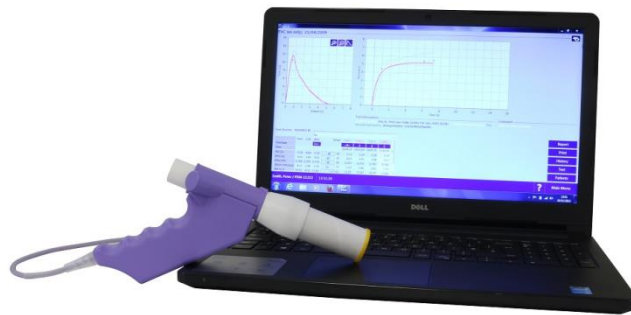
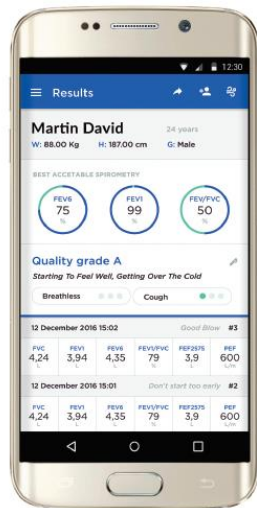


# Comparison of a portable smart spirometer against 2 lab based desktop systems



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# Introduction

- The COVID-19 pandemic has meant that the majority of routine PFT's that would require hospital visits have been cancelled.
- For some patient's with chronic respiratory disease, spirometry is fundamental in helping manage the disease.
- These patient's will also be in the "shielded" category therefore it is not desirable to bring them into a hospital.
- There are several smart device based portable devices on the market that allow spirometry to be performed out-with the lab and in the patient's house.
- the Spirobank<sup>®</sup> smart spirometer manufactured by MIR can be connected to a smart device and used with a disposable flow turbine. It measures FEV<sub>1</sub>, FVC, FEF<sub>25-75</sub> and PEF.

# Aims

- To validate the Spirobank<sup>®</sup> smart spirometer against our current equipment that we use to routinely test our patients with cystic fibrosis.
- We currently use the NDD Easy on-PC during routine clinic and in-patient visits and the Jaeger Masterscreen PFT (Vyair) during annual review visits.
- Compare biological quality control results in 5 physiologists using the Spirobank<sup>®</sup> smart spirometer with the disposable turbine against the NDD Easy on-PC and the Jaeger Masterscreen to ensure no clinically significant differences between the devices.

# Methods

- Biological quality control was performed over a 2 week period.
- 5 physiologists performed their spirometry on the 3 devices for 5 days.
- The results were compared using Bland Altman analysis.
- The intra-test coefficient of variation for each device was analysed.

# Results

## Spirobank - NDD

|                      | Mean Bias   | LLOA-ULOA (95% CI) |
|----------------------|-------------|--------------------|
| FEV <sub>1</sub>     | 82 ml       | -122 to 276        |
| FVC                  | 54 ml       | -211 to 319        |
| FEF <sub>25-75</sub> | 0.138 L/sec | -0.494 to 0.769    |
| PEF                  | 29 L/min    | -55 to 113         |

