应考虑电磁场所的勘测。如果测得血糖仪所处场所的场强高于上述适用的射频符合电平，则应观测血糖仪以验证其能正常运行。如果观测到不正常性能，则补充措施可能是必须的，比如重新调整血糖仪的方向或位置。</p> <p>b.在150kHz ~ 80MHz 整个频率范围，场强应低于3V/m。</p>			

14.4 便携式及移动式射频通信设备和设备或系统之间的推荐隔离距离

便携式及移动式射频通信设备和本仪器之间的推荐隔离距离

本仪器预期在射频辐射骚扰受控的电磁环境中使用。依据通信设备最大额定输出功率，购买者或用户可通过下面推荐的维持便携式及移动式射频通信设备（发射机）和本仪器之间最小距离来防止电磁干扰。

发射机的最大额定输出功率W	对应发射机不同频率的隔离距离/m	
	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.0GHz $d=2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

对于上表未列出的发射机最大额定输出功率，推荐隔离距离d，以米(m)为单位，可用相应发射机频率栏中的公式来确定，这里P是由发射机制造商提供的发射机最大额定输出功率，以瓦特(W)为单位。

注1：在80MHz和800MHz频率点上，采用较高频范围的公式。

注2：这些指南可能不适合所有的情况，电磁传播受建筑物、物体及人体的吸收和反射的影响。

中国2型糖尿病血糖控制目标

(《中国2型糖尿病防治指南》2017年版)

状态	目标范围
空腹	4.4 ~ 7.0mmol/L (79 mg/dL ~ 126 mg/dL)

妊娠期糖尿病患者 (GDM) 妊娠期血糖控制目标

(妊娠合并糖尿病诊治指南 (2014))


状态	范围
餐前	$\leq 5.3\text{mmol/L}$ ($\leq 95\text{mg/dL}$)

正常血糖范围


(《全国临床检验操作规程》第四版)

状态	正常范围
空腹	3.9 ~ 6.1 mmol/L (70 mg/dL ~ 110 mg/dL)

产品中有害物质的名称及含量

部件名称	有害物质		
	铅 (Pb) 及其化合物	汞 (Hg) 及其化合物	镉 (Cd) 及其化合物
印刷电路板	○	○	○
五金件	○	○	○
电子元器件	×	○	○
壳体	○	○	○
	六价铬(Cr(VI)) 化合物	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
印刷电路板	○	○	○
五金件	○	○	○
电子元器件	○	○	○
壳体	○	○	○
<p>○：表示该有害物质在该部件所有均质材料中的含量均在GB/T 26572规定的限量要求以下。</p> <p>×：表示该有害物质至少在该部件的某一均质材料中的含量超出GB/T 26572规定的限量要求。</p> <p>上表中打“×”部分，由于技术原因目前无法实现代替，随着技术上的进步将逐渐改进。</p> <p>*：表示部分产品型号含该部件。</p>			
<p> 用户按照产品说明正常使用时，本产品中含有的有害物质不会发生外泄或突变，不会对环境造成严重污染或对其人身、财产造成严重损害的期限为10年。</p>			

产品中有害物质的名称及含量

部件名称	有害物质		
	铅 (Pb) 及其化合物	汞 (Hg) 及其化合物	镉 (Cd) 及其化合物
*电源线或电源适配器	○	○	○
*电池	○	○	○
*血糖试条	○	○	○
*采血笔	○	○	○
包装及印刷件	○	○	○
/	六价铬(Cr(VI)) 化合物	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
*电源线或电源适配器	○	○	○
*电池	×	○	○
*血糖试条	○	○	○
*采血笔	○	○	○
包装及印刷件	○	○	○
<p>○：表示该有害物质在该部件所有均质材料中的含量均在GB/T 26572规定的限量要求以下。</p> <p>×：表示该有害物质至少在该部件的某一均质材料中的含量超出GB/T 26572规定的限量要求。</p> <p>上表中打“×”部分，由于技术原因目前无法实现代替，随着技术上的进步将逐渐改进。</p> <p>*：表示部分产品型号含该部件。</p>			
<p> 用户按照产品说明正常使用时，本产品中含有的有害物质不会发生外泄或突变，不会对环境造成严重污染或对其人身、财产造成严重损害的期限为10年。</p>			

