



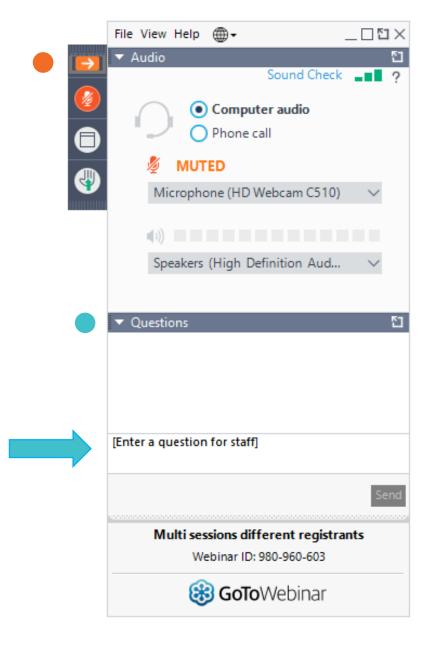
## Before we start

You will be kept on mute during the presentation.

All questions will be answered at the end of the presentation

- Click on this arrow to expand or minimize your GoToMeeting panel
- Add any questions here in the questions panel and we will answer them at the end of the presentation









# Medistim ASA Q3 2021

October 22<sup>nd</sup> 2021



Kari E. Krogstad

PRESIDENT & CEO

Thomas Jakobsen

CFO





## Disclaimer

The information included in this Presentation contains certain forward-looking statements that address activities, events or developments that Medistim ASA ("the Company") expects, projects, believes or anticipates will or may occur in the future. These statements are based on various assumptions made by the Company, which are beyond its control and are subject to certain additional risks and uncertainties. The Company is subject to a large number of risk factors including but not limited to economic and market conditions in the geographic areas and markets where Medistim is or will be operating, IP risks, clinical development risks, regulatory risks, fluctuations in currency exchange rates, and changes in governmental regulations. For a further description of other relevant risk factors, we refer to Medistim's Annual Report for 2020. As a result of these and other risk factors, actual events and our actual results may differ materially from those indicated in or implied by such forward-looking statements. The reservation is also made that inaccuracies or mistakes may occur in this information given above about current status of the Company or its business. Any reliance on the information above is at the risk of the reader, and Medistim disclaims any an all liability in this respect.



## Table of Contents

- 01 Highlights
- 02 Financial statements
- O3 Business segments update
- 04 Implementing the strategy





## 01 Highlights



## Highlights 3<sup>rd</sup> Quarter

|         | Q3 2021           | QoQ              |
|---------|-------------------|------------------|
| Revenue | MNOK 102.1 (83.4) | <b>~</b> +22.5 % |

Currency - 8.1 %

#### Number of units sold or outplaced:

| 30     |                   | 0 %      |
|--------|-------------------|----------|
| 17     |                   | +70 %    |
| 1 996  |                   | +50.9 %  |
| 38     |                   | +137.5 % |
| 18 822 |                   | +28.9 %  |
|        | 17<br>1 996<br>38 | 17       |

### 3rd quarter in a row with sales over MNOK 100

- First time a 3<sup>rd</sup> quarter is above MNOK 100 in sales revenues
  - o Imaging sales up 43.5% in NOK, Flow sales up 16.3% in NOK
  - O Vascular sales up 57.0% in NOK, Cardiac sales up 17.9 %in NOK
  - Currency neutral growth was 30.6% in total and 33.0% for own products:
    - o USA up 24.9%, Europe up 39.3%, Asia up 27.8%, RoW up 126%
- > Third-party products grow by 19.0 %

Solid EBIT growth with margin at 24.6%



## Highlights YTD September

MNOK 314.5 (268.9)

**EBIT** MNOK 96.8 (73.3)

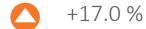
Currency

Revenue

#### Number of units sold or outplaced:

| Flow systems         | 104    |
|----------------------|--------|
| Imaging systems      | 68     |
| Flow probes (ex USA) | 5 727  |
| Imaging probes       | 104    |
| Procedures (USA)     | 54 211 |

#### YTD o YTD



+ 32.0 %

- 7.5 %

- 8.0 %

+ 51.1 %

+ 28.7 % + 36.8 %

+ 28.6 %

#### Best YTD September ever for revenue and EBIT

- > Sales revenue YTD September is up 15% to MNOK 309.2
  - o Imaging sales up 23.2%, Flow up 11.9% in NOK
  - o Vascular sales up 10.1 %, Cardiac up 14.4% in NOK
  - Currency neutral growth was 24.5% in total and 25.3% for own products:
    - o USA up 23.3%, Europe up 25.1%, Asia up 28.3%, RoW down 9.7%
- ➤ Total revenue YTD September is up 17% to MNOK 314.5, due to the extraordinary revenue of MNOK 5.3 from the COVID-related U.S. Paycheck Protection Program granted in Q2
- > Third-party products grow by 20.8 %

EBIT YTD September of MNOK 96.8 is higher than for the full year of 2020 (MNOK 95.5)





