**未解决的异常(漏洞/缺陷）**

**(Unresolved Anomalies**

**(Bugs or Defects))**

项目编号（Project No.）:

文件编号（Document No.）:

文件类型（Document type）：

版本（Version）:

编制（Author）：

审核（Audit）：

批准（Approve）：

{文档背景说明：For Moderate and Major Level of Concern Software Devices, the submission should include a list of all unresolved software anomalies. For each anomaly, we recommend that you indicate the:

· problem

· impact on device performance

· any plans or timeframes for correcting the problem (where appropriate).

We recommend that you annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues. Typically, this list can be generated as an output of a change control board or similar mechanism for evaluation and disposition of unresolved software anomalies. We recommend that you communicate this list to the end user as appropriate to assist in the proper operation of the device. In all instances where it is practical to do so, you should include any mitigations or possible work-arounds for unresolved anomalies; this recommendation applies to Blood Establishment Computer Software in particular.}

1. ***缺陷统计***

*例如：*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***编号(No.)*** | ***模块(module)*** | ***Bug 标题(bug title)*** | ***问题描述(problem description)*** | ***结果(result)*** | ***解决方案(solutions)*** | ***状态(state)*** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |

1. ***结论（Conclusion）***

*XXXXX*