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1. Intended use, Model, Applicable strip, Test Principle

1.1. Intended use

The meter is used with test strip to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The System may not be used for neonates. The System is intended for at-home use outside the body (self-testing) and for use by healthcare professionals in clinical settings in order to assist in the management of diabetes. This System is not for use in diagnosis or screening of diabetes mellitus.

1.2 Model

真睿TRUE METRIX GO

1.3 Applicable test strip

TRUE METRIX blood glucose test strip

1.4 Test Principle

The Test Strip is a plastic strip containing chemicals and electrodes. When inserted into meters, glucose is measured using amperometric technology employing a glucose dehydrogenase-FAD reaction. When whole blood or control solution is drawn into the Sample Tip of the test strip, glucose in the sample reacts with the chemicals and produces an electrical current. The meter measures the current and calculates the amount of glucose. The result is displayed as a plasma value.

2. Structure and Diagram of Meter and Accessories

2.1 Main structure composition

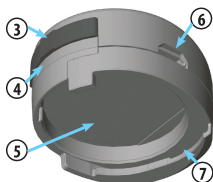
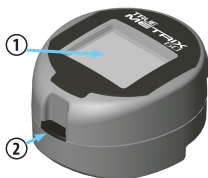
Meter: Meter is composed by PCB board, buttons, LCD display and case.

Accessories: Lancing device (product which already get registration certificate or filing), batteries, docking station (optional), USB cable (optional).

Note: Docking station (optional) only apply to 真睿TRUE METRIX、真睿TRUE METRIX AIR. USB cable (optional) only apply to 真睿TRUE METRIX GO.

2.2 Diagram of Meter and Accessories

2.2.1 Meter



① Display

② Test Port

③ Set Button

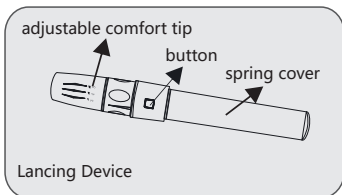
④ Battery Tray

⑤ Meter Label

⑥ Micro USB Port

⑦ Vial Lip Cover

2.2.2 Lancing device

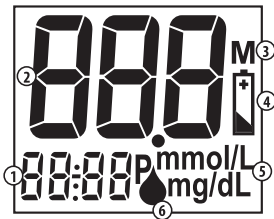


Please refer to lancing device instruction of use for more information.

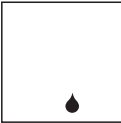
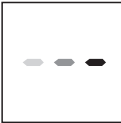

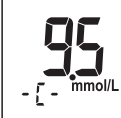



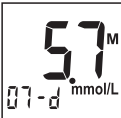

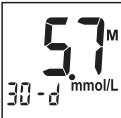


Note: Blood glucose meter can only be used with matched strip. Do not use with other product.

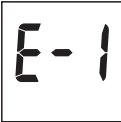
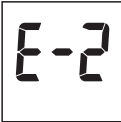
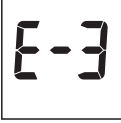
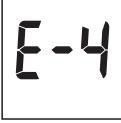

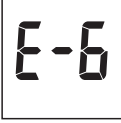
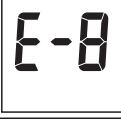
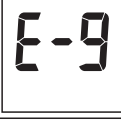
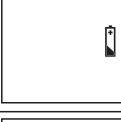
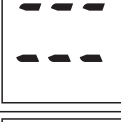