## 02 Financial Statements



## Profit and loss Q3 2021

| Profit & loss                                 | Q3 2021 | Q3 2020 |
|---|---------|---------|
| All numbers in NOK 1000                       |         |         |
| Sales revenue                                 | 102 138 | 83 361  |
| Other revenue                                 | -       | -       |
| Total revenue                                 | 102 138 | 83 361  |
| Cost of goods sold                            | 23 793  | 15 379  |
| Salary and social expenses                    | 35 478  | 31 186  |
| Other operating expenses                      | 11 882  | 10 170  |
| Total operating expenses                      | 71 152  | 56 736  |
| Op. res. before depr. and write-offs (EBITDA) | 30 986  | 26 625  |
| EBITDA %                                      | 30,3 %  | 31,9 %  |
| Depreciation                                  | 5 909   | 5 772   |
| Operating result (EBIT)                       | 25 077  | 20 853  |
| EBIT %  | 24,6 %  | 25,0 %  |
| Financial income                              | 3 258   | 4 678   |
| Financial expenses                            | 4 351   | 6 864   |
| Net finance                                   | -1 093  | -2 185  |
| Pre tax profit                                | 23 984  | 18 668  |
| Tax   | 5 186   | 4 225   |
| Profit after tax                              | 18 798  | 14 442  |
| Dividend                                      | -       | -       |
|   |         |         |

#### Sales per Quarter (TNOK)



#### EBIT per Quarter (TNOK)





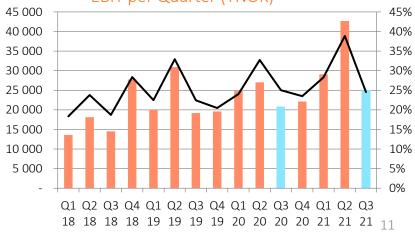
## Profit and loss YTD September 2021

| Profit & loss                                 | YTD 30.09.21 | YTD 30.09.20 |
|---|--------------|--------------|
| All numbers in NOK 1000                       |              |              |
| Sales revenue                                 | 309 244      | 268 949      |
| Other revenue                                 | 5 292        | -            |
| Total revenue                                 | 314 536      | 268 949      |
| Cost of goods sold                            | 69 231       | 54 346       |
| Salary and social expenses                    | 93 089       | 86 889       |
| Other operating expenses                      | 38 000       | 37 517       |
| Total operating expenses                      | 200 319      | 178 752      |
| Op. res. before depr. and write-offs (EBITDA) | 114 217      | 90 197       |
| EBITDA %                                      | 36,3 %       | 33,5 %       |
| Depreciation                                  | 17 400       | 16 848       |
| Operating result (EBIT)                       | 96 817       | 73 348       |
| EBIT %  | 30,8 %       | 27,3 %       |
| Financial income                              | 6 509        | 12 704       |
| Financial expenses                            | 8 670        | 14 367       |
| Net finance                                   | -2 161       | -1 663       |
| Pre tax profit                                | 94 656       | 71 686       |
| Tax   | 19 869       | 15 867       |
| Profit after tax                              | 74 788       | 55 818       |

#### Sales per Quarter (TNOK)



#### EBIT per Quarter (TNOK)





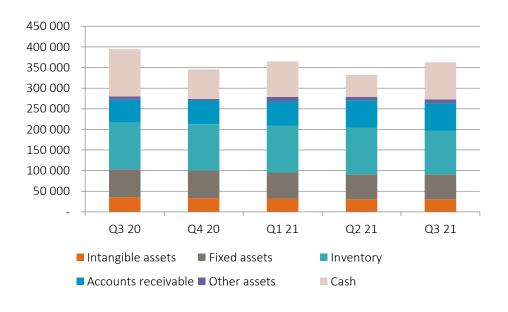
# Balance sheet – Assets

Cash position by end of quarter was MNOK 89.6

Securing end-of-life components and keeping security stocks of components explain the high inventory level

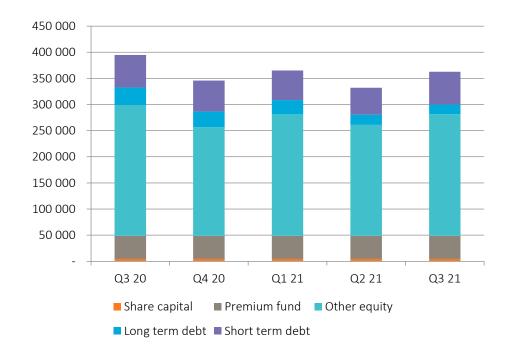
A dividend of NOK 3.00 per share, total MNOK 54.6, was paid in May

| Balance sheet                     | 30.09.2021 | 31.12.2020 |
|-----------------------------------|------------|------------|
| All numbers in NOK 1000           |            |            |
| Assets                            |            |            |
| Intangible assets                 | 30 643     | 33 464     |
| Fixed assets                      | 59 406     | 66 570     |
| Total intangible and fixed assets | 90 048     | 100 034    |
| Inventory                         | 106 128    | 112 667    |
| Customers receivables             | 66 907     | 57 485     |
| Other receivables                 | 9 847      | 3 744      |
| Cash                              | 89 658     | 71 891     |
| Total current assets              | 272 540    | 245 786    |
| Total assets                      | 362 588    | 345 820    |





| Balance sheet              | 30.09.2021 | 31.12.2020 |
|----------------------------|------------|------------|
| All numbers in NOK 1000    |            |            |
|                            |            |            |
| Share capital              | 4 585      | 4 585      |
| Premium fund               | 44 172     | 44 172     |
| Other equity               | 232 907    | 208 089    |
| Total equity               | 281 664    | 256 846    |
|                            |            |            |
| Total long term debt       | 18 339     | 29 497     |
|                            |            |            |
| Total short term debt      | 62 585     | 59 477     |
| Total equity and liability | 362 588    | 345 820    |



# Balance sheet – Equity and Liability

2.25 MNOK in interest-bearing debt

- 23.3 MNOK in obligationsrelated to lease contracts where16.4 MNOK is long term
- Strong balance sheet with 77.7 % equity ratio





