

## Příloha 1

### Tabulky naměřených sil potřebných pro rozpojení spoje

| Vzorek 1           |        |
|--------------------|--------|
| měření             | N      |
| 1                  | 152,83 |
| 2                  | 128,20 |
| 3                  | 141,44 |
| 4                  | 122,07 |
| 5                  | 127,68 |
| 6                  | 152,63 |
| aritmetický průměr | 137,48 |

| Vzorek 2           |        |
|--------------------|--------|
| měření             | N      |
| 1                  | 201,81 |
| 2                  | 230,11 |
| 3                  | 241,45 |
| 4                  | 248,35 |
| 5                  | 233,26 |
| 6                  | 217,76 |
| aritmetický průměr | 228,79 |

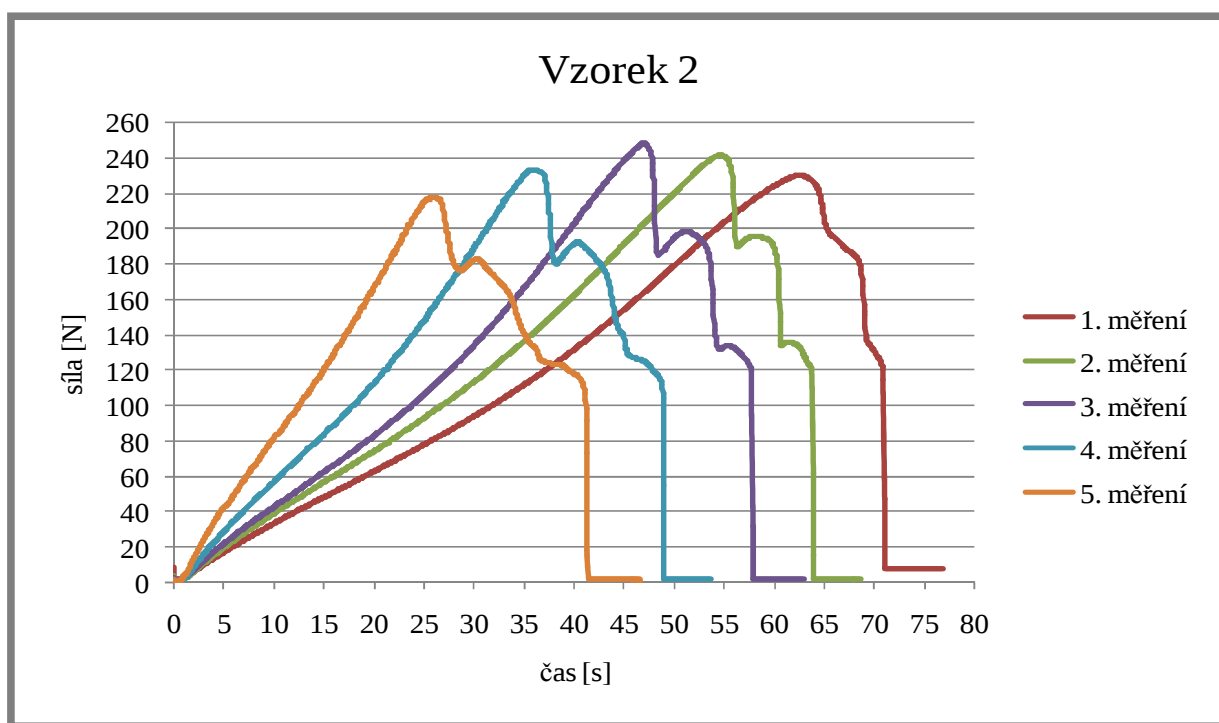
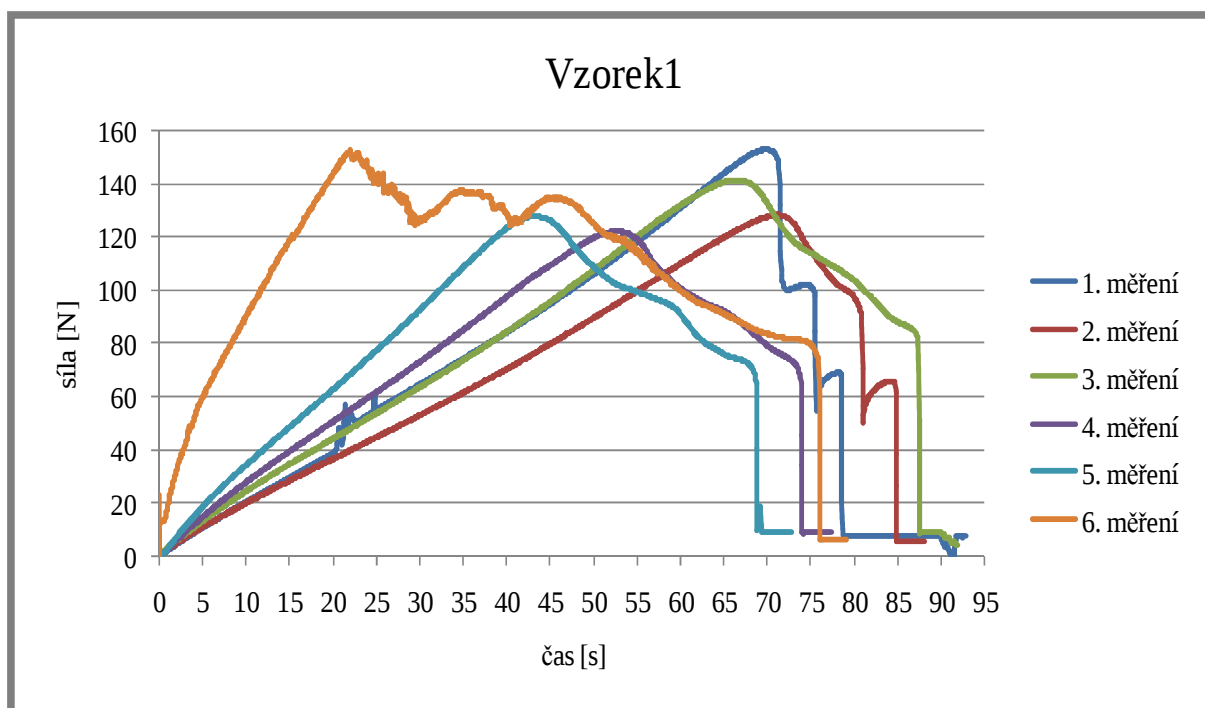
| Vzorek 3           |        |
|--------------------|--------|
| měření             | N      |
| 1                  | 164,64 |
| 2                  | 165,71 |
| 3                  | 146,37 |
| 4                  | 151,17 |
| 5                  | 139,08 |
| 6                  | 146,44 |
| aritmetický průměr | 152,24 |

| Vzorek 4           |        |
|--------------------|--------|
| měření             | N      |
| 1                  | 186,94 |
| 2                  | 176,59 |
| 3                  | 181,24 |
| 4                  | 179,69 |
| 5                  | 182,69 |
| 6                  | 185,69 |
| aritmetický průměr | 182,14 |