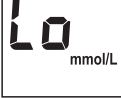
3. Display

Full screen display




- ① Time, Date, Control Symbol (-C-), Alternate Site Symbol (-A-), Average Symbol (7-, 14-, or 30-day)
- ② Test Result
- ③ Memory Result
- ④ Battery Symbol
- ⑤ Units of measure - Factory set to mmol/L or mg/dL, cannot be changed by user.
- ⑥ Drop Symbol

	<p>Waiting for apply sample</p>		<p>During testing</p>
	<p>Blood glucose test result (example)</p>		<p>Control solution test result (example)</p>
	<p>Setting year</p>		<p>Setting date</p>
	<p>Setting time</p>		<p>7-day average test result</p>
	<p>14-day average test result</p>		<p>30-day average test result</p>
	<p>Blood glucose test result in memory (sample)</p>		<p>30-day average test result</p>

	<p>Temperature error Too cold/ Too hot</p>		<p>Sample not detected or Sample Drop on Top of Test Strip</p>
	<p>Used test strip; Test strip outside of vial too long</p>		<p>Sample not detected or Sample Drop on Top of Test Strip</p>
	<p>Test strip Error</p>		<p>Test strip removed during test or Micro USB Cable connected while testing.</p>
	<p>Meter error</p>		<p>Meter error</p>
	<p>Low or dead battery</p>		<p>Broken Display</p>
	<p>WARNING! Out of range - High results > 33.3 mmol/L</p>		<p>WARNING! Out of range - Low results < 1.1 mmol/L</p>

4. Operation

4.1 Changing Battery

 Do not recharge battery. USB cable is only for data transmission. Do not use USB cable to recharge. Battery may explode if mishandled. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local regulations.

The meter use CR2032 lithium battery (non-recharge). Replace battery when display shows low battery error.

1. Remove meter from top of test strip vial by holding the vial and twisting the meter $\frac{1}{4}$ turn counterclockwise. Lift meter from vial top.

2. Turn meter over until the meter label is facing up. Pull Battery Tray out until battery is exposed.

3. Holding the Battery Tray over your hand, press on edge of battery until battery drops out.

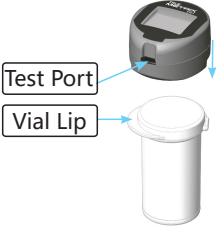

4. Insert new battery into Battery Tray with "+" side facing up. Slide Battery Tray back into meter.

5. Turn meter back over and press Set Button to turn meter on. If meter does not turn on, open Battery Tray and check that the battery was inserted with the "+" side facing up. Close Battery Tray and repeat Step 5. If meter still does not turn on, call the number on the cover of this Booklet for assistance.

4.2 Meter set up

To Attach/Remove Meter to Test Strip Vial

The meter may also be used for testing without attaching to the vial.

<p>To attach:</p> <ol style="list-style-type: none">1. Set test strip vial on flat surface with vial lip facing to the left.2. With Test Port facing front, place bottom of meter firmly on vial top. Meter must be seated flat on top of vial cap.3. Holding the vial, twist the meter 1/4 turn clockwise. The Test Port area on the meter should cover the vial lip if attached properly.	
<p>To remove:</p> <ol style="list-style-type: none">1. Holding the vial, twist the meter 1/4 turn counter clockwise.2. Lift off meter off the vial top.	

Set Time/Date

The meter comes with pre-set time and date. Before using the meter for the first time or after a battery change, check time and date and update as needed.

1. Start with the meter off. Press and hold the Set Button until the full Display appears and begins to blink. Release Set Button.

2. The time appears and the hour begins flashing. Change the number by pressing the Set Button until the desired number appears.

3. After the correct number appears, the number flashes 8 times before going to the minutes.

4. Repeat steps 2-4 to set up minutes, month, day and year.

If meter turns off at any time during Set Up, go back to Step #1 and begin again.

Pressing and releasing the Set Button only makes the numbers increase by one. Once the number reaches its limit, it resets to the lowest number. Pressing and holding the Set Button scrolls the numbers. Release Set Button when desired number is reached

The meter turns on when:

- a test strip is inserted into the Test Port, or
- when Set Button is pressed and released (see Meter Memory and Time/Date Set Up).

