目录

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纸配合使用，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、真睿TRUE METRIX AIR。

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、血糖仪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、真睿TRUE METRIX AIR示意图

① “◀”设置键

② “•”设置键

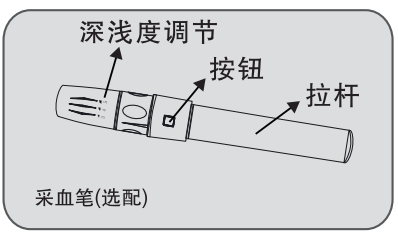
③ “▶”设置键

真睿TRUE METRIX:

真睿TRUE METRIX AIR:

①屏幕 ②试纸插口③试纸退条键④电池盖⑤标签
⑥数据传输连接处（用于连接拓展坞后与PC进行数据传输，拓展坞为选配件,如需购买拓展坞，请联系三诺或其授权经销商取得）

2.2.2 采血笔示意图



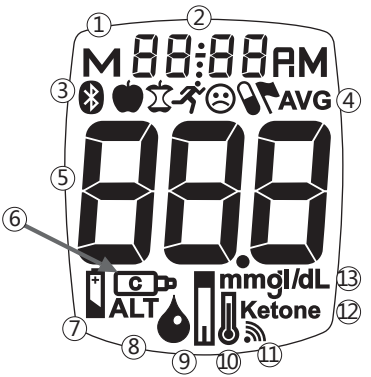
采血笔的使用方法请见采血笔使用说明书

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. 测试值为储存结果符号
2. 时间日期
3. 蓝牙符号（仅适用于真睿TRUE METRIX AIR）和事件标记符号
4. 测试值为平均值符号
5. 测试结果
6. 质控液符号
7. 电池符号
8. 多部位采血符号
9. 滴血符号
10. 温度符号
11. 测试提醒符号
12. 血酮测试提醒符号
13. 单位符号

等待加样

测试中

血糖测试结果(示例)

质控液测试结果(示例)

事件标记关

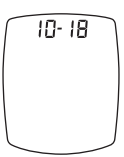
测试提醒开

测试提醒关

血酮测试提醒开

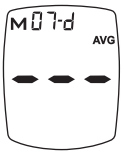
多部位采血

设置年



设置日期

设置时间



无平均值

7天平均值

14天平均值

30天平均值

60天平均值
(仅适用于真睿TRUE METRIX AIR)

90天平均值
(仅适用于真睿TRUE METRIX AIR)

血糖查询结果
(示例)

质控液查询结果
(示例)

蓝牙功能开
(仅适用于真睿TRUE METRIX AIR)

蓝牙功能关
(仅适用于真睿TRUE METRIX AIR)

无效的血细胞压积

超过血糖仪测试
温度范围

未检测出样本
或使用错误试纸

使用过的试纸
或加样错误

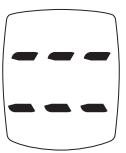
血糖仪错误

试纸错误

测试中移除试纸

通讯错误

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。数据传输线或底座仅用于血糖仪连接电脑传输数据，请不要使用该数据传输线连接任何充电设备进行充电。对电池或血糖仪进行充电可能会导致血糖仪起火或电池泄漏。如果处理不当电池存在爆炸风险。请勿将电池投入火中。请勿拆解电池或充电。请勿随意丢弃，请遵循当地法规要求处理废旧电池。

本血糖仪由1颗3V的CR2032纽扣电池(不可充电)供电。屏幕显示电池电量低时请更换电池。

1.抬起电池盖。

2.取出旧电池，遵循当地法规要求处理废旧电池。

3.使新电池正极朝上，装入新电池。将电池盖关闭。

4.按“•”设置键开机。 如果血糖仪不能正常开机，打开电池盖检查电池是否正负极装反。装上电池盖并重复步骤4。如果血糖仪仍然不能正常开机，请拨打客服电话。

注意：

血糖仪未装入电池或电池电量过低时，血糖仪可能会恢复出厂设置。在每一次更换电池后，请检查时间，日期，血酮测试提醒，测试提醒等设置是否正确。如不正确，请进入血糖仪设置模式更改设置。血糖仪长期未装入电池或电池电量过低时，储存在血糖仪内的测试结果不会被删除。

4.2 血糖仪设置

血糖仪出厂时已经预设默认的时间和日期。事件标记，血酮测试提醒，测试提醒初始为关闭状态。蓝牙功能初始为开启状态（仅适用于真睿TRUE METRIX AIR）。第一次使用血糖仪之前或更换电池之后，请检查时间日期，如有必要，请按以下步骤更新设置：

1.关机状态下长按“•”设置键直到出现全屏显示与蜂鸣声。松开“•”设置键。血糖仪进入设置模式。

注意：

如果在设置过程中，血糖仪关机，请按照步骤1开始重新操作。

设置时间 / 日期

2.进入设置模式后小时开始闪烁。按下“►”设置键或“◄”设置键调整小时。按下“•”设置键确定。

3.确定小时设置后，分钟开始闪烁。按下“►”设置键或“◄”设置键调整分钟。按下“•”设置键确定。

4.重复步骤2设置月，日，年。

备注：每次设置成功后血糖仪发出蜂鸣声。

设置蓝牙功能（仅适用于真睿TRUE METRIX AIR）：

使用蓝牙功能可以使血糖仪通过绑定蓝牙设备传输测试结果。

设置年成功后，按下“►”设置键或 “◄”切换蓝牙开关。按下“•”设置键确定。血糖仪进入事件标记设置。

设置事件标记

事件标记用于记录在特殊情况下的测试结果。事件标记有助于您的医生或专业医护人员管理您的血糖。

真睿TRUE METRIX 设置完年后，真睿TRUE METRIX AIR设置完蓝牙功能后，按下“►”设置键或 “◄”切换事件标记开关。按下“•”设置键确定。血糖仪进入血酮测试提醒设置。