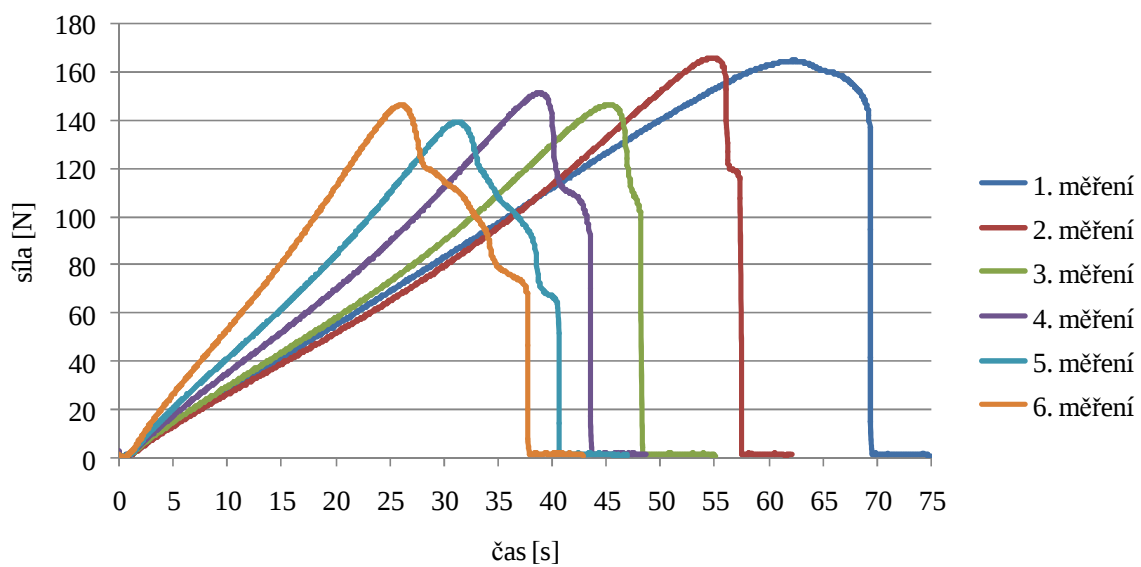
| Vzorek 5           |        |
|--------------------|--------|
| měření             | N      |
| 1                  | 179,00 |
| 2                  | 190,59 |
| 3                  | 194,35 |
| 4                  | 203,28 |
| 5                  | 208,84 |
| 6                  | 206,32 |
| aritmetický průměr | 197,06 |

## Příloha 2

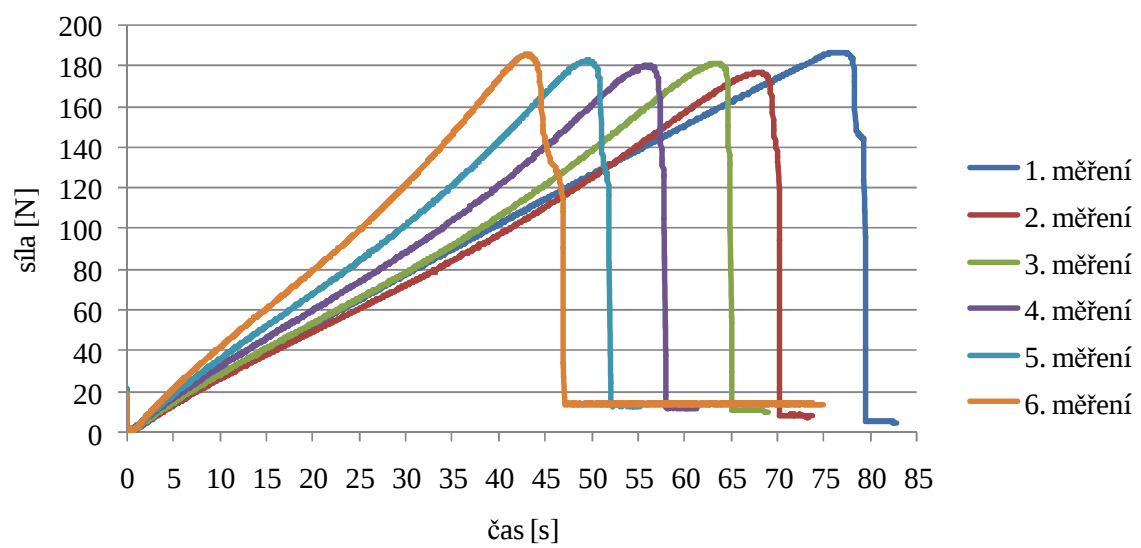
### Grafy průběhu tahových zkoušek pro jednotlivé vzorky