Meter turns off when:

- the test strip is released from the meter,

- the Set Button is pressed and held for 3 seconds, or
- after 2 minutes of non-use.

4.3 Blood Glucose Testing

Refer to lancing device Instructions for Use for detailed instructions.

1. Check dates on test strip vial being used. Do not use if either 4 months after first opening or after date printed next to on label, whichever comes first.

2. Allow vial of test strips and meter to adjust to room temperature for 10 minutes.

3. Wash hands in warm, soapy water. Rinse well and dry thoroughly.

4. Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after taking it out of the vial.

5. Insert test strip firmly into Test Port. Meter turns on.

6. Wait until Drop Symbol appears in the Display. Keep test strip in meter until testing is finished. Do not add blood to test strip before inserting into meter.

7. Set lancing device aside. Lance fingertip. To help blood drop form, lower hand to waist level and gently massage from palm to fingertip. Allow blood drop to form before attempting to apply to the test strip.

8. With test strip in Meter, touch Sample Tip to top of blood drop. Allow blood to be drawn into the test strip.

9. Remove test strip from drop when dashes appear across the meter Display. Meter is testing.

10. After testing is finished, result appears in the meter Display.

11. Remove test strip from meter and discard into an appropriate waste container. Meter turns off. Result is stored in the Memory.

Note:

-If test strip has been out of the vial too long before testing, an error message appears. Remove and discard old test strip. Use new test strip for testing.

-Do not place blood drop on top of test strip.

-Removing the test strip before result is displayed cancels the test. An error message appears. Result is not stored in Memory. Retest with a new test strip. Do not remove before result is displayed.

-Only professional can collect venous samples.

System and Laboratory Testing

When comparing results between the product and a laboratory system, meter blood tests should be performed within 30 minutes of a laboratory test.

4.4 Meter Memory

View Averages (7-, 14-, and 30-Day)

1. With meter off, press and release Set Button.

2. Display scrolls through the 7-, 14-, and 30-day Averages.

Meter turns off after 2 minutes if Set Button is not pressed. If there are no Average values, three dashes are displayed for 7-, 14-, and 30-Day Averages.

View Results

Meter Memory stores 500 results which are displayed from most recent to oldest. Once Memory is full, the oldest result is replaced with the newest result.

1. After meter displays the Averages, press and release Set Button again.

2. The most recent result is shown with the Memory Symbol. Blood test results are shown with the Memory Symbol, the time and date.

3. Continue to press and release the Set Button to scroll through results. Blood test results are shown with the Memory Symbol, the time and date

Note: One Control Test result is stored in Memory. The Control Test result will show the Control Symbol in the lower left corner of the Display.

5.Quality Control Testing

To assure accurate and reliable results, the System offers two kinds of quality control tests, an Automatic Self-Test and a Control Test. These tests ensure that the system is working properly and testing technique is good.

5.1 Automatic Self-Test

Note: The Automatic Self-Test does not take the place of running a Control Test.

1. Insert a test strip into the Test Port.
2. Full Display appears. Check for missing segments.

3. Drop Symbol begins to blink. Meter may be used for testing.


If an error message appears, the meter will not perform a test. See Troubleshooting or contact for assistance.

5.2 Control Test

5.2.1 When to perform control test:

- before using the meter for the first time,
- for practice to ensure your testing technique is good,
- when opening a new vial of test strips,
- occasionally as a vial of test strips is used,
- if results seem unusually high or low,
- if the test strip vial has been left opened, exposed to extreme heat, cold, or humidity,
- whenever a check on the performance of the system is needed,
- if meter damage is suspected (meter was dropped, crushed, wet, etc.).

Note: It is important to perform Control Tests with more than one level of TRUE METRIX Control Solution. Three levels of control solution are available for Control Tests. Use contact on the cover' for more information on how to obtain control solution.