- 餐前–进食之前测试；
- 餐后–进食之后2小时测试；
- 运动–运动中或刚结束运动后测试；
- 用药–用药后测试；
- 生病–生病状态下测试；
- 其他–其他非常规状态下（例如：精神紧张状态下，饮酒后等）

设置血酮测试提醒

当测试结果高于13.3 mmol/L, 血酮测试提醒功能提醒您根据治疗方案检测血酮。

按下“►”设置键或“◄”切换血酮测试提醒开关。按下“•”设置键确定。血糖仪进入测试提醒设置。

注：当血糖仪显示血酮测试符号时，并不代表您的血酮已被检测，请根据医生或专业医护人员的建议及治疗方案检测您的血酮。

设置测试提醒

每天最多可设置4个测试提醒。测试提醒时间到时血糖仪发出10秒蜂鸣声。测试提醒初始为关闭状态。

1. 设置完血酮测试提醒后，屏幕显示第一个测试提醒。按下“►”设置键或“◄”设置键切换测试提醒开关。按下“•”设置键确定。

2. 当开启测试提醒后，按下“•”设置键确定，小时闪烁。按下“►”设置键或 “◄”设置键调整小时。按下“•”设置键确定。

3. 分钟闪烁。按下“►”设置键或 “◄”设置键调整分钟。按下“•”设置键确定。血糖仪进入下一个测试提醒设置。

4. 如有必要，请重复步骤1-3设置其余3个测试提醒。

注：如果设置测试提醒，所有屏幕显示都会显示测试提醒符号。

退出设置模式

长按“•”设置键关机。2分钟内没有任何操作，血糖仪自动关机。设置自动保存。

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期限和开瓶日期。如已超过失效期

限或开瓶日期后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。在测试完成之前保持试纸插入血糖仪的状态。如需要标记测试结果为多部位采血结果（前臂），按下“►”设置键，屏幕显示多部位采血符号。按下“◄”设置键取消标记多部位采血测试结果。

6.等待滴血符号显示。在试纸插入血糖仪之前请勿在试纸上滴加血样。

7.使用采血笔采血。为了加速血液流动，可轻轻按摩采血部位。

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.对测试结果标记事件标记。事件标记功能需开启。事件标记符号闪烁。按下“►”设置键或“◄”设置键选择正确的事件标记。按下“•”设置键确定，事件标记停止闪烁。只有在试纸移除之前才可以标记事件标记。

12.试纸插口朝下，按下试纸退条键，移除试纸丢弃至指定容器内血糖仪关机。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。

注意：

-如果试纸在空气中暴露时间过长，血糖仪显示错误提示。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，血糖仪显示错误提示。该测试结果不储存于血糖仪内。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

当该血糖仪与实验室测试结果对比时，使用血糖仪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

1.血糖仪关机状态下，按下并松开“•”设置键。

2.真睿TRUE METRIX屏幕依次显示7天平均值，14天平均值，30天平均值, 真睿TRUE METRIX AIR屏幕依次显示7天平均值，14天平均值，30天平均值, 60天平均值， 90天平均值。 约2分钟内没有任何操作，血糖仪自动进入历史结果查询界面。如果没有平均值，血糖仪显示3条横线。

3.2分钟内如果没有任何操作，血糖仪自动关机。

查询测试结果

真睿TRUE METRIX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。

真睿TRUE METRIX AIR可储存1000个血糖测试结果，当第1001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.在血糖仪显示平均值后，再次按下并松开“•”设置键。

2.屏幕显示最近的血糖测试值。血糖测试结果与储存结果符号、时间、日期一同显示。

3.按下“►”设置键或 “◄”设置键浏览测试结果。

注意：

如测试结果被标记为多部位采血测试结果，测试结果与多部位采血符号一同显示。质控液测试结果与质控液符号一同显示。如果血酮测试提醒功能开启，当测试结果高于13.3 mmol/L时,测试结果和血酮测试提醒符号一同显示。如测试结果标记了事件标记，测试结果和事件标记符号一同显示。

五、省电功能

1.滴血等待时间约2分钟，超时报错E-2,约10秒后自动关机。

2.测试结果出现后，如果不拔试纸，无任何操作，约2分钟后自动关机。

3.结果查询时，平均结果查询界面下无操作，约2分钟后自动进入历史结果查询界面，历史结果查询界面下无操作，约2分钟后自动关机。

4.血糖仪设置时，如果无任何操作，约2分钟后自动关机。

5.报错条件下，约10秒后自动关机。

六、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，可以确保血糖仪提供准确的检测结果。

6.1 自动自测：

每次试纸插入血糖仪时，血糖仪开始自动自测。

注：自动自测不能代替质控液测试。

1.插入试纸。

2.如果血糖仪工作正常，血糖仪出现全屏显示，时间显示在屏

幕上方，滴血符号闪烁，检查是否有缺漏部分。

3.如果显示错误提示，请勿使用血糖仪进行测试，并查看故障章节。

6.2 质控液测试：

⚠ 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。

6.2.1 何时需要进行质控液测试

-第一次使用血糖仪时；

-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；

-您想检测血糖仪或血糖试纸是否正常工作时；

-怀疑血糖仪损坏时（如血糖仪跌落、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。

6.2.2 质控检查步骤

仅使用真睿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期限。如质控液已超过失效期限或开瓶日期后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。如试纸已超过失效期限或开瓶日期后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.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。