03 Business segments update

### **MEDISTIM**

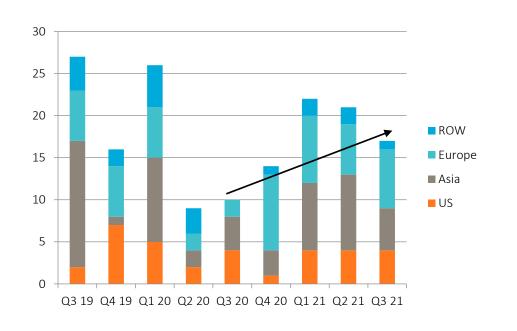
# Imaging probes and systems in units

Unit sales of imaging systems sold as capital equipment

continue to be strong after the COVID slow down, **growing 70%** this quarter

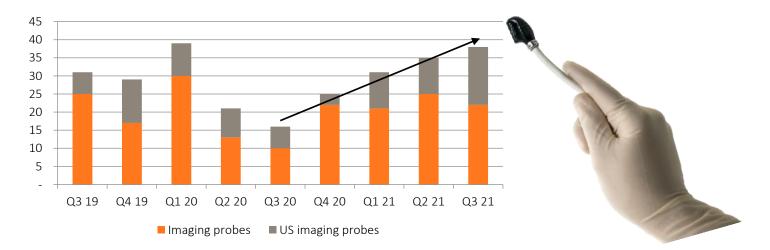
Unit sales of imaging probes arealso back to normal, growing137.5% this quarter

### Imaging systems in units





### Imaging probes in units



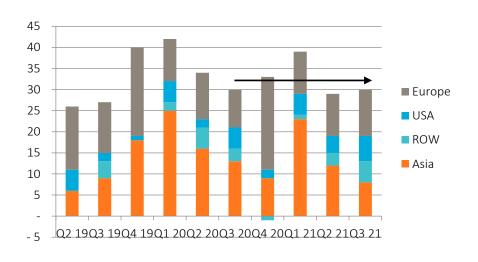


# Flow probes and systems in units

Number of flow systems sold as capital equipment is **flat** from Q3 last year.

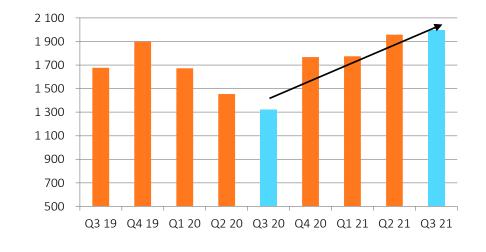
- It is Medistim's strategy to convert the market from Flow-only to Flow-and-Imaging technology
- The total sale of systems (Flow and Flow-and-Imaging) sold as capital equipment shows an increase of 7 units or 17.5%
- 50.9% growth in number of flow probes sold this quarter reflects that the surgical activity level is getting back to normal

#### Flow systems in units (MiraQ capital sales)





#### Flow probes in units (excl USA)







## Revenue performance by region

| Mill NOK                   | Q3 21 | Q3 20 | Q/Q     | YTD 21 | YTD 20 | YTD / YTD | 2020  |
|----------------------------|-------|-------|---------|--------|--------|-----------|-------|
| Europe                     | 45,8  | 35,9  | 27,4 %  | 140,8  | 117,4  | 19,9 %    | 173,3 |
| USA                        | 38,5  | 34,5  | 11,8 %  | 115,0  | 99,4   | 15,7 %    | 126,4 |
| Asia                       | 13,2  | 10,8  | 22,0 %  | 46,5   | 38,0   | 22,4 %    | 46,8  |
| ROW<br>(MEA, CAN, SA, AUS) | 4,6   | 2,1   | 116,4 % | 12,2   | 14,1   | -13,8 %   | 16,7  |
| Total                      | 102,1 | 83,4  | 22,5 %  | 314,5  | 268,9  | 17,0 %    | 363,1 |

- In Europe, Q3 sales of own products increased with 33.0% in NOK and 39.3% currency neutral. YTD September, sales of own products increased with 19.4% in NOK and 25.1% currency neutral. **3. party increased** with 19% in Q3 and 20.8% YTD.
- In the USA, currency neutral sales for the quarter increased with 24.9%. Total revenues YTD include the extraordinary MNOK 5.3 related to the U.S. Paycheck Protection Program. When excluding this, sales revenue YTD was NOK 109.8, a 10.4 % increase. Currency neutral this corresponds to an increase of with 23.3 %.
- In Asia, solid growth both for the quarter and YTD.
- ROW continues to be a small sales territory for Medistim, with significant quarter to quarter variation.



## Revenue performance by product category

| Mill NOK                | Q3 21 | Q3 20 | Q/Q    | YTD 21 | YTD 20 | H1 / H1 | 2020  |
|-------------------------|-------|-------|--------|--------|--------|---------|-------|
| Procedures (USA)        | 28,4  | 25,3  | 12,2 % | 83,2   | 76,0   | 9,4 %   | 99,4  |
| Flow probes             | 30,2  | 23,4  | 28,7 % | 85,4   | 69,8   | 22,3 %  | 92,6  |
| Flow systems (MiraQ)    | 12,0  | 9,9   | 21,3 % | 33,5   | 33,8   | -0,9 %  | 47,2  |
| Imaging systems (MiraQ) | 12,5  | 9,3   | 35,5 % | 42,8   | 34,2   | 25,1 %  | 44,2  |
| Imaging probes          | 1,6   | 0,8   | 96,0 % | 5,1    | 3,9    | 29,5 %  | 5,2   |
| 3rd party               | 17,0  | 14,3  | 19,0 % | 55,9   | 46,3   | 20,8 %  | 67,5  |
| Other                   | 0,5   | 0,4   | 22,6 % | 8,7    | 4,9    | 77,2 %  | 6,9   |
| Total revenues          | 102,1 | 83,4  | 22,5 % | 314,5  | 268,9  | 17,0 %  | 363,1 |