 Ranges printed on test strip vial label are for Control Test results only and are not suggested levels for blood glucose. Do not drink control solution.

5.2.2 How to Test Control Solution

Use ONLY TRUE METRIX Control Solution for Control Test.

1. Check dates on control solution label and test strip vial label. Do not use control solution or test strips if either Use By Dates have passed. (control solution - 3 months after opening or date next to on label, whichever comes first, test strips - 4 months after opening or date next to symbol, whichever comes first.) Discard expired products and use new products.

2. Allow control solution, vial of test strips and meter to adjust to room temperature for 10 minutes.

3. Wash hands, dry thoroughly.

4. Gently swirl or invert control solution bottle to mix. DO NOT SHAKE!

5. Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.

6. Insert test strip into Test Port. Meter turns on. Keep test strip in meter until testing is finished. Do not add control solution to test strip before inserting into meter.

7. Remove cap from control solution bottle. Gently squeeze a drop onto a clean tissue. Wipe off bottle tip and discard tissue. Gently squeeze a drop onto a small piece of unused aluminum foil, clear plastic wrap, or waxed paper for testing.

8. With test strip still in meter, touch Sample Tip of test strip to top of drop of control solution. Allow drop to be drawn into test strip.

9. Remove test strip from drop when meter beeps and begins testing.

10. After testing is finished, result appears in the meter Display with the Control Symbol.

Compare result to Control Test range printed on test strip vial label for level of control solution you are using. If result is in range, system can be used for testing blood. If result does not fall within range, repeat control test using a new test strip. If Control Test result is outside range, test again. If result is still outside range, system should not be used for testing blood. Contact for assistance (see Booklet cover for contact information).

11. After result is shown, remove test strip from meter and discard. Meter turns off. Recap control solution bottle tightly.

6. Preservation and Maintenance

1. Store meter in carrying case to protect from liquids, dust and dirt. Do not keep meter in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.).

2. Clean immediately after getting any blood on the meter or if meter is dirty or before allowing anyone else to handle it. Do not use bleach to clean the meter. Make sure meter is off and a test strip is not inserted. Wipe Meter with a clean, lint free cloth or swab dampened with 75% alcohol or neutral cleaner. Let Meter air dry thoroughly before using to test.

3. If not use meter for long time, wipe Meter with a clean, lint free cloth or swab dampened with 75% alcohol or neutral cleaner. Let Meter air dry thoroughly and remove battery.

4. Do not clean the meter during a test.

5. Never put Meter in liquids or allow any liquids to enter the Test Port.

7. Warranty

Sinocare Inc. warrants this meter to be free of defects in materials and workmanship for 10 years from the date of purchase. If during this 10 year period, the meter does not work properly, Sinocare will replace it with a new meter or equivalent product free of charge. Failure of the meter due to abuse or use not in accordance with the instructions for use is not covered by this Warranty. Use wipe or swab with 75% alcohol to clean meter before send back to Sinocare.

8. Matters need attention

1. Use of meter in a manner not specified in this Owner' s Booklet is not recommended and may affect ability to determine true blood glucose levels.

2. The product is an in vitro (outside body) quantitative system that is used for self-testing of human whole blood only.

3. Do not use this product during a xylose absorption test.

4. NEVER change a treatment plan without consulting a doctor or healthcare professional. Do not use for the diagnosis of or screening for diabetes mellitus or for measuring blood glucose in newborns. If test result do not match the way you feel, repeat the test. If the results still do not match the way you feel, call the doctor or healthcare professional.

5. DO NOT perform testing on the critically ill or newborn.

6. ALL parts of the product could carry blood-borne pathogens after use, even after cleaning and disinfecting. Reuse of devices labeled for single-use may result in product contamination and patient infection. If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned prior to use by the second person.

9. Troubleshooting

1. Use of meter in a manner not specified in this Owner's Booklet is not recommended and may affect ability to determine true blood glucose levels.

2. The product is an in vitro (outside body) quantitative system that is used for self-testing of human whole blood only.