4.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血糖仪的状态。在试纸插入血糖仪之前请勿在试纸上滴加质控液。

5.打开质控液瓶盖，挤出一滴血糖质控液并丢弃，再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。

6.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。

7.当血糖仪开始测试，将血糖试纸从血糖质控液滴移开。

8.测试完成后，测试结果与质控液符号一同在屏幕上显示。

9.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，该血糖仪可用于测试血样。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，请勿使用该血糖仪及试纸进行测试。请致电售后服务机构。

10.结果显示后，使试纸插口朝下，按下试纸退条键将血糖试纸从血糖仪移除并按照医用废弃物处理。血糖仪自动关机。重新盖紧血糖质控液瓶。

七、蓝牙功能

真睿TRUE METRIX AIR血糖仪具备蓝牙通讯功能。

可以通过血糖仪设置蓝牙功能开启或关闭。蓝牙功能开启状态下，血糖仪开机时，蓝牙功能即打开，血糖仪显示界面将出现蓝牙符号。蓝牙连接成功时，蓝牙符号常亮。未连接成功则蓝牙符号持续闪烁；

在蓝牙连接成功状态下，测试出结果后,仪器主动上传本次测试结果。若结果上传成功，蓝牙设备显示本次测试结果；若结果上传失败，仪器关机前，测试结果最多闪烁5秒然后仪器关机。

在结果查询状态下，若蓝牙连接成功，血糖仪存储的历史结果中，未被成功上传到蓝牙设备的历史结果将被重新上传。

血糖仪关机时，蓝牙功能也将关闭。不允许设备连接。

八、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.如血糖仪表面粘有异物，需要马上进行清洁。保持血糖仪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。擦拭完成后让血糖仪自然风干。

3.如长时间不使用血糖仪，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。擦拭完成后让血糖仪自然风干，卸下电池后再保存。

4.请勿在测试中清洁血糖仪。

5.切勿让污垢、尘埃、血渍或液体经插口或缝隙进入血糖仪内 。

九、保修

只有三诺或三诺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。

如血糖仪故障需返回本公司，请将血糖仪用布或棉签蘸取少量的75%酒精擦拭清洁后再寄回本公司。

十、使用注意事项

1.请按照厂商规定的方法使用本血糖仪，否则会对血糖仪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全血样本。

3.请勿在木糖吸收实验后进行测试。

4.本血糖仪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。当您使用本血糖仪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，血糖仪可能会与血液接触。因此使用过的血糖仪有携带感染物的风险。当本血糖仪在医疗场所使用时，医护人员请遵循贵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。

7.儿童或需要监护的特殊用户在使用本血糖仪时必须在其他正常成人的监护下使用，且必须将此血糖仪放在儿童接触不到的地方。

8.为避免其他设备对本产品由电磁干扰而影响测试结果，请测量时远离短波高频设备等强干扰源。

十一、禁忌症

无

十二、故障

1.试纸插入后，不能开启血糖仪

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。
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
血糖仪故障	请与客服联系

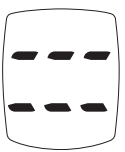
2.加入样本后，血糖仪不能开始测试。

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。
血糖仪故障	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血样进行测试。如果仍然显示错误提示，请与客服联系。
	超过血糖仪测试温度范围	将血糖仪和试纸在5°C-40°C环境下平衡10分钟直至达到测试温度范围。
	未检测出样本或使用错误试纸	使用新试纸按照说明书重新进行测试。
	使用过的试纸	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。

屏幕显示	原因	解决方法
	血糖仪错误	请与客服联系。
	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	使用新试纸进行测试。确认试纸移除前血糖仪显示测试结果。
	通讯错误	请与客服联系。

屏幕显示	原因	解决方法
	电池电量低	更换新电池。
	屏幕损坏	请勿使用该血糖仪进行测试。请与客服联系。
	测试结果高于33.3mmol/L	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。
	测试结果低于1.1mmol/L	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。

十三、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±0.83mmolL（±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%

十四、产品性能参数

测试范围：1.1mmol/L-33.3 mmol/L

用血量：约0.5μL

检测样本：新鲜指尖毛细血全血、前臂毛细血全血、静脉血、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纽扣电池#CR2032（不可拆解、不可充电）

最大额定电流：真睿TRUE METRIX 8 mA、真睿TRUE METRIX AIR 10mA

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。

电池寿命：约1000次测试或1年

生产日期：见标签

软件发布版本：真睿TRUE METRIX: V02

真睿TRUE METRIX AIR: V02

记忆容量：真睿TRUE METRIX: 500 个血糖测试值

真睿TRUE METRIX: AIR 1000个血糖测试值

尺寸：87mm×55mm×18mm

测试环境：相对湿度：:10～80% RH(不结露)，温度: 5℃～40℃

储运条件：10～93%RH(不结露)，-20℃～55℃

血细胞压积：20%～70%

海拔：最高可至3108 米

网络安全：

1.数据接口

真睿TRUE METRIX AIR血糖仪与数据传输模块之间采用串口通讯，8位数据位、1位停止位、无校验，无流控制，波特率固定9600bps;数据为16进制形式传输。