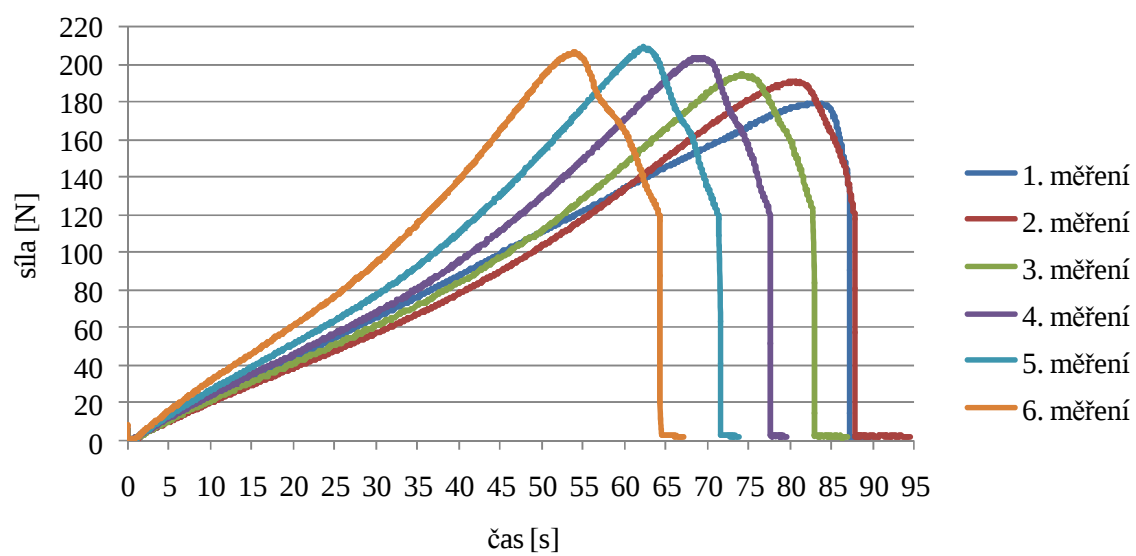
### Vzorek 3



### Vzorek 4

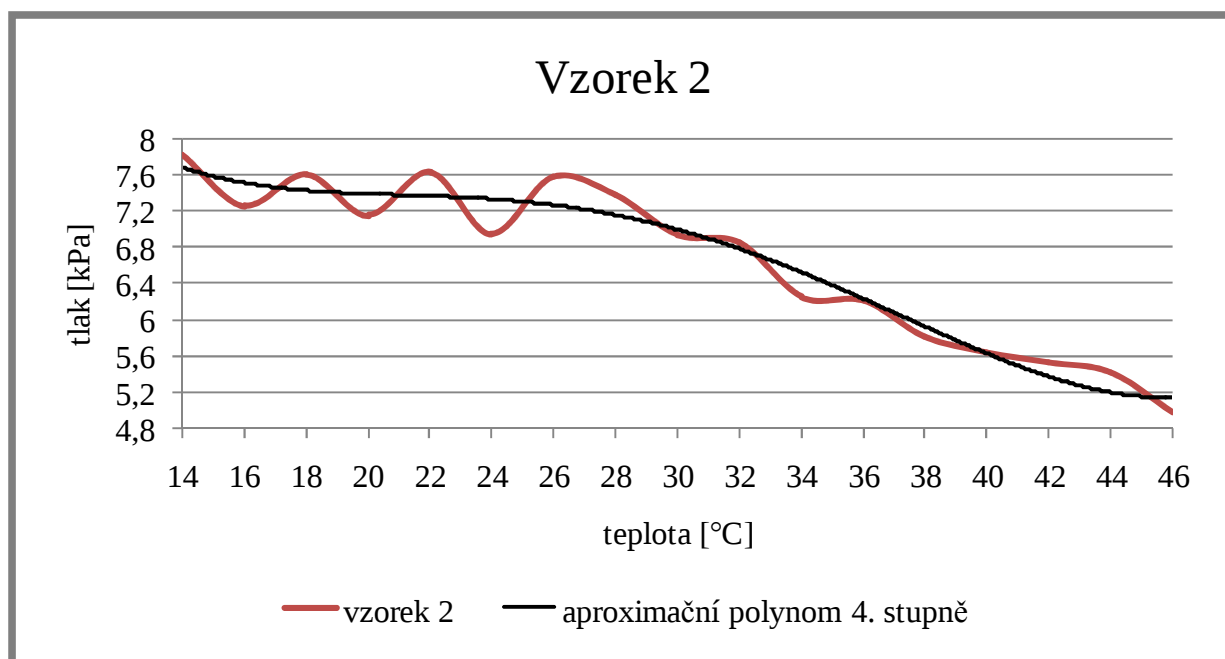
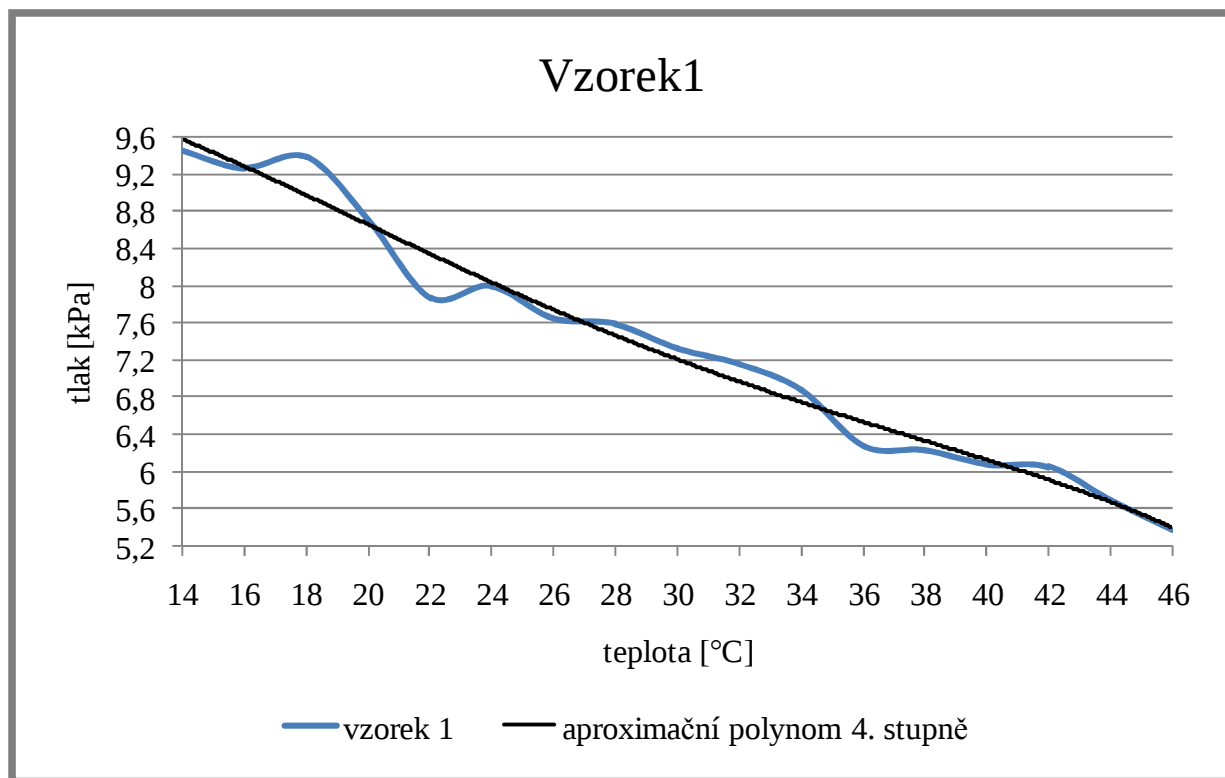