- Procedure sale in the USA: The total number of procedures increased with 28.9% for the quarter and with 28.6 % YTD September. Lower % growth in NOK is explained by unfavorable currency.
- Flow probes: In units the growth is 50.9 % for the quarter and 28.7 % YTD September. The lower % growth in NOK is due to higher sales through distributors and unfavorable currency.
- Flow systems (capital): At the the same level in number of units but higher sales through direct operation increases revenue in NOK.
- Imaging systems (capital): 80% increase in capital units. The lower increase in NOK is related to high sales through distributors this quarter and currency. YTD September, the % growth in number of capital units sold is 51%. The lower increase in NOK has same explanation as for the quarter.
- 3<sup>rd</sup> party products: Strong quarter and YTD September.
- Other: Includes an extraordinary revenue of MNOK 5.3 related to the U.S. Paycheck Protection Program



## Conclusion: We are in recovery from the COVID-19 pandemic



From gradually decreasing impact to strong recovery in 2<sup>nd</sup> and 3<sup>rd</sup> quarter 2021







#### **Currency neutral sales development**

- $\rightarrow$  Q2-20: -19.3 % vs LY
- $\rightarrow$  Q3-20: -9.7 % vs LY
- $\rightarrow$  Q4-20: 7.2 % vs LY
- $\rightarrow$  Q1-21: +4.4 % vs LY
- → Q2-21: +36.7 % vs LY (strongest quarter ever)
- $\rightarrow$  Q3-21: + 30.6 % vs LY

#### Not completely back to normal

- Still some travel and hospital access restrictions
- In some countries, and some states in the U.S.A., elective surgeries may still be postponed

#### A positive outlook

- → Increasing vaccination rates ensure capacity for cardiovascular surgery
- → Medistim remains optimistic about the future





04 Implementing the strategy

## Medistim growth strategy

| Emerging high-growth economies (e.g. BRIC)                         | 3                           |                                    |  |
|--|-----------------------------|------------------------------------|--|
| Developing Medistim markets (e.g. USA, UK, France)                 | 2                           |                                    |  |
| Strong Medistim markets (e.g. Jp, Nordic, Germany) >50% CABG share | 1                           | 4                                  |  |
|  | CABG<br>surgery<br>(2 BNOK) | Vascular<br>surgery<br>(>1.5 BNOK) | Other open<br>heart surgery<br>(1BNOK) |

**APPLICATION AREAS** 

- 1. Convert the routine Flow market to a Flow-and-Imaging market by establishing *Surgical Guidance and Quality Assessment* as the new standard of care through
  - → Early adopter & KOL support
  - → REQUEST study
  - → Ease conversion from flow to imaging with MiraQ
- Achieve routine use of both Flow and Imaging by fighting ignorance, indifference and ease-of-use objections through
  - → Clinical marketing, guidelines and educational programs
  - → Product innovation for ease of use
  - Increased sales force capacity
- Offer an entry-level solution to reach emerging, price-sensitive, high-growth markets
- 4. Build and strengthen position in vascular surgery
  - → Dedicated system (MiraQ Vascular) & probes
  - → Build position with societies and KOLs
- 5. Expand our direct market coverage



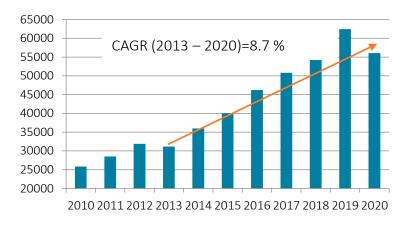


## Sales growth in the USA

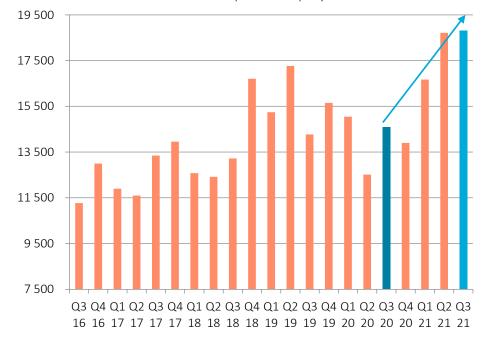


## Performance US sales

- Currency neutral sales revenue grow by 24.9% in Q3 and by 23.3% YTD
  - Total YTD revenue in USD includes the Paycheck Protection Program revenue of TUSD 630. YTD total revenue grows by 29.2%
- Total **number of procedures** was up 28.9% in Q3 and 28.6% YTD
  - Flow procedures up 19.5% in Q3
  - o **Imaging** procedures up 87.8% in Q3
- Capital systems sales:
  - o 10 units in Q3 vs 9 LY
  - o 27 units YTD September vs 23 LY
- Strong growth in new customers
  - o 33 YTD September vs 18 last year