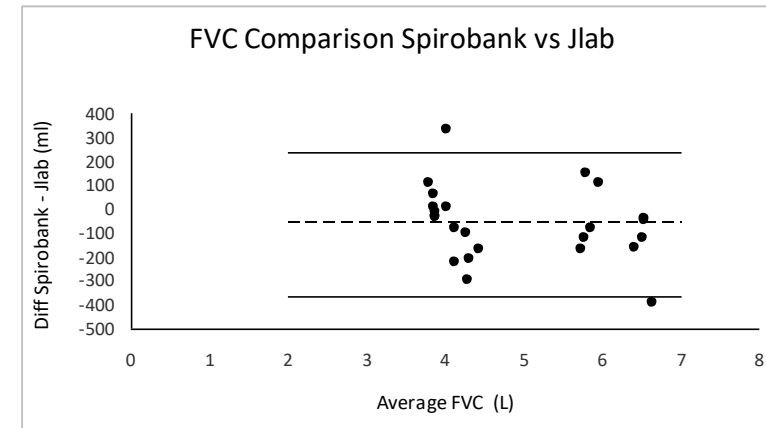
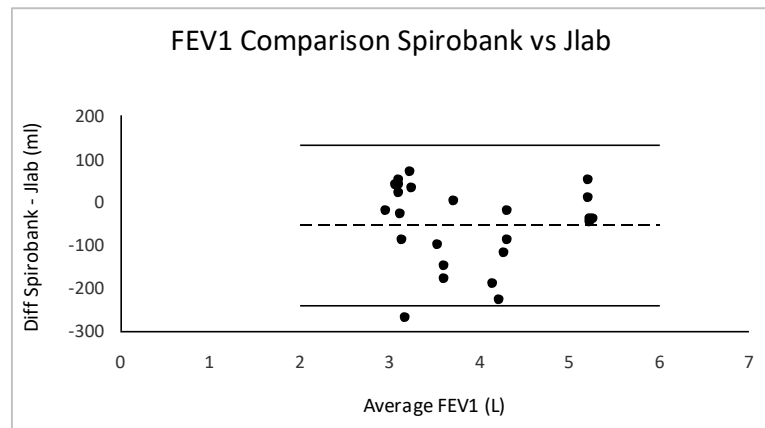
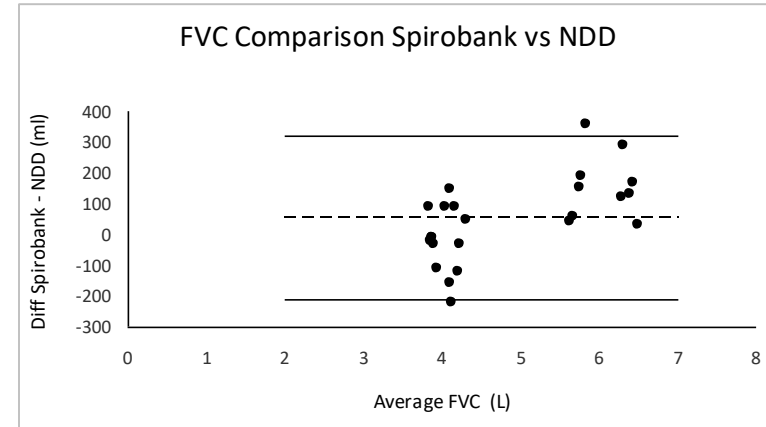
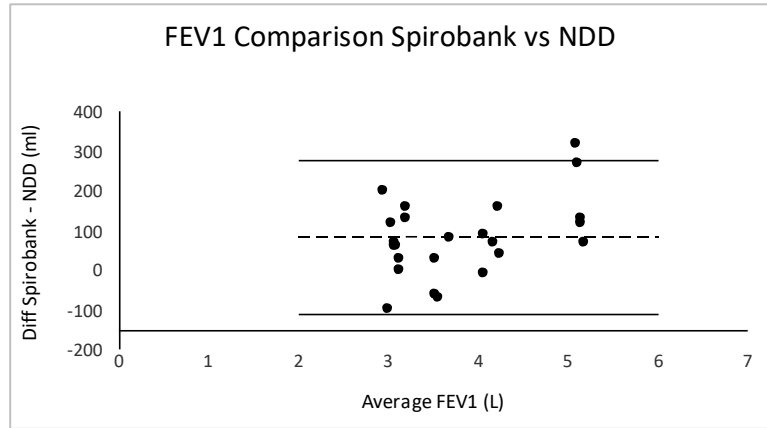