## Vzorek 5

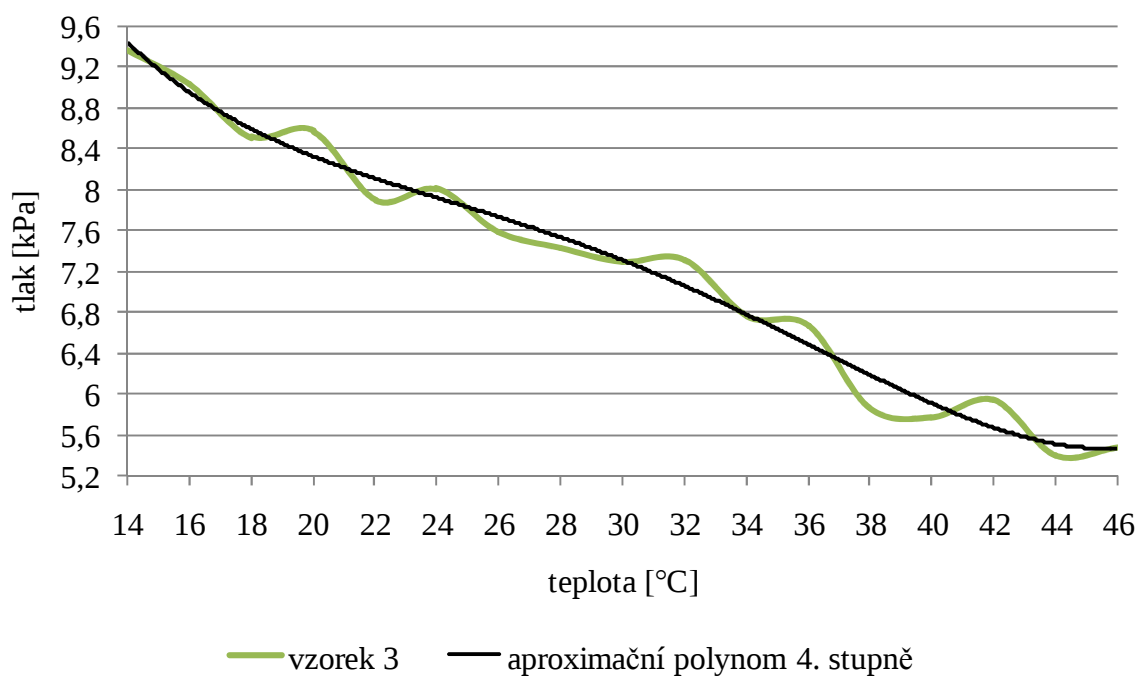


### Příloha 3

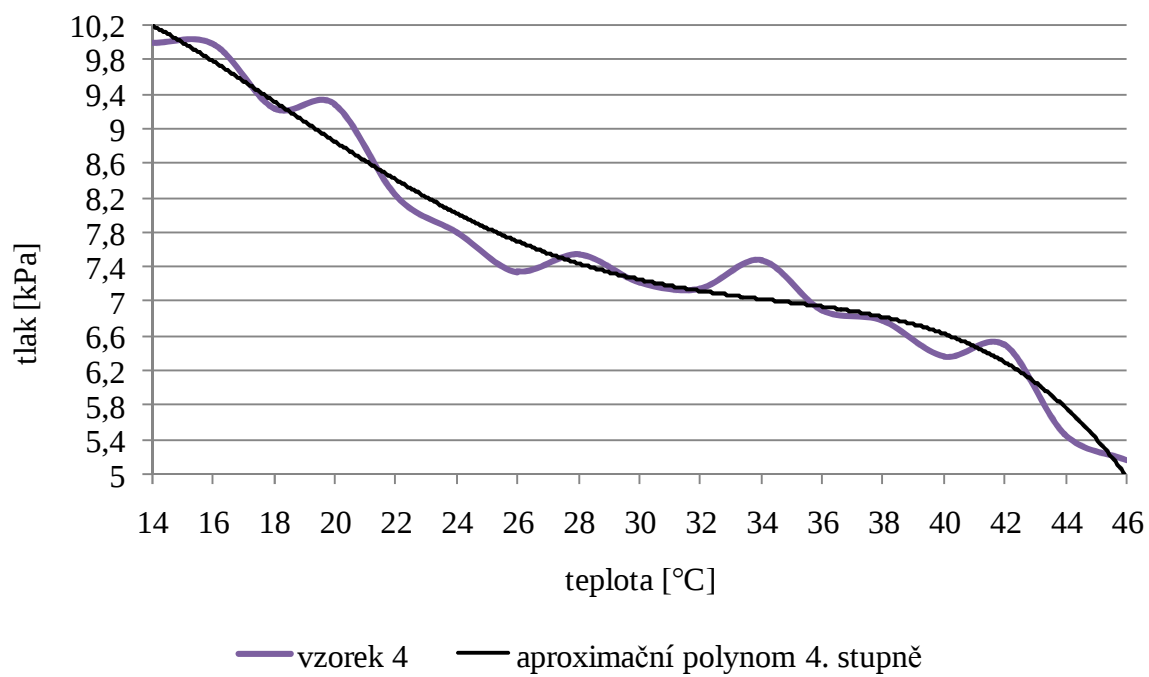
Grafy závislosti tlaku potřebného pro rozpojení spoje na teplotě pro jednotlivé vzorky při měření „na sucho“