## New publications



## Hot off the press: Review-article in CIRCULATION, Oct 5<sup>th</sup> 2021

- Authored by 19 cardiac surgeon experts (4 from REQUEST study) from all over the world
- Published in Circulation, one of the highest ranked journals in cardiology and cardiovascular medicine

|    | Title   | Туре    | <b>↓</b> SJR | H<br>index | Total<br>Docs.<br>(2020) | Total Docs.<br>(3years) | Total Refs.<br>(2020) | Total Cites<br>(3years) | Citable Docs.<br>(3years) | Cites / Doc.<br>(2years) | Ref. / Doc.<br>(2020) |   |   |
|----|---|---------|--------------|------------|--------------------------|-------------------------|-----------------------|-------------------------|---------------------------|--------------------------|-----------------------|---|---|
| 1  | Journal of the American College of Cardiology | journal | 10.315<br>Q1 | 431        | 935                      | 2960                    | 22363                 | 23475                   | 1191                      | 7.44                     | 23.92                 |   |   |
| 2  | Circulation                                   | journal | 7.795<br>Q1  | 607        | 778                      | 2685                    | 22242                 | 26532                   | 1702                      | 9.48                     | 28.59                 |   | > |
| 3  | JACC: Heart Failure                           | journal | 6.123<br>Q1  | 67         | 184                      | 596                     | 2888                  | 2708                    | 262                       | 4.38                     | 15.70                 | = |   |
| 4  | JAMA Cardiology                               | journal | 6.108<br>Q1  | 63         | 349                      | 944                     | 4752                  | 4608                    | 486                       | 4.92                     | 13.62                 |   |   |
| 5  | JACC: Cardiovascular Imaging                  | journal | 5.790<br>Q1  | 120        | 481                      | 1051                    | 9756                  | 4889                    | 422                       | 4.57                     | 20.28                 |   |   |
| 6  | Nature Reviews Cardiology                     | journal | 5.495<br>Q1  | 130        | 175                      | 550                     | 8971                  | 3856                    | 268                       | 7.24                     | 51.26                 |   |   |
| 7  | European Journal of Heart<br>Failure          | journal | 5.149<br>Q1  | 133        | 397                      | 855                     | 12087                 | 5341                    | 445                       | 6.01                     | 30.45                 |   |   |
| 8  | Circulation Research                          | journal | 4.899<br>Q1  | 336        | 352                      | 1256                    | 19861                 | 10880                   | 933                       | 7.71                     | 56.42                 |   |   |
| 9  | European Heart Journal                        | journal | 4.336<br>Q1  | 293        | 1008                     | 2579                    | 16028                 | 14482                   | 1859                      | 5.52                     | 15.90                 |   |   |
| 10 | Journal of Heart and Lung<br>Transplantation  | journal | 3.549<br>Q1  | 135        | 1537                     | 645                     | 4734                  | 3313                    | 371                       | 4.74                     | 3.08                  |   |   |
| 11 | Stroke  | journal | 3.397        | 319        | 775                      | 2080                    | 15700                 | 11233                   | 1632                      | 4.99                     | 20.26                 |   |   |

#### Circulation

#### IN DEPTH

#### The Use of Intraoperative Transit Time Flow Measurement for Coronary Artery Bypass Surgery

Systematic Review of the Evidence and Expert Opinion Statements

Mario Gaudino<sup>®</sup>, MD, MSCE; Sigrid Sandner<sup>®</sup>, MD; Gabriele Di Giammarco, MD; Antonino Di Franco, MD; Hirokuni Arai, MD; Tohru Asai , MD; Faisal Bakaeen, MD; Torsten Doenst, MD; Stephen E, Fremes , MD; David Glineur, MD; Teresa M. Kieser@, MD, PhD; Jennifer S. Lawton, MD; Roberto Lorusso, MD; Nirav Patel, MD; John D. Puskas, MD; James Tatoulis, MD; David P. Taggart, MD; Michael Vallely, MD; Marc Ruel MD

ABSTRACT: Transit time flow measurement (TTFM) allows quality control in coronary artery bypass grafting but remains largely underused, probably because of limited information and the lack of standardization. We performed a systematic review of the evidence on TTFM and other methods for quality control in coronary artery bypass grafting following PRISMA standards and elaborated expert recommendations by using a structured process. A panel of 19 experts took part in the consensus process using a 3-step modified Delphi method that consisted of 2 rounds of electronic voting and a final face-to-face virtual meeting. Eighty percent agreement was required for acceptance of the statements. A 2-level scale (strong, moderate) was used to grade the statements based on the perceived likelihood of a clinical benefit.

The existing evidence supports an association between TTFM readings and graft patency and postoperative clinical outcomes, although there is high methodological heterogeneity among the published series. The evidence is more robust for arterial, rather than venous, grafts and for grafts to the left anterior descending artery. Although TTFM use increases the duration and the cost of surgery, there are no data to quantify this effect. Based on the systematic review, 10 expert statements for TTFM use in clinical practice were formulated. Six were approved at the first round of voting, 3 at the second round, and 1 at the virtual meeting

In conclusion, although TTFM use may increase the costs and duration of the procedure and requires a learning curve, its cost/benefit ratio seems largely favorable, in view of the potential clinical consequences of graft dysfunction. These consensus statements will help to standardize the use of TTFM in clinical practice and provide guidance in clinical

Key Words: coronary artery bypass ■ quality control ■ time

ntraoperative quality control is standard practice in the reluctance to its widespread adoption by the surgiremains underused in coronary artery bypass grafting (CABG). Transit time flow measurement (TTFM) allows quality control in CABG by intraoperative evaluation of coronary graft function, but it is currently adopted in only 30% of the procedures.1

Current myocardial revascularization guidelines provide only generic recommendations on TTFM use, 2.3 and methodological heterogeneity of the published stud-

every aspect of contemporary cardiac surgery but cal community is likely based on limited information, and concerns pertaining to the lack of standardization and familiarity with TTFM interpretation, as well.