内置蓝牙（4.2）是基于Bluetooth Low Energy标准设计的透传模块，与其它蓝牙设备建立连接后，可以实现双向数据传输。

数据传输条件：血糖仪和蓝牙设备蓝牙功能打开。

2.用户访问控制

用户只有获取特定的通讯协议才能准确的解析数据，血糖仪与外界进行数据交换必须遵循通讯协议的要求。

3.运行环境

软件环境详见操作指南。

十五、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颗3V纽扣电池#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。

拓展坞（选配）

十六、符号的解释

IVD 体外诊断医疗器械	参考使用说明
SN 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
CMIIT ID: 无线电发射设备型号核准代码	

十七、电磁兼容性声明

本血糖仪符合EMC标准GB/T 18268.1-2010及GB/T18268.26-2010的发射和抗扰度要求。EMC基本性能“显示屏正常显示，设备连续无故障运行，数据正常传输。”

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血糖仪的性能。

（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。

17.1 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		
本血糖仪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	1组	本血糖仪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。
射频发射GB 4824	B类	
谐波发射GB 17625.1	不适用	/
电压波动/闪烁发射GB 17625.2	不适用	

17.2 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			
本血糖仪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：±2kV;±4 kV;±8 kV 接触放电：±2 kV;±4 kV	空气放电：±2kV;±4 kV;±8 kV 接触放电：±2 kV;±4 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/T17626.8	3A/m，50Hz	3A/m，50Hz	如果血糖仪工作异常，有必要使血糖仪远离工频磁场源。建议用户评估预期使用场所的工频磁场确保其足够低。
电压暂降 GB/T17626.11	0% 1周期	不适用	/
	40% 5周期	不适用	
	70% 25周期	不适用	
电压中断 GB/T17626.11	5%，持续时间：250周期	不适用	
脉冲群 GB/T17626.4	1kV（5/50ns，50kHz）	不适用	/
浪涌 GB/T17626.5	线对地：2kV 线对线：1kV	不适用	

17.3 指南和制造商的声明–电磁抗扰度

指南和制造商的声明—电磁抗扰度			
本血糖仪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
射频传导 GB/T17626.6	3V （有效值） 150kHz ~ 80MHz	不适用	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自动微生物分析系统的任何部分使用，包括电缆。该距离应由发射机频率相应的公式计算。 推荐的间隔距离 $d=1.2\sqrt{P}$ 80MHz ~ 800MHz $d=2.3\sqrt{P}$800MHz ~ 2.0GHz 式中： P—根据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； d—推荐的隔离距离，以米(m)为单位。 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。 在标记下列符号的设备附近可能出现干扰
射频辐射 GB/T17626.3	3V/m 80MHz ~ 2.0GHz	3V/m 80MHz ~ 2.0GHz	

注1：在 80MHz 和 800MHz频率点上, 采用较高频段的公式。
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。

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。
b.在150kHz ~ 80MHz 整个频率范围，场强应低于3V/m。

17.4 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血糖仪之间的推荐隔离距离			
本血糖仪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）和本血糖仪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		
	150kHz～80MHz $d=1.2\sqrt{P}$	80MH～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	7.3
100	12	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	≤5.3mmol/L(≤95mg/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	○	○	○

○：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。
×：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。
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。
*：表示部分产品型号含该部件。

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。

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	○	○	○

○：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。
×：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。
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。
*：表示部分产品型号含该部件。

10 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。

附录1：保修卡（客户自留） Sinocare三诺

非常感谢您使用本公司生产的血糖仪。本血糖仪为自测用体外诊断医疗器械，广泛应用于血糖监测。

本血糖仪操作简单，使用方便，用血量少，无需调码，是您血糖监测的良好工具。

在您使用血糖仪前，请您先仔细阅读使用说明书。您有任何关于本血糖仪的使用问题，请拨打我们的客服电话：400-887-0036。

请将您的有效信息完整的填写在我们的保修卡上，返回到经销商或本公司，您将成为关怀俱乐部的会员，将会享受到会员服务。

_____

购机日期

_____

仪器编号

请保留此部分，维修时出示此卡

附录2：保修卡（返生产厂家）

Sinocare三诺

姓名：　　电话：

年龄：　　性别：

购机日期：　　仪器编号：

通讯地址：

糖尿病发现时间：

购买用途：　☐ 自用　☐ 代别人购买

购机点全称：

（请将您的有效信息完整的填写在我们的保修卡上，返回到经销商或本公司，您将成为关怀俱乐部的会员，将会享受到会员服务）

catalog

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

1.1 Intended use

The product can be used with applicable blood glucose test strip to test glucose in whole blood sample. It can be used at clinical setting or self-testing by diabetes and other groups. The product is only use for monitoring glucose, not for use in diagnosis of diabetes mellitus.