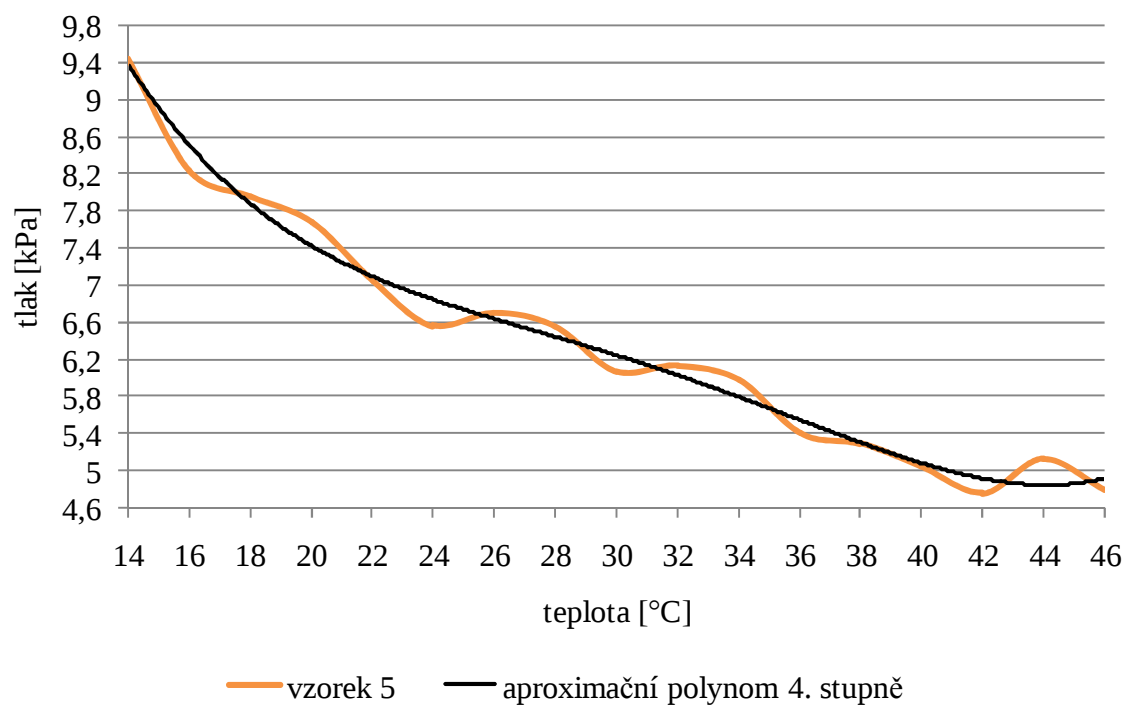
### Vzorek 3



### Vzorek 4

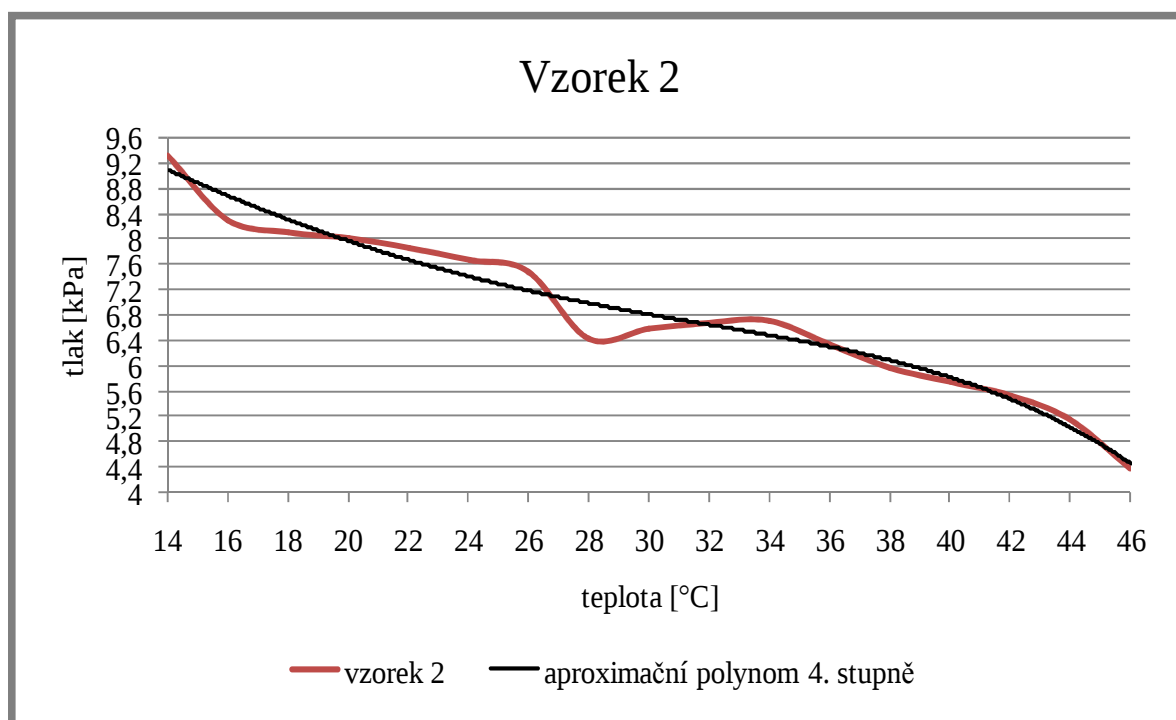
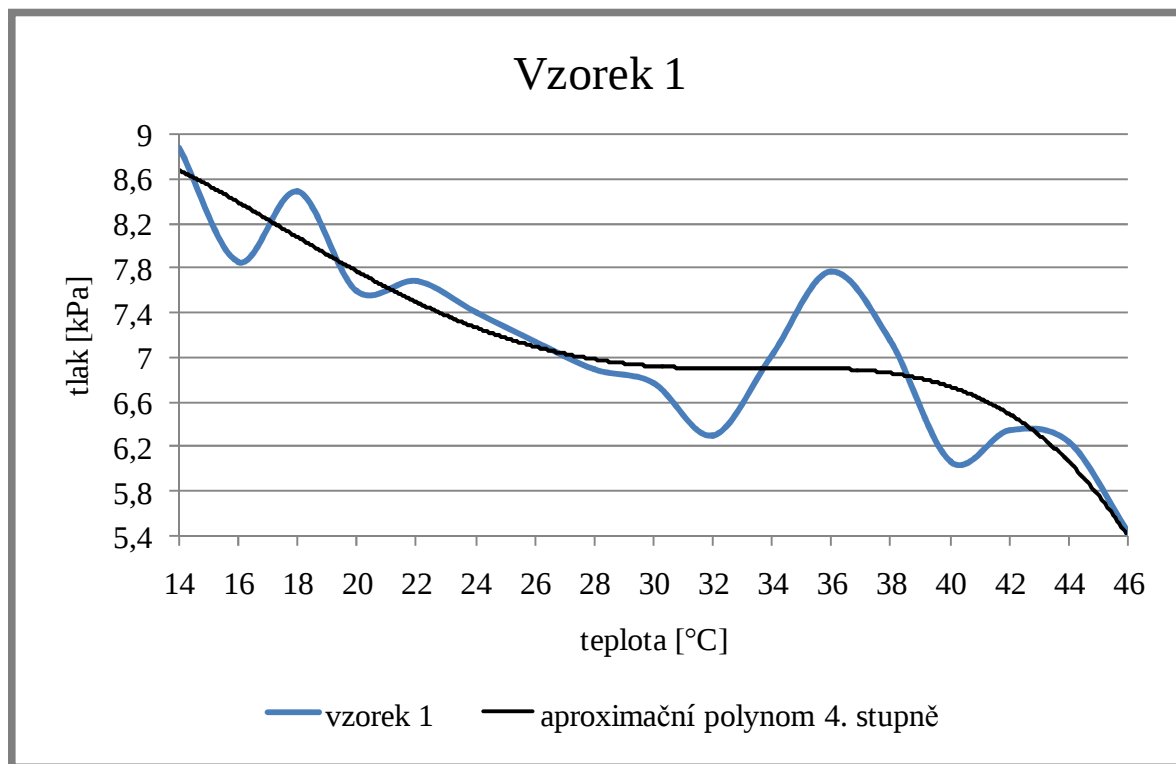