In this article, a group of coronary surgeons with extensive experience with TTFM performed a systematic review of the existing evidence and critically evaluated the available data. Because of the high statistical and

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association

Correspondence to: Mario Gaudino, MD, MSCE, FEBCTS, FACC, Department of Cardiothoracic Surgery, Weill Cornell Medicine, 525 East 68th St, New York, NY 10065. Email mfg9004@med.cornelled

The Data Supplement is available with this article at https://www.ahajournals.org/doi/suppl/10.1161/CIRCULATIONAHA.121.054311

For Sources of Funding and Disclosures, see page xxx

© 2021 American Heart Association, Inc. Circulation is available at www.ahajournals.org/journal/circ

Circulation, 2021:144:00-00, DOI: 10.1161/CIRCULATIONAHA.121.054311

October 5, 2021



## "The Use of Intraoperative TTFM for CABG"

Circulation, October 2021

#### Method

- Systematic review of 229 publications
  - 2,200 articles identified
  - 1,550 screened
  - 38 cited in the review
- 10 expert statements for TTFM use were formulated
  - 2 x electronic voting, 1 F2F
  - 80% agreement was required for acceptance of the statements
  - 2-level scale for clinical benefit (strong, moderate)

#### Conclusion

- "...TTFM's cost/benefit ratio seems largely favorable, in view of the potential clinical consequences of graft dysfunction."
- "These consensus statements will help to standardize the use of TTFM in clinical practice and provide guidance in clinical decision-making"

#### **10 CONSENSUS STATEMENTS:**

#1 reads:

"TTFM should be used in every CABG case"

#### Circulation

#### IN DEPTH

#### The Use of Intraoperative Transit Time Flow Measurement for Coronary Artery Bypass Surgery

Systematic Review of the Evidence and Expert Opinion Statements

Mario Gaudino MD, MSCE; Sigrid Sandner MD; Gabriele Di Giammarco, MD; Antonino Di Franco, MD; Hirokuni Arai, MD; Tohru Asai, MD; Faisal Bakaeen, MD; Torsten Doenst, MD; Stephen E. Fremes, MD; David Glineur, MD: Teresa M, Kieser D, MD, PhD: Jennifer S, Lawton, MD: Roberto Lorusso, MD: Niray Patel, MD: John D. Puskas, MD; James Tatoulis, MD; David P. Taggart, MD; Michael Vallely, MD; Marc Ruel®, MD

ABSTRACT: Transit time flow measurement (TTFM) allows quality control in coronary artery bypass grafting but remains largely underused, probably because of limited information and the lack of standardization. We performed a systematic review of the evidence on TTFM and other methods for quality control in coronary artery bypass grafting following PRISMA standards and elaborated expert recommendations by using a structured process. A panel of 19 experts took part in the consensus process using a 3-step modified Delphi method that consisted of 2 rounds of electronic voting and a final face-to-face virtual meeting. Eighty percent agreement was required for acceptance of the statements. A 2-level scale (strong, moderate) was used to grade the statements based on the perceived likelihood of a clinical benefit.

The existing evidence supports an association between TTFM readings and graft patency and postoperative clinical outcomes, although there is high methodological heterogeneity among the published series. The evidence is more robust for arterial, rather than venous, grafts and for grafts to the left anterior descending artery. Although TTFM use increases the duration and the cost of surgery, there are no data to quantify this effect. Based on the systematic review, 10 expert statements for TTFM use in clinical practice were formulated. Six were approved at the first round of voting, 3 at the second round, and 1 at the virtual meeting.

In conclusion, although TTFM use may increase the costs and duration of the procedure and requires a learning curve, its cost/benefit ratio seems largely favorable, in view of the potential clinical consequences of graft dysfunction. These consensus statements will help to standardize the use of TTFM in clinical practice and provide guidance in clinical

Key Words: coronary artery bypass ■ quality control ■ time

ntraoperative quality control is standard practice in every aspect of contemporary cardiac surgery but remains underused in coronary artery bypass grafting (CABG). Transit time flow measurement (TTFM) allows quality control in CABG by intraoperative evaluation of coronary graft function, but it is currently adopted in only 30% of the procedures.1

Current myocardial revascularization guidelines provide only generic recommendations on TTFM use,23 and

the reluctance to its widespread adoption by the surgical community is likely based on limited information, and concerns pertaining to the lack of standardization and familiarity with TTFM interpretation, as well.

In this article, a group of coronary surgeons with extensive experience with TTFM performed a systematic review of the existing evidence and critically evaluated the available data. Because of the high statistical and methodological heterogeneity of the published stud-

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association

Correspondence to: Mario Gaudino, MD, MSCE, FEBCTS, FACC, Department of Cardiothoracic Surgery, Weill Cornell Medicine, 525 East 68th St, New York, NY

For Sources of Funding and Disclosures, see page xxx.

© 2021 American Heart Association, Inc.