3. Do not use this product during a xylose absorption test.




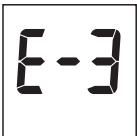
1. After inserting test strip, meter does not turn on.





Reason	Action
Test strip inserted upside down or backwards	Remove test strip. Re-insert correctly into the meter.
Test strip not fully inserted	Remove test strip. Re-insert test strip fully into meter
Test strip error	Remove test strip from meter. Repeat with new test strip.
Meter is dead or there is no battery	Remove test strip from meter. Replace battery. Use new test strip for testing.
Battery in the meter backwards	Battery must be placed in meter with positive ("+") side must face up.
Meter error	Contact for assistance.


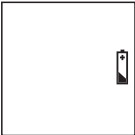
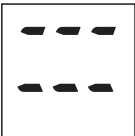

2. After applying sample, test does not start/meter does not begin testing.


Reason	Action
Sample drop too small	Repeat test with new test strip and larger drop.
Sample applied after two minute shut-off	Repeat test with new test strip. Apply sample within 2 minutes of inserting test strip.
Test Strip Error	Repeat with new test strip. If testing still has not begun, contact for assistance.
Meter Error	Contact for assistance.

3. Messages

Display	Reason	Action
	Invalid Hematocrit	Repeat with new test strip, using capillary whole blood from the finger, forearm or venous whole blood collected only in a sodium heparin blood collection tube. If error persists, contact for assistance.
	Temperature error Too cold/Too hot	Move meter and test strips to area between 5°C-40°C; wait 10 minutes for system to reach room temperature before testing.
	Sample not detected or Sample Drop on Top of Test Strip	Retest with new test strip and larger sample. Make sure Sample Tip of test strip touched top of sample drop.
	Used test strip; Test strip outside of vial too long.	Repeat with new test strip. If error persists, contact for assistance.

Display	Reason	Action
	Meter error	Contact for assistance.
	Test strip Error or Very High Blood Glucose Result (higher than 33.3 mmol/L)	Retest with new test strip. If error persists, contact for assistance. If you have symptoms such as fatigue, excess urination, thirst or blurry vision, follow a doctor or healthcare professional's advice for high blood glucose.
	Test strip removed during test or Micro USB Cable connected while testing.	Unplug Micro USB cable. Retest with new test strip. Make sure result is displayed before removing test strip. If error persists, contact for assistance.
	Meter error	Contact for assistance.

Display	Reason	Action
	Meter error	Contact for assistance.
	Low or dead battery	Replace battery
	Broken Display	WARNING! Retest with new test strip. If result is still "Hi" (High) contact doctor or healthcare professional immediately.
	WARNING! Out of range - High results > 33.3 mmol/L	Repeat with new test strip. If error persists, contact for assistance.

Display	Reason	Action
	<p>WARNING! Out of range - Low results < 1.1 mmol/L</p>	<p>WARNING! Retest with new test strip. If result is still "Lo" (Low) contact doctor or healthcare professional immediately.</p>

10. Performance

Accuracy and repeatability criteria for this product refer to national standard GB/T19634-2005 In vitro diagnostic test systems -General technical requirements for blood-glucose monitoring systems for self-testing and International standard EN ISO 15197:2015 In vitro diagnostic test systems —Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

Accuracy requirement: $\geq 95\%$ of test result bias shall meet table 1 requirement.

Repeatability requirement: test result shall meet table 2 requirement.