## Vzorek 5

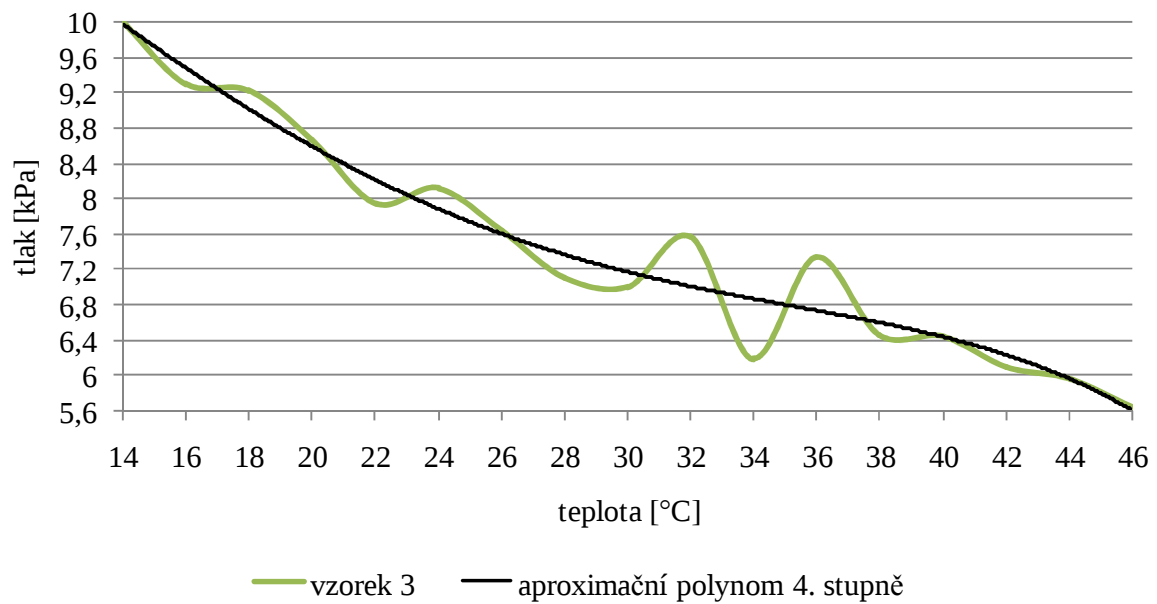


## Příloha 4

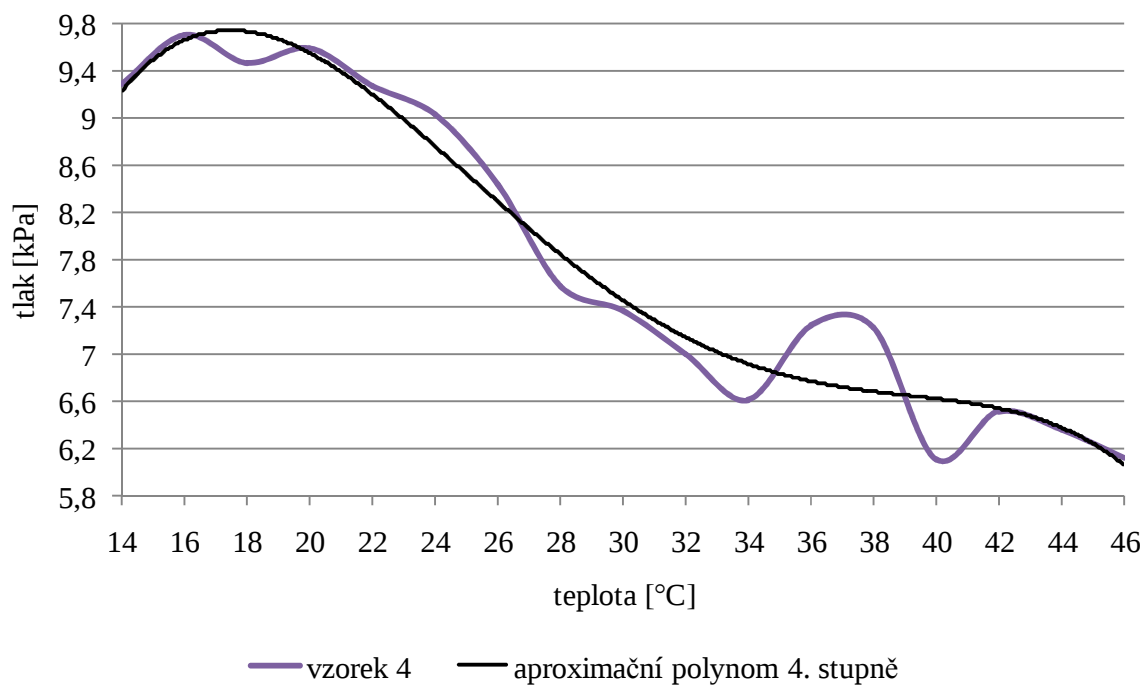
Grafy závislosti tlaku potřebného pro rozpojení spoje na teplotě pro jednotlivé vzorky při měření „na mokro“



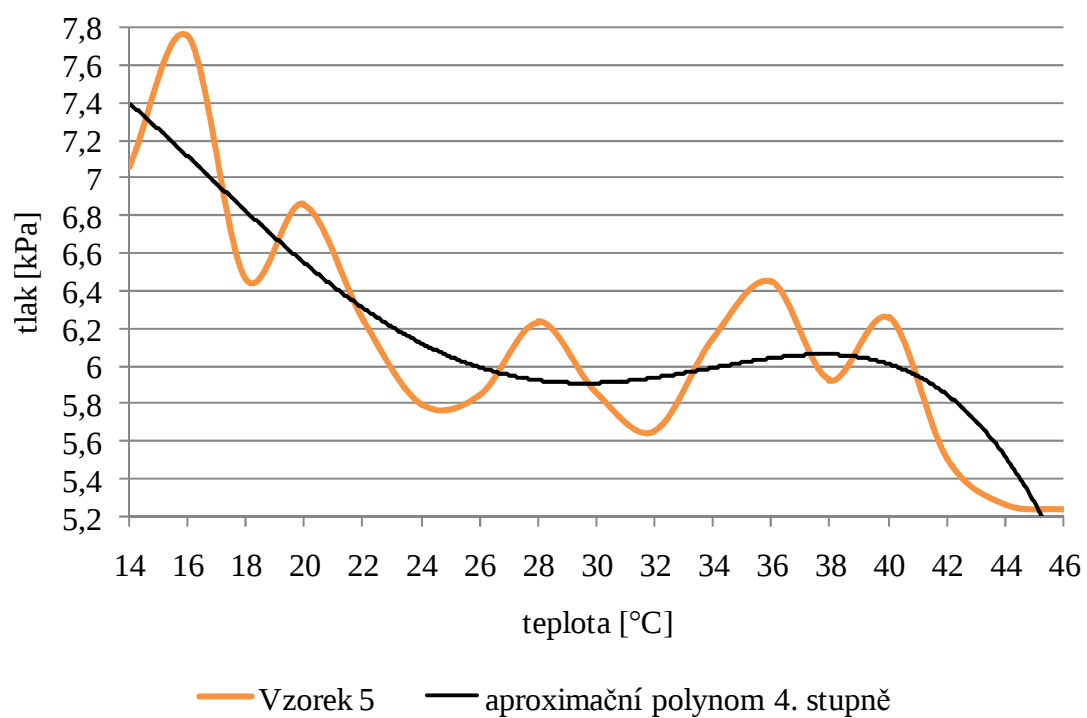
### Vzorek 3



### Vzorek 4



## Vzorek 5



|                                                                                                                                                                                        |  |                                         |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------|--------------------|
|  <b>SORIN GROUP</b><br><small>AT THE HEART OF MEDICAL TECHNOLOGY</small><br>Sorin Group Italia S.r.l. |  | <b>ENGINEERING REPORT</b>               |                    |
| <b>TITLE:</b> Connection resistance between the Sorin coated tube and the connector of the cannula                                                                                     |  |                                         | <b>PAGE 6 OF 6</b> |
| <b>DATE:</b> 10/07/2013                                                                                                                                                                |  | <b>DOCUMENT CODE:</b> MISC_1307_00_MISC |                    |
| <b>AUTHOR:</b> MATTEO FERRARINI                                                                                                                                                        |  |                                         |                    |