Circulation is available at www.ahajournals.org/journal/cir

Circulation, 2021;144:00-00, DOI: 10.1161/CIRCULATIONAHA.121.054311

October 5, 2021

# Several expert consensus statements published in 2021

- The **advocacy** is getting loader and more prominent
- Influencing peers; driving routine use and setting the standard-of-care
- Reasonable to expect new and stronger clinical guideline endorsements

#### **Intraoperative Graft Patency Assessment:** Time to Recognize the Elephant Outside the Operating Room?

Gregory D. Trachiotis<sup>1</sup>, MD. Michael A. Napolitano<sup>1,2</sup>, MD <sup>®</sup>, Ethan S. Rosenfeld<sup>1,2</sup>, MD. and David P. Taggart<sup>3</sup>, MD, PhD

Introduction

Coronary artery bypass grafting (CAB commonly performed procedure for t on decreasing mortality, improving quali symptom severity. All of these outcom echnical success of the operation itself tion of adequately patent bypass grafts.

developed in recent years to improve clin surgery,2 less attention has been given to th ing the technical success of the procedure several tools are available, including tran ment (TTFM; Fig. 1), high-frequency (HFUS; Fig. 2, Fig. 3), thermal coronary a erative fluorescence imaging. In structural echocardiography to immediately evalua valve replacement/repair is widely accente tice.3,4 However, although CABG is technic distal anastomosis is <1 mm, there is no st operative quality assessment of grafts or wl should be. Furthermore, it is inconceivable cardiologist would not perform a completio ing a stent in a coronary artery, a proceed demanding than a bypass graft. It is also both off-pump CABG (OPCAB) and use of which have well-defined roles in partici increase that level of technical complexity.

Perioperative graft failure may occur in 9% of patients undergoing CABG surgery. rarely discussed "elephant outside (Supplemental Video). The first published i CABG date back to 1994 in 2 separate publ as well as Canver and Dame. Since that timbeen well validated as a means of intrao ment, and from 2010 through its most rec European Society of Cardiology and Eur

#### The 10 Commandments for **Multiarterial Grafting**

Article reuse guidelines

Rami Akhrass', MD and Faisal G. Bakaeen', MD @

#### EDITORIAL

Coronary artery bypass grafting (CABG), int neered over 50 years ago at the Cleveland Cli-Favalloro, has remained the gold standard in t multivessel coronary artery disease with heavy burden. While utilizing the internal thoracic bypass the left anterior descending artery (LA cornerstone of CABG since 1986.2 there has be sensus on the importance of multiarterial graft graft has been somewhat equivocal, although with 3, compared to 2, arterial grafts.6

percutaneous coronary intervention is most e nounced in patients that receive at least one ITA conduits, in particular the ITA, are rarely affe sclerosis making them ideal conduits to use with rates. The ITA has unique biological charact increased nitric oxide levels that may also expla

undergoing CABG receive more than one arteri: graft quality control measure in place in coronary surgery? barriers are implicated in the lack widespread ad decade from index operation, until the impact of ir procedures in the United States. with MAG is generally realized 3-5

While MAG may not be suitable to all CAl use of arterial grafts is encouraged and shou (i) a lack of standardization of how TTFM should be perform ization strategy.5 The strategy of revascula among patients, taking into consideration ov

#### Transit time flow measurement in coronary artery bypass grafting: For every patient and every surgeon

the use of at least 2 arterial grafts, resulting ii Quality assurance in cardiac surgery has evolved over the past vival and freedom from major adverse cardiac ( decade to include intraoperative performance measures, prereinterventions. 3.4 Indeed, the most recent CA dicated on the fact that intraoperative evaluation of quality leads to set forth by the Society of Thoracic Surgeons improved patient outcomes. Routine intraoperative quality control measupplementation of the ITA graft to the LAD, sures have been implemented in most aspects of cardiac surgery inmultivessel disease, with the use of additional I cluding treatment of structural valve disease, and congenital and pediatric artery (RA) grafts. The incremental benefit o cardiac surgery. However, this is not the case in coronary surgery.

In the United States, 18.2 million adults age 20 and older of observational studies suggested better lon have coronary artery disease. With close to 200,000 coronary artery bypass graft (CABG) surgeries performed in the U.S per The outcome advantage attained with CAE year,2 this is the most frequently performed cardiac surgical procedure. The STS Adult Cardiac Surgery performance measure assesses surgical performance based on a combination of CABG process and outcomes measures, including risk-adjusted operative mortality and morbidity, use of an internal mammary artery and secondary prevention measures at discharge.3 And yet, the ultimately relevant outcomes for the patient-survival and symptom relief-are based on a single primary underlying In spite of the above, in the United States, over premise—that the patient leaves the operating room with are saphenous vein grafts (SVG) and less than functioning grafts. So why is there no routine intraoperative

Several modalities for intraoperative quality assessment of CABG including increased technical complexity and op exist, among them coronary angiography and intraoperative fluorescence lier suboptimal results with RA use, wound healii imaging. However, these are limited mainly by cost and/or practical apbilateral ITA (BITA) harvesting especially in dial: plicability. Intraoperative transit time flow measurement (TTFM) is the tion to the somewhat long latency period, ust technology most frequently adopted, yet it is used in only 20% of CABG

The most frequently cited limitations to widespread adoption ar

- heart-team discussion in determining the opti (ii) a lack of standardization of how TTFM measurements should be interpreted, based on the concern that some grafts may be revised unnecessarily
  - (iii) the expectation that TTFM should be able to predict not only the immediate intraoperative status of the graft but also long-term patency and clinical outcomes, for which there is little robust evidence
  - (iv) intraoperative quality control is not addressed in current clinical practice guidelines of any of the North American cardiovascular societies; and
  - (v) differences in opinion among CABG leaders exist as to when TTFM should be used.

J Card Surg. 2021;1-4.