1.2 Model

TRUE METRIX、TRUE METRIX AIR。

1.3 Applicable test strip

TRUE METRIX blood glucose test strip (if need to buy test strip, contact sinocare or its authorized dealer to obtain it)

1.4 Test Principle

Blood glucose test strip reaction zone has specific chemicals, glucose in whole blood sample react with these chemicals and produce an electrical current. The meter measures the current and calculates the amount of glucose. The result is diaplayed 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 真睿TRUE METRIX、真睿TRUE METRIX AIR Schematic diagram

① “◀” **Button**

② “•” **Button**

③ “▶” **Button**

真睿TRUE METRIX:

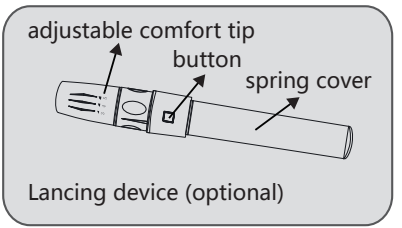
真睿TRUE METRIX AIR:

① Display Screen
② Test Port
③ Strip Release Button
④ Battery Door

④ Battery Door
⑤ Meter Label
⑥ Docking Station Contacts

(It is used for data transmission with PC after connecting Docking station. Docking station is an optional accessory. If you need to buy Docking station, please contact sinocare or its authorized dealer to obtain it)

2.2.2 Lancing device

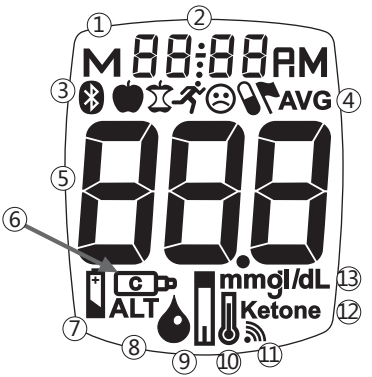


Please refer to lancing device instruction of use for more information.

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

3.Display

Full screen display



1.Result is from Memory
2.Time, Date
3.Bluetooth Symbol
(only for 真睿 TRUE METRIX AIR) and Event Tag Symbols
4.Average value symbol
5.Test Result
6.Control Symbol
7.Battery Symbol
8.Alternate Site (ALT) Symbol
9.Drop Symbol
10.Temperature Symbol
11.Test Reminder Symbol
12.Ketone Test Alert Symbol
13.Units Symbol

Waiting for apply sample

During testing

Blood glucose test result
(example)

Control solution test result
(example)

Event tag

Test reminder on

Test reminder off

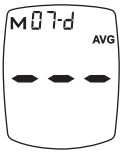
Ketone alert on

ALT testing

Setting year

Setting date

Setting time



No average result

7-day average test result

14-day average test result

30-day average test result

60-day average test result
(Only for 真睿TRUE METRIX AIR)

90-day average test result
(Only for 真睿TRUE METRIX AIR)

Blood glucose test result in memory
(sample)

Control solution test result in memory
(sample)

Bluetooth function on
(Only for 真睿 TRUE METRIX AIR)

Bluetooth function off
(Only for 真睿 TRUE METRIX AIR)

Invalid Hematocrit

Temperature error
Too cold/Too hot

Sample not detected or used wrong test strip

Used test strip or apply the sample error

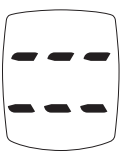
Meter error

Test strip error

Test strip removed during test.

Communication error

Low battery



Broken Display

Out of range -
High results > 33.3 mmol/L

Out of range -
Low results < 1.1 mmol/L

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. Don't throw away, dispose according to local regulations.

The meter use one 3V CR2032 lithium battery (non-re-charge). Replace battery when display shows low battery error.

1.Lift tab on Battery Door.

2.Turn meter over, dispose according to local regulations.

3.Insert new battery, positive（“+”）side facing up. Close Battery Door

4.Press “•” Button to turn meter on. If meter does not turn on, check that battery was installed properly. Install the battery cover and repeat step 4.Contact for assistance if problem persists.

Note: If battery is out of meter or low battery, meter may reset to original factory settings. Verify settings are correct after replacing battery by, going into Meter Set Up and checking time, date, Ketone Testing Alert, and Testing Reminders. If not, please enter the setting mode and change the setting. Results in Memory are not deleted, if battery is low or removed for any length of time.

4.2 Meter set up

Meter comes with pre-set time and date. The Event Tags, Ketone Test Alert and all Test Reminders are off. Bluetooth function is initially turned on (only for 真睿 TRUE METRIX AIR). Before using the meter for the first time or after a battery change, please check the time, date. Follow these steps to update the Settings if needed.

1.With meter off, press and hold "•" Button until the full Display is shown and a series of beeps sound. Release "•" Button. Meter goes into Set Up.

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

Set Time/Date

1. The hour flash after enter the setting mode. Press "►" or "◄" Button on top of the meter to select the hour. Press "•" Button to set.

2. The minute flash after setting hour. Press "►" Button or "◄" to select the minutes. Press "•" Button to set.

3. Repeat step 2 to set month, date and year.

Note: Meter beeps every time a setting is confirmed.

Set Bluetooth Smart (only for 真睿 TRUE METRIX AIR)

Uploading results using the Bluetooth Smart feature allows meter to send results by connecting Bluetooth device.

After setting the year, press "►" or "◄" Button to turn on or off the Bluetooth Smart feature. Press "•" Button to set. Meter goes to set Event Tags.

Event Tags

Event Tags are used to mark a test result that was taken during a specific event. Event tagging may assist you and your doctor or healthcare professional with managing your diabetes.

After turning on or off the Bluetooth Smart feature (for 真睿TRUE METRIX AIR meter) or after setting the year (for 真睿 TRUE METRIX meter) , press "►" or "◄" Button to turn Event Tags on or off. Press "•" Button to set. The meter goes to set Ketone Test Alert.