Table 1: Accuracy Requirement

Test Range	Accept Bias
1.10mmol/L ~ 5.55mmol/L (20mg/dL ~ 100mg/dL)	Within ± 0.83 mmol/L (± 15 mg/dL)
5.55mmol/L ~ 33.30mmol/L (100mg/dL ~ 600mg/dL)	Within $\pm 15\%$

Table 2 : Repeatability Requirement

Test Range	Precision
1.10mmol/L ~ 5.55mmol/L (20mg/dL ~ 100mg/dL)	SD < 0.34mmol/L (6 mg/dL)
5.55mmol/L ~ 33.30mmol/L (100mg/dL ~ 600mg/dL)	CV < 6%

11. Specification

Result Range: 1.1 - 33.3 mmol/L

Sample Size: 0.5 microliter (0.5 μ L)

Sample: Fresh capillary whole blood or control solution

Test Time: Results in as fast as 4 seconds

Result Value: Plasma values

Assay Method: Electrochemical

Power Supply: One 3V lithium battery #CR2032 (non-re-chargeable), Maximum rated current: 10mA

Battery Life: Approximately 1000 tests or 1 year

Manufacture date: Refer to meter label.

Shelf life: 10 years (based on every day perform 7 tests)

Software release version: V01

Memory Size: 500 glucose results

Size: 40mm \times 36mm \times 22mm

Operating Range

Relative Humidity: 10%-80% (Non-condensing)

Temperature: 5°C - 40°C

Hematocrit: 20%-70%

Storage condition: 10~93%RH, -20~55°C

Altitude: Up to and including 3108 meters











12. Accessory list

Lancing device: 1 pcs, product which already get registration certificate. Operation method please refer to lancing device instruction of use.

Battery: One 3V lithium battery #CR2032 (non-rechargeable). Details please check "4.1 Changing Battery"

USB cable : Optional

13. Explanation of symbols

 For in vitro Diagnostic Testing Only	 Attention! Read Instructions for Use
 Serial Number	 Keep away from direct sunlight
 Keep Dry	 Electronic and electrical hazardous substance symbol
 Fragile, handle with care	 Manufactured By
 Caution!	 Biological Harm

14. EMC Statement

This meter meets the electromagnetic emissions requirements as per GB/T 18268.1-2010 and GB/T 18268.26-2010.

Note:

(1) In dry environment, especially with artificial material (artificial textile. carpet), using this meter may cause electrostatic discharge and lead to incorrect result.

(2) Portable device or mobile radio emission device may effect performance of this meter.

(3) Do not use this meter near substantial radiation source, otherwise may effect performance of this meter.

(4) User should make sure the meter can work normally during electromagnetic compatibility environment.

14.1 Guidance and manufacturer' s declaration-electromagnetic emission

Guidance and manufacturer' s declaration-electromagnetic emission		
The equipment is intended for sue in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions GB4824	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions GB 4824	Class B	
Harmonic emissions GB 17625.1	Not applicable	/
Voltage fluctuations/ flicker emissions GB 17625.2	Not applicable	

14.2 Guidance and manufacturer' s declaration- electromagnetic immunity

Guidance and manufacturer' s declaration- electromagnetic immunity			
The equipment is intended for sue in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) GB/T 17626.2	Air : $\pm 2\text{kV}; \pm 4 \text{ kV};$ $\pm 8 \text{ kV}$ Contact : $\pm 2 \text{ kV}; \pm 4 \text{ kV}$	Air : $\pm 2\text{kV}; \pm 4 \text{ kV};$ $\pm 8 \text{ kV}$ Contact : $\pm 2 \text{ kV}; \pm 4 \text{ kV}$	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency magnetic field GB/T17626.8	3A/m , 50Hz	3A/m , 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips GB/T17626.11	0% for cycle 1	N/A	/
	40% for cycle 5	N/A	
	70% for cycle 25	N/A	
Surge GB/T17626.5	$\pm 1\text{kV}$ lines to earth $\pm 1\text{Kv}$ lines to lines	N/A	/

14.3 Guidance and manufacturer' s declaration- electromagnetic immunity

Guidance and manufacturer' s declaration- electromagnetic immunity

The equipment is intended for sue in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	Test level	Compliance level	Electromagnetic environment-guidance
Conducted RF GB/T17626.6	3V (Valid values) 150kHz ~ 80MHz	N/A	Portable and mobile RF communications equipment should be used to no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \cdot \sqrt{P}$ 80MHz ~ 800MHz $d=2.3 \cdot \sqrt{P}$ 800MHz ~ 2.0GHz Where: P —maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer. d —the recommended separation distance in metres.
Radiated RF GB/T17626.3	3V/m 80MHz ~ 2.0GHz	3V/m 80MHz ~ 2.0GHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1 : At 80MHz and 800MHz, the higher frequency range applies.