## CONCLUSION

The connection between the Sorin coated tube (019061RPC) and the connector of the cannula (CalMed and Sorin) show the following mechanical characteristics:

| TEST                                        | S01: CANNULA CALMED (NA-4536)<br>CONNECTED TO SORIN COATED TUBE<br>(019061RPC)                                                                                                                       | S02: CANNULA SORIN (A212-65A)<br>CONNECTED TO SORIN COATED TUBE<br>(019061RPC)                                                                                                                       |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Blood pathway dynamic integrity test</b> | The connection is able to withstand to a pressure of 1,5 bar for 6 hours, undergone to a recirculation with a changing of the test liquid temperature every hours (from 10°C to 40°C and vice versa) | The connection is able to withstand to a pressure of 1,5 bar for 6 hours, undergone to a recirculation with a changing of the test liquid temperature every hours (from 10°C to 40°C and vice versa) |
| <b>Pull test</b>                            | The mean force for disconnection is 44,7 kg (438N)                                                                                                                                                   | The mean force for disconnection is 40,3 kg (395N)                                                                                                                                                   |
| <b>Burst test</b>                           | The mean pressure for disconnection is 6,63 bar                                                                                                                                                      | The mean pressure for disconnection is 5,94 bar                                                                                                                                                      |

**TITLE:** Connection resistance between the Sorin coated tube and the connector of the cannula

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**DATE:** 10/07/2013

**DOCUMENT CODE:** MISC\_1307\_00\_MISC

**AUTHOR:** MATTEO FERRARINI

## RESULT

### TEST 1: Blood pathway dynamic integrity test

S01= No leak detected

S02= No leak detected

### TEST 2: Pull test

| S01: CANNULA CALLMED<br>(NA-4536) |             |            |
|-----------------------------------|-------------|------------|
| Sample                            | Kg          | N          |
| 1                                 | 39,4        | 386        |
| 2                                 | 41,4        | 406        |
| 3                                 | 48,4        | 475        |
| 4                                 | 49,5        | 485        |
| 5                                 | 45,6        | 447        |
| 6                                 | 44,2        | 434        |
| <b>Mean</b>                       | <b>44,7</b> | <b>438</b> |

| S02: CANNULA SORIN<br>(A212-65A) |             |            |
|----------------------------------|-------------|------------|
| Sample                           | Kg          | N          |
| 1                                | 44,5        | 436        |
| 2                                | 34,8        | 341        |
| 3                                | 42,5        | 417        |
| 4                                | 40,2        | 394        |
| 5                                | 43,3        | 425        |
| 6                                | 36,6        | 359        |
| <b>Mean</b>                      | <b>40,3</b> | <b>395</b> |

### TEST 3: Burst Test

| S01: CANNULA CALLMED<br>(NA-4536) |                              |
|-----------------------------------|------------------------------|
| Sample                            | Disconnection pressure (bar) |
| 1                                 | 6,7                          |
| 2                                 | 6,42                         |
| 3                                 | 6,9                          |
| 4                                 | 6,42                         |
| 5                                 | 6,63                         |
| 6                                 | 6,71                         |
| <b>Mean</b>                       | <b>6,63</b>                  |

| S02: CANNULA SORIN<br>(A212-65A) |                              |
|----------------------------------|------------------------------|
| Sample                           | Disconnection pressure (bar) |
| 1                                | 6,02                         |
| 2                                | 5,9                          |
| 3                                | 6,42                         |
| 4                                | 5,86                         |
| 5                                | 5,74                         |
| 6                                | 5,68                         |
| <b>Mean</b>                      | <b>5,94</b>                  |

|                                                                                                                                                                                        |  |                                         |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------|--------------------|
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| <b>TITLE:</b> Connection resistance between the Sorin coated tube and the connector of the cannula                                                                                     |  |                                         | <b>PAGE 4 OF 6</b> |
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| <b>AUTHOR:</b> MATTEO FERRARINI                                                                                                                                                        |  |                                         |                    |

## EQUIPMENT USED

### TEST 1: Blood pathway dynamic integrity test

| Equipment ID | Designation         | Calibration due Date |
|--------------|---------------------|----------------------|
| EQU 4816     | Timer               | 16/08/2013           |
| EQU 3967     | Flow probe          | 10/08/2013           |
| EQU 1442     | Flow meter          | 10/08/2013           |
| EQU 5095     | Temperature probe   | 16/04/2014           |
| EQU 3870     | Temperature monitor | 16/07/2013           |
| EQU 4348     | Pressure meter      | 28/03/2014           |
| EQU 4362     | Roller pump         | 16/07/2013           |

### TEST 2: Pull test

| Equipment ID | Designation | Calibration due Date |
|--------------|-------------|----------------------|
| H089         | Dynamometer | 30/04/2014           |

### TEST 3: Burst test

| Equipment ID | Designation                    | Calibration Date |
|--------------|--------------------------------|------------------|
| Cod.914443   | Pressure meter (burst machine) | 12/04/2013       |

|                                                                                                                                                                         |                                         |                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------|
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| <b>TITLE:</b> Connection resistance between the Sorin coated tube and the connector of the cannula                                                                      |                                         | <b>PAGE 3 OF 6</b> |
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| <b>AUTHOR:</b> MATTEO FERRARINI                                                                                                                                         |                                         |                    |