- Before meal –test was taken just before a meal;
- After meal –test was taken 2 hours after the start of a meal;
- Exercise – test was taken during or just after exercise;
- Medications – test was taken after medication;
- Sick – test was taken when sick;
- Other – any other reason that the test is unique or different in some way (example: stress, drinking alcohol).

Ketone Test Alert

When a blood glucose result is over 13.3 mmol/L, the Ketone Test Alert is a reminder to check ketones per the treatment plan.

Press "►" or "◄" Button to turn Alert on or off. Press "•" Button to set. Meter goes to set Test Reminder.

Note: When a Ketone Test Alert Symbol appears, it does not mean that ketones have been detected in the blood. Perform a ketone test per the treatment plan, as prescribed by the doctor or healthcare professional

Test Reminder

Up to four Test Reminders per day may be set. Meter reminder sounds at set time for 10 seconds. Test reminders are initially turned off.

1. After pressing "•" Button to set Ketone Test Alert, display shows first Reminder setting. Press "►" or "◄" Button to turn Reminder on or off. Press "•" Button to set.

2. When "on" is chosen, press "•" Button. The hour flashes. Press "►" or "◄" Button to set the hour. Press "•" Button to set.

3. The minutes flash. Press "►" or "◄" Button to set the minutes. Press "•" Button to set. Meter goes to the next Test Reminder.

4. Turn Reminders on and repeat steps 1-3 to set the time for next 3 Reminders (if needed).

Note: If Test Reminders are set, the Test Reminder Symbol appears in all Displays.

Exit setting mode

Press and hold "•" Button until meter turns off. Meter also turns off after 2 minutes of non-use. Set-up choices are saved.

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. And use new test strip for testing.

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

3. Clean hands and area to be lanced with an approved disinfectant. Dry thoroughly.

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

5. With meter off, insert a test strip Contact End (blocks facing up) into Test Port. Meter turns on. Keep test strip in meter until testing is finished. To mark test as alternate site (forearm) result if needed, press "►" Button. ALT Symbol appears in Display. Press "◄" Button to remove ALT Symbol.

6. Wait until Drop Symbol appears in Display. Do not apply samples before insert strip into meter.

7. Lance fingertip or forearm. Obtain a blood sample, allow drop to form.

8. With test strip still in meter, touch Sample Tip of test strip to top of blood drop and allow blood to be drawn into test strip.

9. Remove Sample Tip from blood drop immediately when the meter beeps.

10. After the test is finished, result is displayed. Recording test results.

11. To mark the result with an Event Tag, Event Tags must be turned on. The Event Tag icons flash. Press "►" or "◄" Button to go to the correct Event Tag. Press "•" Button to set, event Tags stop flashing . Event tags can only be marked before the strip is removed.

12. Hold meter with test strip pointing down. Press Strip Release Button to discard test strip in the appropriate container. Meter turns off. Result is stored in Memory.
The used test strip and lancet should be treated as medical waste.

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

1. With meter off press and release " • " Button.

2. Display scrolls through 7-, 14-, and 30-Day average values for 真睿 TRUE METRIX meter. Display scrolls through 7-, 14-, 30-, 60 and 90-Day Average values for 真睿 TRUE METRIX AIR meter. Without any operation for about 2

minutes, the blood glucose meter automatically enters the interface of historical results query. If there is no average, the glucose meter shows three dashes.

3. Meter turns off after 2 minutes if no buttons are pressed.

View Results

Meter Memory stores 500 results for 真睿 TRUE METRIX meter , When the 501th blood glucose test result is stored, the earliest blood glucose test result is automatically covered.

Meter stores 1000 results for 真睿 TRUE METRIX AIR meter. When the 1001th blood glucose test result is stored, the earliest blood glucose test result is automatically covered.

1. Press and release "•" Button after meter displays Averages value.

2. The screen shows the latest blood glucose test value. Blood glucose test results are displayed together with storage results symbol, time and date.

3. Press "►" Button or "◄" Button to Browse test results .

Note: If test results marked as alternate site display ALT Symbol, test results display the ALT Symbol. Control Test results display the Control Symbol. If the Ketone Test Alert function on, when test results above 13.3 mmol/L, test results display Ketone Test Alert Symbol. If test results mark the event tags, test results display the event tags.

5. Power saving function

1. The waiting time for applying sample is about 2 minutes, the error of E-2 is given if over time, and the mater turns off automatically after about 10 seconds.

2. After the test result appears, if the test strip is not pulled out and there is no operation, the mater turns off automatically after about 2 minutes.

3. During the result query, there is no operation under the average result query interface, and it will automatically enter the historical result query interface after about 2 minutes. There is no operation under the historical result query interface, and it will automatically turn off after about 2 minutes.

4. When setting the blood glucose meter, if there is no operation, it will automatically turn off after about 2 minutes.

5. Automatically shut down after about 10 seconds under the condition of error reporting.

6. Check The System

Daily quality control as a means of testing the running state of the blood glucose test system. The System offers two kinds of quality control tests to let you know that the system is working properly and testing technique is good. Regular systematic inspection can ensure accurate results of blood glucose meter.

6.1 Automatic Self-Test

Each time the test strip is inserted into the blood glucose meter, the blood glucose meter starts to automatically measure itself.

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. If the blood glucose meter works normally, the blood glucose meter will display in full screen, the time will be displayed on the top of the screen, and the symbol of blood drop will blink, check for missing segments.

3. If an error message appears, do not use the blood glucose meter for testing and see Troubleshooting.

6.2 Control Test

⚠The quality control range affixed to the test strip bottle is not the recommended blood glucose level, and is only used for reference to the quality control solution test results. Do not take the quality control solution.