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

a. Field strength from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

b. Over the frequency range 150kHz ~ 80MHz, filed strengths should be less than 3 V/m

14.4 Recommended separation distances between portable and mobile RF communications equipment and the equipment

Recommended separation distances between portable and mobile RF communications equipment and the equipment			
The equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the equipment as recommended below, according to maximum output power of the communication equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter/m		
	150kHz ~ 80MHz $d = 1.2 \sqrt{P}$	80MHz ~ 800MHz $d = 1.2 \sqrt{P}$	800MHz ~ 2.0GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	3.8
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.</p> <p>Note 1 : At 80MHz and 800MHz, the higher frequency range applies.</p> <p>Note 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

China type 2 diabetes blood glucose control range

(《China type 2 diabetes prevention guideline》 2017)

State	Range
Before meal	4.4 ~ 7.0mmol/L (79 mg/dL ~ 126 mg/dL)

Gestational diabetes mellitus (GDM) glucose control range

Gestational diabetes mellitus prevention guideline (2014))

State	Range
Preprandial plasma glucose (before meal)	≤ 5.3 mmol/L(≤ 95 mg/dL)

Normal glucose range


(National clinical laboratory operating procedures Fourth Edition)

State	Normal range
Before meal	3.9 ~ 6.1 mmol/L (70 mg/dL ~ 110 mg/dL)

Hazardous substance and content in product

Component	Hazardous substance		
	Lead(Pb)and its compound	Mercury(Hg)and its compound	Cadmium(Cd)and its compound
PCB board	○	○	○
Hardware	○	○	○
Electronic components	×	○	○
Meter case	○	○	○
/	Hexavalent chromium and its compound	Polybrominated biphenyls (PBB)	polybrominated diphenyl ethers (PBDE)
PCB board	○	○	○
Hardware	○	○	○
Electronic components	○	○	○
Meter case	○	○	○

This table is refers to SJ/T 11364 Electrical product hazardous substance limited use regulation.
 ○ : Means this hazardous substance in all component meet GB/T 26572 requirement.
 × : Means this hazardous substance in some component do not meet GB/T 26572 requirement.
 (Electronic components include ceramic resistor, National suggest contamination control attestation limit substance application exception do not require limit value for ceramic resistor.)
 * : some products content this accessories.

 When user use this product refer to user manual, the hazardous substances in this product will not reveal or cause severe pollution to environment in 10 years.

Hazardous substance and content in product

Component	Hazardous substance		
	Lead(Pb)and its compound	Mercury(Hg)and its compound	Cadmium(Cd)and its compound
*power line or power adapter	○	○	○
*battery	○	○	○
*test strips	○	○	○
* Lancing device	○	○	○
Packaging and printing	○	○	○
/	Hexavalent chromium and its compound	Polybrominated biphenyls (PBB)	polybrominated diphenyl ethers (PBDE)
*power line or power adapter	○	○	○
*battery	×	○	○
*test strips	○	○	○
* Lancing device	○	○	○
Packaging and printing	○	○	○

This table is refers to SJ/T 11364 Electrical product hazardous substance limited use regulation.

○ : Means this hazardous substance in all component meet GB/T 26572 requirement.

× : Means this hazardous substance in some component do not meet GB/T 26572 requirement.

(Electronic components include ceramic resistor, National suggest contamination control attestation limit substance application exception do not require limit value for ceramic resistor.)

* : some products content this accessories.



When user use this product refer to user manual, the hazardous substances in this product will not reveal or cause severe pollution to environment in 10 years.