Circulation

CARDIAC SURGERY WILEY

#### The Use of Intraoperative Transit Time Flow Measurement for Coronary Artery Bypass Surgery

Systematic Review of the Evidence and Expert Opinion Statements

Mario Gaudino, MD, MSCE; Sigrid Sandner, MD; Gabriele Di Giammarco, MD; Antonino Di Franco, MD; Hirokuni Arai, MD; Tohru Asai MD; Faisal Bakaeen, MD; Torsten Doenst, MD; Stephen E. Fremes MD; MD; David Glineur, MD; Teresa M. Kieser®, MD, PhD; Jennifer S. Lawton, MD; Roberto Lorusso, MD; Nirav Patel, MD; John D. Puskas, MD; James Tatoulis, MD; David P. Taggart, MD; Michael Vallely, MD; Marc Ruel®, MD

ABSTRACT: Transit time flow measurement (TTFM) allows quality control in coronary artery bypass grafting but remains largely underused, probably because of limited information and the lack of standardization. We performed a systematic review of the evidence on TTFM and other methods for quality control in coronary artery bypass grafting following PRISMA standards and elaborated expert recommendations by using a structured process. A panel of 19 experts took part in the consensus process using a 3-step modified Delphi method that consisted of 2 rounds of electronic voting and a final face-to-face virtual meeting. Eighty percent agreement was required for acceptance of the statements. A 2-level scale (strong, moderate) was used to grade the statements based on the perceived likelihood of a clinical benefit.

The existing evidence supports an association between TTFM readings and graft patency and postoperative clinical outcomes, although there is high methodological heterogeneity among the published series. The evidence is more robust for arterial, rather than venous, grafts and for grafts to the left anterior descending artery. Although TTFM use increases the duration and the cost of surgery, there are no data to quantify this effect. Based on the systematic review, 10 expert statements for TTFM use in clinical practice were formulated. Six were approved at the first round of voting, 3 at the second

In conclusion, although TTFM use may increase the costs and duration of the procedure and requires a learning curve, its cost/benefit ratio seems largely favorable, in view of the potential clinical consequences of graft dysfunction These consensus statements will help to standardize the use of TTFM in clinical practice and provide guidance in clinical decision-making.

Key Words: coronary artery bypass ■ quality control ■ time

ntraoperative quality control is standard practice in the reluctance to its widespread adoption by the surgievery aspect of contemporary cardiac surgery but remains underused in coronary artery bypass grafting (CABG). Transit time flow measurement (TTFM) allows quality control in CABG by intraoperative evaluation of coronary graft function, but it is currently adopted in only 30% of the procedures.1

cal community is likely based on limited information, and concerns pertaining to the lack of standardization and familiarity with TTFM interpretation, as well.

In this article, a group of coronary surgeons with extensive experience with TTFM performed a systematic review of the existing evidence and critically evaluated

## **MEDISTIM**





## 20 largest shareholders per October 19th

| Rank | Name                                 | Holding   | % of total | Citizenship          | Type of account |
|------|--------------------------------------|-----------|------------|----------------------|-----------------|
|      | 1 AETERNUM CAPITAL AS                | 1 862 500 | 10,16 %    | Norway               | Ordinary        |
|      | 2 VERDIPAPIRFOND ODIN NORDEN         | 1 800 000 | 9,82 %     | Norway               | Ordinary        |
|      | 3 INTERTRADE SHIPPING AS             | 1 285 000 | 7,01 %     | Norway               | Ordinary        |
|      | 4 State Street Bank and Trust Comp   | 1 238 675 | 6,75 %     | United States        | Nominee         |
|      | 5 State Street Bank and Trust Comp   | 1 103 921 | 6,02 %     | United States        | Nominee         |
|      | 6 Skandinaviska Enskilda Banken AB   | 1 029 728 | 5,62 %     | Sweden               | Nominee         |
|      | 7 FOLLUM CAPITAL AS                  | 970 000   | 5,29 %     | Norway               | Ordinary        |
|      | 8 State Street Bank and Trust Comp   | 616 154   | 3,36 %     | <b>United States</b> | Nominee         |
|      | 9 Skandinaviska Enskilda Banken AB   | 598 092   | 3,26 %     | Denmark              | Nominee         |
|      | 10 State Street Bank and Trust Comp  | 466 805   | 2,55 %     | United States        | Nominee         |
|      | 11 Skandinaviska Enskilda Banken AB  | 409 723   | 2,23 %     | Sweden               | Nominee         |
|      | 12 SKANDINAVISKA ENSKILDA BANKEN AB  | 387 682   | 2,11 %     | Luxembourg           | Nominee         |
|      | 13 FD INVT TR: FD SRS INTL SML CP FD | 382 845   | 2,09 %     | United States        | Ordinary        |
|      | 14 BUANES                            | 379 936   | 2,07 %     | Norway               | Ordinary        |
|      | 15 The Bank of New York Mellon SA/NV | 257 500   | 1,40 %     | Denmark              | Nominee         |
|      | 16 Skandinaviska Enskilda Banken AB  | 238 314   | 1,30 %     | Sweden               | Nominee         |
|      | 17 BNP Paribas Securities Services   | 233 392   | 1,27 %     | Italy                | Nominee         |
|      | 18 Euroclear Bank S.A./N.V.          | 232 559   | 1,27 %     | Belgium              | Nominee         |
|      | 19 Danske Invest Norge Vekst         | 228 000   | 1,24 %     | Norway               | Ordinary        |
|      | 20 The Bank of New York Mellon SA/NV | 210 931   | 1,15 %     | Ireland              | Nominee         |

| Date:                      | 19.10.2021   |
|----------------------------|--------------|
| Name: MEDISTIM ASA         | Medistim ASA |
| ISIN: NO0010159684         | NO0010159684 |
| Number of investors: 1009  | 1 009        |
| Number of shares: 18337336 | 18 337 336   |

# **MEDISTIM**