6.2.1 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;

-whenever a check on the glucose meter or test strips is working properly;

-if meter damage is suspected (meter was dropped, crushed, wet, etc.);

Important note: Three levels of control solution are available for Control Tests. Please use at least 2 concentrations of control solution to test whether the system is working properly.

6.2.2 How to Test Control Solution

Use ONLY 真睿 TRUE METRIX Control Solution for Control Test.

1. Check dates on control solution label and test strip vial label. Do not use control solution if control solution - 3 months after opening or date next to on label (whichever comes first), and test with a new blood glucose control solution. Do not use test strips - 4 months after opening or date next to symbol (whichever comes first), and use new test strip for testing.

2. Allow control solution, vial of test strips and meter to adjust to room temperature for 10 minutes before use. If it is the first time to open the blood glucose quality control bottle, please mark the date on the bottle label.

3. Gently swirl or invert control solution bottle to mix.DO NOT SHAKE! Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.

4. 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.

5. 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.

6. Touch Sample Tip of test strip to top of drop of control solution. Allow drop to be drawn into test strip.

7. Remove test strip from drop when meter begins testing.

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

9. When the glucose meter shows results, 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 result is still outside range, do not use this blood glucose meter and test strips to test. Please call the after-sales service.

10. After result is shown, Hold glucose meter with test strip pointing down, Press Strip Release Button to discard test strip, And according to medical waste disposal. Meter turns off. Recap control solution bottle tightly.

7. Bluetooth

真睿TRUE METRIX AIR glucose meter has Bluetooth communication function.

The Bluetooth function can be turned on or off by setting the blood glucose meter. When the Bluetooth function is turned on, the Bluetooth function will be turned on and the Bluetooth symbol will appear on the display interface of the glucose meter. When the Bluetooth connection is successful, the Bluetooth symbol is always on. The Bluetooth symbol continues to flash if the connection is not successful.

When the Bluetooth connection is successful, the blood glucose meter will upload the test result to Bluetooth device. Bluetooth device will display the test result when upload successfully; and the test result will be flicker at most 5 seconds before the blood glucose meter power off when upload failed

In the state of result query, if the Bluetooth connection is successful, the historical results stored by the glucose meter that have not been successfully uploaded to the Bluetooth device will be uploaded again.

When the glucose meter is turned off, the Bluetooth function will also be turned off. No device connection allowed.

8. 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.

9. Warranty

Only Sinocare or Sinocare 's agency can inspect or supply any spare parts.

In normal use, if the product fails, the company promises 10 years warranty. Please fill in the warranty card carefully and return the parts that need to be returned to our company.

If blood glucose meter need to return to our company in case of failure, use wipe or swab with 75% alcohol to clean meter then send back to our company.

10. 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. The test results of this blood glucose meter can only be used for blood glucose monitoring, and cannot be used as the basis for diabetes diagnosis. NEVER change a treatment

plan without consulting a doctor or healthcare professional. When you use this blood glucose meter to get test results inconsistent with the symptoms, you should immediately go to the hospital for examination.

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

6. During the test, the blood glucose meter may come into contact with blood. There is therefore a risk of infection with a used glucose meter. When the glucose meter is used in a medical setting, health care workers should follow the appropriate infection control procedures for your health equipment, such as wearing gloves or other personal protection.

7. Children or special users in need of monitoring must use this blood glucose meter under the supervision of other normal adults, and the blood glucose meter must be placed out of the reach of children.

8. In order to avoid electromagnetic interference from other devices affecting the test results of this product, please keep the measurement away from strong interference sources such as short-wave high-frequency equipment.

11. Contraindications

NONE

12. Troubleshooting

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.
Test strip not fully inserted	Remove test strip. Re-insert test strip fully into meter
Test strip error	Repeat with new test strip.
Low battery	Replace battery.
Meter error	Reinstall the battery, let battery positive (“+”) side face up.
Battery in backwards	Contact for assistance.

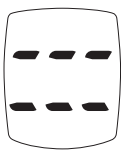
2. After applying sample, test does not start.

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 you are still unable to start the test, please contact for assistance
Meter Error	Contact for assistance.

3. Error messages

Display	Reason	Action
	Invalid Hematocrit	Repeat with new test strip, using capillary whole blood from the finger. If error persists, contact for assistance.
	Temperature error Too cold/Too hot	Move meter and test strips to area between5°C-40°C, wait10 minutes for system to reach room temperature before testing.
	Sample not detected or using wrong test strip	Retest with new test strip according to the instructions.
	Used test strip	Repeat with new test strip. If error persists, contact for assistance.

Display	Reason	Action
	Meter error	Contact for assistance.
	Test strip error	Retest with new test strip. If error persists, contact for assistance.
	Test strip removed during test	Retest with new test strip. Make sure result is displayed before removing test strip.
	Communication error	Contact for assistance.

Display	Reason	Action
	Low battery	Change new battery.
	Broken Display	Do not use meter for testing. Contact for assistance.
	Out of range - High results > 33.3 mmol/L	Retest with new test strip. If result is still "Hi" (High) contact doctor or healthcare professional immediately.
	Out of range - Low results < 1.1 mmol/L	Retest with new test strip. If result is still "Lo" (Low) contact doctor or healthcare professional immediately.