## Spirobank - Masterscreen

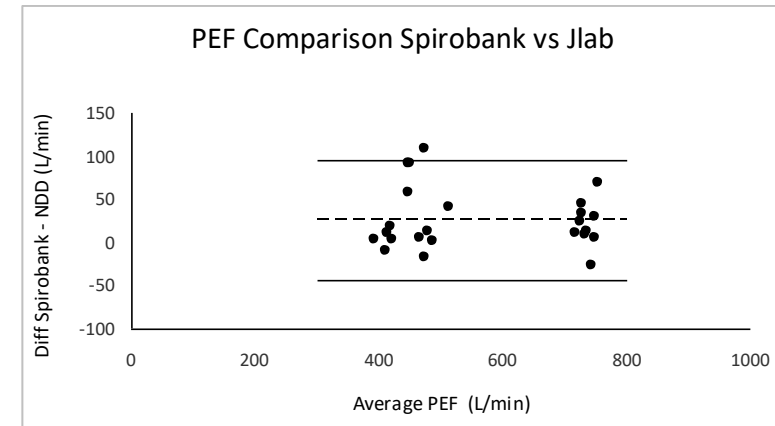
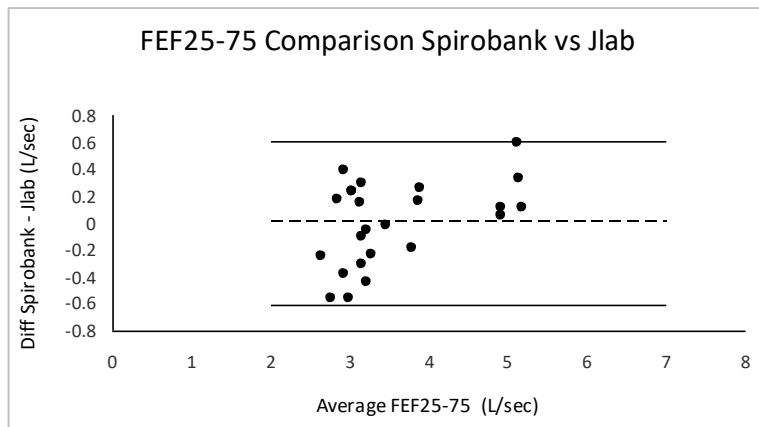
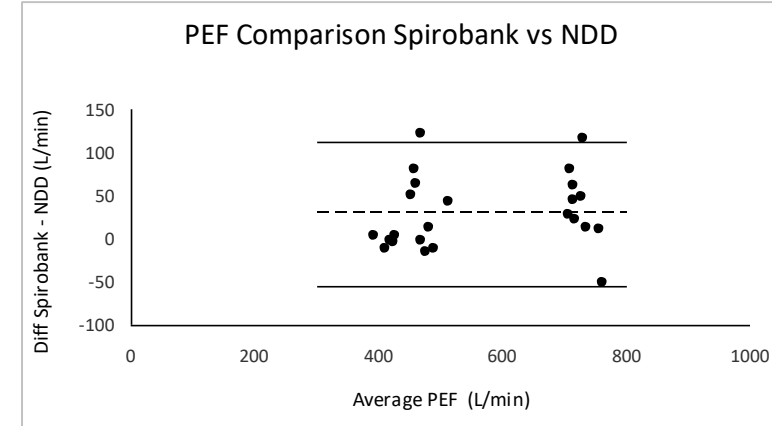
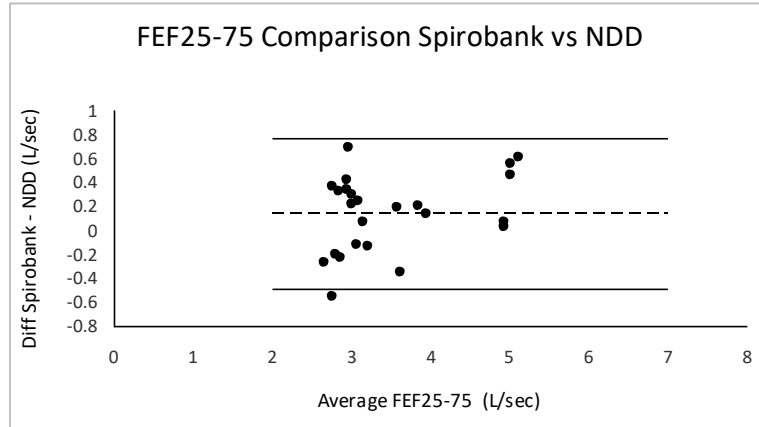
|                      | Mean Bias   | LLOA-ULOA (95% CI) |
|----------------------|-------------|--------------------|
| FEV <sub>1</sub>     | -55 ml      | -241 to 132        |
| FVC                  | -63 ml      | -363 to 238        |
| FEF <sub>25-75</sub> | 0.001 L/sec | -0.609 to -0.612   |
| PEF                  | 26 L/min    | -43 to 95          |



# Results – Bland Altman FEV<sub>1</sub> & FVC



# Results – Bland Altman FEF<sub>25-75</sub> & PEF



# Results – Coefficient of variation

| <b>Group Average NDD</b> |      |
|--------------------------|------|
| <b>FEV1</b>              | 1.08 |
| <b>FVC</b>               | 1.32 |
| <b>FEF25-75</b>          | 2.43 |
| <b>PEF</b>               | 2.51 |

| <b>Group Average Jlab</b> |     |
|---------------------------|-----|
| <b>FEV1</b>               | 1.5 |
| <b>FVC</b>                | 1.4 |
| <b>FEF25-75</b>           | 3.2 |
| <b>PEF</b>                | 2.1 |

| <b>Group Average Spirobank</b> |     |
|--------------------------------|-----|
| <b>FEV1</b>                    | 1.2 |
| <b>FVC</b>                     | 1.4 |
| <b>FEF25-75</b>                | 3.1 |
| <b>PEF</b>                     | 2.6 |



# Discussion

- The mean bias for FEV<sub>1</sub>, FVC, FEF<sub>25-75</sub> and PEF was clinically acceptable when comparing the Spirobank<sup>®</sup> to the NDD and Masterscreen PFT.
- The 95% limits of agreement for all the parameters were not too wide.
- The Spirobank<sup>®</sup> tended to read slightly higher than the NDD and lower than the Masterscreen PFT for FEV<sub>1</sub> and FVC.
- The intra test Coefficient of variation for the Spirobank<sup>®</sup> was clinically acceptable and not significantly different to the other 2 devices.

# Conclusion

- The Spirobank<sup>®</sup> smart spirometer is a valid device when used with the FlowMIR disposable turbine.
- The measures of FEV<sub>1</sub>, FVC, FEF<sub>25-75</sub> and PEF were comparable to the NDD Easy on-PC and Jaeger Masterscreen PFT.
- The intra-test coefficient of variation for all devices was within acceptable limits.
- We would always recommend the test is performed supervised in a virtual setting with a qualified healthcare professional.

# Limitations/Future research

- This was validated in normal subjects with no significant respiratory disease. It should also be looked at in patients with abnormal spirometry and smaller volumes.
- We only validated the Disposable turbine therefore the re-usable turbine would need to be validated separately.
- Although the device was accurate over a 2 week period, it cannot be calibrated therefore its long-term stability should be looked at. For this reason we would recommend using a new disposable turbine for each testing session.
- If patient's results are reading low they should be brought into the hospital to verify this on a system that can be physically calibrated and/or verified with a 3L syringe.