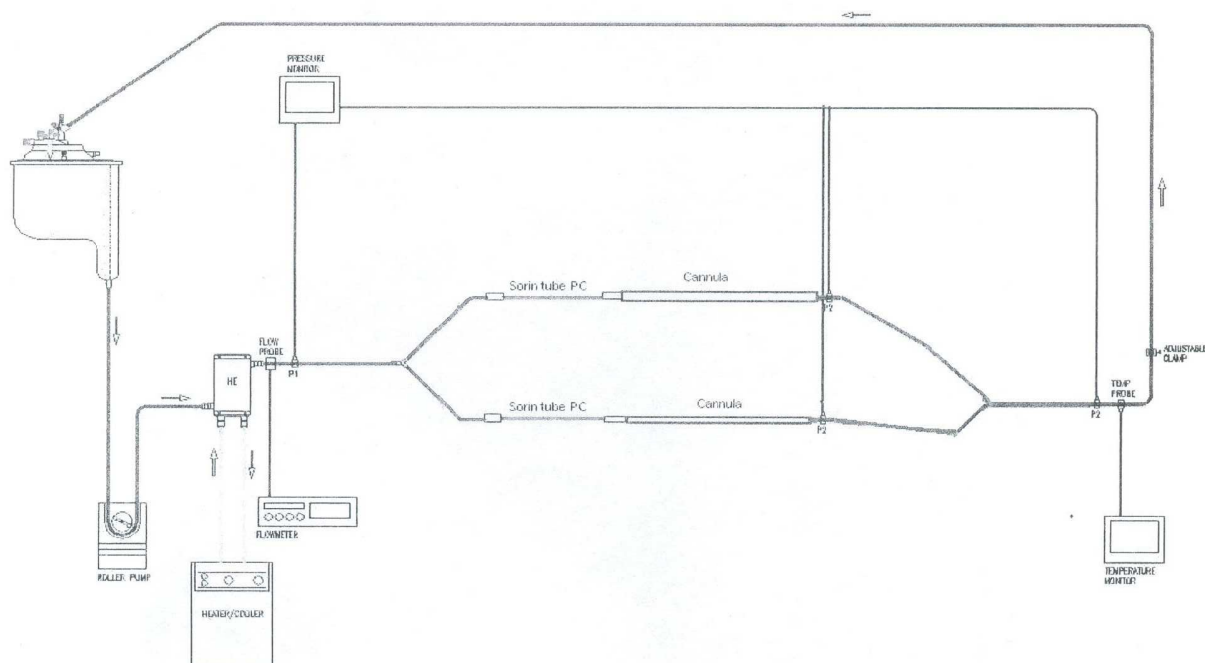


Figure 1: test circuit set-up

#### TEST 2: Pull test

1. Connect the Sorin coated tube to the connector of the cannula, using only alcohol.
2. Place the sample in the grips of the dynamometer.
3. Start with the longitudinal traction until the disconnection of the tube from the connector of the cannula
4. Register the peak of the force applied.

#### TEST 3: Burst test

1. Connect the Sorin coated tube to the connector of the cannula, using only alcohol.
5. Close the loose end of the Sorin Tube
6. Connect to the cannula to an pressure line and an pressure gauge.
7. Start gradually the pressurization line and increase gradually the pressure inside the device until the disconnection of the tube from the connector of the cannula.
8. Note the pressure value for tube disconnection.

|                                                                                                                                                                         |                                         |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--|
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| <b>TITLE:</b> Connection resistance between the Sorin coated tube and the connector of the cannula                                                                      | <b>PAGE 2 OF 6</b>                      |  |
| <b>DATE:</b> 10/07/2013                                                                                                                                                 | <b>DOCUMENT CODE:</b> MISC_1307_00_MISC |  |
| <b>AUTHOR:</b> MATTEO FERRARINI                                                                                                                                         |                                         |  |

**TEST 2: Pull test**

| Test article ID | Size |
|-----------------|------|
| S01             | 6    |
| S02             | 6    |

**TEST 3: Burst test**

| Test article ID | Size |
|-----------------|------|
| S01             | 6    |
| S02             | 6    |

**METHOD****TEST 1: Blood pathway dynamic integrity test**

1. Assemble a circuit as per figure 1. All the connections on the circuit will be insured with ties, except for the connection between cannula's connector and Sorin tube coated that will be carried out only with alcohol.
2. Connect a heater cooler to a heat exchanger that has been inserted in the blood pathway of the circuit.
3. Fill the blood side circuit with saline and debubble it.
4. Increase slowly the blood side flow rate to ensure a minimum flow rate of 6 LPM on the circuit.
5. Using a clamp, set the outlet pressure P2 to a value of  $1,5 \pm 0,1$  bar (corresponding to 1,5 time the maximum rated pressure for the device), and verifying at the same time that the inlet P1 are  $1,5 \pm 0,1$  bar.
6. Set the temperature of the heater coolers to  $10 \pm 2$  °C inside the circuit. After one hour change it to  $40 \pm 2$  °C. Repeat the same "heating-cooling" cycle 3 times, in order to thermally stress the device's blood side pathway for 6 consecutive hours.
7. During the test, check the integrity of connection between Sorin tube and the cannula to identify a the presence of leaks. To evidence the presence of leakage, the circulating fluid can be stained with methyl blue.
8. The test shall be considered PASS if no leak appears on each tested device during the 6 hours of recirculation.

|                                                                                                                                                                                               |  |                                         |                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------|--------------------|
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| <b>TITLE:</b> Connection resistance between the Sorin coated tube and the connector of the cannula                                                                                            |  |                                         | <b>PAGE 1 OF 6</b> |
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| <b>AUTHOR:</b> MATTEO FERRARINI                                                                                                                                                               |  |                                         |                    |

## PURPOSE

The aim is to evaluate the resistance of connection between the Sorin coated tube and the connector of the Sorin cannula.

Two types of cannula will be used for the test:

- CalMed NA-4536
- Sorin A212-65A

Since the difference of hardness between the Sorin soft tube and the Sorin hard tube does not affect the characteristic on exam (resistance of connection), only a tube will be chosen as representative for all Sorin coated tube. The tube that will be used for the tests is the code 019061RPC

The connection resistance will be verified through the following tests:

### 1. Blood pathway dynamic integrity test

The connection will be undergone to a pressure of 1.5 bar (corresponding to 1,5 time the maximum rated pressure for the device) for 6 hours, alternating the temperature of the liquid of recirculation every hour (10°C and 40°C).

### 2. Pull test

The connection will be undergone to a pull force, gradually increased until the disconnection of the tube on the cannula connector.

### 3. Burs test

The connection will be undergone to a pressure, gradually increased until the disconnection of the tube on the cannula connector.

## TEST ARTICLES

| ID  | Units to be tested [ UNITÀ DA PROVARE ]                             | Notes<br>[ COMMENTI ] |
|-----|---------------------------------------------------------------------|-----------------------|
| S01 | Cannula CalMed (NA-4536) connected to Sorin Coated Tube (019061RPC) |                       |
| S02 | Cannula Sorin (A212-65A) connected to Sorin Coated Tube (019061RPC) |                       |

## SAMPLE SIZE

### TEST 1: Blood pathway dynamic integrity test

| Test article ID | Size |
|-----------------|------|
| S01             | 1    |
| S02             | 1    |