13. Performance

Accuracy and repeatability criteria for this product is 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: ≥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
1.1mmol/L ~ 5.55mmol/L (20mg/dL ~ 100mg/dL)	Within ±0.83mmol/L (±15mg/dL)
5.55mmol/L ~ 33.3mmol/L (100mg/dL ~ 600mg/dL)	Within ±15%

Table 2 : Repeatability Requirement

Test Range	Precision
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%

14. Product performance parameters

Result Range: 1.1 - 33.3 mmol/L

Sample Size: 0.5 microlitre (0.5 μL)

Sample: Fresh capillary whole blood, venous whole blood collected in sodium or lithium heparin blood collection tubes, or EDTA blood collection tubes, or control solution

Test Time: 4~7 seconds

Result Value: Plasma values

Assay Method: Amperometric

Power Supply: One 3V lithium battery #CR2032 (non-dismountable and non-rechargeable)

maximum current rating: 真睿TRUE METRIX 8 mA、真睿TRUE METRIX AIR 10mA

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

The use period of this product is based on every day perform 7 tests. During the use, users should maintain and maintain the product according to the requirements of the product manual. After maintenance, products that are confirmed to maintain basic safety and effectiveness can be used normally.

Battery Life: Approximately 1000 tests or 1 year

Manufacture date: Refer to meter label

Software release: 真睿 TRUE METRIX meter: V02

真睿 TRUE METRIX AIR meter: V02

Memory Size: 500 glucose results and 1 control result for 真睿 TRUE METRIX meter

1000 glucose results and 1 control result for 真睿 TRUE METRIX AIR meter

Size: 87mm×55mm×18mm

Operating Range: Relative Humidity: 10%-80%RH (Non-condensing), Temperature: 5℃- 40℃

Storage and transportation conditions: 10%-93%RH (Non-condensing), -20℃-55℃

Hematocrit: 20%-70%

Altitude: Up to 3108 meters

Network security:

1. Data interface

Serial port communication is adopted between the TRUE METRIX AIR glucose meter and the data transmission module. There are 8 data bits, 1 stop bit, no check, no flow control, and the baud rate is fixed at 9600bps.Data is transmitted in hexadecimal format.

Built-in Bluetooth (4.2) is a pass-through module designed based on Bluetooth Low Energy standard. After connection with other Bluetooth devices, two-way data transmission can be realized.

Data transmission conditions: the blood glucose meter and Bluetooth device are enabled.

2. User access control

Only by obtaining specific communication protocols can users analyze data accurately, and data exchange between glucose meters and the outside world must follow the requirements of communication protocols.

3. Operating environment

See operating instructions for software environment.

15. 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”.

Docking station (Optional)

16. Explanation of symbols

IVD	For in vitro Diagnostic Testing Only		Attention! Read Instructions for Use
SN	Serial Number		Keep away from direct sunlight
	Keep Dry		Electronic and electrical hazardous substance symbol
	Fragile, handle with care		Manufactured By
	Caution, Refer to the attached document		Biological Harm
CMIIT ID:	Wireless meter model approval code		

17. EMC Statement

This meter meets the electromagnetic emissions requirements as per GB/T 18268.1-2010 and GB/T 18268.26-2010. EMC basic performance: "the display screen is normally displayed, the equipment is running without fault continuously, and data transmission is normal."

Note:

(1) In dry environment, especially with artificial material (artificial textile. carpet), using this meter may cause electro-static 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 (such as non-shielded RF sources), otherwise may effect performance of this meter.

(4) User should make sure the meter can work normally during electromagnetic compatibility environment. It is recommended to evaluate the electromagnetic environment before using the meter.

17.1 Guidance and manufacturer’ s declaration-
electromagnetic emission

<table>
<tr><th colspan="3">Guidance and manufacturer’ s declaration-
electromagnetic emission</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>RF emissions
GB4824</td><td>Group 1</td><td rowspan="2">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.</td></tr>
<tr><td>RF emissions
GB 4824</td><td>Class B</td></tr>
<tr><td>Harmonic emissions
GB 17625.1</td><td>Not applicable</td><td rowspan="2">/</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
GB 17625.2</td><td>Not applicable</td></tr>
</table>

17.2 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： ±2kV;±4 kV; ±8 kV Contact： ±2 kV;±4 kV	Air： ±2kV;±4 kV; ±8 kV Contact： ±2 kV;±4 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	
Voltage interruption GB/T17626.11	5%, Duration: 250 cycles	N/A	
Pulse train GB/T17626.4	1kV（5/50ns，50kHz）	N/A	/
Surge GB/T17626.5	2kV lines to earth 1kV lines to lines	N/A	

17.3 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 $d=1.2\sqrt{P}$ 80MHz ~ 800MHz $d=2.3\sqrt{P}$ 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. 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:
Radiated RF GB/T17626.3	3V/m 80MHz ~ 2.0GHz	3V/m 80MHz ~ 2.0GHz	
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			

17.4 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 $d=1.2\sqrt{P}$	80MH～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

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.
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.

China type 2 diabetes blood glucose control range

(《China type 2 diabetes prevention guideline》2017)

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

Normal glucose range

(《The National Clinical Test Regulation of Operation 》 the 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
Meter case	○	○	○
Hardware	○	○	○
PCB board	○	○	○
Electronic components	×	○	○
	Hexavalent chromium and its compound	polybrominated biphenyls (PBB)	polybrominated diphenyl ethers (PBDE)
Meter case	○	○	○
Hardware	○	○	○
PCB board	○	○	○
Electronic components	○	○	○

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.
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(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.